

---

# Safety Assessment of Polyglyceryl Fatty Acid Esters as Used in Cosmetics

---

Status: Draft Report for Panel Review  
Release Date: March 7, 2016  
Panel Meeting Date: March 31-April 1, 2016

The 2016 Cosmetic Ingredient Review Expert Panel members are: Chairman, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Ronald A. Hill, Ph.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; James G. Marks, Jr., M.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The CIR Director is Lillian J. Gill, D.P.A. This safety assessment was prepared by Monice M. Fiume, Assistant Director/Senior Scientific Analyst/Writer and Bart Heldreth, Ph.D., Chemist.

---

*Commitment & Credibility since 1976*

### Memorandum

To: CIR Expert Panel Members and Liaisons  
 From: Monice M. Fiume *MMF*  
 Assistant Director/Senior Scientific Analyst  
 Date: March 7, 2016  
 Subject: Safety Assessment of Polyglyceryl Fatty Acid Esters as Used in Cosmetics

Enclosed is the Draft Report of the Safety Assessment of Polyglyceryl Fatty Acid Esters as Used in Cosmetics (*PGlyFE032016rep*). This is the first time the Panel is seeing this safety assessment of 275 ingredients that are structurally constituted of the esterification products of polyglycerin chains and fatty acids. The Scientific Literature Review was issued on January 19, 2016.

You may recall that the Panel reviewed a final report on the safety of the monoglyceryl monoesters in December, and concluded that the 44 monoglyceryl monoesters named in that report are safe in the present practices of use and concentration. Monoglyceryl monoesters and polyglyceryl fatty acid esters both consist of the same starting materials, and they have the same potential metabolites. The difference between these two families of ingredients is that monoglyceryl monoesters are structurally constituted of the esterification products of only one equivalent of glycerin and one equivalent of a carboxylic acid, as opposed to the varying number of equivalents of glycerin and fatty acids in the polyglyceryl esters.

Several submissions on the maximum concentration of use of these ingredients by FDA product category have been made by the Council. The submissions are identified as *PGlyFE032016data\_1* through *PGlyFE032016data\_4*.

The following unpublished data also have been submitted:

1. Anonymous. (2016) Composition and physical and chemical properties of Polyglyceryl-4 Oleate (*PGlyFE032016data\_5*);
2. Anonymous. (2016) Summary information on Palm Oil Polyglyceryl-4 Esters, Apricot Kernel Oil Polyglyceryl-4 Esters, and Polyglyceryl-3 Diisostearate (*PGlyFE032016data\_6*);
3. Progressus s.r.l. (2015) This submission includes material safety data sheets for PROLIX RB (Polyglyceryl-3 Rice Branate) and PROLIX RO (Rice Bran Oil Polyglyceryl-3 Esters) (*PGlyFE032016data\_7*);
4. Anonymous. (2009) Material safety data sheet on a trade name mixture containing 60% Polyglyceryl-10 Eicosanedioate/Tetradecanedioate (*PGlyFE032016data\_8*);
5. Nikko Chemicals Co., Ltd. (2016) This submission includes safety information sheets on several Polyglyceryl-10 esters (*PGlyFE032016data\_9*);
6. Lubrizol Advanced Materials, Inc. (2007; 2016). This submission includes information sheets for Polyglyceryl-3 Laurate, Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate, and Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate (*PGlyFE032106data\_10*);
7. Anonymous. (2016). This submission includes summary data sheets for Polyglyceryl-3 Isostearate, Polyglyceryl-3 Caprate, Polyglyceryl-3 Caprylate, Polyglyceryl-3 Oleate, Polyglyceryl-4 Caprate, and Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate. (*PGlyFE032016data\_11*);
8. Notox BV (1996); Globecrown Services LTD (1997); Harlan Laboratories, Ltd. (2010). This submission includes skin and ocular irritation studies and genotoxicity studies performed by these 3 laboratories. Ingredients tested include Polyglyceryl-2 Isostearate, Polyglyceryl-4 Laurate/Sebacate, Polyglyceryl-4 Laurate/Succinate, and Polyglyceryl-6 Caprylate/Caprate. (*PGlyFE032106data\_12*); and

9. Evonik. (2016) Power point of general information on polyglyceryl esters, entitled Polyglycerol esterification for highly effective and natural-based ingredients. (*PGlyFE032016data\_13*).

The report currently includes 2015 FDA VCRP data (*PGlyFE032016FDA*). The next iteration of the report will be updated to include the 2016 VCRP data.

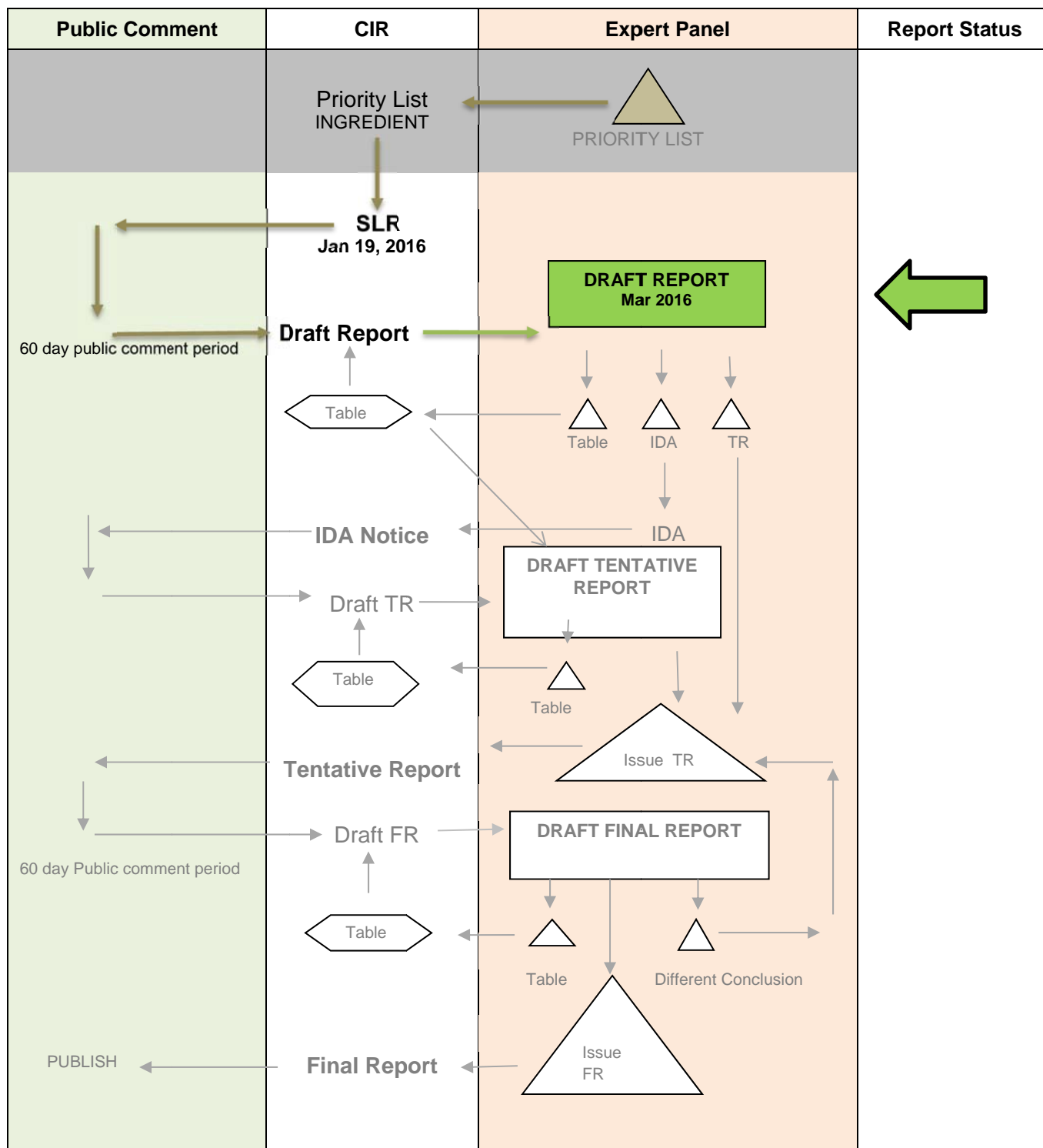
Comments on the SLR (*PGlyFE032016pcpc*) were received from the Council and have been addressed.

If the data included in this report adequately addresses the safety of the polyglyceryl fatty acid esters, the Panel should be prepared to formulate a tentative conclusion, provide the rationale to be described in the Discussion, and issue a Tentative Report for public comment. If the data are not sufficient for making a determination of safety, then an Insufficient Data Announcement should be issued that provides a listing of the additional data that are needed.

# SAFETY ASSESSMENT FLOW CHART

INGREDIENT/FAMILY Polyglyceryl Fatty Acid Esters

MEETING Mar 2016





[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

**Polyglyceryl Fatty Acid Esters**

	CAS #	Use	InfoBase	PubMed	SciFinder	ChemID	NTIS	FDA	ECHA	HPV	IUCLID/ SIDS	WHO/ JEFCA	EU	NICNAS	Web
Generic terms, Polyglyceryl Fatty Acid Esters, etc				X	X		---	CFR		---		X			
Acacia Decurrens/Jojoba/ Sunflower Seed Wax Polyglyceryl 3 Esters	---		---					---	---	---	---		no r		X
Adansonia Digitata Seed Oil Polyglyceryl-6 Esters	---		---					---	---	---	---		no r	---	X
Almond Oil/Polyglyceryl-10 Esters	---		---										no r		---
Apricot Kernel Oil Polyglyceryl-10 Esters	---		---					---	---	---	---		no r	---	X
Apricot Kernel Oil Polyglyceryl-3 Esters	---		---					---	---	---	---		no r	---	---
Apricot Kernel Oil Polyglyceryl-4 Esters (Dub Aprilose +)	---		---		---	---	---	---	---		---	---	no r	---	---
Apricot Kernel Oil Polyglyceryl-5 Esters	---		---					---	---	---	---	---	no r	---	---
Apricot Kernel Oil Polyglyceryl-6 Esters	---		---					---	---	---	---	---	no r	---	X
Argan Oil Polyglyceryl-6 Esters	---		---					---	---	---	---	---	no r	---	X
Astrocaryum Vulgare Oil Polyglyceryl-6 Esters	---		---					---	---	---	---	---	no r	---	---
Avocado Oil Polyglyceryl-6 Esters	---		---					---	---	---	---	---	no r	---	---
Babassu Oil Polyglyceryl-4 Esters	---		---		---	---	---	---	---		---	---	no r	---	X
Babassu Oil Polyglyceryl-6 Esters	---		---					---	---	---	---	---	no r	---	X
Bertholletia Excelsa Seed Oil Polyglyceryl-6 Esters	---		---					---	---	---	---	---	no r	---	X
Borage Seed Oil Polyglyceryl-4 Esters	---		---		---	---	---	---	---		---	---	no r	---	---
Borage Seed Oil Polyglyceryl-6 Esters	---		---					---	---	---	---	---	no r	---	X
Candelilla/Jojoba/Rice Bran Polyglyceryl-3 Esters	---		---					---	---	---	---		no r	---	---
Caprylic/Capric Glycerides Polyglyceryl-10 Esters (	---		---										no r		X
Carapa Guaianensis Oil Polyglyceryl-6 Esters (	---		---					---	---	---	---	---	no r	---	---
Castor Oil Polyglyceryl-6 Esters	---		---					---	---	---	---	---	no r	---	X
Cocoa Butter Polyglyceryl-6 Esters	---		---					---	---	---	---	---	no r	---	X
Coconut Oil Polyglyceryl-6 Esters	---		---										no r		X
Coffee Seed Oil Polyglyceryl-6 Esters	---		---					---	---		---	---	no r	---	---
Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate	187547-43-9 <sup>1</sup>		---										no r		X
Glyceryl/Polyglyceryl-6 Isostearate/ Behenate Esters	---		---		---	---	---	---	---		---	---	no r	---	---
Hazelnut Seed Oil Polyglyceryl-6 Esters	---		---										no r		X
Linseed Oil Polyglyceryl-4 Esters	---		---		---	---	---	---	---		---	---	no r	---	---
Macadamia Seed Oil Polyglyceryl 6 Esters	85711-62-2 <sup>2</sup>		---		---	---	---	---	---		---	---	no r	---	X



	CAS #	Use	InfoBase	PubMed	SciFinder	ChemID	NTIS	FDA	ECHA	HPV	IUCLID/ SIDS	WHO/ JEFCA	EU	NICNAS	Web
Macadamia Seed Oil Polyglyceryl 6 Esters Behenate	---		---										no r		---
Mauritia Flexuosa Seed Oil Polyglyceryl-6 Esters	---		---		---	---	---	---	---		---	---	no r	---	---
Olive Oil Polyglyceryl-3 Esters	---		---										no r		---
Olive Oil Polyglyceryl-4 Esters	---		---		---	---	---	---	---		---	---	no r	---	X
Olive Oil Polyglyceryl-6 Esters	---		---										no r		X
Palm Kernel Oil Polyglyceryl-4 Esters	---		---		---	---	---	---	---		---	---	no r	---	---
Palm Oil Polyglyceryl-3 Esters	---		---										no r		---
Palm Oil Polyglyceryl-4 Esters	---		---		---	---	---	---	---		---	---	no r	---	---
Palm Oil Polyglyceryl-5 Esters	---		---					---	---	---	---	---	no r	---	---
Palm Oil Polyglyceryl-6 Esters	---		---		---	---	---	---	---		---		no r	---	---
Parinari Curatellifolia Oil Polyglyceryl-6 Esters	---		---		---	---	---	---	---		---		no r	---	---
Pinus Sibirica Seed Oil Polyglyceryl-6 Esters	---		---		---	---	---	---	---		---		no r	---	---
Polyglyceryl-10 Apricot Kernelate	---		---		---	---	---	CFR	---		---		no r	---	X
Polyglyceryl-10 Behenate/Eicosadioate	457632-32-5 <sup>3</sup>		---		---	---	---	---	---		---		no r	---	X
Polyglyceryl-10 Caprate	---		---		---	---	---	---	---		---		no r	---	---
Polyglyceryl-10 Caprylate	51033-41-1		---		---	---	---	---	---		---		no r	---	---
Polyglyceryl-10 Caprylate/Caprate	---		---		---	---	---	---	---		---		no r	---	X
Polyglyceryl-10 Cocoate	---		---		---	---	---	---	---		---		no r	---	---
Polyglyceryl-10 Decaethylhexanoate	---		---										no r		---
Polyglyceryl-10 Decahydroxystearate	---		---										no r		X
Polyglyceryl-10 Decaisostearate	95461-48-6 <sup>4</sup>		---										no r		X
Polyglyceryl-10 Decalinoleate	68900-96-9												no r		---
Polyglyceryl-10 Decamacadamate	---		---					X					no r		---
Polyglyceryl-10 Decaoleate	11094-60-3 <sup>3</sup>		---					X	preR				no r		X
Polyglyceryl-10 Decastearate	39529-26-5		---					X					no r		---
Polyglyceryl-10 Dicocoate	---		---					X					no r		---
Polyglyceryl-10 Didecanoate	182015-59-4												no r		---
Polyglyceryl-10 Diisostearate	102033-55-6; 63705-03-3 (generic)		---						X				no r		X
Polyglyceryl-10 Dilaurate													no r		---
Polyglyceryl-10 Dimyristate													no r		---
Polyglyceryl-10 Dioleate	33940-99-7		---					X					no r		X
Polyglyceryl-10 Dipalmitate	---		---					X					no r		X
Polyglyceryl-10 Distearate	12764-60-2		---					X					no r		X
Polyglyceryl-10 Dodecabeheate													no r		---
Polyglyceryl-10 Dodecacaprate													no r		---
Polyglyceryl-10 Dodecacaprylate													no r		---



	CAS #	Use	InfoBase	PubMed	SciFinder	ChemID	NTIS	FDA	ECHA	HPV	IUCLID/ SIDS	WHO/ JEFCA	EU	NICNAS	Web
Polyglyceryl-10 Triisostearate													no r		
Polyglyceryl-10 Trilaurate													no r		
Polyglyceryl-10 Trioleate	102051-00-3		---					X					no r		
Polyglyceryl-10 Tristearate	12709-64-7		---					X					no r		
Polyglyceryl-10 Undecylenate	---		---		---	---		---	---		---	---	no r	---	---
Polyglyceryl-15 Diisostearate													no r		
Polyglyceryl-2 Caprate	156153-06-9		---						PreR	---	---		no r		X
Polyglyceryl-2 Caprylate	---		---				---		---	---	---	---	no r		---
Polyglyceryl-2 Diisostearate	67938-21-0; 63705-03-3 (generic)		---			X		---	X		---	---	no r	---	X
Polyglyceryl-2 Dioleate	67965-56-4; 60219-68-3		---					---	preR		---	---	no r	---	---
Polyglyceryl-2 Distearate	9009-32-9		---					---	preR		---	---	no r	---	---
Polyglyceryl-2 Isopalmitate	---		---					---	---	---	---		no r	---	---
Polyglyceryl-2 Isopalmitate/Sebacate	---		---						---	---	---		no r	---	X
Polyglyceryl-2 Isostearate	73296-86-3 81752-33-2		---						PreR	---	---		no r	---	X
Polyglyceryl-2 Laurate	96499-68-2; 74504-64-6 (generic)		---						PreR	---	---		no r	---	X
Polyglyceryl-2 Myristate	---		---						---	---	---		no r	---	
Polyglyceryl-2 Oleate	9007-48-1 (generic); 49553-76-6								X	---	---		no r	---	X
Polyglyceryl-2 Palmitate	---		---					---	---	---			no r	---	---
Polyglyceryl-2 Sesquicaprylate	---		---					---	---	---			no r	---	
Polyglyceryl-2 Sesquiisostearate (Hostacerin® DGI)	170211-20-8		---					---	---	---			no r	---	X
Polyglyceryl-2 Sesquioleate													no r		
Polyglyceryl-2 Sesquistearate	9009-32-9		---					---	---	---			no r	---	---
Polyglyceryl-2 Stearate	12694-22-3 9009-32-9 (generic)								preR	---	---		no r	---	X
Polyglyceryl-2 Tetrabeheenate/ Macadamiate/Sebacate													no r		
Polyglyceryl-2 Tetraisostearate	121440-30-0		---					---	---	---			no r	---	X
Polyglyceryl-2 Tetraoleate													no r		
Polyglyceryl-2 Tetrastearate	72347-89-8		---			---		---	preR		---	---	no r	---	X
Polyglyceryl-2 Triisostearate	120486-24-0		---			---		---	preR		---	---	no r	---	---
Polyglyceryl-20 Docosabeheenate/ Isostearate													no r		---
Polyglyceryl-20 Docosabeheenate/Laurate													no r		---

	CAS #	Use	InfoBase	PubMed	SciFinder	ChemID	NTIS	FDA	ECHA	HPV	IUCLID/ SIDS	WHO/ JEFCA	EU	NICNAS	Web
Polyglyceryl-20 Docosabehenate/Oleate													no r		---
Polyglyceryl-20 Heptacaprylate													no r		---
Polyglyceryl-20 Heptadecabehenate/Laurate													no r		
Polyglyceryl-20 Hexacaprylate													no r		
Polyglyceryl-20 Octadecabehenate/Laurate													no r		
Polyglyceryl-20 Octaiononanoate													no r		
Polyglyceryl-3 Beeswax	136097-93-3		---										no r		X
Polyglyceryl-3 Behenate	1207543-50-7 <sup>9</sup>		---										no r		X
Polyglyceryl-3 Caprate	133654-02-1; 51033-30-8; 74504-65-7		---						PreR	---	---		no r	---	X
Polyglyceryl-3 Caprylate	108777-93-1		---						---	---	---		no r	---	X
Polyglyceryl-3 Cocoate	223706-47-6		---					X	---				no r		---
Polyglyceryl-3 Di Hydroxystearate													no r		X
Polyglyceryl-3 Dicaprte													no r		---
Polyglyceryl-3 Dicitrate/Stearate													no r		---
Polyglyceryl-3 Dicocoate	223706-47-6		---					X					no r		---
Polyglyceryl-3 Diisostearate	66082-42-6; 63705-03-3 (generic)		---						X				no r		X
Polyglyceryl-3 Dioleate	33940-99-7 <sup>10</sup> 79665-94-4		---			X		X	preR	---	---		no r	---	X
Polyglyceryl-3 Distearate	9009-32-9 94423-19-5		---					X					no R		
Polyglyceryl-3 Isostearate	127512-63-4		---					---	---				no R		---
Polyglyceryl-3 Laurate	51033-31-9 <sup>11</sup>		---					X	---	---	---		no R	---	X
Polyglyceryl-3 Myristate	---		---					X	---	---	---		no R	---	---
Polyglyceryl-3 Oleate	33940-98-6; 9007-48-1 (generic)							X	PreR	---	---		no R	---	X
Polyglyceryl-3 Palmitate	143701-24-1							X	---	---	---		no R		X
Polyglyceryl-3 Pentacaprylate/Caprte	---												no R		
Polyglyceryl-3 Pentaolive													no R		X
Polyglyceryl-3 Pentaricinoleate	221354-73-0												no R		
Polyglyceryl-3 Rice Branate	1166833-04- 0 <sup>12</sup> 1166833-52-8		---						---	---	---		no R	---	X
Polyglyceryl-3 Ricinoleate	29894-35-7		---					---	PreR				no R		X
Polyglyceryl-3 Soyate/Shea Butterate	---		---					---	***	---	---		no R	---	X
Polyglyceryl-3 Stearate	26855-43-6; 27231-72-8; 37349-34-1 (generic)		---					X	preR	---	---		no R	---	X

	CAS #	Use	InfoBase	PubMed	SciFinder	ChemID	NTIS	FDA	ECHA	HPV	IUCRID/ SIDS	WHO/ JECCA	EU	NICNAS	Web
Polyglyceryl-3 Stearate SE													no R		
Polyglyceryl-3 Triisostearate	66082-43-7												no R		
Polyglyceryl-3 Triolivate													no R		
Polyglyceryl-4 Almond/Shea Butterate	---		---		---	---	---	---	---		---	---	no R	---	---
Polyglyceryl-4 Caprate	160391-93-5; 74504-65-7		---					---	PreR	---	---	---	no R	---	X
Polyglyceryl-4 Caprylate								---	---	---	---	---	no R	---	---
Polyglyceryl-4 Caprylate/Caprate	---		---										no R		---
Polyglyceryl-4 Cocoate	---		---		---	---	---	X	---		---	---	no R	---	X
Polyglyceryl-4 Dilaurate													no R		
Polyglyceryl-4 Distearate													no R		
Polyglyceryl-4 Hazelnutseedate	---		---		---	---	---	---	---		---	---	no R	---	---
Polyglyceryl-4 Isostearate	63705-03-3; 91824-88-3		---					---	X	---	---	---	no R	---	X
Polyglyceryl-4 Isostearate/Laurate													no R		
Polyglyceryl-4 Laurate	75798-42-4; 74504-64-6 (generic)		---					---	---	---	---	---	no R	X	X
Polyglyceryl-4 Oleate	71012-10-7 9007-48-1		---			X	---	---	---	---	---	---	no R	---	---
Polyglyceryl-4 Pentaoleate	103230-29-1		---					X					no R		
Polyglyceryl-4 Pentapalmitate/Stearate													no R		
Polyglyceryl-4 Pentastearate	99570-00-0												no R		
Polyglyceryl-4 Punicate	---		---		---	---	---	---	---		---	---	no R	---	---
Polyglyceryl-4 Stearate	26855-44-7; 68004-11-5; 37349-34-1 (generic)		---			X	---	---	pre-R	---	---	---	no R	---	---
Polyglyceryl-4 Sweet Almond/ate													no R		
Polyglyceryl-4 Tristearate	99734-29-9		---					X					no R		
Polyglyceryl-5 Caprate	---		---					---	---	---	---	---	no R		---
Polyglyceryl-5 Dicaprylate	108777-93-1												no R		
Polyglyceryl-5 Dilaurate													no R		
Polyglyceryl-5 Dioleate	---		---					X					no R		X
Polyglyceryl-5 Hexastearate	---		---					X					no R		
Polyglyceryl-5 Isostearate	---		---					---	---	---	---	---	no R	---	---
Polyglyceryl-5 Laurate	128738-83-0; 74504-64-6 (generic)		---					X	---	---	---	---	no R	---	X
Polyglyceryl-5 Myristate	---		---					X		---	---	---	no R	---	---
Polyglyceryl-5 Oleate	86529-98-8		---					X	preR	---	---	---	no R	---	X

	CAS #	Use	InfoBase	PubMed	SciFinder	ChemID	NTIS	FDA	ECHA	HPV	IUCLID/ SIDS	WHO/ JEFCA	EU	NICNAS	Web
Polyglyceryl-5 Pentamyristate													no R		
Polyglyceryl-5 Ricinoleate	---		---					---	---	---	---	---	no R	---	---
Polyglyceryl-5 Stearate	37349-34-1 (generic)		---					X	preR	---	---	---	no R	---	---
Polyglyceryl-5 Tribehenate													no R		
Polyglyceryl-5 Triisostearate													no R		
Polyglyceryl-5 Trimyristate													no R		
Polyglyceryl-5 Trioleate	---		---					X					no R		
Polyglyceryl-5 Tristearate	9009-32-9 (generic)												no R		
Polyglyceryl-6 Adansonia Digitata Seedate	---		---										no r		---
Polyglyceryl-6 Apricot Kernelate													no r		X
Polyglyceryl-6 Argan Kernelate			---										no r		X
Polyglyceryl-6 Behenate	---		---					---	---	---	---	---	no R	---	---
Polyglyceryl-6 Caprate	---		---					---	---	---	---	---	no R	---	---
Polyglyceryl-6 Caprylate	---		---					---	---	---	---	---	no R	---	X
Polyglyceryl-6 Caprylate/Caprate	---		---					---	---	---	---	---	no R	---	---
Polyglyceryl-6 Citrullus Lanatus Seedate	---		---					---	---	---	---	---	no R	---	---
Polyglyceryl-6 Dicaprate													no r		
Polyglyceryl-6 Diisostearate													no r		
Polyglyceryl-6 Dioleate	76009-37-5		---					X					no r		
Polyglyceryl-6 Dipalmitate	---		---					X					no r		
Polyglyceryl-6 Distearate	34424-97-0		---					X					no r		X
Polyglyceryl-6 Heptacaprylate													no r		
Polyglyceryl-6 Hexaoleate	95482-05-6		---					X					no r		
Polyglyceryl-6 Hexastearate	---		---					X					no r		
Polyglyceryl-6 Isostearate	126928-07-2		---					---	---	---	---	---	no R	---	---
Polyglyceryl-6 Laurate	51033-38-6		---					X	---	---	---	---	no R	---	---
Polyglyceryl-6 Myristate	---		---					X	---	---	---	---	no R	---	---
Polyglyceryl-6 Octacaprylate													no r		
Polyglyceryl-6 Octastearate													no r		X
Polyglyceryl-6 Oleate	9007-48-1; 79665-92-2		---					X	preR	---	---	---	no R	---	---
Polyglyceryl-6 Palmitate	99734-31-3		---					X	---	---	---	---	no R	---	---
Polyglyceryl-6 Palmitate/Succinate													no R		
Polyglyceryl-6 Pentacaprylate													no r		
Polyglyceryl-6 Pentaoleate	104934-17-0		---					X					no r		
Polyglyceryl-6 Pentaricinoleate													no r		
Polyglyceryl-6 Pentastearate	99734-30-2												no r		
Polyglyceryl-6 Ricinoleate	107615-51-0		---					---	---	---	---	---	no R	---	---
Polyglyceryl-6 Schinziophyton Rautanenii Kernelate	---		---			---		---	---		---	---	no r	---	---







**SciFinder – :**

Polyglyceryl – 199 hits/4 useful

Esterification products of glycerin and fatty acids – 456 hits

9007-48-1	63705-03-3	85711-62-2	126928-07-2
9009-32-9	65573-03-7	86529-98-8	127512-63-4
11094-60-3	66082-42-6	86637-84-5	128738-83-0
12694-22-3	66082-43-7	87390-32-7	128774-95-8
12709-64-7	67938-21-0	91824-88-3	133654-02-1
12764-60-2	67965-56-4	94423-19-5	133738-23-5
26855-43-6	68004-11-5	95461-48-6	136097-93-3
26855-44-7	68900-96-9	95461-64-6	148618-57-9
27321-72-8	71012-10-7	95461-65-7	155808-79-0
29894-35-7	72347-89-8	95482-05-6	156153-06-9
33940-98-6	73296-86-3	99126-54-2	160391-93-5
33940-99-7	74504-64-6	99570-00-0	182015-59-4
34406-66-1	74504-65-7	99734-29-9	187547-43-9
34424-97-0	75719-56-1	99734-30-2	217782-56-4
34424-98-1	75719-57-2	102033-55-6	368869-33-4
37349-34-1	75798-42-4	102051-00-3	457632-32-5
39529-26-5	76009-37-5	103175-09-3	946492-22-4
49553-76-6	71185-87-0	103230-29-1	946492-23-5
51033-30-8	79665-92-2	104934-17-0	1072006-19-9
51033-31-9	79665-93-3	108777-93-1	1166833-04-0
51033-38-6	79665-94-4	112939-69-2	1207543-50-7
51033-41-1	79777-30-3	120486-24-0	
60219-68-3	81752-33-2	121440-30-0	

CAS # AND polyglycerol esters AND polyglycerin esters AND glycerol esters, without polyglyceryl – 1256 hits

Refine so only English – 895 hits

**PubMed –:** Polyglyceryl – 31 hits/2 useful

Polyglycerol and ester# - 84 hits

(glycerol AND ((fatty AND acid) OR ester)) AND (toxic# OR dermal OR sensitiz# OR sensitiS# OR irita# OR carcinogen# OR mutagen# OR genotoxic# OR teratogen#) – 508 HITS

9007-48-1 [EC/RN Number] OR 9009-32-9 [EC/RN Number] OR 11094-60-3 [EC/RN Number] OR 12694-22-3 [EC/RN Number] OR 12709-64-7 [EC/RN Number] OR 12764-60-2 [EC/RN Number] OR 26855-43-6 [EC/RN Number] OR 26855-44-7 [EC/RN Number] OR 27321-72-8 [EC/RN Number] OR 29894-35-7 [EC/RN Number] OR 33940-98-6 [EC/RN Number] OR 33940-99-7 [EC/RN Number] OR 34406-66-1 [EC/RN Number] OR 34424-97-0 [EC/RN Number] OR 34424-98-1 [EC/RN Number] OR 37349-34-1 [EC/RN Number] OR 39529-26-5 [EC/RN Number] OR 49553-76-6 [EC/RN Number] OR 51033-30-8 [EC/RN Number] OR 51033-31-9 [EC/RN Number] OR 51033-38-6 [EC/RN Number] OR 51033-41-1 [EC/RN Number] OR 60219-68-3 [EC/RN Number] OR 63705-03-3 [EC/RN Number] OR 65573-03-7 [EC/RN Number] OR 66082-42-6 [EC/RN Number] OR 66082-43-7 [EC/RN Number] OR 67938-21-0 [EC/RN Number] OR 67965-56-4 [EC/RN Number] OR 68004-11-5 [EC/RN Number] OR 68900-96-9 [EC/RN Number] OR 71012-10-7 [EC/RN Number] OR 72347-89-8 [EC/RN Number] OR 73296-86-3 [EC/RN Number] OR 74504-64-6 [EC/RN Number] OR 74504-65-7 [EC/RN Number] OR 75719-56-1 [EC/RN Number] OR 75719-57-2 [EC/RN Number] OR 75798-42-4 [EC/RN Number] OR 76009-37-5 [EC/RN Number] OR 71185-87-0 [EC/RN Number] OR 79665-92-2 [EC/RN Number] OR 79665-93-3 [EC/RN Number] OR 79665-94-4 [EC/RN Number] OR 79777-30-3 [EC/RN Number] OR 81752-33-2 [EC/RN Number] OR 85711-62-2 [EC/RN Number] OR 86529-98-8 [EC/RN Number] OR 86637-84-5 [EC/RN Number] OR 87390-32-7 [EC/RN Number] OR 91824-88-3 [EC/RN Number] OR 94423-19-5 [EC/RN Number] OR 95461-48-6 [EC/RN Number] OR 95461-64-6 [EC/RN Number] OR 95461-65-7 [EC/RN Number] OR 95482-05-6 [EC/RN Number] OR 99126-54-2 [EC/RN Number] OR 99570-00-0 [EC/RN Number] OR 99734-29-9 [EC/RN Number] OR 99734-30-2 [EC/RN Number] OR 102033-55-6 [EC/RN Number] OR 102051-00-3 [EC/RN Number] OR 103175-09-3 [EC/RN Number] OR 103230-29-1 [EC/RN Number] OR 104934-17-0 [EC/RN Number] OR 108777-93-1 [EC/RN Number] OR 112939-69-2 [EC/RN Number] OR 120486-24-0 [EC/RN Number] OR 121440-30-0 [EC/RN Number] OR 126928-07-2 [EC/RN Number] OR 127512-63-4 [EC/RN Number] OR 128738-83-0 [EC/RN Number] OR 128774-95-8 [EC/RN Number] OR 133654-02-1 [EC/RN Number] OR 133738-23-5 [EC/RN Number] OR 136097-93-3 [EC/RN Number] OR 148618-57-9 [EC/RN Number] OR 155808-79-0 [EC/RN Number] OR 156153-06-9 [EC/RN Number] OR 160391-93-5 [EC/RN Number] OR 182015-59-4 [EC/RN Number] OR 187547-43-9 [EC/RN Number] OR 217782-56-4 [EC/RN Number] OR 368869-33-4 [EC/RN Number] OR 457632-32-5 [EC/RN Number] OR 946492-22-4 [EC/RN Number] OR 946492-23-5 [EC/RN Number] OR 1072006-19-9 [EC/RN Number] OR 1166833-04-0 [EC/RN Number] OR 1207543-50-7 [EC/RN Number] – 0 hits

## **Safety Assessment of Polyglyceryl Fatty Acid Esters as Used in Cosmetics**

---

Status: Draft Report for Panel Review  
Release Date: March 7, 2016  
Panel Meeting Date: March 31-April 1, 2016

The 2016 Cosmetic Ingredient Review Expert Panel members are: Chairman, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Ronald A. Hill, Ph.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; James G. Marks, Jr., M.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The CIR Director is Lillian J. Gill, D.P.A. This safety assessment was prepared by Monice M. Fiume, Assistant Director/Senior Scientific Analyst/Writer and Bart Heldreth, Ph.D., Chemist.

## **INTRODUCTION**

This is a safety assessment of the polyglyceryl fatty acid esters as used in cosmetic formulations. Each of the esters in this group is a polyether comprising 2 to 20 glyceryl residues, end-capped by esterification with simple carboxylic acids, such as fatty acids. The 275 ingredients included in this report are listed alphabetically in Table 1. Table 2 and Table 3 present these ingredients based initially by increasing polyglyceryl chain length and second by increasing alkyl chain length; however, when there is a mixture of fatty acid constituents, those ingredients are presented by chain length for the polyglyceryl moiety and alphabetically based on the fatty acid component. Test data are presented based on increasing chain length (i.e., the order provided in Table 2 and Table 3).

According to the *International Cosmetic Ingredient Dictionary and Handbook*, most of these ingredients are reported to function in cosmetics as skin-conditioning agents and/or surfactants<sup>1</sup> (Table 3). Additional functions have also been reported.

In 2011, the Cosmetic Ingredient Review (CIR) Expert Panel (Panel) published a safety assessment of a family of ingredients that included Polyglyceryl-20 Octaiononanoate; the Panel concluded that all of the ingredients named in that report are safe in the present practices of use and concentration identified in that assessment.<sup>2</sup> Because Polyglyceryl-20 Octaiononanoate is a polyglyceryl fatty acid ester and is structurally related to the ingredients in this report, it is being included in this safety assessment.

The Panel has recently reviewed the safety of monoglyceryl monoesters, and concluded that the monoglyceryl monoesters are safe in cosmetics in the present practices of use and concentration described in that safety assessment.<sup>3</sup> Monoglyceryl monoesters and the polyglyceryl fatty acid esters both consist of the same starting materials, and they have the same potential metabolites. The difference between these two families of ingredients is that monoglyceryl monoesters are structurally constituted of the esterification products of only one equivalent of glycerin and one equivalent of a carboxylic acid, as opposed to the varying number of equivalents of glycerin and fatty acids in the polyglyceryl esters.

The Panel has previously reviewed the safety of ingredients that represent some of the starting materials of the polyglyceryl fatty acid esters that may persist as residual impurities in the polyglyceryl esters products, or may represent potential metabolites (e.g., from the action of esterases in the skin), such as glycerin and free fatty acids. A list of relevant ingredients that have been reviewed and the associated conclusions, is provided in Table 4. (The full reports can be found on the CIR website: <http://www.cir-safety.org/ingredients>). Other ingredients, such as dipropylene glycol and polypropylene glycols (PPGs), have also been reviewed and are also included in Table 4 because they have similar properties and functions.

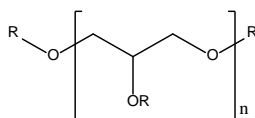
Much of the toxicity data included in this safety assessment was found on the European Chemicals Agency (ECHA) website.<sup>4</sup> The ECHA website provides summaries of information generated by industry, and it is the summary data that are reported in this safety assessment when ECHA is cited. Also, when deemed appropriate, read-across data from ECHA are included in this report. In some cases in the ECHA dossier, such as in 1,2,3-propanetriol, homopolymer, diisooctadecanoate, the number of polyglyceryl chains is not defined. Because the number of polyglyceryl chains is not defined, and it therefore is unclear what specific ingredient is being studied, the data are presented as potential read-across data.

Several studies that are summarized in this safety assessment examined the toxicity of a “polyglyceryl ester”. The exact composition of the test material was not identified in many of the studies and, generally, very few details were provided. However, this information is included in this safety assessment for completeness.

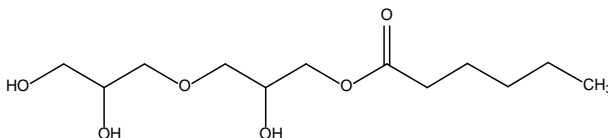
## **CHEMISTRY**

### **Definition and Structure**

The ingredients in this report are each structurally constituted of the esterification products of polyglycerin chains and fatty acids. These ingredients vary in the number of equivalents of glycerin and fatty acids, and the length of those fatty acids (Figures 1 and 2).



**Figure 1.** Generic structure of polyglyceryl esters, wherein R represents hydrogen or the residue of certain fatty acids, and n varies from 2 to 20



**Figure 2.** Polyglyceryl-2 caprate (wherein R, in the general structure in Figure 1, is hydrogen in 3 instances and caprate in 1 instance; and n is 2)

The polymerization process used to produce polyglycerol yields a distribution of different oligomers that have a primarily linear structure.<sup>5</sup> In addition to the linear configuration, a significant part of the polyglycerol is of the branched types, e.g., originating from 1,2- and 2,2-*O*-ether linkages.

Polyglyceryl esters of fatty acids have a hydrophilic polyglycerol group that consists of a finite number of hydroxyethers of glycerol and a hydrophobic fatty acid chain within the same compound.<sup>6</sup> These ingredients are non-ionic compounds, and a range of polarities is possible because of the variation of the degree of polymerization and number of fatty acids per head-group.

### Physical and Chemical Properties

The physical properties and appearance of polyglyceryl esters of fatty acids mainly depends on their molecular structure. Typically, the physical form of those with a higher degree of polymerization and shorter or unsaturated fatty acid chains ranges from viscous liquids to plastic pastes, and the polyglyceryl esters with a lower degree of polymerization and longer, saturated fatty acid chains are generally powders, flakes or small beads.<sup>6</sup> The color of the esters is dependent on the source of the fatty acids, but the polyglycerol will contribute to the color.<sup>5</sup> The solubility of polyglyceryl esters in organic solvents depends on the nature of the solvent and the polarity of the ester but, generally, the esters will show best solubility in protic and polar aprotic solvents, such as lower alcohols and dimethyl sulfoxide (DMSO).

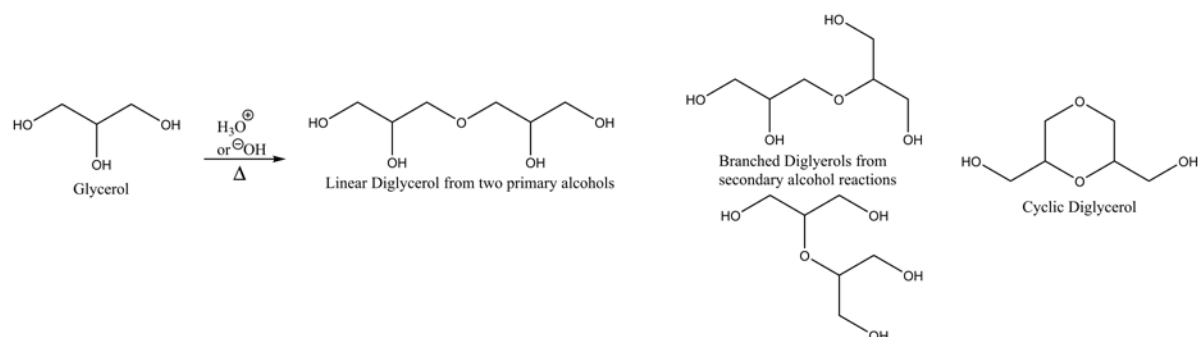
Polyglyceryl esters of fatty acids are polar or amphiphilic lipids, and the amphiphilic properties in water exhibit mesomorphic activities forming lyotropic liquid crystals.<sup>6</sup> The polyglyceryl ester as a polar emulsifier will form aggregated bodies, such as micelles, at low concentrations in water. Polyglyceryl esters of fatty acids become unstable with water and high temperatures, and the instability is enhanced in the presence of alkaline substances. The presence of an alkali or acid results in the partial hydrolysis of fatty acids and the formation of free polyglycerol.

Polyglyceryl esters are comparable to monoglycerides with respect to hydrolysis. In enzymatic systems, lipases will hydrolyze the polyglyceryl ester, as seen in the case of other glycerides.<sup>5</sup>

The average fatty acid compositions (when available) are described in Table 5, and the physical and chemical properties of many of the ingredients included in this safety assessment are presented in Table 6.

### Method of Manufacture

The synthesis of polyglyceryl esters of fatty acids is achieved by the polymerization of a hydrophilic headgroup, and then esterification of the headgroup with the hydrophobic tails.<sup>6</sup> Polyglycerols are generally prepared from an alkaline condensation of glycerol molecules at elevated temperature, with the removal of water. Because one glycerol molecule possesses 3 reactive sites (1 secondary alcohol (center position) and 2 primary alcohols (terminal positions)), several kinds of diglycerol molecules can be formed. If the polymerization proceeds to tri-, tetra-, or higher glycerols, then the number of possible linear or branched isomers increases exponentially. Moreover, once a dimer is formed, cyclic products can result from intra-molecular ring-closure reactions (Figure 3).



**Figure 3.** polymerization of glycerol<sup>7</sup>

Polyglycerols can be used as produced, or they may be stripped of excess glycerol and cyclic glycerols by steam distillation at reduced pressure.<sup>7</sup> Alternatively, stripping processes have been developed using mesoporous and zeolite catalysts under milder conditions.

Other possible processes for production of a polyglycerol use reactive petrochemical substances such as epichlorohydrine (1-chloro-2,3-dihydroxypropane), which is allowed to react with glycerol in an etherification process. However, epichlorohydrine is a hazardous material, and the purification of the polyglycerol complicates the process.<sup>5</sup> Glycidol is also used for the production of polyglycerol, and the oxirane group easily reacts with glycerol or epichlorohydrine, depending on the

conditions of the reaction and the type of polyglycerol required. However, these processes use chemicals that make the process non-competitive in relation to a glycerol based process.

According to the World Health Organization (WHO) Food and Agriculture Organization (FAO), polyglyceryl esters of fatty acids (as used in foods) are formed by reacting polymerized glycerols with edible fats, oils (edible fats and oils are primarily triglycerides), or fatty acids.<sup>8</sup> The degree of polymerization varies, and is specified by a number (such as tri-) that is related to the average number of glycerol residues per polyglycerol molecule.

Polyglyceryl esters of fatty acids also can be prepared by direct esterification between polyolethers and fatty acids at elevated temperatures ( $T > 200^{\circ}\text{C}$ ) with the removal of water.<sup>5,6</sup> The esterification is normally carried out under alkaline conditions and can be stopped by simply adding an acid and lowering the reaction temperature. To obtain a large amount of mono- and diesters, the synthesis is generally carried out with an excess of polyglycerol. Some unreacted polyglycerol can be removed by simple gravimetric settling, and the remaining fraction by extraction with water combined with salts in a charge-wise separation process. Alternatively, polyglyceryl esters can be prepared by an inter-esterification (or transesterification) between polyglycerols and triglycerides; this is a reaction carried out at a high temperature and under conditions similar to direct esterification, but the degree of polymerization is not as high as obtained with direct esterification. Transesterification between polyglycerol and alcohol esters of fatty acids is another possible method of synthesis; using this process, methanol is continuously removed from the reactor, and the process includes a second step to reduce the remaining unreacted oxirane oxygen.

### Composition and Impurities

Joint FAO/WHO Expert Committee on Food Additives (JECFA) specifications for polyglyceryl esters of fatty acids used in foods state “the polyglycerol moiety shall be composed of not less than 70% of di-, tri- and tetraglycerols and shall contain not more than 10% of polyglycerols equal to or higher than heptaglycerol”; that acids other than fatty acids shall not be detectable; and that not more than 2 mg/kg lead is detectable.<sup>8</sup> Minor amounts of mono-, di-, and triglycerides, free glycerol and polyglycerols, free fatty acids, and sodium salts of fatty acids may be present.

Trace amounts of unreacted glycerol and fatty acid soaps can be found in polyglyceryl esters of fatty acids.<sup>6</sup> Specifications, impurities or constituents of some of the ingredients included in this report are provided in Table 7.

### USE

#### Cosmetic

The safety of the cosmetic ingredients included in this safety assessment is evaluated based on data received from the U.S. Food and Drug Administration (FDA) and the cosmetics industry on the expected use of these ingredients in cosmetics. Use frequencies of individual ingredients in cosmetics are collected from manufacturers and reported by cosmetic product category in FDA’s Voluntary Cosmetic Registration Program (VCRP) database. Use concentration data are submitted by Industry in response to surveys, conducted by the Personal Care Products Council (Council), of maximum reported use concentrations by product category.

The safety of the cosmetic ingredients included in this assessment is evaluated on the basis of the expected use in cosmetics, in accordance with data received from the U.S. Food and Drug Administration (FDA) and the cosmetics industry. The data received from the FDA are collected from manufacturers on the use of individual ingredients in cosmetics, by product category. Data from the cosmetic industry were submitted in response to surveys of maximum use concentrations, by product category, conducted by the Personal Care Products Council (Council).

Based on 2015 VCRP data and the results of the Council surveys, 75 of the 275 ingredients included in this report are reported to be in use. According to 2015 VCRP registration data, Polyglyceryl-3 Diisostearate has the most reported uses of the ingredients included in this report; of the 356 reported uses, 350 are in leave-on formulations, 260 of which are in lipsticks<sup>9</sup> (Table 8). Polyglyceryl-4 Isostearate has the second highest number of reported use; of the 269 uses, all but one are in leave-on products. The results of the concentration of use surveys conducted by the Council indicate Polyglyceryl-2 Triisostearate and Polyglyceryl-3 Diisostearate have the highest concentration of use in a leave-on formulation; these ingredients are used at 40% and 39%, respectively<sup>10-14</sup> (Table 8). Additionally, supplier-recommended use concentrations are provided; most of the recommended use levels are  $\leq 10\%$  (Table 9).

Use concentrations were reported for several ingredients that were not reported as used in the VCRP; it should be presumed there is at least one use in every category for which a concentration is reported. Additionally, several ingredients have uses reported in the VCRP, but concentration of use data were not received. The 200 ingredients with no reported uses in both the VCRP and industry survey are listed in Table 10.

Many of these polyglyceryl fatty acid esters are used in products applied to the eye area, products that can result in incidental ingestion, or products that come into contact with mucous membranes. The highest reported concentrations of use for these types of exposures are 24.1% Polyglyceryl-4 Isostearate in “other” eye make-up preparations and 40% Polyglyceryl-2 Triisostearate in lipstick formulations (resulting in incidental ingestion and mucous membrane exposure).<sup>11</sup> A few of the polygly-

ceryl fatty acid esters are reported to be used in baby products; Polyglyceryl-3 Diisostearate has the highest reported use in a baby product, i.e., 2% in baby lotions, oils, and creams.

Additionally, some of the polyglyceryl fatty acid esters are used in cosmetic sprays and could possibly be inhaled; for example, Polyglyceryl-3 Distearate is reported to be used at 3% spray body and hand creams. In practice, 95% to 99% of the droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters  $>10\ \mu\text{m}$ , with propellant sprays yielding a greater fraction of droplets/particles  $<10\ \mu\text{m}$  compared with pump sprays.<sup>15,16</sup> Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and thoracic regions of the respiratory tract and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount.<sup>17,18</sup>

All of the polyglyceryl fatty acids named in this report are listed in the European Union inventory of cosmetic ingredients, and none of the listed ingredients are restricted from use in any way under the rules governing cosmetic products in the European Union.<sup>19</sup> In Australia, according to a National Industrial Chemicals Notification and Assessment Scheme (NICNAS), Polyglyceryl-10 Laurate (~60% pure, with ~40% polyglycerin-10 and ~2% sodium laurate) is not considered to pose an unreasonable risk to public health when used in the proposed manner (i.e.,  $\leq 3\%$  in skin lotions), and cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* or the *Approved Criteria for Classifying Hazardous Substances*.<sup>20</sup>

### Non-Cosmetic

Polyglyceryl esters of fatty acids, up to and including the decaglycerol esters, are permitted as multipurpose direct food additives when (1) they are prepared from corn oil, cottonseed oil, lard, palm oil from fruit, peanut oil, safflower oil, sesame oil, soybean oil, and tallow and the fatty acids derived from these substances (hydrogenated and non-hydrogenated) and/or oleic acid derived from tall oil fatty acids; (2) they are used as emulsifiers in food, in amounts not greater than that required to produce the intended physical or technical effect; (3) polyglyceryl esters of a mixture of stearic, oleic, and coconut fatty acids are used as a cloud inhibitor in vegetable and salad oils when use is not precluded by standards of identity, and oleic acid derived from tall oil fatty acids may be used as a substitute for, or together with, the oleic acid; and (4) polyglyceryl esters of butter oil fatty acids are used as emulsifiers in combination with other approved emulsifiers in dry, whipped topping base, when used at a level not in excess of the amount required to perform their emulsifying effect. [21CFR172.854]

JECFA established an acceptable daily intake (ADI) of 0-25 mg/kg bw for polyglyceryl esters of fatty acids having an average chain length of up to 3 glycerol units,<sup>21</sup> and an ADI of 0-7.5 mg/kg bw for polyglyceryl esters of interesterified ricinoleic acid.<sup>22</sup> In the EU, the esters are listed as food additives at concentrations between 5000 and 10,000 mg/kg in certain foods, and up to 7% free glycerol/polyglycerol is allowed (i.e., 700 mg/kg).<sup>23</sup> Polyglyceryl-10 Caprylate/Caprate<sup>24</sup> and Polyglyceryl-10 Oleate<sup>25</sup> are polysorbate replacers, dispersing agents, and emulsifiers foods.

Polyglyceryl-3 Dioleate is used in human pharmaceutical products and in veterinary products.<sup>26</sup> It is reported to be suitable for hard and soft gelatin capsules, adsorption onto neutral carrier powders for use in tablets, capsule filling and sachets, and use in topical ointments, microemulsions and emulsions.

Polyglyceryl-10 Oleate is used as an internal lubricant for polyvinyl chloride (PVC) sheet and film and as an anti-fog agent in plasticized PVC film formulations.<sup>25</sup>

## TOXICOKINETICS

### Absorption, Distribution, Metabolism, and Excretion (ADME)

#### Oral

Metabolic studies of polyglyceryl esters indicated that these esters are hydrolyzed in the gastrointestinal (GI) tract, and utilization and digestibility studies supported the assumption that the fatty acid moiety is metabolized in the normal manner.<sup>27</sup> Analytical studies have produced no evidence of accumulation of the polyglycerol moiety in body tissues.

Albino Wistar rats were fed a diet containing 5 or 10% polyglyceryl ester; the exact composition of the ester was not provided, but it was stated that the ester was mostly prepared with stearic and oleic acids.<sup>28</sup> Control animals were given untreated feed. The number of animals per group and duration of dosing also was not specified, however some animals were fed the test diet for up to 14 mos, and some were maintained through 3 generations. Feed consumption was determined for 2 males and 2 females per group, and feces were collected for these animals for 24 days. Fecal lipids were increased in the test groups when compared to the controls; however, the researchers stated that at least 95-98% of the polyglyceryl esters were digested.

Similarly, groups of Wistar rats were fed a diet containing 5% polyglyceryl ester prepared with oleic acid or with linseed oil, and feed consumption was measured and feces collected for 2 males and 2 females per group for 24 days.<sup>28</sup> The polyglyceryl esters were almost completely utilized.

Groups of 8 male Sherman rats were fed a restricted diet consisting of 1 g of a polyglyceryl ester in 5 g basic diet/day for 3 wks, followed by 8 wks feeding, *ad libitum*, of a diet containing 8% of the test material.<sup>29</sup> The esters used in the study ranged in size from 2 to 30 glyceryl radicals, with hydrogenated cottonseed oil or peanut oil. Fecal fat excretion, calculated as total lipid extract, absorption, and digestibility values, were determined during the restricted and *ad libitum* feeding periods. The

fecal lipids from rats fed the polyglyceryl hydrogenated cottonseed oil esters were higher in palmitic, stearic, and oleic acids, and lower in linoleic acid, than those fed the polyglyceryl peanut oil esters. Gas-liquid chromatography (GLC) analysis of the fatty acids of the extracted lipids from the epididymal fat pads determined that only triglycerides were present and no appreciable amounts of polyglycerols were deposited.

A study was conducted in which rats were fed a polyglyceryl ester with a high melting point for 8 mos.<sup>30</sup> No residues were detected in depot fat, or in fat of muscle, liver, kidney or spleen. (Details were not provided.)

#### Polyglyceryl Oleates and Decaoleate

The metabolism of Polyglyceryl-3 Oleate, Polyglyceryl-10 Oleate, and Polyglyceryl-10 Decaoleate was investigated in male Sprague-Dawley rats.<sup>31</sup> Groups of 4 rats were dosed with 1% Polyglyceryl-3 [<sup>14</sup>C]Oleate, Polyglyceryl-10 [<sup>14</sup>C]Oleate, [<sup>14</sup>C]Polyglyceryl-10 Oleate, Polyglyceryl-10 [<sup>14</sup>C]Decaoleate, and [<sup>14</sup>C]Polyglyceryl-10 Decaoleate by stomach tube in a liquid diet; the diet contained 7-14  $\mu$ Ci of <sup>14</sup>C. The study also included 2 polyglyceryl esters that are not cosmetic ingredients, but are similar to ingredients reviewed in this report: triglycerol [<sup>14</sup>C]tetraoleate and polyglycerin-10 [<sup>14</sup>C]monoecicosanoate. Catabolism studies were conducted by administering the test diet, collecting expired CO<sub>2</sub>, feces, and urine with the use of metabolism chambers, and collecting GI tract contents and examining the carcass of each animal after 51 h. In additional groups of 4 animals, simultaneous catabolism-absorption studies were conducted by inserting a thoracic duct cannula in each animal, dosing the animals, and then using a metabolism chamber for the collection of lymph, respiratory CO<sub>2</sub>, feces, and urine (each as a single fraction) for 51 h. Lipids were extracted from the lymph of animals dosed with fatty-acid labelled esters to determine whether any intact polyglyceryl esters were present. The metabolism of the esters was also compared to glycerol-1,3-<sup>14</sup>C, [<sup>14</sup>C]polyglycerin-3, and [<sup>14</sup>C]polyglycerin-10.

The disposition of radioactivity following administration of each compound is presented in Table 11. In the catabolism studies, total recovery of the radioactivity ranged from 88-98% of the dose. The distribution of the absorbed [<sup>14</sup>C]Polyglyceryl-10 Oleate and [<sup>14</sup>C]Polyglyceryl-10 Decaoleate was considerably different from that of glycerol. The absorbed polyglyceryls were excreted primarily in the urine (33.5-37%) with less than 4% of the <sup>14</sup>C appearing in the respiratory CO<sub>2</sub> and less than 5.5% in the carcass; ~44.5-46.5% was found in the GI contents. Only small amounts of radioactivity from the [<sup>14</sup>C]oleic acid moiety were recovered in feces (~0.1-0.9%) and GI content (~2.8-4.0%), and the fatty acid appeared to be equally well-absorbed as the polyglyceryl-3 and the polyglyceryl-10 ester. Radioactivity from labeled oleic acid moieties of the esters appeared in expired CO<sub>2</sub> at close to the same rates as that from glycerol; however, recovery of labeled polyglycerin-3 and polyglycerin-10 in expired CO<sub>2</sub> was less than 4% of the dose, with unpolymerized glycerol accounting for most of what was recovered. Radioactivity from the eicosanoic acid-labeled ester was excreted in CO<sub>2</sub> at a lower rate (55.5%) than that for the oleic acid-labeled compounds.

In the catabolism-absorption studies, 83-102% of the radioactivity was recovered. No more than 5% of the glycerol-labeled esters were absorbed via the lymphatic system; however, ~67.5-78.5% of the radioactivity from the oleic acid-labeled polyglyceryl esters was recovered in the lymph, and ~54% was recovered in the lymph of animals given the eicosanoate-labeled polyglyceryl ester. Lipids from the oleate- (and eicosanoate-) labeled compounds contained 97-99% of the total lymph radioactivity.

*In vitro* hydrolysis studies confirmed that the oleic acid ester bond in the polyglyceryl-3 and polyglyceryl-10 esters was readily cleaved. Additionally, it was shown that the eicosanoate bond was cleaved more slowly than the oleate bond. The researchers concluded that the polyglycerols were not catabolized, the ether linkages are inert to normal enzymatic hydrolysis, and the polyglycerols were absorbed and rapidly excreted in the urine without being catabolized.

Groups of 10 male and 10 female Sprague-Dawley rats were fed a diet containing 2.5, 5.0, or 10.0% Polyglyceryl-10 Decaoleate for 90 days, and the control group was fed a diet containing soybean oil as the dietary fat.<sup>32</sup> The percentage of dietary fatty acids absorbed decreased as the levels of Polyglyceryl-10 Decaoleate in the diet increased. Fat absorption by males and females of the 5 and 10% test groups was statistically significantly less than controls at wks 4 and 10, and was statistically significantly decreased in females of the 2.5% group at wk 4 and males of the 2.5% group at wk 10. GLC analysis revealed excretion of oleic acid increased in a dose-related manner, indicating that the absorption of dietary Polyglyceryl-10 Decaoleate was not complete.

### **In Vitro**

#### Polyglyceryl-2 Diisostearate

The metabolism of Polyglyceryl-2 Diisostearate was evaluated using a lipase assay; olive oil was used as a reference substance.<sup>33</sup> Both Polyglyceryl-2 Diisostearate and olive oil increased the fatty acid concentration in all reaction vials in a time dependent manner, and the speed of fatty acid formation was comparable for both substrates. The *in vitro* experimental results support the hypothesis that accumulation of Polyglyceryl-2 Diisostearate in the gut is unlikely.



## Penetration Enhancement

### Polyglyceryl-3 Diisostearate

Polyglyceryl-3 Diisostearate was not a penetration enhancer in a study that evaluated the skin penetration enhancing effects of several excipients on the hydrophilic drug 5-fluorouracil.<sup>34</sup> The ability to enhance skin penetration was determined *in vitro* by measuring skin permeability coefficients for human abdominal skin samples.

### Polyglyceryl-3 Dioleate

Polyglyceryl-3 Dioleate is reported to be a water-in-oil surfactant/solubilizer associated with enhanced drug penetration.<sup>26</sup>

### Polyglyceryl-4 Laurate and Polyglyceryl-4 Oleate

The effect of 2 microemulsions on the rate and extent of release and penetration of ceramide AP was evaluated using an *in vitro*, multi-layer, membrane model with 4 layers of circular 40-mm membrane films arranged one over the other.<sup>35</sup> One test microemulsion, an o/w emulsion, contained 15% Polyglyceryl-4 Laurate, 15% Polyglyceryl-4 Oleate, and 60% water-1,2 pentanediol (1:9); the other, a w/o emulsion, contained 30% Polyglyceryl-4 Laurate, 15% isopropyl palmitate/linoleic acid (5:2), and 55% water-1,2 pentanediol (1.5-8.5). Both test formulations contained 0.4% ceramide AP. A non-ionic hydrophilic cream containing 0.5% ceramide AP was used as a reference formulation. Each test substance, in an amount that contained 50 µg ceramide AP, was spread evenly over a 4 cm<sup>2</sup> area. The formulation was left in place for 15-180 min; the unabsorbed test material was then removed and the ceramide was extracted from the membranes. When compared to the reference cream, the microemulsions increased the rate and extent of penetration of ceramide AP. Within 15 min, a higher percentage of ceramide AP was released from the microemulsions and penetrated into the deeper membrane layers; ceramide AP was not detected in the 3<sup>rd</sup> and 4<sup>th</sup> layers when the reference cream was used. Also, the amount that penetrated into each layer at each time point was greater with the microemulsions than with the cream. The total percent ceramide AP released and penetrated was 93.4% with the microemulsion containing 15% Polyglyceryl-4 Laurate and 15% Polyglyceryl-4 Oleate, 84.2% for the second test formulation, and 73.3% with the reference formulation.

The effect of similar microemulsions and microemulsion gels on the permeation of ceramide NP was evaluated in human thigh skin samples using Franz diffusion cells.<sup>36</sup> Several microemulsions were evaluated; the formulations were composed of 30 or 35% Polyglyceryl-4 Laurate/Polyglyceryl-4 Oleate (1:1), 10-15% isopropyl palmitate/linoleic acid (9:12), 50-60% water/1,2 pentanediol (1.5:8.5), 0.2% ceramide AP, and 0.1% deuterated ceramide NP. The gels were prepared by dispersing 2.5% Carbopol® 940 into the microemulsion. Some of the formulations were o/w, and some were bicontinuous. A hydrophilic cream containing 0.2% deuterated ceramide NP was used as a reference formulation. Twenty mg of each formulation was applied to the skin surface (3.1416 cm<sup>2</sup>) and allowed to permeate for 300 min. After 300 min, the skin surface was wiped and the stratum corneum layer was removed with 10 tape strips over a 2.016 cm<sup>2</sup> area. Subsequently, 3 skin punches were taken and the epidermal layer was removed. Permeation was deeper from the microemulsions, as compared to the cream and the microemulsion gels; additionally, penetration was deeper with the o/w formulations compared to the bicontinuous formulations. Deuterated ceramide NP in the cream did not permeate into the deeper layers of the stratum corneum and other skin layers. Permeation from the gel was shallow due to its high viscosity.

### Polyglyceryl-10 Trioleate

The effect of Polyglyceryl-10 Trioleate on the permeation of tenoxicam (a non-steroidal anti-inflammatory drug) in a propylene glycol solution was examined *in vitro* using dorsal skin from male Hartley strain guinea pigs.<sup>37</sup> The test solution was prepared by suspending 0.3 g tenoxicam in a mixed solution of 3.0 g propylene glycol and 1.5 g Polyglyceryl-10 Trioleate, and the suspension was adjusted to a pH of 6.0. Using a Franz-type diffusion chamber, 1 g of the resulting suspension, which contained 1% tenoxicam, 10% propylene glycol, and 5% Polyglyceryl-10 Trioleate, was applied to the donor skin, and 1.0 ml of the receptor solution was sampled every 3 h for 48 h. The flux of tenoxicam was statistically significantly enhanced by the inclusion of Polyglyceryl-10 Trioleate, from  $8.11 \times 10^{-5}$  µg/s·cm<sup>2</sup> to 28.48 µg/s·cm<sup>2</sup>.

## TOXICOLOGICAL STUDIES

### Acute Toxicity

Acute toxicity studies are summarized in Table 12.<sup>27,33,38-48</sup>

In an acute dermal toxicity study in rats, the LD<sub>50</sub> of 1,2,3-propanetriol, homopolymer, diisooctadecanoate was >5 g/kg. Low toxicity was reported in acute oral studies. In rats, the LD<sub>50</sub> >2 g/kg for Polyglyceryl-3 Caprate, Polyglyceryl-3 Caprylate, Polyglyceryl-4 Caprate, Diisostearoyl Polyglyceryl-3 dimer Dilinoleate, and the LD<sub>50</sub> was >5 g/kg for Polyglyceryl-3 Iso-stearate, Polyglyceryl-3Oleate, Polyglyceryl-2 Diisostearate and Polyglyceryl-3 Diisostearate.

## **Repeated Dose Toxicity**

### **Animal**

#### **Oral**

##### **Polyglyceryl Esters - general**

In rats, repeated oral dosing with 10 g/kg bw polyglyceryl ester daily over 5 days caused no deaths.<sup>27</sup> (No details were provided.)

Groups of 25 male and 25 female mice were fed a diet with 5% polyglyceryl ester for 80 wks.<sup>27</sup> No adverse effects on body weight, feed consumption, hematology values, or survival rate were noted. Carcass fat of the test group showed no polyglycerol residues. The levels of free fatty acids, unsaponifiable material, and the fatty acid composition of carcass fat were the same for the test group compared to a control group fed 5% ground nut oil in the diet. The only differences noted in organ weights were for the liver and kidneys of female mice, which were significantly higher. Microscopic examination of all major organs showed nothing remarkable.

In the ADME study described previously, in which Wistar rats were fed a diet containing 5 or 10% polyglyceryl ester (prepared mostly with stearic and oleic acid), no abnormalities were observed upon microscopic examination of tissues (details not provided).<sup>28</sup>

The feeding of a restricted diet consisting of 1 g of a polyglyceryl ester in 5 g basic diet/day for 3 wks to Sherman rats, followed by 8 wks feeding, *ad libitum*, of a diet containing 8% of the test material (8 males/group; study described in the ADME section) did not result in any microscopic abnormalities in the liver, kidneys, or ileum.<sup>29</sup>

##### **Polyglyceryl Stearate**

Two groups of 4 male albino rats were administered a suspension of 1 g/kg bw/day of polyglyceryl stearate (glyceryl chain length not stated) in an aqueous solution of 0.5% carboxymethylcellulose (CMC) and 0.1% Tween 80 for 10 wks; one group was fed a basic diet, and the other a diet supplemented with 5% hydrogenated fat.<sup>49</sup> Two untreated control groups, one fed a basal diet and one the fat-supplemented diet, were used. Polyglyceryl stearate was not toxic, and it did not have an effect on red blood cell count, white blood cell count, or hemoglobin values.

##### **Polyglyceryl-2 Diisostearate**

In a dietary study, 5 male and 5 female rats per group were given feed containing 0, 0.012, 0.12, or 1.2% Polyglyceryl-2 Diisostearate (for a targeted dose of 0, 10, 100, or 1000 mg/kg/day, respectively) for 28 days, and a control group was given untreated feed.<sup>33</sup> There were no mortalities, clinical signs of toxicity, effects on body weight, clinical pathology, or gross or histopathology alterations that were considered related to the dietary administration of the test substance and/or considered to be of toxicological significance. The no observed adverse effect level (NOAEL) was 845 mg/kg/day in males and 922 mg/kg/day in females, corresponding to the highest dietary concentration tested.

##### **Polyglyceryl-10 Decaoleate**

Groups of 10 male and 10 female Sprague-Dawley rats were fed a diet containing 2.5, 5.0, or 10.0% Polyglyceryl-10 Decaoleate for 90 days, and the control group was fed a diet containing soybean oil as the dietary fat.<sup>32</sup> Urine was collected from each group during wks 3 and 9, total fatty acid absorption was determined in feces collected during wks 4 and 10, and hematological studies were conducted during wks 5 and 11, and at study termination. No test article-related signs of toxicity were observed. Gross and microscopic examination of the testes and ovaries and other organs did not reveal any signs of toxicity or microscopic lesions, and relative and absolute organ weights were unremarkable.

### **Human**

#### **Oral**

##### **Polyglyceryl Esters - general**

For 3 wks, 37 subjects were fed 2-20 g/day polyglyceryl ester in their diet.<sup>27</sup> No abnormalities were detected in the hematology or clinical chemistry values or urinary or fecal parameters that were examined.

## **REPRODUCTIVE AND DEVELOPMENTAL TOXICITY**

#### **Oral**

##### **Polyglyceryl Esters - general**

A test group of 22 rats was fed a diet containing 1.5% polyglycerol for 3 generations.<sup>27</sup> A group of 28 rats was used as a control. The animals were kept for over 1 year without significant variation in fertility or reproductive performance. Gross and microscopic examination of the third generation revealed no consistent abnormality attributable to the test substance. No details were provided.

**Polyglyceryl-3 Diisostearate**

A combined repeated dose oral toxicity study with a reproduction/developmental toxicity screening test (OECD Guideline 422) was conducted in Wistar rats.<sup>38</sup> The animals were dosed once daily by gavage with 0, 100, 300, or 1000 mg/kg bw/day 1,2,3-propanetriol, homopolymer, diisooctadecanoate (n not defined; this substance is most likely Polyglyceryl-3 Diisostearate) in corn oil. Initially, the groups consisted of 12 males and 12 females. However, because a disturbance of the light/dark cycle was believed to cause a reduction in mating rate of the females of the first delivery, additional male and female rats were added in a second delivery for breeding to meet guideline requirements for the number of gravid females per group. The additional animals were used in the entire study as the animals from the first delivery, with the exception that the males of the second delivery were necropsied on day 24 after mating, not on day 16 of mating. Therefore, Polyglyceryl-3 Diisostearate was administered to male rats for up to 28 days (first delivery) and up to 41 days (second delivery) and to female rats for 14 days prior to mating, through the mating and gestation periods, and until the F<sub>1</sub> generation reached day 4 post-partum.

Because an impact caused by the light/dark cycle disturbance could not be excluded (i.e., a prolonged duration of gestation and an increased post-implantation loss at the high dose), the study was repeated with a third delivery with control and high-dose groups under proper light conditions. The test article was administered to 12 male rats/group for 33 days and to 12 female rats/group for 14 days prior to mating, through mating and gestation, and until day 4 post-partum.

Five males and 5 females/group killed at the end of the study were selected for hematology and clinical chemistry examinations, and some additional organs were weighed. The NOEL and NOAEL for systemic effects were  $\geq 300$  mg/kg bw/day and  $\geq 1000$  mg/kg bw/day 1,2,3-propanetriol, homopolymer, diisooctadecanoate, respectively, in both males and females. No adverse effects on body weights and body weight gains, feed consumption, hematology, clinical chemistry, neurobehavior, or gross or microscopic lesions were observed. Statistically significant increases in absolute and relative liver and kidney weights in males and females of the 1000 mg/kg bw/day were not considered to be adverse effects because there was no evidence for an impairment of organ function by clinical pathology and histopathology. Additionally, increases in the absolute and relative heart weights in high-dose females were without histopathological correlation and considered to be incidental.

**GENOTOXICITY**

Genotoxicity studies are summarized in Table 13.<sup>20,33,38-44,46,50-52</sup>

Generally, negative results were obtained in genotoxicity tests. Polyglyceryl-2 Oleate, Polyglyceryl-2 Diisostearate, and 1,2,3-propanetriol, homopolymer, diisooctadecanoate were not genotoxic in the Ames test, mammalian cell gene mutation assay, or chromosomal aberration assay, with or without metabolic activation. Polyglyceryl-3 Caprate, Polyglyceryl-Caprylate, Polyglyceryl-3 Laurate, Polyglyceryl-3 Isostearate, Polyglyceryl-4 Caprate, Polyglyceryl-4 Isostearate, Polyglyceryl-4 Laurate/Succinate, and Diisostearyl Polyglyceryl-3 Dimer Dilinoleate were negative in the Ames test. Polyglyceryl-6 Caprylate/Caprate Polyglyceryl-10 Laurate (~60% pure) gave equivocal results in the absence and positive results in the presence of metabolic activation when tested at concentrations up to 125 and 2250  $\mu$ g/ml, respectively, in a chromosomal aberration assay using Chinese hamster V79 cells, but was not clastogenic in a chromosomal aberration assay in human peripheral lymphocytes, with or without activation.

According to the European Food Safety Authority (EFSA) Panel, the impurities of polyglyceryl fatty acid esters, i.e. free fatty acids and their esters, have no structural alerts for genotoxicity.<sup>23</sup>

**CARCINOGENICITY****Oral**

In a 2-yr study, 28 male and 28 female rats were fed 5% polyglyceryl ester in the diet.<sup>27</sup> No adverse effects on body weight, feed consumption, hematology values, or survival rate were noted. Liver function tests and renal function tests performed at 59 and 104 wks of the study were comparable between the test group and a control group fed 5% ground nut oil. The carcass fat contained no polyglycerol, and the levels of free fatty acid, unsaponifiable residue and fatty acid composition of carcass fat were not different from the controls. Organ weights, tumor incidence and tumor distribution were similar in control and test groups. A complete histological examination of major organs showed nothing remarkable.

**IRRITATION AND SENSITIZATION****Skin Irritation/Sensitization**

Dermal irritation and sensitization studies are summarized in Table 14.<sup>33,38-45,46,50,53-62</sup>

Apricot Kernel Oil Polyglyceryl-4 Esters and Palm Oil Polyglyceryl-4 Esters were classified as non-irritant in the SkinEthic<sup>TM</sup> irritation test, and Polyglyceryl-4 Laurate/Sebacate, Polyglyceryl-4 Laurate/Succinate, and Polyglyceryl-6 Caprylate/Caprate were considered to be non-irritant in the EpiSkin<sup>TM</sup> model for skin irritation.

In rabbits, Polyglyceryl-3 Caprate, a polyglyceryl mono/diester of capric acid (read-across for Polyglyceryl-3 Caprylate), Polyglyceryl-4 Caprate, Polyglyceryl-3 Diisostearate and 1,2,3-propanetriol, homopolymer, diisooctadecanoate were not irritating to the skin. Polyglyceryl-2 Isostearate was mildly irritating, Polyglyceryl-2 Diisostearate was slightly irritating, and Polyglyceryl-3 Isostearate and Polyglyceryl-3 Oleate were moderate irritants in rabbit skin. Polyglyceryl-3 Caprate, Polyglyceryl-3 Caprylate, Polyglyceryl-3 Isostearate, Polyglyceryl-4 Caprate, Polyglyceryl-4 Isostearate, Polyglyceryl-2 Diisostearate, and Polyglyceryl-4 Diisostearate/Polyhydroxystearate/Sebacate (read-across for Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate) were not sensitizers in guinea pig studies. Polyglyceryl-3 Diisostearate was not a sensitizer in guinea pigs in one sensitization study (50% at induction and challenge; 25% at rechallenge), but results were inconclusive in a guinea pig maximization test (0.1% or 0.2% at intradermal induction; 40% at epicutaneous induction; 10 and 15% at challenge; 8 and 4% at rechallenge).

In a clinical study, 7% Polyglyceryl-2 Isostearate elicited slight irritation. In other studies, 10% Polyglyceryl-10 Myristate, 10% Polyglyceryl-10 Stearate, 20% active 1,2,3-propanetriol, homopolymer, diisooctadecanoate, 50% Polyglyceryl-10 Pentaisostearate, a mixture containing 60% Polyglyceryl-10 Eicosanedioate/Tetradecanedioate, and undiluted Polyglyceryl-2 Sesquiisostearate, Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate, and Polyglyceryl-10 Decaoleate were not irritants. Polyglyceryl-3 Laurate and undiluted Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate were not irritants or sensitizers.

### **Ocular Irritation**

Ocular irritation studies are summarized in Table 15.<sup>20,33,36,38-47,58-60,63-67</sup>

Polyglyceryl-3 Laurate, a mixture containing 60% Polyglyceryl-10 Eicosanedioate/Tetradecanedioate, and Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate (10% in corn oil) were classified as non-irritating using an EpiOcular™ tissue model. In the hen's egg test chorioallantoic membrane (HET-CAM) assay, microemulsions containing 30% or 40% Polyglyceryl-4 Laurate, Apricot Kernel Oil Polyglyceryl-4 Esters, Palm Oil Polyglyceryl-4 Esters, and Polyglyceryl-2 Dioleate were classified as non-irritant, and Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate produced minor irritation. Polyglyceryl-4 Laurate/Sebacate, Polyglyceryl-4 Laurate/Succinate, and Polyglyceryl-6 Caprylate/Caprate were considered non-irritant in the SkinEthic™ reconstituted human corneal epithelium model, and Polyglyceryl-10 Myristate, Polyglyceryl-10 Stearate, and Polyglyceryl-10 Diisostearate were non-irritating using the SIRC-neutral red (NR) method.

Polyglyceryl-3 Caprate, a polyglyceryl mono/diester of capric acid (read-across for Polyglyceryl-3 Caprylate), Polyglyceryl-4 Caprate, Polyglyceryl-2 Diisostearate, Polyglyceryl-2 Dioleate, Polyglyceryl-3 Diisostearate, and 1,2,3-propanetriol, homopolymer, diisooctadecanoate were not irritating to rabbit eyes, and Polyglyceryl-3 Isostearate and Polyglyceryl-3 Oleate were slightly irritating to rabbit eyes. Polyglyceryl-10 Laurate (~60% pure) was possibly slightly irritating to the eyes of humans.

### **Case Reports**

A case report described the incidence of recurring pruritic erythema over a 3-mo period in an 80-yr old female.<sup>68</sup> A 48-h closed patch test with the subject's cosmetics was positive (++). Subsequent testing with the individual ingredients was positive (+) with 0.5% aqueous (aq.) Polyglyceryl-10 Laurate, and the irritation caused by this substance was still present in this patient 7 days after exposure. Positive reactions (+) were reported at all concentrations with additional testing of 0.05-1% aq. Polyglyceryl-10 Laurate. After 6 mos, patch tests with 0.1-1% Polyglyceryl-10 Laurate (obtained from several suppliers), as well as to 0.5-1% Polyglyceryl-4 Laurate and Polyglyceryl-6 Laurate, were positive. No reactions were reported with 0.1-1% aq. Polyglyceryl-10 Myristate, Polyglyceryl-10 Isostearate, Polyglyceryl-10 Stearate, and Polyglyceryl-10 Oleate, or with the control test materials.

### **SUMMARY**

This assessment reviews the safety of 275 polyglyceryl fatty acid esters as used in cosmetics. Each of the esters in this group is a polyether comprising 2 to 20 glyceryl residues, end-capped by esterification with simple carboxylic acids, such as fatty acids. Most of these ingredients are reported to function in cosmetics as skin-conditioning agents and/or surfactants.

Seventy-five of the 275 ingredients included in this report are reported to be in use. Polyglyceryl-3 Diisostearate has the most reported uses (356, 260 of which are in lipsticks) of the ingredients included in this report, and Polyglyceryl-4 Isostearate has the second highest number of reported uses (269). Polyglyceryl-2 Triisostearate and Polyglyceryl-3 Diisostearate have the highest concentration of use in a leave-on formulation; these ingredients are used at 40% and 39%, respectively. Many of these polyglyceryl fatty acid esters are used in products applied to the eye area, products that can result in incidental ingestion, or products that come into contact with mucous membranes, and a few of the polyglyceryl fatty acid esters are reported to be used in baby products. Additionally, some of the polyglyceryl fatty acid esters are used in cosmetic sprays and could possibly be inhaled.

Polyglyceryl esters of fatty acids, up to and including the decaglycerol esters, are permitted as multipurpose direct food additives. JECFA established an ADI of 0-25 mg/kg bw for polyglyceryl esters of fatty acids having an average chain length of up to 3 glycerol units, and an ADI of 0-7.5 mg/kg bw for polyglyceryl esters of interesterified ricinoleic acid. In the EU, the esters are listed as food additives at levels between 5000 and 10,000 mg/kg in certain foods, and up to 7% free glycerol/polyglycerol is allowed (i.e., 700 mg/kg).

Polyglyceryl esters are hydrolyzed in the GI tract, and the fatty acid moiety is metabolized in a normal manner. Analytical studies have produced no evidence of accumulation of the polyglycerol moiety in body tissues.

The ability to enhance skin penetration was examined for several of the polyglyceryl fatty acid esters. Polyglyceryl-3 Dioleate is reported to be a water-in-oil surfactant/solubilizer associated with enhanced drug penetration. Polyglyceryl-10 Trioleate enhanced the flux of tenoxicam in an *in vitro* study. Microemulsions containing Polyglyceryl-4 Laurate and Polyglyceryl-4 Oleate increased ceramide permeation into skin.

In an acute dermal toxicity study in rats, the LD<sub>50</sub> of 1,2,3-propanetriol, homopolymer, diisooctadecanoate was >5 g/kg. Low toxicity was reported in acute oral studies. In rats, the LD<sub>50</sub> >2 g/kg for Polyglyceryl-3 Caprate, Polyglyceryl-3 Caprylate, Polyglyceryl-4 Caprate, Diisostearoyl Polyglyceryl-3 dimer Dilinoleate, and the LD<sub>50</sub> was >5 g/kg for Polyglyceryl-3 Isostearate, Polyglyceryl-3 Oleate, Polyglyceryl-2 Diisostearate and Polyglyceryl-3 Diisostearate.

Dietary studies with polyglyceryl ester, polyglyceryl stearate, Polyglyceryl-2 Diisostearate, and Polyglyceryl-10 Decaoate did not produce any remarkable effects. No test-article related adverse effects were observed in multi-generational studies with polyglyceryl esters or 1,2,3-propanetriol, homopolymer, diisooctadecanoate.

Generally, negative results were obtained in genotoxicity tests. Polyglyceryl-2 Oleate, Polyglyceryl-2 Diisostearate, and 1,2,3-propanetriol, homopolymer, diisooctadecanoate were not genotoxic in the Ames test, mammalian cell gene mutation assay, or chromosomal aberration assay, with or without metabolic activation. Polyglyceryl-3 Caprate, Polyglyceryl-3 Caprylate, Polyglyceryl-3 Laurate, Polyglyceryl-3 Isostearate, Polyglyceryl-4 Caprate, Polyglyceryl-4 Isostearate, Polyglyceryl-4 Laurate/Succinate, and Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate were negative in the Ames test. Polyglyceryl-6 Caprylate/Caprate Polyglyceryl-10 Laurate (~60% pure) gave equivocal results in the absence and positive results in the presence of metabolic activation when tested at concentrations up to 125 and 2250 µg/ml, respectively, in a chromosomal aberration assay using Chinese hamster V79 cells, but was not clastogenic in a chromosomal aberration assay in human peripheral lymphocytes, with or without activation. The impurities of polyglyceryl fatty acid esters, i.e. free fatty acids and their esters, have no structural alerts for genotoxicity.

In a 2-yr dietary study in rats, 5% polyglyceryl ester was not carcinogenic and did not produce any adverse effects.

Apricot Kernel Oil Polyglyceryl-4 Esters and Palm Oil Polyglyceryl-4 Esters were classified as non-irritant in the SkinEthic™ irritation test, and Polyglyceryl-4 Laurate/Sebacate, Polyglyceryl-4 Laurate/Succinate, and Polyglyceryl-6 Caprylate/Caprate were considered to be non-irritant in the EpiSkin™ model for skin irritation. In rabbits, Polyglyceryl-3 Caprate, a polyglyceryl mono/diester of capric acid (read-across for Polyglyceryl-3 Caprylate), Polyglyceryl-4 Caprate, Polyglyceryl-3 Diisostearate and 1,2,3-propanetriol, homopolymer, diisooctadecanoate were not irritating to the skin. Polyglyceryl-2 Isostearate was mildly irritating, Polyglyceryl-2 Diisostearate was slightly irritating, and Polyglyceryl-3 Isostearate and Polyglyceryl-3 Oleate were moderate irritants in rabbit skin. Polyglyceryl-3 Caprate, Polyglyceryl-3 Caprylate, Polyglyceryl-3 Isostearate, Polyglyceryl-4 Caprate, Polyglyceryl-4 Isostearate, Polyglyceryl-2 Diisostearate, and Polyglyceryl-4 Diisostearate/Polyhydroxystearate/Sebacate (read-across for Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate) were not sensitizers in guinea pig studies. Polyglyceryl-3 Diisostearate was not a sensitizer in guinea pigs in one sensitization study (50% at induction and challenge; 25% at rechallenge), but results were inconclusive in a guinea pig maximization test (0.1% or 0.2% at intradermal induction; 40% at epicutaneous induction; 10 and 15% at challenge; 8 and 4% at rechallenge).

In a clinical study, 7% Polyglyceryl-2 Isostearate elicited slight irritation. In other studies, 10% Polyglyceryl-10 Myristate, 10% Polyglyceryl-10 Stearate, 20% active 1,2,3-propanetriol, homopolymer, diisooctadecanoate, 50% Polyglyceryl-10 Pentaisostearate, a mixture containing 60% Polyglyceryl-10 Eicosanedioate/Tetradecanedioate, and undiluted Polyglyceryl-2 Sesquiisostearate, Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate, and Polyglyceryl-10 Decaoate were not irritants. Polyglyceryl-3 Laurate and undiluted Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate were not irritants or sensitizers.

Polyglyceryl-3 Laurate, a mixture containing 60% Polyglyceryl-10 Eicosanedioate/Tetradecanedioate, and Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate (10% in corn oil) were classified as non-irritating using an EpiOcular™ tissue model. In the hen's egg test chorioallantoic membrane (HET-CAM) assay, microemulsions containing 30% or 40% Polyglyceryl-4 Laurate, Apricot Kernel Oil Polyglyceryl-4 Esters, Palm Oil Polyglyceryl-4 Esters, and Polyglyceryl-2 Dioleate were classified as non-irritant, and Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate produced minor irritation. Polyglyceryl-4 Laurate/Sebacate, Polyglyceryl-4 Laurate/Succinate, and Polyglyceryl-6 Caprylate/Caprate were considered non-irritant in the SkinEthic™ reconstituted human corneal epithelium model, and Polyglyceryl-10 Myristate, Polyglyceryl-10 Stearate, and Polyglyceryl-10 Diisostearate were non-irritating using the SIRC-neutral red (NR) method.

Polyglyceryl-3 Caprate, a polyglyceryl mono/diester of capric acid (read-across for Polyglyceryl-3 Caprylate), Polyglyceryl-4 Caprate, Polyglyceryl-2 Diisostearate, Polyglyceryl-2 Dioleate, Polyglyceryl-3 Diisostearate, and 1,2,3-propanetriol, homopolymer, diisooctadecanoate were not irritating to rabbit eyes, and Polyglyceryl-3 Isostearate and Polyglyceryl-3 Oleate were slightly irritating to rabbit eyes. Polyglyceryl-10 Laurate (~60% pure) was possibly slightly irritating to the eyes of humans.

## **DISCUSSION**

To be developed.

## **CONCLUSION**

To be determined.

**TABLES****Table 1. Polyglyceryl Fatty Acid Esters – presented alphabetically**

Acacia Decurrens/Jojoba/Sunflower Seed Wax Polyglyceryl 3 Esters	Polyglyceryl-3 Dicocoate
Adansonia Digitata Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Di-Hydroxystearate
Almond Oil/Polyglyceryl-10 Esters	Polyglyceryl-3 Diisostearate
Apricot Kernel Oil Polyglyceryl-3 Esters	Polyglyceryl-3 Dioleate
Apricot Kernel Oil Polyglyceryl-4 Esters	Polyglyceryl-3 Distearate
Apricot Kernel Oil Polyglyceryl-5 Esters	Polyglyceryl-3 Isostearate
Apricot Kernel Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Laurate
Apricot Kernel Oil Polyglyceryl-10 Esters	Polyglyceryl-3 Myristate
Argan Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Oleate
Astrocaryum Vulgare Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Palmitate
Avocado Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Pentacaprylate/Caprates
Babassu Oil Polyglyceryl-4 Esters	Polyglyceryl-3 Pentaolive
Babassu Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Pentaricinoleate
Bertholletia Excelsa Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Rice Branate
Borage Seed Oil Polyglyceryl-4 Esters	Polyglyceryl-3 Ricinoleate
Borage Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Soyate/Shea Butterate
Candelilla/Jojoba/Rice Bran Polyglyceryl-3 Esters	Polyglyceryl-3 Stearate
Caprylic/Capric Glycerides Polyglyceryl-10 Esters	Polyglyceryl-3 Stearate SE
Carapa Guaianensis Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Triisostearate
Castor Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Triolive
Cocoa Butter Polyglyceryl-6 Esters	Polyglyceryl-4 Almond/Shea Butterate
Coconut Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Caprate
Coffee Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Caprylate
Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate	Polyglyceryl-4 Caprylate/Caprates
Glycerol/Polyglyceryl-6 Isostearate/Behenate Esters	Polyglyceryl-4 Cocoate
Hazelnut Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Dilaurate
Linseed Oil Polyglyceryl-4 Esters	Polyglyceryl-4 Distearate
Macadamia Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Hazelnutseedate
Macadamia Seed Oil Polyglyceryl-6 Esters Behenate	Polyglyceryl-4 Isostearate
Mauritia Flexuosa Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Isostearate/Laurate
Olive Oil Polyglyceryl-3 Esters	Polyglyceryl-4 Laurate
Olive Oil Polyglyceryl-4 Esters	Polyglyceryl-4 Laurate/Sebacate
Olive Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Laurate/Succinate
Palm Kernel Oil Polyglyceryl-4 Esters	Polyglyceryl-4 Oleate
Palm Oil Polyglyceryl-3 Esters	Polyglyceryl-4 Pentaoleate
Palm Oil Polyglyceryl-4 Esters	Polyglyceryl-4 Pentapalmitate/Stearate
Palm Oil Polyglyceryl-5 Esters	Polyglyceryl-4 Pentastearate
Palm Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Punicate
Parinari Curatellifolia Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Stearate
Pinus Sibirica Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Sweet Almond
Polyglyceryl-2 Caprate	Polyglyceryl-4 Tristearate
Polyglyceryl-2 Caprylate	Polyglyceryl-5 Caprate
Polyglyceryl-2 Diisostearate	Polyglyceryl-5 Dicaprylate
Polyglyceryl-2 Dioleate	Polyglyceryl-5 Dilaurate
Polyglyceryl-2 Distearate	Polyglyceryl-5 Dioleate
Polyglyceryl-2 Isopalmitate	Polyglyceryl-5 Hexastearate
Polyglyceryl-2 Isopalmitate/Sebacate	Polyglyceryl-5 Isostearate
Polyglyceryl-2 Isostearate	Polyglyceryl-5 Laurate
Polyglyceryl-2 Laurate	Polyglyceryl-5 Myristate
Polyglyceryl-2 Myristate	Polyglyceryl-5 Oleate
Polyglyceryl-2 Oleate	Polyglyceryl-5 Pentamyristate
Polyglyceryl-2 Palmitate	Polyglyceryl-5 Ricinoleate
Polyglyceryl-2 Sesquicaprylate	Polyglyceryl-5 Stearate
Polyglyceryl-2 Sesquiisostearate	Polyglyceryl-5 Tribehenate
Polyglyceryl-2 Sesquiolate	Polyglyceryl-5 Triisostearate
Polyglyceryl-2 Sesquisteate	Polyglyceryl-5 Trimyristate
Polyglyceryl-2 Stearate	Polyglyceryl-5 Trioleate
Polyglyceryl-2 Tetrabehenate/ Macadamiate/Sebacate	Polyglyceryl-5 Tristearate
Polyglyceryl-2 Tetraisostearate	Polyglyceryl-6 Adansonia Digitata Seedate
Polyglyceryl-2 Tetraoleate	Polyglyceryl-6 Apricot Kernelate
Polyglyceryl-2 Tetrastearate	Polyglyceryl-6 Argan Kernelate
Polyglyceryl-2 Triisostearate	Polyglyceryl-6 Behenate
Polyglyceryl-3 Beeswax	Polyglyceryl-6 Caprate
Polyglyceryl-3 Behenate	Polyglyceryl-6 Caprylate
Polyglyceryl-3 Caprate	Polyglyceryl-6 Caprylate/Caprates
Polyglyceryl-3 Caprylate	Polyglyceryl-6 Citrullus Lanatus Seedate
Polyglyceryl-3 Cocoate	Polyglyceryl-6 Dicaprate
Polyglyceryl-3 Dicaprate	Polyglyceryl-6 Diisostearate
Polyglyceryl-3 Dicitrate/Stearate	Polyglyceryl-6 Dioleate

Polyglyceryl-6 Dipalmitate	Polyglyceryl-10 Mono/Dioleate
Polyglyceryl-6 Distearate	Polyglyceryl-10 Myristate
Polyglyceryl-6 Heptacaprylate	Polyglyceryl-10 Nonaerucate
Polyglyceryl-6 Hexaoleate	Polyglyceryl-10 Nonaisostearate
Polyglyceryl-6 Hexastearate	Polyglyceryl-10 Oleate
Polyglyceryl-6 Isostearate	Polyglyceryl-10 Palmate
Polyglyceryl-6 Laurate	Polyglyceryl-10 Palmitate
Polyglyceryl-6 Myristate	Polyglyceryl-10 Pentacaprylate
Polyglyceryl-6 Octacaprylate	Polyglyceryl-10 Pentahydroxystearate
Polyglyceryl-6 Octastearate	Polyglyceryl-10 Pentaisostearate
Polyglyceryl-6 Oleate	Polyglyceryl-10 Pentalaurate
Polyglyceryl-6 Palmitate	Polyglyceryl-10 Pentalinoleate
Polyglyceryl-6 Palmitate/Succinate	Polyglyceryl-10 Pentaoleate
Polyglyceryl-6 Pentacaprylate	Polyglyceryl-10 Pentaricinoleate
Polyglyceryl-6 Pentaoleate	Polyglyceryl-10 Pentastearate
Polyglyceryl-6 Pentaricinoleate	Polyglyceryl-10 Sesquisteate
Polyglyceryl-6 Pentastearate	Polyglyceryl-10 Stearate
Polyglyceryl-6 Ricinoleate	Polyglyceryl-10 Tetradecanedioate
Polyglyceryl-6 Schinziophyton Rautanenii Kernelate	Polyglyceryl-10 Tetralaurate
Polyglyceryl-6 Sclerocarya Birrea Seedate	Polyglyceryl-10 Tetraoleate
Polyglyceryl-6 Sesquicaprylate	Polyglyceryl-10 Tricocoate
Polyglyceryl-6 Sesquiosostearate	Polyglyceryl-10 Tridecanoate
Polyglyceryl-6 Sesquisteate	Polyglyceryl-10 Trierucate
Polyglyceryl-6 Stearate	Polyglyceryl-10 Triisostearate
Polyglyceryl-6 Tetrabehenate	Polyglyceryl-10 Trilaurate
Polyglyceryl-6 Tetracaprylate	Polyglyceryl-10 Trioleate
Polyglyceryl-6 Tetraoleate	Polyglyceryl-10 Tristearate
Polyglyceryl-6 Tricaprylate	Polyglyceryl-10 Undecylenate
Polyglyceryl-6 Trichilia Emetica Seedate	Polyglyceryl-15 Diisostearate
Polyglyceryl-6 Tristearate	Polyglyceryl-20 Docosabehenate/Isostearate
Polyglyceryl-6 Undecylenate	Polyglyceryl-20 Docosabehenate/Laurate
Polyglyceryl-6 Ximenia Americana Seedate	Polyglyceryl-20 Docosabehenate/Oleate
Polyglyceryl-8 C12-20 Acid Ester	Polyglyceryl-20 Heptacaprylate
Polyglyceryl-8 Decabehenate/Caprata	Polyglyceryl-20 Heptadecabehenate/Laurate
Polyglyceryl-8 Decaerucate/Decaisostearate/ Decaricinoleate	Polyglyceryl-20 Hexacaprylate
Polyglyceryl-8 Oleate	Polyglyceryl-20 Octadecabehenate/Laurate
Polyglyceryl-8 Stearate	Polyglyceryl-20 Octaisnonanoate
Polyglyceryl-10 Apricot Kernelate	Pumpkin Seed Oil Polyglyceryl-4 Esters
Polyglyceryl-10 Behenate/Eicosadioate	Pumpkin Seed Oil Polyglyceryl-4 Esters Succinate
Polyglyceryl-10 Caprate	Rice Bran Oil Polyglyceryl-3 Esters
Polyglyceryl-10 Caprylate	Rosa Rubiginosa Seed Oil Polyglyceryl-6 Esters
Polyglyceryl-10 Caprylate/Caprata	Safflower Seed Oil Polyglyceryl-6 Esters
Polyglyceryl-10 Cocoate	Schinziophyton Rautanenii Kernel Oil Polyglyceryl-6 Esters
Polyglyceryl-10 Decaethylhexanoate	Sclerocarya Birrea Seed Oil Polyglyceryl-6 Esters
Polyglyceryl-10 Decahydroxystearate	Sclerocarya Birrea Seed Oil Polyglyceryl-10 Esters
Polyglyceryl-10 Decaisostearate	Sesame Oil Polyglyceryl-6 Esters
Polyglyceryl-10 Decalinoleate	Shea Butter Polyglyceryl-3 Esters
Polyglyceryl-10 Decamacadamiate	Shea Butter Polyglyceryl-4 Esters
Polyglyceryl-10 Decaoleate	Shea Butter Polyglyceryl-6 Esters
Polyglyceryl-10 Decastearate	Soybean Oil Polyglyceryl-6 Esters
Polyglyceryl-10 Dicocoate	Sunflower Seed Oil Polyglyceryl-3 Esters
Polyglyceryl-10 Didecanoate	Sunflower Seed Oil Polyglyceryl-4 Esters
Polyglyceryl-10 Diisostearate	Sunflower Seed Oil Polyglyceryl-5 Esters
Polyglyceryl-10 Dilaurate	Sunflower Seed Oil Polyglyceryl-6 Esters
Polyglyceryl-10 Dimyristate	Sunflower Seed Oil Polyglyceryl-10 Esters
Polyglyceryl-10 Dioleate	Sweet Almond Oil Polyglyceryl-4 Esters
Polyglyceryl-10 Dipalmitate	Sweet Almond Oil Polyglyceryl-6 Esters
Polyglyceryl-10 Distearate	Theobroma Grandiflorum Seed Butter Polyglyceryl-6 Esters
Polyglyceryl-10 Dodecabehenate	Trichilia Emetica Seed Oil Polyglyceryl-6 Esters
Polyglyceryl-10 Dodecacaprata	Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate
Polyglyceryl-10 Dodecacaprylate	Watermelon Seed Oil Polyglyceryl-6 Esters
Polyglyceryl-10 Dodeca-Caprylate/ Caprate	Watermelon Seed Oil Polyglyceryl-10 Esters
Polyglyceryl-10 Eicosanedioate/Tetradecanedioate	Ximenia Americana Seed Oil Polyglyceryl-6 Esters
Polyglyceryl-10 Hepta(Behenate/Stearate)	
Polyglyceryl-10 Heptahydroxystearate	
Polyglyceryl-10 Heptaoleate	
Polyglyceryl-10 Heptastearate	
Polyglyceryl-10 Hexaerucate	
Polyglyceryl-10 Hexaisostearate	
Polyglyceryl-10 Hexaoleate	
Polyglyceryl-10 Hydroxystearate/Stearate/Eicosadioate	
Polyglyceryl-10 Isostearate	
Polyglyceryl-10 Laurate	
Polyglyceryl-10 Linoleate	

---



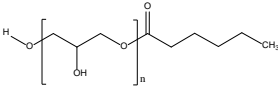
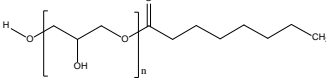
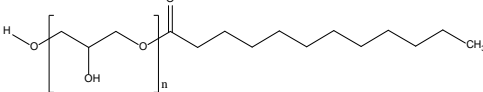
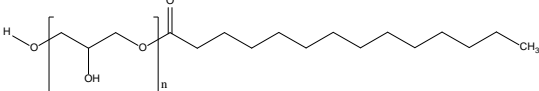
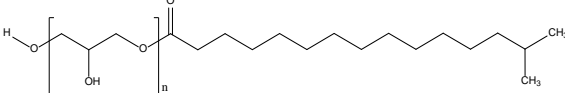
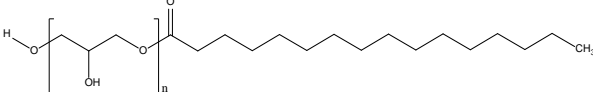
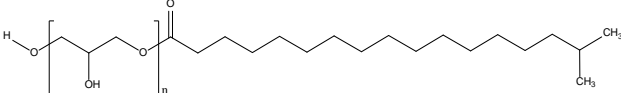
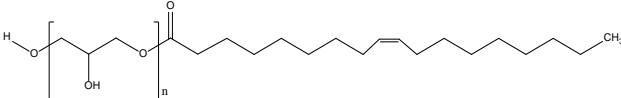
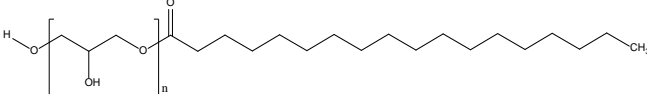
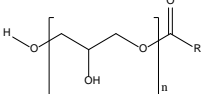
**Table 2. Polyglyceryl Fatty Acid Esters – arranged by polyglyceryl chain length**

Polyglyceryl Monoesters		
<u><i>Polyglyceryl-2 discrete esters</i></u>	<u><i>Polyglyceryl-5 discrete esters</i></u>	<u><i>Polyglyceryl-6 mixed esters (con't)</i></u>
Polyglyceryl-2 Caprate	Polyglyceryl-5 Caprate	Soybean Oil Polyglyceryl-6 Esters
Polyglyceryl-2 Caprylate	Polyglyceryl-5 Laurate	Sunflower Seed Oil Polyglyceryl-6 Esters
Polyglyceryl-2 Laurate	Polyglyceryl-5 Myristate	Sweet Almond Oil Polyglyceryl-6 Esters
Polyglyceryl-2 Myristate	Polyglyceryl-5 Isostearate	Theobroma Grandiflorum Seed Butter
Polyglyceryl-2 Isopalmitate	Polyglyceryl-5 Oleate	Polyglyceryl-6 Esters
Polyglyceryl-2 Palmitate	Polyglyceryl-5 Stearate	Trichilia Emetica Seed Oil Polyglyceryl-6 Esters
Polyglyceryl-2 Isostearate	Polyglyceryl-5 Ricinoleate	Watermelon Seed Oil Polyglyceryl-6 Esters
Polyglyceryl-2 Oleate		Ximenia Americana Seed Oil Polyglyceryl-6 Esters
Polyglyceryl-2 Stearate		
<u><i>Polyglyceryl-2 mixed esters</i></u>	<u><i>Polyglyceryl-5 mixed esters</i></u>	<u><i>Polyglyceryl-8 discrete esters</i></u>
Polyglyceryl-2 Isopalmitate/Sebacate	Apricot Kernel Oil Polyglyceryl-5 Esters	Polyglyceryl-8 Oleate
	Palm Oil Polyglyceryl-5 Esters	Polyglyceryl-8 Stearate
	Sunflower Seed Oil Polyglyceryl-5 Esters	
<u><i>Polyglyceryl-3 discrete esters</i></u>	<u><i>Polyglyceryl-6 discrete esters</i></u>	<u><i>Polyglyceryl-8 mixed esters</i></u>
Polyglyceryl-3 Caprate	Polyglyceryl-6 Caprate	Polyglyceryl-8 C12-20 Acid Ester
Polyglyceryl-3 Caprylate	Polyglyceryl-6 Caprylate	
Polyglyceryl-3 Laurate	Polyglyceryl-6 Undecylenate	<u><i>Polyglyceryl-10 discrete esters</i></u>
Polyglyceryl-3 Myristate	Polyglyceryl-6 Laurate	Polyglyceryl-10 Caprate
Polyglyceryl-3 Palmitate	Polyglyceryl-6 Myristate	Polyglyceryl-10 Caprylate
Polyglyceryl-3 Isostearate	Polyglyceryl-6 Palmitate	Polyglyceryl-10 Undecylenate
Polyglyceryl-3 Oleate	Polyglyceryl-6 Isostearate	Polyglyceryl-10 Laurate
Polyglyceryl-3 Stearate	Polyglyceryl-6 Oleate	Polyglyceryl-10 Myristate
Polyglyceryl-3 Stearate SE	Polyglyceryl-6 Stearate	Polyglyceryl-10 Palmitate
Polyglyceryl-3 Ricinoleate	Polyglyceryl-6 Ricinoleate	Polyglyceryl-10 Isostearate
Polyglyceryl-3 Behenate	Polyglyceryl-6 Behenate	Polyglyceryl-10 Linoleate
		Polyglyceryl-10 Oleate
<u><i>Polyglyceryl-3 mixed esters</i></u>	<u><i>Polyglyceryl-6 mixed esters</i></u>	Polyglyceryl-10 Stearate
Acacia Decurrens/Jojoba/Sunflower Seed Wax	Adansonia Digitata Seed Oil Polyglyceryl-6 Esters	<u><i>Polyglyceryl-10 mixed esters</i></u>
Polyglyceryl 3 Esters	Apricot Kernel Oil Polyglyceryl-6 Esters	Almond Oil/Polyglyceryl-10 Esters
Apricot Kernel Oil Polyglyceryl-3 Esters	Argan Oil Polyglyceryl-6 Esters	Apricot Kernel Oil Polyglyceryl-10 Esters
Candelilla/Jojoba/Rice Bran Polyglyceryl-3 Esters	Astrocaryum Vulgare Oil Polyglyceryl-6 Esters	Caprylic/Capric Glycerides Polyglyceryl-10 Esters
Olive Oil Polyglyceryl-3 Esters	Avocado Oil Polyglyceryl-6 Esters	Polyglyceryl-10 Apricot Kernelate
Palm Oil Polyglyceryl-3 Esters	Babassu Oil Polyglyceryl-6 Esters	Polyglyceryl-10 Behenate/Eicosadioate
Polyglyceryl-3 Beeswax	Bertholletia Excelsa Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-10 Caprylate/Caprata
Polyglyceryl-3 Cocoate	Borage Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-10 Cocoate
Polyglyceryl-3 Rice Branate	Carapa Guaianensis Oil Polyglyceryl-6 Esters	Polyglyceryl-10 Eicosanedioate/Tetradecanedioate
Polyglyceryl-3 Soyate/Shea Butterate	Castor Oil Polyglyceryl-6 Esters	Polyglyceryl-10 Hydroxystearate/Stearate/
Rice Bran Oil Polyglyceryl-3 Esters	Cocoa Butter Polyglyceryl-6 Esters	Eicosadioate
Shea Butter Polyglyceryl-3 Esters	Coconut Oil Polyglyceryl-6 Esters	Polyglyceryl-10 Palmate
Sunflower Seed Oil Polyglyceryl-3 Esters	Coffee Seed Oil Polyglyceryl-6 Esters	Sclerocarya Birrea Seed Oil Polyglyceryl-10 Esters
	Glycerol/Polyglyceryl-6 Isostearate/Behenate Esters	Sunflower Seed Oil Polyglyceryl-10 Esters
<u><i>Polyglyceryl-4 discrete esters</i></u>	Hazelnut Seed Oil Polyglyceryl-6 Esters	Watermelon Seed Oil Polyglyceryl-10 Esters
Polyglyceryl-4 Caprate	Macadamia Seed Oil Polyglyceryl-6 Esters	
Polyglyceryl-4 Caprylate	Mauritia Flexuosa Seed Oil Polyglyceryl-6 Esters	
Polyglyceryl-4 Laurate	Olive Oil Polyglyceryl-6 Esters	
Polyglyceryl-4 Isostearate	Palm Oil Polyglyceryl-6 Esters	
Polyglyceryl-4 Oleate	Parinari Curatellifolia Oil Polyglyceryl-6 Esters	
Polyglyceryl-4 Stearate	Pinus Sibirica Seed Oil Polyglyceryl-6 Esters	
	Polyglyceryl-6 Adansonia Digitata Seedate	
<u><i>Polyglyceryl-4 mixed esters</i></u>	Polyglyceryl-6 Apricot Kernelate	
Apricot Kernel Oil Polyglyceryl-4 Esters	Polyglyceryl-6 Argan Kernelate	
Babassu Oil Polyglyceryl-4 Esters	Polyglyceryl-6 Caprylate/Caprata	
Borage Seed Oil Polyglyceryl-4 Esters	Polyglyceryl-6 Citrullus Lanatus Seedate	
Linseed Oil Polyglyceryl-4 Esters	Polyglyceryl-6 Palmitate/Succinate	
Olive Oil Polyglyceryl-4 Esters	Polyglyceryl-6 Schinziophyton Rautanenii	
Palm Kernel Oil Polyglyceryl-4 Esters	Kernelate	
Palm Oil Polyglyceryl-4 Esters	Polyglyceryl-6 Sclerocarya Birrea Seedate	
Polyglyceryl-4 Almondate/Shea Butterate	Polyglyceryl-6 Trichilia Emetica Seedate	
Polyglyceryl-4 Caprylate/Caprata	Polyglyceryl-6 Ximenia Americana Seedate	
Polyglyceryl-4 Cocoate	Rosa Rubiginosa Seed Oil Polyglyceryl-6 Esters	
Polyglyceryl-4 Hazelnutseedate	Safflower Seed Oil Polyglyceryl-6 Esters	
Polyglyceryl-4 Isostearate/Laurate	Schinziophyton Rautanenii Kernel Oil	
Polyglyceryl-4 Laurate/Sebacate	Polyglyceryl-6 Esters	
Polyglyceryl-4 Laurate/Succinate	Sclerocarya Birrea Seed Oil Polyglyceryl-6 Esters	
Polyglyceryl-4 Punicate	Sesame Oil Polyglyceryl-6 Esters	
Polyglyceryl-4 Sweet Almondate	Shea Butter Polyglyceryl-6 Esters	
Shea Butter Polyglyceryl-4 Esters		
Sunflower Seed Oil Polyglyceryl-4 Esters		
Sweet Almond Oil Polyglyceryl-4 Esters		

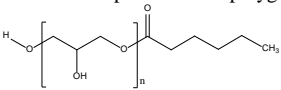
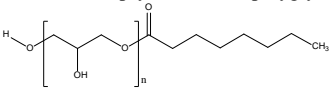
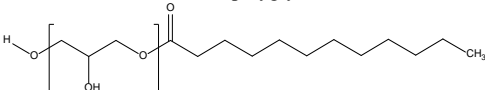
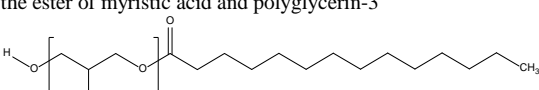
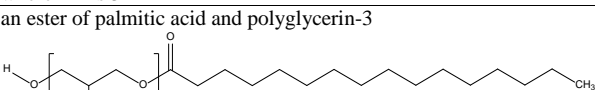
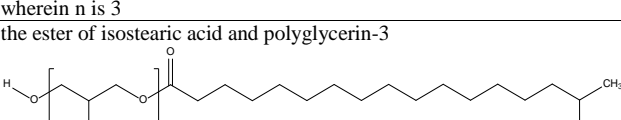
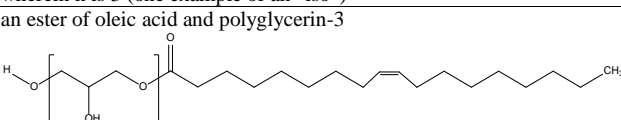
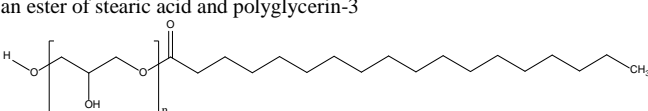
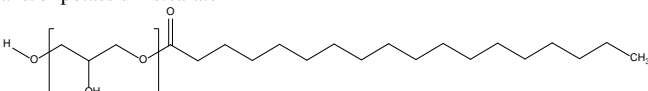
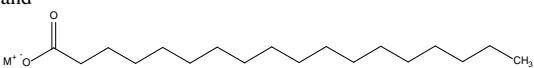
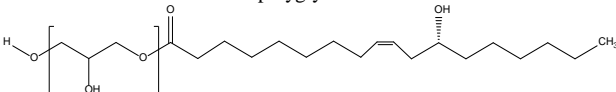
**Table 2. Polyglyceryl Fatty Acid Esters – arranged by polyglyceryl chain length**

Polyglyceryl Multi-esters (i.e., not mono-esters and not “polyesters”)		
<u><i>Polyglyceryl-2 discrete multi-esters</i></u>	<u><i>Polyglyceryl-6 discrete multi-esters</i></u>	<u><i>Polyglyceryl-10 discrete multi-esters (con't)</i></u>
Polyglyceryl-2 Sesquicaprylate	Polyglyceryl-6 Sesquicaprylate	Polyglyceryl-10 Pentaricinoleate
Polyglyceryl-2 Sesquiosostearate	Polyglyceryl-6 Dicaprate	Polyglyceryl-10 Hexaoleate
Polyglyceryl-2 Diisostearate	Polyglyceryl-6 Tricaprylate	Polyglyceryl-10 Heptaoleate
Polyglyceryl-2 Triisostearate	Polyglyceryl-6 Tetracaprylate	Polyglyceryl-10 Decaoleate
Polyglyceryl-2 Tetraisostearate	Polyglyceryl-6 Pentacaprylate	Polyglyceryl-10 Distearate
Polyglyceryl-2 Dioleate	Polyglyceryl-6 Heptacaprylate	Polyglyceryl-10 Tristearate
Polyglyceryl-2 Sesquioleate	Polyglyceryl-6 Octacaprylate	Polyglyceryl-10 Pentastearate
Polyglyceryl-2 Tetraoleate	Polyglyceryl-6 Dipalmitate	Polyglyceryl-10 Pentahydroxystearate
Polyglyceryl-2 Sesquisteate	Polyglyceryl-6 Sesquiosostearate	Polyglyceryl-10 Heptahydroxystearate
Polyglyceryl-2 Distearate	Polyglyceryl-6 Diisostearate	Polyglyceryl-10 Heptastearate
Polyglyceryl-2 Tetrastearate	Polyglyceryl-6 Dioleate	Polyglyceryl-10 Decahydroxystearate
	Polyglyceryl-6 Tetraoleate	Polyglyceryl-10 Decastearate
<u><i>Polyglyceryl-2 mixed multi-esters</i></u>	Polyglyceryl-6 Pentaoleate	Polyglyceryl-10 Dodecabehenate
Polyglyceryl-2 Tetrabehenate/ Macadamiate/Sebacate	Polyglyceryl-6 Hexaoleate	Polyglyceryl-10 Trierucate
	Polyglyceryl-6 Sesquisteate	Polyglyceryl-10 Hexaerucate
	Polyglyceryl-6 Distearate	
<u><i>Polyglyceryl-3 discrete multi-esters</i></u>	Polyglyceryl-6 Tristearate	<u><i>Polyglyceryl-10 mixed multi-esters</i></u>
Polyglyceryl-3 Dicaprate	Polyglyceryl-6 Pentastearate	Polyglyceryl-10 Decamacadamiate
Polyglyceryl-3 Diisostearate	Polyglyceryl-6 Hexastearate	Polyglyceryl-10 Dicoate
Polyglyceryl-3 Triisostearate	Polyglyceryl-6 Octastearate	Polyglyceryl-10 Didecanoate
Polyglyceryl-3 Dioleate	Polyglyceryl-6 Pentaricinoleate	Polyglyceryl-10 Dodeca-Caprylate/ Caprate
Polyglyceryl-3 Distearate	Polyglyceryl-6 Tetrabehenate	Polyglyceryl-10 Hepta(Behenate/Stearate)
Polyglyceryl-3 Di-Hydroxystearate		Polyglyceryl-10 Mono/Dioleate
Polyglyceryl-3 Pentaricinoleate	<u><i>Polyglyceryl-6 mixed multi-ester</i></u>	Polyglyceryl-10 Sesquisteate
	Macadamia Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-10 Tetradecanedioate
	Behenate	Polyglyceryl-10 Tricocoate
<u><i>Polyglyceryl-3 mixed multi-esters</i></u>	<u><i>Polyglyceryl-8 mixed multi-esters</i></u>	<u><i>Polyglyceryl-15 discrete multi-ester</i></u>
Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate	Polyglyceryl-8 Decabehenate/Caprato	Polyglyceryl-15 Diisostearate
Polyglyceryl-3 Dicitrate/Stearate	Polyglyceryl-8 Decaerucate/Decaisostearate/ Decaricinoleate	
Polyglyceryl-3 Dicoate		<u><i>Polyglyceryl-20 discrete multi-esters</i></u>
Polyglyceryl-3 Pentacaprylate/Caprato		Polyglyceryl-20 Hexacaprylate
Polyglyceryl-3 Pentaolive		Polyglyceryl-20 Heptacaprylate
Polyglyceryl-3 Triolive		Polyglyceryl-20 Octaiononanoate
Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate	<u><i>Polyglyceryl-10 discrete multi-esters</i></u>	
	Polyglyceryl-10 Decaethylhexanoate	<u><i>Polyglyceryl-20 mixed multi-esters</i></u>
<u><i>Polyglyceryl-4 discrete multi-esters</i></u>	Polyglyceryl-10 Dodecacaprato	Polyglyceryl-20 Docosabehenate/Isostearate
Polyglyceryl-4 Dilaurate	Polyglyceryl-10 Pentacaprylate	Polyglyceryl-20 Docosabehenate/Laurate
Polyglyceryl-4 Pentaoleate	Polyglyceryl-10 Dodecacaprylate	Polyglyceryl-20 Docosabehenate/Oleate
Polyglyceryl-4 Distearate	Polyglyceryl-10 Tridecanoate	Polyglyceryl-20 Heptadecabehenate/Laurate
Polyglyceryl-4 Tristearate	Polyglyceryl-10 Dilaurate	Polyglyceryl-20 Octadecabehenate/Laurate
Polyglyceryl-4 Pentastearate	Polyglyceryl-10 Trilaurate	
	Polyglyceryl-10 Tetralaurate	
<u><i>Polyglyceryl-4 mixed multi-esters</i></u>	Polyglyceryl-10 Pentalaurate	
Polyglyceryl-4 Pentapalmitate/Stearate	Polyglyceryl-10 Dimyristate	
Pumpkin Seed Oil Polyglyceryl-4 Esters	Polyglyceryl-10 Dipalmitate	
Pumpkin Seed Oil Polyglyceryl-4 Esters Succinate	Polyglyceryl-10 Diisostearate	
	Polyglyceryl-10 Triisostearate	
<u><i>Polyglyceryl-5 discrete multi-esters</i></u>	Polyglyceryl-10 Pentaisostearate	
Polyglyceryl-5 Dicaprylate	Polyglyceryl-10 Hexaisostearate	
Polyglyceryl-5 Dilaurate	Polyglyceryl-10 Nonaisostearate	
Polyglyceryl-5 Trimyristate	Polyglyceryl-10 Decaisostearate	
Polyglyceryl-5 Pentamyristate	Polyglyceryl-10 Pentalinoleate	
Polyglyceryl-5 Triisostearate	Polyglyceryl-10 Decalinoleate	
Polyglyceryl-5 Dioleate	Polyglyceryl-10 Dioleate	
Polyglyceryl-5 Trioleate	Polyglyceryl-10 Trioleate	
Polyglyceryl-5 Tristearate	Polyglyceryl-10 Tetraoleate	
Polyglyceryl-5 Hexastearate	Polyglyceryl-10 Pentaoleate	
Polyglyceryl-5 Tribehenate		

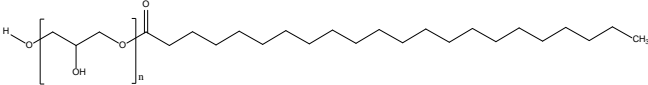
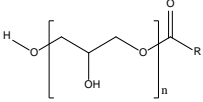
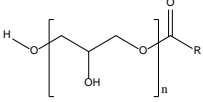
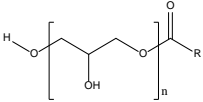
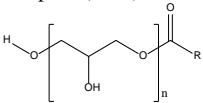
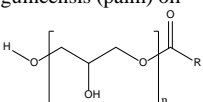
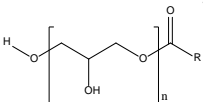
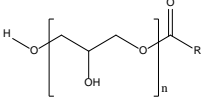
**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

Ingredient CAS No.	Definition & Structure	Function(s)
<b>Polyglyceryl Monoesters</b>		
<i>Polyglyceryl-2 discrete esters</i>		
Polyglyceryl-2 Caprate 156153-06-9	the ester of capric acid and diglycerin  wherein n is 2	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-2 Caprylate	the ester of caprylic acid and diglycerin  wherein n is 2	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-2 Laurate 96499-68-2	the ester of lauric acid and diglycerin  wherein n is 2	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-2 Myristate	the monoester of myristic acid and diglycerol  wherein n is 2	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-2 Isopalmitate	an ester of isopalmitic acid and diglycerin  wherein n is 2 (one example of an "iso")	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-2 Palmitate	the monoester of palmitic acid and diglycerol  wherein n is 2	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-2 Isostearate 73296-86-3 81752-33-2	the ester of isostearic acid and diglycerin  wherein n is 2 (one example of an "iso")	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-2 Oleate 49553-76-6 9007-48-1 (generic)	an ester of oleic acid and diglycerin  wherein n is 2	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-2 Stearate 12694-22-3 9009-32-9 (generic)	the ester of stearic acid and diglycerin  wherein n is 2	skin-conditioning agent - emollient; surfactant - emulsifying agent
<i>Polyglyceryl-2 mixed esters</i>		
Polyglyceryl-2 Isopalmitate/Sebacate	the mixed ester of isopalmitic acid, sebacic acid and diglycerin  wherein RC(O)- represents the residue of isopalmitic or sebacic acid, and n is 2	surfactant - emulsifying agent

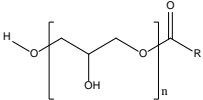
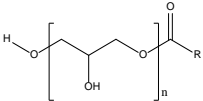
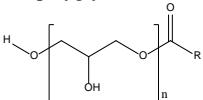
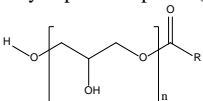
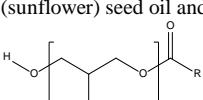
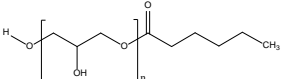
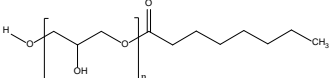
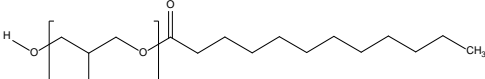
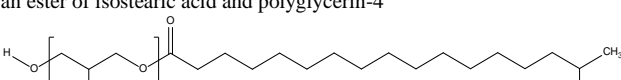
**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

Ingredient CAS No.	Definition & Structure	Function(s)
<i>Polyglyceryl-3 discrete esters</i>		
Polyglyceryl-3 Caprate 133654-02-1 51033-30-8 74504-65-7	an ester of capric acid and polyglycerin-3  wherein n is 3	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-3 Caprylate 108777-93-1	the ester of caprylic acid and polyglycerin-3  wherein n is 3	deodorant agent; surfactants - emulsifying agent
Polyglyceryl-3 Laurate 51033-31-9	the ester of lauric acid and polyglycerin-3  wherein n is 3	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-3 Myristate	the ester of myristic acid and polyglycerin-3  wherein n is 3	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-3 Palmitate	an ester of palmitic acid and polyglycerin-3  wherein n is 3	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-3 Isostearate 127512-63-4	the ester of isostearic acid and polyglycerin-3  wherein n is 3 (one example of an “iso”)	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-3 Oleate 33940-98-6 9007-48-1 (generic)	an ester of oleic acid and polyglycerin-3  wherein n is 3	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-3 Stearate 26855-43-6 27321-72-8 37349-34-1 (generic)	an ester of stearic acid and polyglycerin-3  wherein n is 3	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-3 Stearate SE	a self-emulsifying grade of polyglyceryl-3 stearate that contains some sodium and/or potassium stearate  wherein n is 3 and  wherein M is sodium or potassium	surfactant - emulsifying agent
Polyglyceryl-3 Ricinoleate 29894-35-7 (generic)	an ester of ricinoleic acid and polyglycerin-3  wherein n is 3	skin-conditioning agent - emollient; surfactant - emulsifying agent

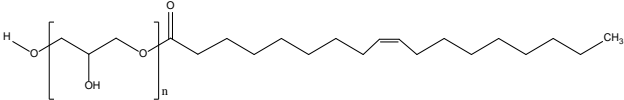
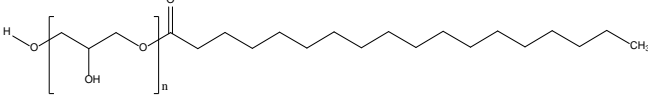
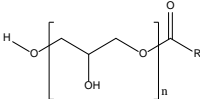
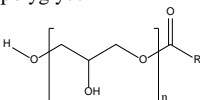
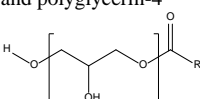
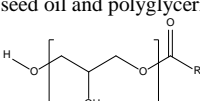
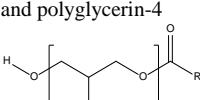
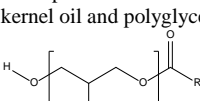
**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-3 Behenate	the ester of behenic acid and polyglycerin-3  wherein n is 3	emulsion stabilizer; slip modifier; surface modifier
<i>Polyglyceryl-3 mixed esters</i>		
Acacia Decurrens/Jojoba/Sunflower Seed Wax Polyglyceryl 3 Esters	the product obtained by the transesterification of polyglycerin-3 with a mixture of acacia decurrens flower wax, simmondsia chinensis (jojoba) seed wax, and helianthus annuus (sunflower) seed wax  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from acacia decurrens flower wax, simmondsia chinensis (jojoba) seed wax, and helianthus annuus (sunflower) seed wax, and n is 3	skin-conditioning agent - emollient
Apricot Kernel Oil Polyglyceryl-3 Esters	the product obtained by the transesterification of prunus armeniaca (apricot) kernel oil and polyglycerin-3  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from prunus armeniaca (apricot) kernel oil, and n is 3	skin-conditioning agent - emollient; surfactant - emulsifying agent
Candelilla/Jojoba/Rice Bran Polyglyceryl-3 Esters	a product obtained by the transesterification of polyglycerin-3 and euphorbia cerifera (candelilla) wax, and simmondsia chinensis (jojoba) seed wax and oryza sativa (rice) bran wax  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from euphorbia cerifera (candelilla) wax, and simmondsia chinensis (jojoba) seed wax and oryza sativa (rice) bran wax, and n is 3	emulsion stabilizer; surfactant - emulsifying agent
Olive Oil Polyglyceryl-3 Esters	the product obtained by the transesterification of polyglycerin-3 and olea europaea (olive) fruit oil  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from olea europaea (olive) fruit oil, and n is 3	surfactant – emulsifying agent
Palm Oil Polyglyceryl-3 Esters	the product obtained by the transesterification of polyglycerin-3 and elaeis guineensis (palm) oil  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from elaeis guineensis (palm) oil, and n is 3	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-3 Beeswax 136097-93-3	an ester of beeswax fatty acids and polyglycerin-3  wherein RC(O)- represents the residue of beeswax fatty acids, and n is 3	surfactant – emulsifying agent
Polyglyceryl-3 Cocoate	the ester of coconut acid and polyglycerin-3  wherein RC(O)- represents the residue of coconut acid, and n is 3	surfactant – emulsifying agent

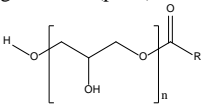
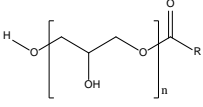
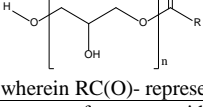
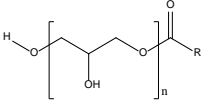
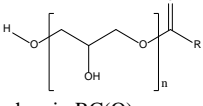
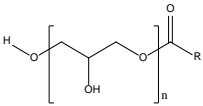
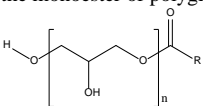
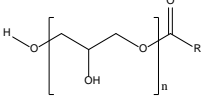
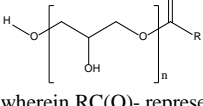
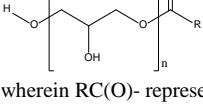
**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-3 Rice Branate	the monoester of polyglycerin-3 and rice bran acid  wherein RC(O)- represents the residue of rice bran acid, and n is 3	surfactant – emulsifying agent
Polyglyceryl-3 Soyate/Shea Butterate	an ester of a mixture of fatty acids derived from glycine soja (soybean) oil and butyrospermum parkii (shea) butter with polyglycerin-3  wherein RC(O)- represents the residue of the fatty acids obtained from glycine soja (soybean) oil and butyrospermum parkii (shea) butter, and n is 3	surfactant – emulsifying agent
Rice Bran Oil Polyglyceryl-3 Esters	the product obtained by the transesterification of oryza sativa (rice) bran oil and polyglycerin-3  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from oryza sativa (rice) bran oil, and n is 3	surfactants - emulsifying agent
Shea Butter Polyglyceryl-3 Esters	the product obtained by the transesterification of polyglycerin-3 and butyrospermum parkii (shea) butter  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from butyrospermum parkii (shea) butter, and n is 3	emulsion stabilizer; hair conditioning agent; skin-conditioning agent – miscellaneous; surfactant - emulsifying agent; viscosity increasing agent - aqueous
Sunflower Seed Oil Polyglyceryl-3 Esters	the product obtained by the transesterification of helianthus annuus (sunflower) seed oil and polyglycerin-3  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from helianthus annuus (sunflower) seed oil, and n is 3	skin-conditioning agent - emollient; surfactant - emulsifying agent
<b>Polyglyceryl-4 discrete esters</b>		
Polyglyceryl-4 Caprate 160391-93-5 74504-65-7	the ester of capric acid and polyglycerin-4  wherein n is 4	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-4 Caprylate	the monoester of caprylic acid and polyglycerin-4  wherein n is 4	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-4 Laurate 75798-42-4; 74504-64-6 (generic);	the ester of lauric acid and polyglycerin-4  wherein n is 4	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-4 Isostearate 63705-03-3 91824-88-3	an ester of isostearic acid and polyglycerin-4  wherein n is 4 (one example of an “iso”)	skin-conditioning agent - emollient; surfactant - emulsifying agent

**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

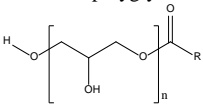
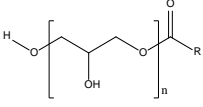
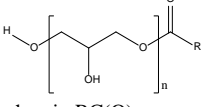
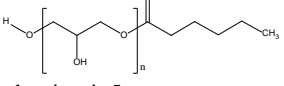
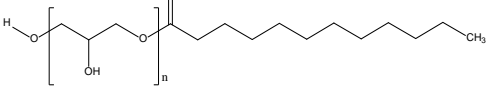
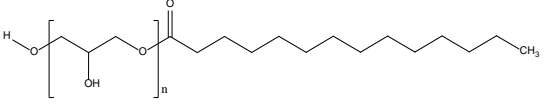
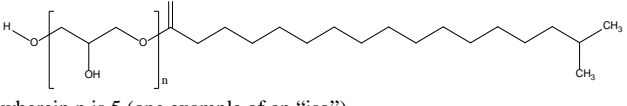
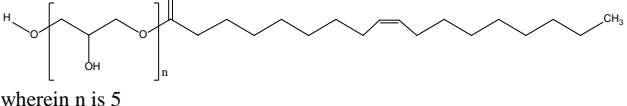
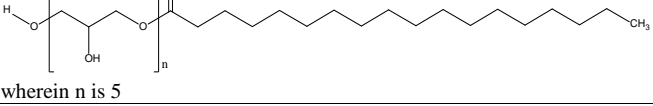
Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-4 Oleate 71012-10-7 9007-48-1 (generic)	<p>an ester of oleic acid and polyglycerin-4</p>  <p>wherein n is 4</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-4 Stearate 26855-44-7 37349-34-1 (generic) 68004-11-5	<p>an ester of stearic acid and polyglycerin-4</p>  <p>wherein n is 4</p>	surfactant - emulsifying agent
<i>Polyglyceryl-4 mixed esters</i>		
Apricot Kernel Oil Polyglyceryl-4 Esters	<p>the product obtained by the transesterification of prunus armeniaca (apricot) kernel oil and polyglycerin-4</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from prunus armeniaca (apricot) kernel oil, and n is 4</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Babassu Oil Polyglyceryl-4 Esters	<p>the product of the transesterification of orbignya oleifera seed oil and polyglycerin-4</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from orbignya oleifera seed oil, and n is 4</p>	surfactant - solubilizing agent
Borage Seed Oil Polyglyceryl-4 Esters	<p>the product obtained by the transesterification of borago officinalis seed oil and polyglycerin-4</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from borago officinalis seed oil, and n is 4</p>	opacifying agent; surfactant - emulsifying agent; surfactant - solubilizing agent
Linseed Oil Polyglyceryl-4 Esters	<p>the product obtained by the transesterification of linum usitatissimum (linseed) seed oil and polyglycerin-4</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from linum usitatissimum (linseed) seed oil, and n is 4</p>	opacifying agent; surfactant - emulsifying agent; surfactant - solubilizing agent
Olive Oil Polyglyceryl-4 Esters	<p>the product obtained by the transesterification of olea europaea (olive) fruit oil and polyglycerin-4</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from olea europaea (olive) fruit oil, and n is 4</p>	surfactant - solubilizing agent
Palm Kernel Oil Polyglyceryl-4 Esters	<p>is the product obtained by the transesterification of elaeis guineensis (palm) kernel oil and polyglycerin-4</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from elaeis guineensis (palm) kernel oil, and n is 4</p>	opacifying agent; surfactant - emulsifying agent; surfactant - solubilizing agent

**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

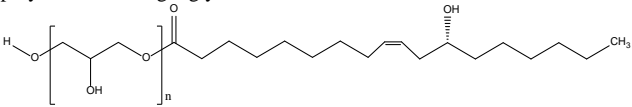
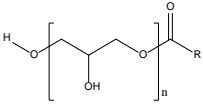
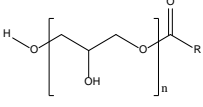
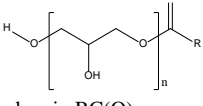
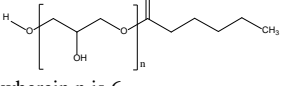
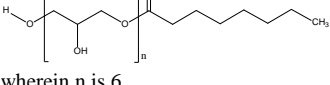
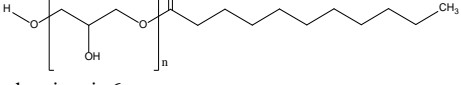
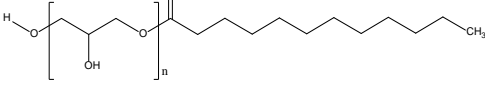
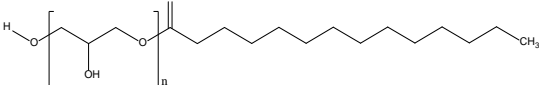
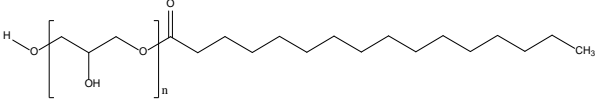
Ingredient CAS No.	Definition & Structure	Function(s)
Palm Oil Polyglyceryl-4 Esters	the product obtained by the transesterification of polyglycerin-4 and elaeis guineensis (palm) oil  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from elaeis guineensis (palm) oil, and n is 4	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-4 Almondate/Shea Butterate	an ester of a mixture of fatty acids derived from almond oil and butyrospermum parkii (shea) butter with polyglycerin-4  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from butyrospermum parkii (shea) butter, and n is 4	surfactant - emulsifying agent
Polyglyceryl-4 Caprylate/Caprates	the monoester of polyglycerin-4 and a mixture of caprylic and capric acids  wherein RC(O)- represents the residue of capric or caprylic acid, and n is 4	surfactant – hydro-trope; surfactant – solubilizing agent
Polyglyceryl-4 Cocoate	an ester of coconut acid and polyglycerin-4  wherein RC(O)- represents the residue of coconut acid, and n is 4	surfactant - emulsifying agent
Polyglyceryl-4 Hazelnutseedate	an ester of the fatty acids derived from corylus avellana (hazelnut) seed oil with polyglycerin-4  wherein RC(O)- represents the residue of the fatty acids derived from corylus avellana (hazelnut) seed oil, and n is 4	surfactant - emulsifying agent
Polyglyceryl-4 Isostearate/Laurate	the ester of a mixture of isostearic and lauric acids with polyglycerin-4  wherein RC(O)- represents the residue of isostearic or lauric acid, and n is 4	dispersing agent - nonsurfactant; emulsion stabilizer; surfactant - emulsifying agent; surfactant - foam booster
Polyglyceryl-4 Laurate/Sebacate	the monoester of polyglycerin-4 and a mixture of lauric and sebacic acids  wherein RC(O)- represents the residue of lauric or sebacic acid, and n is 4	surfactant – hydrotrope; surfactant – solubilizing agent
Polyglyceryl-4 Laurate/Succinate	the monoester of polyglycerin-4 and a mixture of lauric and succinic acids  wherein RC(O)- represents the residue of lauric or succinic acid, and n is 4	surfactant - emulsifying agent
Polyglyceryl-4 Punicate	the ester of polyglycerin-4 and punicic acid  wherein RC(O)- represents the residue of punicic acid, and n is 4	surfactant - emulsifying agent
Polyglyceryl-4 Sweet Almondate	an ester of the fatty acids derived from sweet almond oil and polyglycerin-4  wherein RC(O)- represents the residue of the fatty acids obtained from sweet almond oil, and n is 4	skin-conditioning agent - misc; surfactant - emulsifying agent



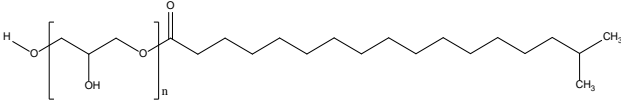
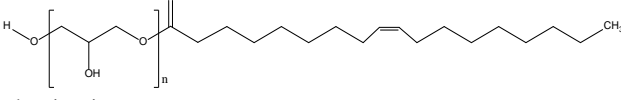
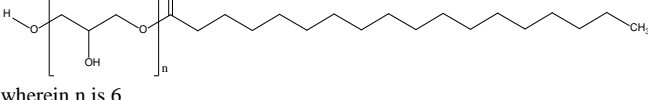
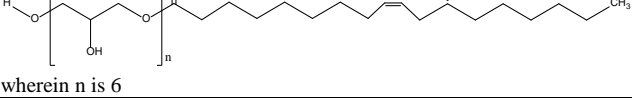
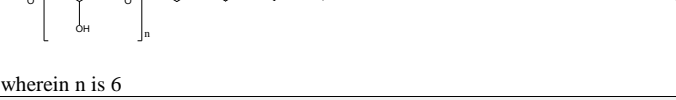
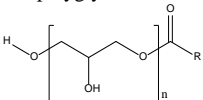
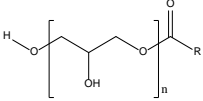
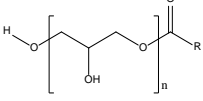
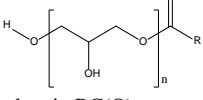
**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

Ingredient CAS No.	Definition & Structure	Function(s)
Shea Butter Polyglyceryl-4 Esters	the product obtained by the transesterification of butyrospermum parkii (shea) butter and polyglycerin-4  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from butyrospermum parkii (shea) butter, and n is 4</p>	emulsion stabilizer; skin-conditioning agent – emollient
Sunflower Seed Oil Polyglyceryl-4 Esters	the product obtained by the transesterification of helianthus annuus (sunflower) seed oil and polyglycerin-4  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from helianthus annuus (sunflower) seed oil, and n is 4</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Sweet Almond Oil Polyglyceryl-4 Esters 1072006-19-9 (generic)	the product obtained by the transesterification of prunus amygdalus dulcis (sweet almond) oil and polyglycerin-4  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from prunus amygdalus dulcis (sweet almond) oil, and n is 4</p>	surfactants - solubilizing agent
<i>Polyglyceryl-5 discrete esters</i>		
Polyglyceryl-5 Caprate	the monoester of capric acid and polyglycerin-5  <p>wherein n is 5</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-5 Laurate 128738-83-0; 74504-64-6 (generic)	the ester of lauric acid and a glycerin polymer containing an average of 5 glycerin units  <p>wherein n is 5</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-5 Myristate	the monoester of myristic acid and a glycerin polymer containing 5 units of glycerin  <p>wherein n is 5</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-5 Isostearate	the ester of isostearic acid and a glycerin polymer containing an average of 5 glycerin units  <p>wherein n is 5 (one example of an “iso”)</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-5 Oleate 86529-98-8 9007-48-1 (generic)	the ester of oleic acid and a glycerin polymer containing an average of 5 glycerin units  <p>wherein n is 5</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-5 Stearate 37349-34-1 (generic)	the monoester of stearic acid and a glycerin polymer containing 5 units of glycerin  <p>wherein n is 5</p>	surfactant - emulsifying agent

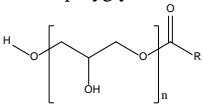
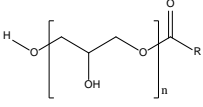
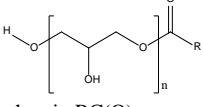
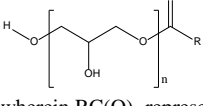
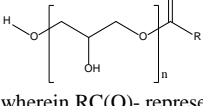
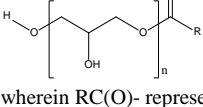
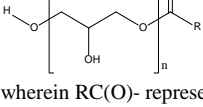
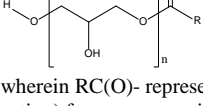
**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-5 Ricinoleate	is the product obtained by the reaction of ricinoleic acid with a glycerin polymer containing 5 glycerin units  wherein n is 5	surfactant - emulsifying agent
<i>Polyglyceryl-5 mixed esters</i>		
Apricot Kernel Oil Polyglyceryl-5 Esters	the product obtained by the transesterification of prunus armeniaca (apricot) kernel oil and polyglycerin-5  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from prunus armeniaca (apricot) kernel oil, and n is 5	skin-conditioning agent - emollient; surfactant - emulsifying agent
Palm Oil Polyglyceryl-5 Esters	the product obtained by the transesterification of a glycerin polymer containing 5 units of glycerin and elaeis guineensis (palm) oil  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from elaeis guineensis (palm) oil, and n is 5	skin-conditioning agent - emollient; surfactant - emulsifying agent
Sunflower Seed Oil Polyglyceryl-5 Esters	the product obtained by the transesterification of helianthus annuus (sunflower) seed oil and a glycerin polymer containing 5 units of glycerin  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from helianthus annuus (sunflower) seed oil, and n is 5	skin-conditioning agent - emollient; surfactant - emulsifying agent
<i>Polyglyceryl-6 discrete esters</i>		
Polyglyceryl-6 Caprate	the monoester of capric acid and polyglycerin-6  wherein n is 6	surfactant - cleansing agent; surfactant - emulsifying agent
Polyglyceryl-6 Caprylate	the monoester of caprylic acid and polyglycerin-6  wherein n is 6	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Undecylenate	an ester of undecylenic acid and polyglycerin-6  wherein n is 6	surfactant - emulsifying agent
Polyglyceryl-6 Laurate 51033-38-6; 74504-64-6 (generic)	the ester of lauric acid and polyglycerin-6  wherein n is 6	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Myristate	the monoester of myristic acid and polyglycerin-6  wherein n is 6	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Palmitate 99734-31-3	the ester of palmitic acid and polyglycerin-6  wherein n is 6	skin-conditioning agent - emollient; surfactant - emulsifying agent

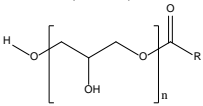
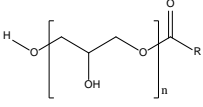
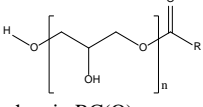
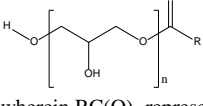
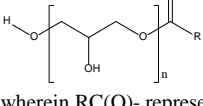
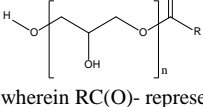
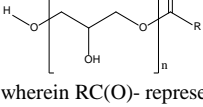
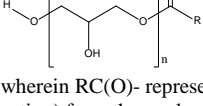
**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-6 Isostearate 126928-07-2	the ester of isostearic acid and polyglycerin-6 	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Oleate 79665-92-2 9007-48-1 (generic)	wherein n is 6 (one example of an “iso”) the ester of oleic acid and polyglycerin-6 	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Stearate 95461-65-7	wherein n is 6 the ester of stearic acid and polyglycerin-6 	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Ricinoleate 107615-51-0	wherein n is 6 the ester of polyglycerin-6 and ricinoleic acid 	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Behenate	wherein n is 6 the monoester of behenic acid and polyglycerin-6 	emulsion stabilizer; slip modifier; surface modifier
<i>Polyglyceryl-6 mixed esters</i>		
Adansonia Digitata Seed Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of adansonia digitata seed oil and polyglycerin-6 	skin-conditioning agent - emollient; surfactant - emulsifying agent
Apricot Kernel Oil Polyglyceryl-6 Esters	wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from adansonia digitata seed oil, and n is 6 the product obtained by the transesterification of prunus armeniaca (apricot) kernel oil and polyglycerin-6 	skin-conditioning agent - emollient; surfactant - emulsifying agent
Argan Oil Polyglyceryl-6 Esters	wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from prunus armeniaca (apricot) kernel oil, and n is 6 the product obtained by the transesterification of argania spinosa kernel oil and polyglycerin-6 	skin-conditioning agent - emollient; surfactant - emulsifying agent
Astrocaryum Vulgare Oil Polyglyceryl-6 Esters	wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from argania spinosa kernel oil, and n is 6 the product obtained by the transesterification of astrocaryum vulgare kernel oil and polyglycerin-6 	skin-conditioning agent - misc; surfactant - emulsifying agent
	wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from astrocaryum vulgare kernel oil, and n is 6	

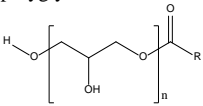
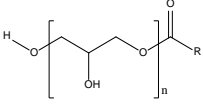
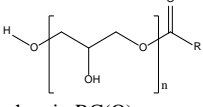
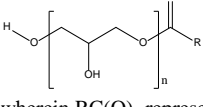
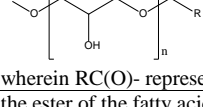
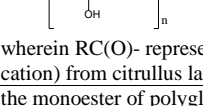
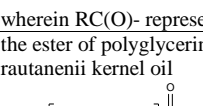
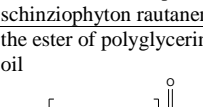
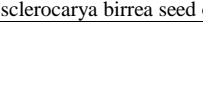
**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

Ingredient CAS No.	Definition & Structure	Function(s)
Avocado Oil Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of persea gratissima (avocado) oil and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from persea gratissima (avocado) oil, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Babassu Oil Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of orbignya oleifera seed oil and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from orbignya oleifera seed oil, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Bertholletia Excelsa Seed Oil Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of bertholletia excelsa seed oil and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from bertholletia excelsa seed oil, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Borage Seed Oil Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of borago officinalis seed oil and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from borago officinalis seed oil, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Carapa Guaianensis Oil Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of carapa guaianensis seed oil and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from carapa guaianensis seed oil, and n is 6</p>	skin-conditioning agent - emollient
Castor Oil Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of ricinus communis (castor) seed oil and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from ricinus communis (castor) seed oil, and n is 6</p>	skin-conditioning agent - emollient; skin conditioning agent – misc; surfactant - emulsifying agent
Cocoa Butter Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of theobroma cacao (cocoa) seed butter and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from theobroma cacao (cocoa) seed butter, and n is 6</p>	skin-conditioning agent - emollient
Coconut Oil Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of cocos nucifera (coconut) oil with polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from cocos nucifera (coconut) oil, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent

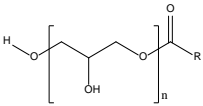
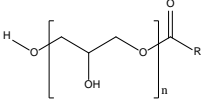
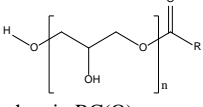
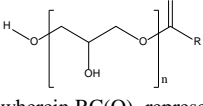
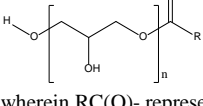
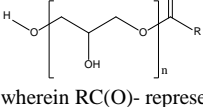
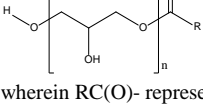
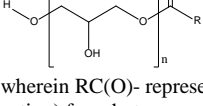
**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

Ingredient CAS No.	Definition & Structure	Function(s)
Coffee Seed Oil Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of polyglycerin-6 and coffea arabica (coffee) seed oil</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from coffea arabica (coffee) seed oil, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Glyceryl/Polyglyceryl-6 Isostearate/Behenate Esters	<p>the mixture of esters formed by the reaction of glycerin and polyglycerin-6 with isostearic acid and behenic acid</p>  <p>wherein RC(O)- represents the residue of isostearic or behenic acid, and n is 1 or 6</p>	skin-conditioning agent - emollient
Hazelnut Seed Oil Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of corylus avellana (hazelnut) seed oil and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from corylus avellana (hazelnut) seed oil, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Macadamia Seed Oil Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of macadamia ternifolia seed oil and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from macadamia ternifolia seed oil, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Mauritia Flexuosa Seed Oil Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of the oil obtained from the seeds of <i>Mauritia flexuosa</i> and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from the seeds of <i>Mauritia flexuosa</i>, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Olive Oil Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of olea europaea (olive) fruit oil and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from olea europaea (olive) fruit oil, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Palm Oil Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of polyglycerin-6 and elaeis guineensis (palm) oil</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from elaeis guineensis (palm) oil, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Parinari Curatellifolia Oil Polyglyceryl-6 Esters	<p>the product of the transesterification of the oil obtained from the seeds of <i>Parinari curatellifolia</i> and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from the seeds of <i>Parinari curatellifolia</i>, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent

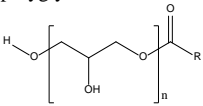
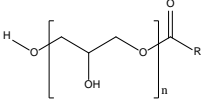
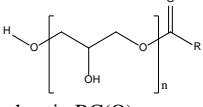
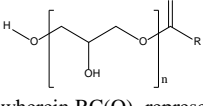
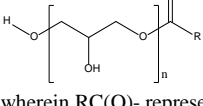
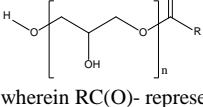
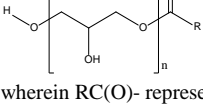
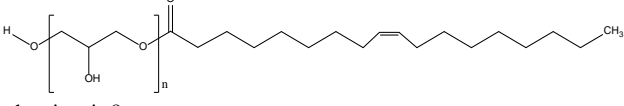
**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

Ingredient CAS No.	Definition & Structure	Function(s)
Pinus Sibirica Seed Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of pinus sibirica seed oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from pinus sibirica seed oil, and n is 6	surfactant - emulsifying agent
Polyglyceryl-6 Adansonia Digitata Seedate	the ester of the fatty acids obtained from adansonia digitata seed oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from adansonia digitata seed oil, and n is 6	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Apricot Kernelate	the ester of the fatty acids derived from prunus armeniaca (apricot) kernel oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from prunus armeniaca (apricot) kernel oil, and n is 6	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Argan Kernelate	the ester of polyglycerin-6 and the fatty acids obtained from argania spinosa kernel oil  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from argania spinosa kernel oil, and n is 6	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Caprylate/Caprates	the monoester of polyglycerin-6 and a mixture of caprylic and capric acids  wherein RC(O)- represents the residue of capric or caprylic acid, and n is 6	surfactant - hydrotrope; surfactant - solubilizing agent
Polyglyceryl-6 Citrullus Lanatus Seedate	the ester of the fatty acids derived from citrullus lanatus (watermelon) seed oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from citrullus lanatus (watermelon) seed oil, and n is 6	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Palmitate/Succinate	the monoester of polyglycerin-6 and a mixture of palmitic and succinic acids  wherein RC(O)- represents the residue of palmitic or succinic acid, and n is 6	surfactant - emulsifying agent
Polyglyceryl-6 Schinziophyton Rautanenii Kernelate	the ester of polyglycerin-6 and the fatty acids obtained from schinziophyton rautanenii kernel oil  wherein RC(O)- represents the residue of the fatty acids obtained from schinziophyton rautanenii kernel oil, and n is 6	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Sclerocarya Birrea Seedate	the ester of polyglycerin-6 and the fatty acids obtained sclerocarya birrea seed oil  wherein RC(O)- represents the residue of the fatty acids obtained from sclerocarya birrea seed oil, and n is 6	skin-conditioning agent - emollient; surfactant - emulsifying agent

**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

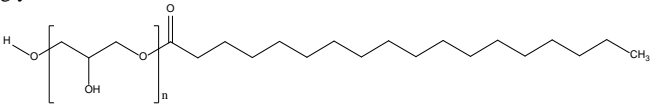
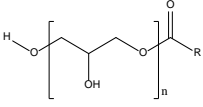
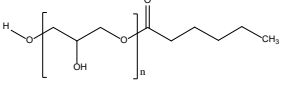
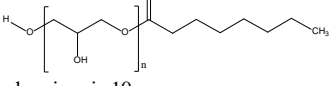
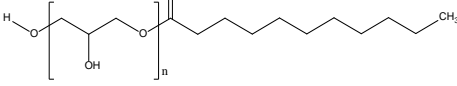
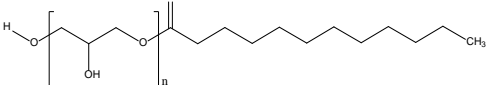
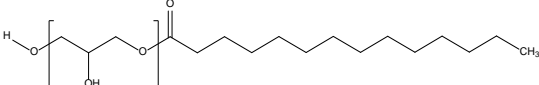
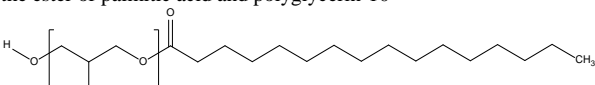
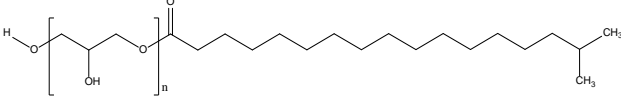
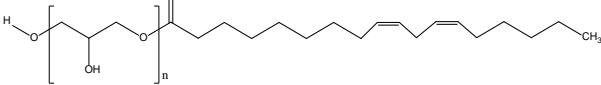
Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-6 Trichilia Emetica Seedate	<p>the ester of polyglycerin-6 and the fatty acids obtained from trichilia emetica seed butter</p>  <p>wherein RC(O)- represents the residue of the fatty acids obtained from trichilia emetica seed butter, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Ximenia Americana Seedate	<p>the ester of polyglycerin-6 and the fatty acids obtained from ximenia americana seed oil</p>  <p>wherein RC(O)- represents the residue of the fatty acids obtained from ximenia americana seed oil, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Rosa Rubiginosa Seed Oil Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of rosa rubiginosa seed oil and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from rosa rubiginosa seed oil, and n is 6</p>	skin-conditioning agent - emollient; skin-conditioning agent - miscellaneous; surfactant - emulsifying agent
Safflower Seed Oil Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of carthamus tinctorius (safflower) seed oil and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from carthamus tinctorius (safflower) seed oil, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Schinziophyton Rautanenii Kernel Oil Polyglyceryl-6 Esters	<p>the product formed by the transesterification of schinziophyton rautanenii kernel oil and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from schinziophyton rautanenii kernel oil, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Sclerocarya Birrea Seed Oil Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of sclerocarya birrea seed oil with polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from sclerocarya birrea seed oil, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Sesame Oil Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of sesamum indicum (sesame) oil and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from sesamum indicum (sesame) oil, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Shea Butter Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of butyrospermum parkii (shea) butter and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from butyrospermum parkii (shea) butter, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent

**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

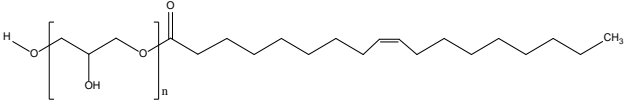
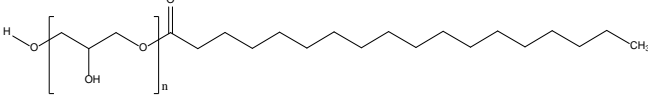
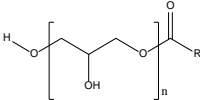
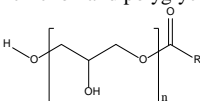
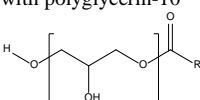
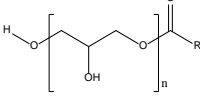
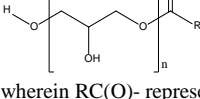
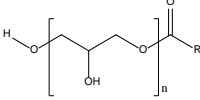
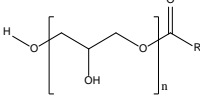
<b>Ingredient CAS No.</b>	<b>Definition &amp; Structure</b>	<b>Function(s)</b>
Soybean Oil Polyglyceryl-6 Esters	<p>the product of the transesterification of glycine soja (soybean) oil and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from glycine soja (soybean) oil, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Sunflower Seed Oil Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of helianthus annuus (sunflower) seed oil and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from helianthus annuus (sunflower) seed oil, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Sweet Almond Oil Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of prunus amygdalus dulcis (sweet almond) oil and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from prunus amygdalus dulcis (sweet almond) oil, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Theobroma Grandiflorum Seed Butter Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of theobroma grandiflorum seed butter and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from theobroma grandiflorum seed butter, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Trichilia Emetica Seed Oil Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of trichilia emetica seed butter and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from trichilia emetica seed butter, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Watermelon Seed Oil Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of citrullus lanatus (watermelon) seed oil with polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from citrullus lanatus (watermelon) seed oil, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Ximenia Americana Seed Oil Polyglyceryl-6 Esters	<p>the product obtained by the transesterification of ximenia americana seed oil and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from ximenia americana seed oil, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
<b>Polyglyceryl-8 discrete esters</b>		
Polyglyceryl-8 Oleate 75719-56-1 9007-48-1 (generic)	<p>an ester of oleic acid and a glycerin polymer containing an average of 8 glycerin units</p>  <p>wherein n is 8</p>	skin-conditioning agent - misc.; surfactant - emulsifying agent



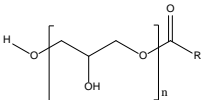
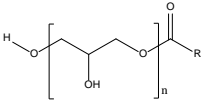
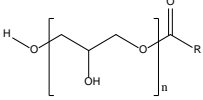
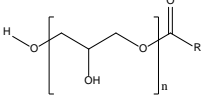
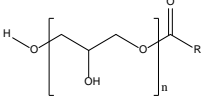
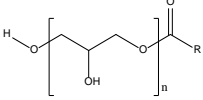
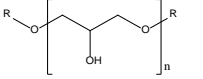
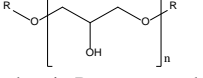
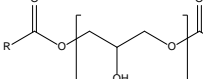
**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-8 Stearate 37349-34-1 (generic) 75719-57-2	an ester of stearic acid and a glycerin polymer containing an average of 8 glycerin units  wherein n is 8	surfactant - emulsifying agent
<i>Polyglyceryl-8 mixed esters</i>		
Polyglyceryl-8 C12-20 Acid Ester	the ester of a glycerin polymer containing 8 units of glycerin and a synthetic mixture of saturated acids containing 12 to 20 carbons in the alkyl chain  wherein RC(O)- represents the residue of a fatty acid containing 12 to 20 carbons in the alkyl chain, and n is 8	surfactant - emulsifying agent
<i>Polyglyceryl-10 discrete esters</i>		
Polyglyceryl-10 Caprate	the ester of capric acid and polyglycerin-10  wherein n is 10	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Caprylate 51033-41-1	the monoester of caprylic acid and polyglycerin-10  wherein n is 10	surfactant - emulsifying agent
Polyglyceryl-10 Undecylenate	an ester of Undecylenic Acid and polyglycerin-10  wherein n is 10	surfactant - emulsifying agent
Polyglyceryl-10 Laurate 34406-66-1 74504-64-6 (generic)	an ester of lauric acid and polyglycerin-10  wherein n is 10	skin-conditioning agent - misc; surfactant - emulsifying agent
Polyglyceryl-10 Myristate 87390-32-7	an ester of myristic acid and polyglycerin-10  wherein n is 10	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Palmitate 79777-31-4	the ester of palmitic acid and polyglycerin-10  wherein n is 10	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Isostearate 133738-23-5	the ester of isostearic acid and polyglycerin-10  wherein n is 10 (one example of an "iso")	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Linoleate	the monoester of linoleic acid and polyglycerin-10  wherein n is 10	skin-conditioning agent - emollient; surfactant - emulsifying agent

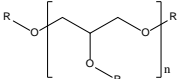
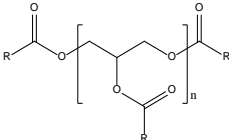
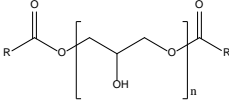
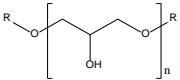
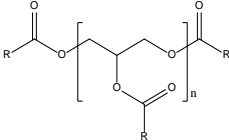
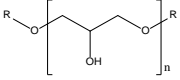
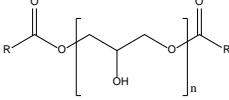
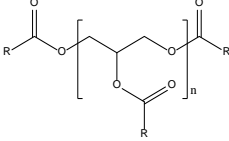
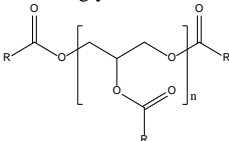
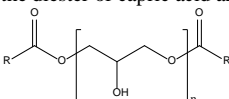
**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-10 Oleate 79665-93-3 9007-48-1 (generic)	an ester of oleic acid and polyglycerin-10  <p>wherein n is 10</p>	skin-conditioning agent - misc; surfactant - emulsifying agent
Polyglyceryl-10 Stearate 79777-30-3 9009-32-9 (generic)	an ester of stearic acid and polyglycerin-10  <p>wherein n is 10</p>	skin-conditioning agent - misc; surfactant - emulsifying agent
<i>Polyglyceryl-10 mixed esters</i>		
Almond Oil/Polyglyceryl-10 Esters	the product obtained by the transesterification of prunus amygdalus dulcis (sweet almond) oil and polyglycerin-10  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from prunus amygdalus dulcis (sweet almond) oil, and n is 10</p>	surfactant - emulsifying agent
Apricot Kernel Oil Polyglyceryl-10 Esters	the product obtained by the transesterification of prunus armeniaca (apricot) kernel oil and polyglycerin-10  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from prunus armeniaca (apricot) kernel oil, and n is 10</p>	skin-conditioning agent - emollient; surfactant – emulsifying agent
Caprylic/Capric Glycerides Polyglyceryl-10 Esters	the product obtained by the transesterification of caprylic/capric glycerides with polyglycerin-10  <p>wherein RC(O)- represents the residue of caprylic or capric acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant – emulsifying agent; surfactant – solubilizing agent
Polyglyceryl-10 Apricot Kernelate	the ester of the fatty acids derived from prunus armeniaca (apricot) kernel oil and polyglycerin-10  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from prunus armeniaca (apricot) kernel oil, and n is 10</p>	skin-conditioning agent - emollient; skin-conditioning agent – miscellaneous; surfactant - emulsifying agent
Polyglyceryl-10 Behenate/Eicosadioate	the monoester of polyglycerin-10 and a blend of behenic and eicosadioic acids  <p>wherein RC(O)- represents the residue of behenic or eicosadioic acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Caprylate/Caprate	the monoester of polyglycerin-10 and a blend of caprylic and capric acids  <p>wherein RC(O)- represents the residue of capric or caprylic acid, and n is 10</p>	emulsion stabilizer; solvent; surfactant – emulsifying agent
Polyglyceryl-10 Cocoate	the ester of coconut acid and polyglycerin-10  <p>wherein RC(O)- represents the residue of coconut acid, and n is 10</p>	surfactant-cleansing agent; surfactant-emulsifying agent

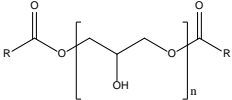
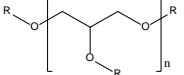
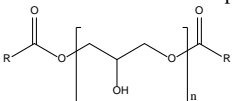
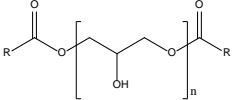
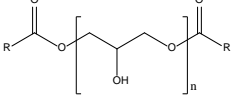
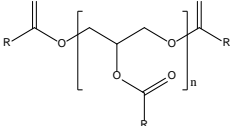
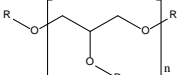
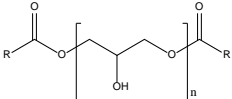
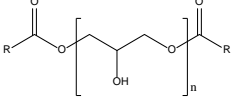
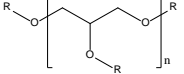
**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-10 Eicosanedioate/Tetradecanedioate	the ester of polyglycerin-10 with a mixture of eicosanedioic and tetradecanedioic acids  wherein RC(O)- represents the residue of eicosanedioic or tetradecanedioic acid, and n is 10	hair conditioning agent; skin conditioning agent - occlusive
Polyglyceryl-10 Hydroxystearate/Stearate/Eicosadioate	the monoester of polyglycerin-10 with a blend of hydroxystearic, stearic and eicosandioic acids  wherein RC(O)- represents the residue of hydroxystearic, stearic and eicosandioic acids, and n is 10	skin-conditioning agent - emollient
Polyglyceryl-10 Palmate	the ester of palm acid and polyglycerin-10  wherein RC(O)- represents the residue of palm acid, and n is 10	skin-conditioning agent - misc; surfactant - emulsifying agent
Sclerocarya Birrea Seed Oil Polyglyceryl-10 Esters	the product obtained by the transesterification of sclerocarya birrea seed oil with polyglycerin-10  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from sclerocarya birrea seed oil, and n is 10	skin-conditioning agent - emollient; surfactant - emulsifying agent
Sunflower Seed Oil Polyglyceryl-10 Esters	the product obtained by the transesterification of helianthus annuus (sunflower) seed oil and polyglycerin-10  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from helianthus annuus (sunflower) seed oil, and n is 10	skin-conditioning agent - emollient; surfactant - emulsifying agent
Watermelon Seed Oil Polyglyceryl-10 Esters	the product obtained by the transesterification of citrullus lanatus (watermelon) seed oil with polyglycerin-10  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from citrullus lanatus (watermelon) seed oil, and n is 10	skin-conditioning agent - emollient; surfactant - emulsifying agent
<b>Polyglyceryl Multi-esters (i.e., not mono-esters and not “polyesters”)</b>		
<i>Polyglyceryl-2 discrete multi-esters</i>		
Polyglyceryl-2 Sesquicaprylate	a mixture of mono- and diesters of caprylic acid and diglycerin  wherein R- represents hydrogen or the residue of caprylic acid, and n is 2	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-2 Sesquiisostearate 170211-20-8	a mixture of mono and diesters of isostearic acid and diglycerin  wherein R- represents hydrogen or the residue of isostearic acid, and n is 2	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-2 Diisostearate 63705-03-3 (generic) 67938-21-0	the diester of isostearic acid and diglycerin  wherein RC(O)- represents the residue of isostearic acid, and n is 2	skin-conditioning agent - emollient; surfactant - emulsifying agent

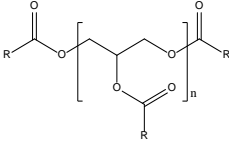
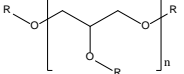
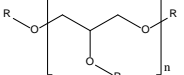
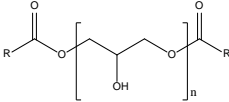
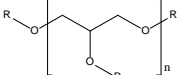
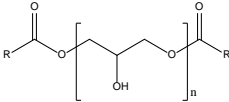
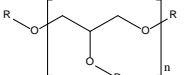
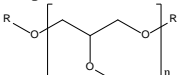
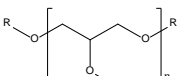
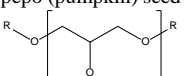
**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-2 Triisostearate 120486-24-0	the triester of isostearic acid and diglycerin 	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-2 Tetraisostearate 121440-30-0	wherein R- represents hydrogen or the residue of isostearic acid, and n is 2 the tetraester of isostearic acid and a dimer of glycerin 	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-2 Dioleate 60219-68-3 67965-56-4	wherein RC(O)- represents the residue of isostearic acid, and n is 2 a diester of oleic acid and diglycerin 	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-2 Sesquioleate	wherein RC(O)- represents the residue of oleic acid, and n is 2 a mixture of mono and diesters of oleic acid and diglycerin 	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-2 Tetraoleate	wherein R- represents hydrogen or the residue of oleic acid, and n is 2 the tetraester of oleic acid and diglycerin 	skin-conditioning agent - misc; surfactant - emulsifying agent
Polyglyceryl-2 Sesquistearate 9009-32-9 (generic)	wherein RC(O)- represents the residue of oleic acid, and n is 2 a mixture of mono- and diesters of stearic acid and diglycerin 	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-2 Distearate 61725-93-7 9009-32-9 (generic)	wherein R- represents hydrogen or the residue of stearate acid, and n is 2 the diester of stearic acid and diglycerin 	surfactant - emulsifying agent
Polyglyceryl-2 Tetrastearate 72347-89-8 9009-32-9 (generic)	wherein RC(O)- represents the residue of stearic acid, and n is 2 the tetraester of stearic acid and diglycerin 	skin-conditioning agent - emollient; surfactant - emulsifying agent
<i>Polyglyceryl-2 mixed multi-esters</i>		
Polyglyceryl-2 Tetra behenate/ Macadamiate/Sebacate	the tetraester of a mixture of behenic, sebacic and macadamia acids with a dimer of glycerin 	skin-conditioning agent - emollient
<i>Polyglyceryl-3 discrete multi-esters</i>		
Polyglyceryl-3 Dicaprate	the diester of capric acid and polyglycerin-3 	skin-conditioning agent - emollient; surfactant - emulsifying agent
wherein RC(O)- represents the residue of capric acid, and n is 3		

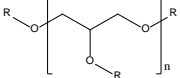
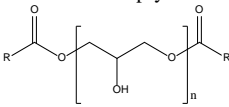
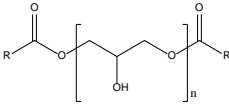
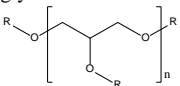
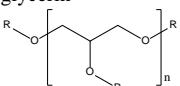
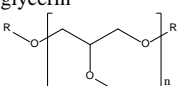
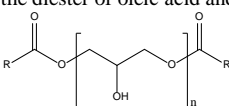
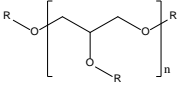
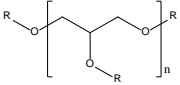
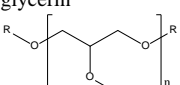
**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-3 Diisostearate 63705-03-3 (generic) 66082-42-6	a diester of isostearic acid and polyglycerin-3  <p>wherein RC(O)- represents the residue of isostearic acid, and n is 3</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-3 Triisostearate 66082-43-7	the triester of isostearic acid and polyglycerin-3  <p>wherein R- represents hydrogen or the residue of isostearic acid, and n is 3</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-3 Dioleate 79665-94-4	a diester of oleic acid and polyglycerin-3  <p>wherein RC(O)- represents the residue of oleic acid, and n is 3</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-3 Distearate 94423-19-5 9009-32-9 (generic) 61725-93-7 (generic)	the diester of stearic acid and polyglycerin-3  <p>wherein RC(O)- represents the residue of stearic acid, and n is 3</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-3 Di-Hydroxystearate	the diester of hydroxystearic acid and polyglycerin-3  <p>wherein RC(O)- represents the residue of hydroxystearic acid, and n is 3</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-3 Pentaricinoleate	the pentaester of ricinoleic acid and polyglycerin-3  <p>wherein RC(O)- represents the residue of ricinoleic acid, and n is 3</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
<i>Polyglyceryl-3 mixed multi-esters</i>		
Diisostearyl Polyglyceryl-3 Dimer Dilinoleate	the diester of dilinoleic acid and Polyglyceryl-3 Diisostearate  <p>wherein R- represents the residue of isostearic acid or dilinoleic acid, and n is 3</p>	skin-conditioning agent - emollient
Polyglyceryl-3 Dicitrate/Stearate	the diester of polyglycerin-3 with a mixture of citric acid and stearic acid  <p>wherein RC(O)- represents the residue of citric or stearic acid, and n is 3</p>	surfactant - emulsifying agent
Polyglyceryl-3 Dicocoate	the diester of coconut acid and polyglycerin-3  <p>wherein RC(O)- represents the residue of coconut acid, and n is 3</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-3 Pentacaprylate/Caprate	the pentaester of a mixture of caprylic acid and capric acid with polyglycerin-3  <p>wherein R- represents hydrogen or the residue of capric or caprylic acid, and n is 3</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent; surfactant – solubilizing agent

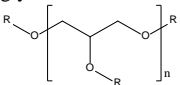
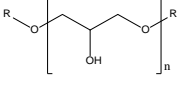
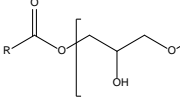
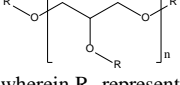
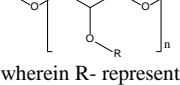
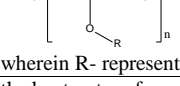
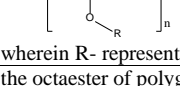
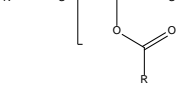
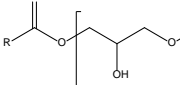
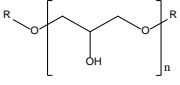
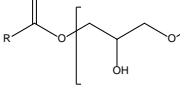
**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-3 Pentaolivate	<p>is the pentaester of polyglycerin-3 and olive acid</p>  <p>wherein RC(O)- represents the residue of olive acid, and n is 3</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-3 Triolivate	<p>the triester of polyglycerin-3 and olive acid</p>  <p>wherein R- represents hydrogen or the residue of olive acid, and n is 3</p>	surfactant - emulsifying agent
Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate	<p>the diester of dilinoleic acid and polyglyceryl-3 triisostearate</p>  <p>wherein R- represents the residue of isostearic acid or dilinoleic acid, and n is 3</p>	skin-conditioning agent - emollient
<i>Polyglyceryl-4 discrete multi-esters</i>		
Polyglyceryl-4 Dilaurate	<p>the diester of lauric acid and polyglycerin-4</p>  <p>wherein RC(O)- represents the residue of lauric acid, and n is 4</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-4 Pentaoleate 103230-29-1	<p>the pentaester of oleic acid and polyglycerin-4</p>  <p>wherein R- represents hydrogen or the residue of oleic acid, and n is 4</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-4 Distearate	<p>a diester of polyglycerin-4 with stearic acid</p>  <p>wherein RC(O)- represents the residue of stearic acid, and n is 4</p>	surfactant - emulsifying agent
Polyglyceryl-4 Tristearate 99734-29-9	<p>the triester of stearic acid and polyglycerin-4</p>  <p>wherein R- represents hydrogen or the residue of stearic acid, and n is 4</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-4 Pentastearate 99570-00-0	<p>the pentaester of stearic acid and polyglycerin-4</p>  <p>wherein R- represents hydrogen or the residue of stearic acid, and n is 4</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
<i>Polyglyceryl-4 mixed multi-esters</i>		
Polyglyceryl-4 Pentapalmitate/Stearate	<p>the pentaester of a mixture of palmitic acid and stearic acid with polyglycerin-4</p>  <p>wherein R- represents hydrogen or the residue of palmitic or stearic acid, and n is 4</p>	surfactant - emulsifying agent
Pumpkin Seed Oil Polyglyceryl-4 Esters	<p>the complex mixture of esters formed by the transesterification of cucurbita pepo (pumpkin) seed oil and polyglycerin-4</p>  <p>wherein R- represents hydrogen or the residue of the fatty acids derived from cucurbita pepo (pumpkin) seed oil (via transesterification), and n is 4</p>	emulsion stabilizer; surfactant - emulsifying agent

**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

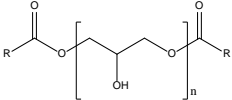
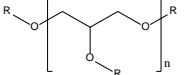
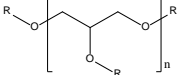
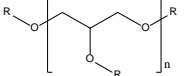
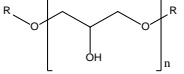
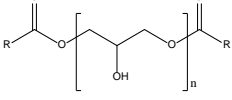
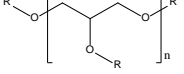
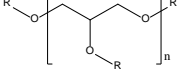
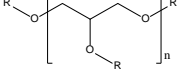
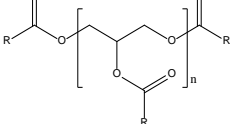
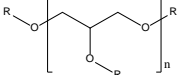
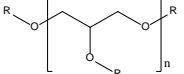
Ingredient CAS No.	Definition & Structure	Function(s)
Pumpkin Seed Oil Polyglyceryl-4 Esters Succinate	<p>the complex mixture of esters formed by the transesterification of cucurbita pepo (pumpkin) seed oil and polyglycerin-4 reacted with succinic acid</p>  <p>wherein R- represents hydrogen or the residue of succinic acid or the fatty acids derived from cucurbita pepo (pumpkin) seed oil (via transesterification), and n is 4</p>	emulsion stabilizer; surfactant - emulsifying agent
<i>Polyglyceryl-5 discrete multi-esters</i>		
Polyglyceryl-5 Dicaprylate 108777-93-1 (generic)	<p>the diester of caprylic acid with a glycerin polymer containing 5 glycerin units</p>  <p>wherein RC(O)- represents the residue of caprylic acid, and n is 5</p>	skin-conditioning agent - emollient; surfactant – cleansing agent; surfactant - emulsifying agent
Polyglyceryl-5 Dilaurate	<p>the diester of lauric acid and a glycerin polymer containing 5 units of glycerin</p>  <p>wherein RC(O)- represents the residue of lauric acid, and n is 5</p>	surfactant - emulsifying agent
Polyglyceryl-5 Trimyristate	<p>the triester of myristic acid and a glycerin polymer containing 5 units of glycerin</p>  <p>wherein R- represents hydrogen or the residue of myristic acid, and n is 5</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-5 Pentamyristate	<p>the pentaester of myristic acid and a glycerin polymer containing 5 units of glycerin</p>  <p>wherein R- represents hydrogen or the residue of myristic acid, and n is 5</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-5 Triisostearate	<p>the triester of isostearic acid and a glycerin polymer containing 5 units of glycerin</p>  <p>wherein R- represents hydrogen or the residue of isostearic acid, and n is 5</p>	surfactant – cleansing agent; surfactant – dispersing agent; surfactant - emulsifying agent
Polyglyceryl-5 Dioleate	<p>the diester of oleic acid and a glycerin polymer containing 5 units of glycerin</p>  <p>wherein RC(O)- represents the residue of oleic acid, and n is 5</p>	surfactant - emulsifying agent
Polyglyceryl-5 Trioleate	<p>the triester of oleic acid and a glycerin polymer containing 5 units of glycerin</p>  <p>wherein R- represents hydrogen or the residue of oleic acid, and n is 5</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-5 Tristearate 9009-32-9 (generic)	<p>the triester of stearic acid and a glycerin polymer containing 5 units of glycerin</p>  <p>wherein R- represents hydrogen or the residue of stearic acid, and n is 5</p>	surfactant – cleansing agent; surfactant – dispersing agent; surfactant - emulsifying agent
Polyglyceryl-5 Hexastearate	<p>the hexaester of stearic acid and a glycerin polymer containing 5 units of glycerin</p>  <p>wherein R- represents hydrogen or the residue of stearic acid, and n is 5</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent

**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

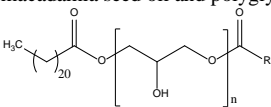
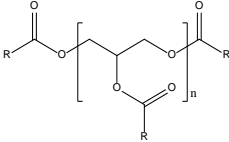
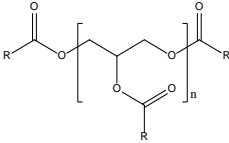
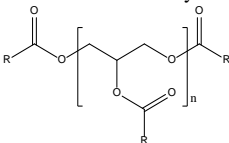
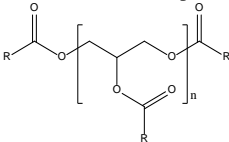
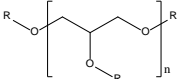
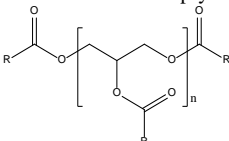
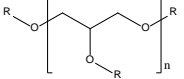
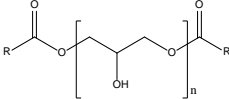
Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-5 Tribehenate	the triester of behenic acid and a glycerin polymer containing 5 units of glycerin  wherein R- represents hydrogen or the residue of behenic acid, and n is 5	skin-conditioning agent - emollient; surfactant - emulsifying agent
<i>Polyglyceryl-6 discrete multi-esters</i>		
Polyglyceryl-6 Sesquicaprylate 108777-93-1 (generic) 946492-22-4 (generic) 946492-23-5 (generic)	a mixture of mono- and diesters of caprylic acid and polyglycerin-6  wherein R- represents hydrogen or the residue of caprylic acid, and n is 6	skin-conditioning agent - emollient; surfactant – cleansing agent; surfactant - emulsifying agent
Polyglyceryl-6 Dicaprate	the diester of capric acid and polyglycerin-6  wherein RC(O)- represents the residue of capric acid, and n is 6	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Tricaprylate	the triester of caprylic acid and polyglycerin-6  wherein R- represents hydrogen or the residue of caprylic acid, and n is 6	surfactant – cleansing agent
Polyglyceryl-6 Tetracaprylate	the tetraester of caprylic acid and polyglycerin-6  wherein R- represents hydrogen or the residue of caprylic acid, and n is 6	surfactant – cleansing agent
Polyglyceryl-6 Pentacaprylate	the pentaester of caprylic acid and polyglycerin-6  wherein R- represents hydrogen or the residue of caprylic acid, and n is 6	surfactant – cleansing agent
Polyglyceryl-6 Heptacaprylate	the heptaester of caprylic acid and polyglycerin-6  wherein R- represents hydrogen or the residue of caprylic acid, and n is 6	surfactant - emulsifying agent
Polyglyceryl-6 Octacaprylate	the octaester of polyglycerin-6 and caprylic acid  wherein RC(O)- represents the residue of caprylic acid, and n is 6	skin-conditioning agent - emollient
Polyglyceryl-6 Dipalmitate	the diester of palmitic acid and polyglycerin-6  wherein RC(O)- represents the residue of palmitic acid, and n is 6	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Sesquiisostearate	a mixture of mono- and diesters of isostearic acid and polyglycerin-6  wherein R- represents hydrogen or the residue of isostearic acid, and n is 6	surfactant - emulsifying agent
Polyglyceryl-6 Diisostearate	the diester of isostearic acid and polyglycerin-6  wherein RC(O)- represents the residue of isostearic acid, and n is 6	skin-conditioning agent - emollient; surfactant - emulsifying agent



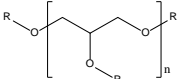
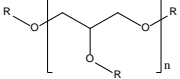
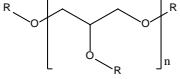
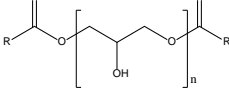
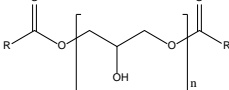
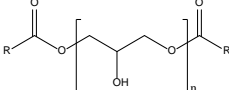
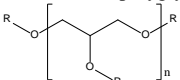
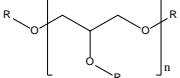
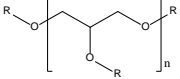
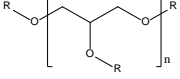
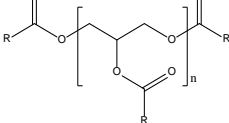
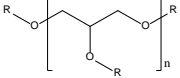
**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-6 Dioleate 76009-37-5	a diester of oleic acid and polyglycerin-6  <p>wherein RC(O)- represents the residue of oleic acid, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Tetraoleate 128774-95-8	the tetraester of Oleic Acid and polyglycerin-6  <p>wherein R- represents hydrogen or the residue of oleic acid, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Pentaoleate 104934-17-0	the pentaester of oleic acid and polyglycerin-6  <p>wherein R- represents hydrogen or the residue of oleic acid, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Hexaoleate 95482-05-6	a hexaester of oleic acid and polyglycerin-6  <p>wherein R- represents hydrogen or the residue of oleic acid, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Sesquistearate 112939-69-2	a mixture of mono- and diesters of stearic acid and polyglycerin-6  <p>wherein R- represents hydrogen or the residue of stearic acid, and n is 6</p>	surfactant - emulsifying agent
Polyglyceryl-6 Distearate 34424-97-0 9009-32-9 (generic)	a diester of stearic acid and polyglycerin-6  <p>wherein RC(O)- represents the residue of stearic acid, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Tristearate 71185-87-0 9009-32-9 (generic)	the triester of stearic acid and polyglycerin-6  <p>wherein R- represents hydrogen or the residue of stearic acid, and n is 6</p>	surfactant - emulsifying agent
Polyglyceryl-6 Pentastearate 9009-32-9 (generic) 99734-30-2	the pentaester of stearic acid and polyglycerin-6  <p>wherein R- represents hydrogen or the residue of stearic acid, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Hexastearate	the hexaester of stearic acid and polyglycerin-6  <p>wherein R- represents hydrogen or the residue of stearic acid, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Octastearate	the octaester of stearic acid and polyglycerin-6  <p>wherein RC(O)- represents the residue of stearic acid, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Pentaricinoleate	the pentaester of ricinoleic acid and polyglycerin-6  <p>wherein R- represents hydrogen or the residue of ricinoleic acid, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-6 Tetra behenate	the tetraester of behenic acid and polyglycerin-6  <p>wherein R- represents hydrogen or the residue of behenic acid, and n is 6</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent

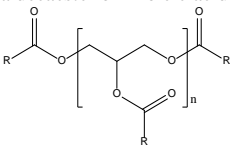
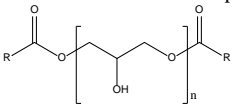
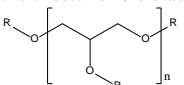
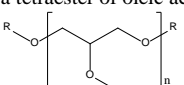
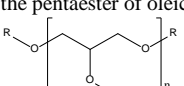
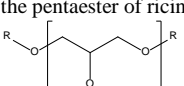
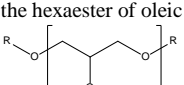
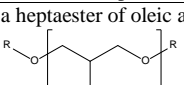
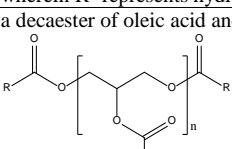
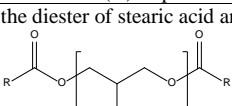
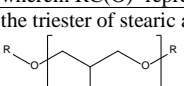
**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

Ingredient CAS No.	Definition & Structure	Function(s)
<i>Polyglyceryl-6 mixed multi-ester</i>		
Macadamia Seed Oil Polyglyceryl-6 Esters Behenate	<p>the behenic acid ester of the product obtained by the transesterification of macadamia seed oil and polyglycerin-6</p>  <p>wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from macadamia ternifolia seed oil, and n is 6</p>	skin-conditioning agent - emollient
<i>Polyglyceryl-8 mixed multi-esters</i>		
Polyglyceryl-8 Decabehenate/Caprates	<p>the decaester of a mixture of behenic acid and capric acid with a glycerin polymer containing 8 units of glycerin</p>  <p>wherein RC(O)- represents the residue of capric or behenic acid, and n is 8</p>	viscosity increasing agent - nonaqueous
Polyglyceryl-8 Decaerucate/Decaisostearate/Decaricinoleate	<p>the decaester of a glycerin polymer containing 8 units of glycerin with a mixture of erucic acid, isostearic acid and ricinoleic acid</p>  <p>wherein RC(O)- represents the residue of erucic, isostearic, or ricinoleic acid, and n is 8</p>	skin-conditioning agent - emollient
<i>Polyglyceryl-10 discrete multi-esters</i>		
Polyglyceryl-10 Decaethylhexanoate	<p>the decaester of 2-ethylhexanoic acid and polyglycerin-10</p>  <p>wherein RC(O)- represents the residue of 2-ethylhexanoic acid, and n is 10</p>	skin conditioning agent - humectant
Polyglyceryl-10 Dodecacaprate	<p>the dodecaester of capric acid and polyglycerin-10</p>  <p>wherein RC(O)- represents the residue of capric acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Pentacaprylate	<p>the pentaester of caprylic acid and polyglycerin-10</p>  <p>wherein R- represents hydrogen or the residue of caprylic acid, and n is 10</p>	surfactant – cleansing agent; surfactant - emulsifying agent; surfactant – solubilizing agent
Polyglyceryl-10 Dodecaprylate	<p>the dodecaester of caprylic acid and polyglycerin-10</p>  <p>wherein RC(O)- represents the residue of caprylic acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Tridecanoate 217782-56-4	<p>the triester of decanoic acid and polyglycerin-10</p>  <p>wherein R- represents hydrogen or the residue of decanoic acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Dilaurate	<p>the diester of lauric acid and polyglycerin-10</p>  <p>wherein RC(O)- represents the residue of lauric acid, and n is 10</p>	surfactant – cleansing agent

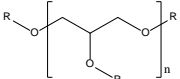
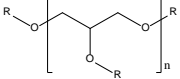
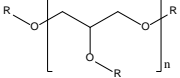
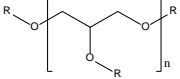
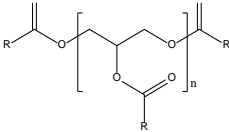
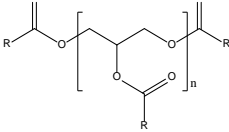
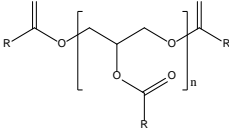
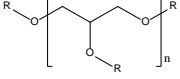
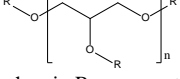
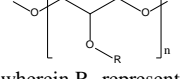
**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

<b>Ingredient CAS No.</b>	<b>Definition &amp; Structure</b>	<b>Function(s)</b>
Polyglyceryl-10 Trilaurate	the triester of lauric acid and polyglycerin-10 	surfactant – cleansing agent
Polyglyceryl-10 Tetralaurate	wherein R- represents hydrogen or the residue of lauric acid, and n is 10 the tetraester of lauric acid and polyglycerin-10 	surfactant – cleansing agent
Polyglyceryl-10 Pentalaurate	wherein R- represents hydrogen or the residue of lauric acid, and n is 10 the pentaester of lauric acid and polyglycerin-10 	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Dimyristate	wherein R- represents hydrogen or the residue of lauric acid, and n is 10 the diester of myristic acid and polyglycerin-10 	surfactant - emulsifying agent
Polyglyceryl-10 Dipalmitate	wherein RC(O)- represents the residue of myristic acid, and n is 10 the diester of palmitic acid and polyglycerin-10 	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Diisostearate 102033-55-6 63705-03-3 (generic)	wherein RC(O)- represents the residue of palmitic acid, and n is 10 a diester of isostearic acid and polyglycerin-10 	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Triisostearate	wherein RC(O)- represents the residue of isostearic acid, and n is 10 the triester of polyglycerin-10 and isostearic acid 	surfactant - emulsifying agent
Polyglyceryl-10 Pentaistearate	wherein R- represents hydrogen or the residue of isostearic acid, and n is 10 the pentaester of isostearic acid and polyglycerin-10 	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Hexaistearate	wherein R- represents hydrogen or the residue of isostearic acid, and n is 10 the hexaester of polyglycerin-10 and isostearic acid 	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Nonaisostearate	wherein R- represents hydrogen or the residue of isostearic acid, and n is 10 the nonaester of polyglycerin-10 and isostearic acid 	skin-conditioning agent - emollient
Polyglyceryl-10 Decaisostearate	wherein R- represents hydrogen or the residue of isostearic acid, and n is 10 the ester of polyglycerin-10 and isostearic acid 	skin-conditioning agent - emollient
Polyglyceryl-10 Pentalinoleate	wherein RC(O)- represents the residue of isostearic acid, and n is 10 the pentaester of linoleic acid and polyglycerin-10 	skin-conditioning agent - emollient; surfactant - emulsifying agent
	wherein R- represents hydrogen or the residue of linoleic acid, and n is 10	

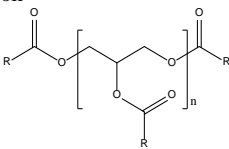
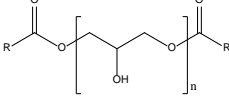
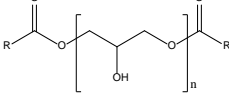
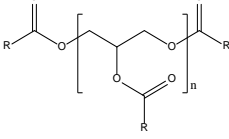
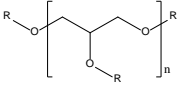
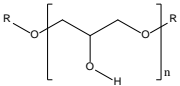
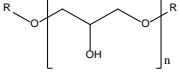
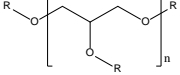
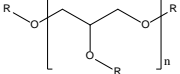
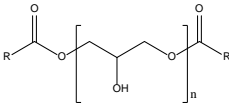
**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

<b>Ingredient CAS No.</b>	<b>Definition &amp; Structure</b>	<b>Function(s)</b>
Polyglyceryl-10 Decalinoate 68900-96-9	a decaester of linoleic acid and polyglycerin-10  <p>wherein RC(O)- represents the residue of linoleic acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Dioleate 33940-99-7	a diester of oleic acid and polyglycerin-10  <p>wherein RC(O)- represents the residue of oleic acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Trioleate 102051-00-3	the triester of oleic acid and polyglycerin-10  <p>wherein R- represents hydrogen or the residue of oleic acid, and n is 10</p>	surfactant - emulsifying agent
Polyglyceryl-10 Tetraoleate 34424-98-1	a tetraester of oleic acid and polyglycerin-10  <p>wherein R- represents hydrogen or the residue of oleic acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Pentaoleate 86637-84-5	the pentaester of oleic acid and polyglycerin-10  <p>wherein R- represents hydrogen or the residue of oleic acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Pentaricinoleate	the pentaester of ricinoleic acid and polyglycerin-10  <p>wherein R- represents hydrogen or the residue of ricinoleic acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Hexaoleate 65573-03-7	the hexaester of oleic acid and polyglycerin-10  <p>wherein R- represents hydrogen or the residue of oleic acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Heptaoleate 103175-09-3	a heptaester of oleic acid and polyglycerin-10  <p>wherein R- represents hydrogen or the residue of oleic acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Decaoleate 11094-60-3	a decaester of oleic acid and polyglycerin-10  <p>wherein RC(O)- represents the residue of oleic acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Distearate 12764-60-2 9009-32-9 (generic)	the diester of stearic acid and polyglycerin-10  <p>wherein RC(O)- represents the residue of stearic acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Tristearate 12709-64-7 9009-32-9 (generic)	the triester of stearic acid and polyglycerin-10  <p>wherein R- represents hydrogen or the residue of stearic acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent

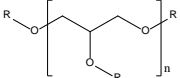
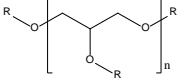
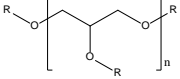
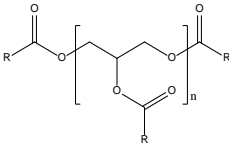
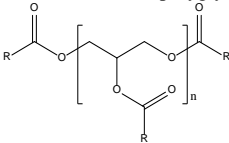
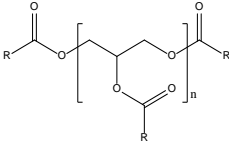
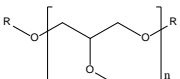
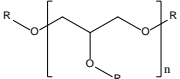
**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-10 Pentastearate 9009-32-9 (generic) 95461-64-6	a pentaester of stearic acid and polyglycerin-10  <p>wherein R- represents hydrogen or the residue of stearic acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Pentahydroxystearate	the pentaester of hydroxystearic acid and polyglycerin-10  <p>wherein R- represents hydrogen or the residue of hydroxystearic acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Heptahydroxystearate	a heptaester of hydroxystearic acid and polyglycerin-10  <p>wherein R- represents hydrogen or the residue of hydroxystearic acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Heptastearate 99126-54-2 9009-32-9 (generic)	the heptaester of stearic acid and polyglycerin-10  <p>wherein R- represents hydrogen or the residue of stearic acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Decahydroxystearate	the decaester of hydroxystearic acid and polyglycerin-10  <p>wherein RC(O)- represents the residue of hydroxystearic acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Decastearate 39529-26-5	a decaester of stearic acid and polyglycerin-10  <p>wherein RC(O)- represents the residue of stearic acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Dodecabenate	the dodecaester of behenic acid and polyglycerin-10  <p>wherein RC(O)- represents the residue of behenic, and n is 10</p>	surfactant - emulsifying agent
Polyglyceryl-10 Trierucate	the triester of polyglycerin-10 and erucic acid  <p>wherein R- represents hydrogen or the residue of erucic acid, and n is 10</p>	surfactant – dispersing agent; surfactant - emulsifying agent
Polyglyceryl-10 Hexaerucate	the hexaester of polyglycerin-10 and erucic acid  <p>wherein R- represents hydrogen or the residue of erucic acid, and n is 10</p>	surfactant – dispersing agent; surfactant - emulsifying agent
Polyglyceryl-10 Nonaerucate 155808-79-0	the nonaester of erucic acid and polyglycerin-10  <p>wherein R- represents hydrogen or the residue of erucic acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent

**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

Ingredient CAS No.	Definition & Structure	Function(s)
<i>Polyglyceryl-10 mixed multi-esters</i> Polyglyceryl-10 Decamacadamate	a decaester of polyglycerin-10 and the fatty acids derived from macadamia nut oil  <p>wherein RC(O)- represents the residue of the fatty acids derived from macadamia nut oil, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Dicocoate	the diester of coconut acid and polyglycerin-10  <p>wherein RC(O)- represents the residue of coconut acid, and n is 10</p>	surfactant – cleansing agent; surfactant - emulsifying agent
Polyglyceryl-10 Didecanoate 182015-59-4	the diester of decanoic acid and polyglycerin-10  <p>wherein RC(O)- represents the residue of decanoic acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Dodeca-Caprylate/ Caprate	the dodecaester of a mixture of caprylic and capric acids with polyglycerin-10  <p>wherein RC(O)- represents the residue of capric or caprylic acid, and n is 10</p>	skin-conditioning agent - occlusive
Polyglyceryl-10 Hepta(Behenate/Stearate)	the heptaester of polyglycerin-10 with a mixture of behenic acid and stearic acid  <p>wherein R- represents hydrogen or the residue of behenic acid and stearic acid, and n is 10</p>	surfactant - emulsifying agent
Polyglyceryl-10 Mono/Dioleate	a mixture of mono- and diesters of oleic acid and polyglycerin-10  <p>wherein R- represents hydrogen or the residue of oleic acid, and n is 10</p>	skin-conditioning agent - emollient; surfactant - emulsifying agent
Polyglyceryl-10 Sesquistearate	a mixture of mono- and diesters of stearic acid and polyglycerin-10  <p>wherein R- represents hydrogen or the residue of stearate acid, and n is 10</p>	surfactant - emulsifying agent
Polyglyceryl-10 Tetradecanedioate	the ester of tetradecanedioic acid and polyglycerin-10  <p>wherein R- represents hydrogen or the residue of tetradecanedioic acid, and n is 10</p>	hair conditioning agent; skin conditioning agent - humectant
Polyglyceryl-10 Tricocoate	the triester of coconut acid and polyglycerin-10  <p>wherein R- represents hydrogen or the residue of coconut acid, and n is 10</p>	surfactant – cleansing agent; surfactant - emulsifying agent
<i>Polyglyceryl-15 discrete multi-ester</i> Polyglyceryl-15 Diisostearate	a diester of isostearic acid and a glycerin polymer containing 15 glycerin units  <p>wherein RC(O)- represents the residue of isostearic acid, and n is 15</p>	hair conditioning agent; surfactant – cleansing agent; surfactant - emulsifying agent

**Table 3.** Definitions, idealized structures, and function <sup>1</sup> ( CIR Staff)

Ingredient CAS No.	Definition & Structure	Function(s)
<b><i>Polyglyceryl-20 discrete multi-esters</i></b>		
Polyglyceryl-20 Hexacaprylate	<p>the hexaester of caprylic acid and polyglycerin-20</p>  <p>wherein R- represents hydrogen or the residue of caprylic acid, and n is 20</p>	<p>surfactant – cleansing agent; surfactant - emulsifying agent; surfactant – solubilizing agent</p>
Polyglyceryl-20 Heptacaprylate	<p>the heptaester of caprylic acid and polyglycerin-20</p>  <p>wherein R- represents hydrogen or the residue of caprylic acid, and n is 20</p>	<p>surfactant – cleansing agent; surfactant - emulsifying agent; surfactant – solubilizing agent</p>
Polyglyceryl-20 Octaisiononanoate	<p>the octaester of isononanoic acid and polyglycerin-20</p>  <p>wherein R- represents hydrogen or the residue of isononanoic acid, and n is 20</p>	<p>surfactant – cleansing agent; surfactant - emulsifying agent; surfactant – solubilizing agent</p>
<b><i>Polyglyceryl-20 mixed multi-esters</i></b>		
Polyglyceryl-20 Docosabehenate/Isostearate	<p>the docosaester of polyglycerin-20 with a mixture of behenic and isostearic acids</p>  <p>wherein RC(O)- represents the residue of behenic or isostearic acid, and n is 20</p>	<p>skin-conditioning agent - emollient; surfactant - emulsifying agent</p>
Polyglyceryl-20 Docosabehenate/Laurate	<p>the docosaester of polyglycerin-20 with a mixture of behenic and lauric acids</p>  <p>wherein RC(O)- represents the residue of behenic or lauric acid, and n is 20</p>	<p>skin-conditioning agent - emollient; surfactant - emulsifying agent</p>
Polyglyceryl-20 Docosabehenate/Oleate	<p>the docosaester of polyglycerin-20 with a mixture of behenic and oleic acids</p>  <p>wherein RC(O)- represents the residue of behenic or oleic acid, and n is 20</p>	<p>skin-conditioning agent - emollient; surfactant - emulsifying agent</p>
Polyglyceryl-20 Heptadecabehenate/Laurate	<p>the heptadecaester of polyglycerin-20 with a mixture of behenic and lauric acids</p>  <p>wherein R- represents hydrogen or the residue of behenic or lauric acid, and n is 20</p>	<p>skin-conditioning agent - emollient; surfactant - emulsifying agent</p>
Polyglyceryl-20 Octadecabehenate/Laurate	<p>the octadecaester of polyglycerin-20 and a mixture of behenic and lauric acids</p>  <p>wherein R- represents hydrogen or the residue of behenic or lauric acid, and n is 20</p>	<p>skin-conditioning agent - emollient; surfactant - emulsifying agent</p>

**Table 4. Previously Reviewed Components and Related Ingredients**

Component	Conclusion	Reference
Glycerin	safe in cosmetics in the present practices of use and concentration (was used in 15,654 formulations, 10,046 of which were leave-ons; the maximum use concentrations were 79.2% in leave-on products, 99.4% in rinse-off products, and 47.9% in products diluted for the bath)	69
Dipropylene Glycol	safe as used	70,71
Tripropylene Glycol	safe in the present practices of use and concentration when formulated to be non-irritating	72
Polypropylene Glycols (and PPG $\geq$ 3)	safe in the present practices of use and concentration when formulated to be non-irritating	72
Monoglyceryl Monoesters	safe in the present practices of use and concentration	73
Glyceryl Alginate	safe in the present practices of use and concentration	73
Glyceryl Isostearate/Myristate	safe in the present practices of use and concentration	74
Glyceryl Myristate		
Citric Acid	safe in the present practices of use and concentration	75
Coconut Acid	safe for use as a cosmetic ingredient	76
Hydroxystearic Acid	safe as a cosmetic ingredient in the present practices of use	77
Isostearic Acid	safe as a cosmetic ingredient in the present practices of use	78
Lauric Acid	safe in the present practices of use and concentration	79
Myristic Acid	safe in the present practices of use and concentration	74
Oleic Acid	safe in the present practices of use and concentration	79
Olive Acid	safe in the present practices of use and concentration	80
Palm Acid	safe in the present practices of use and concentration	80
Palmitic Acid	safe in the present practices of use and concentration	79
Rice Bran Acid	safe in the present practices of use and concentration	80
Ricinoleic Acid	safe in the present practices of use and concentration	81
Sebacic Acid	safe in the present practices of use and concentration	82
Stearic Acid	safe in the present practices of use and concentration	79
Potassium Stearate		83,84
Sodium Stearate		83,84
Acacia Decurrens Flower Wax	data were insufficient to support the safety of Acacia Decurrens and Acacia Farnesiana Flower Wax in cosmetic products	85
this wax has not been reviewed, but Acacia Decurrens and Acacia Farnesiana Flower Wax have been reviewed		
Adansonia Digitata Seed Oil	safe in the present practices of use and concentration	80
Argania Spinosa Kernel Oil	safe in the present practices of use and concentration	80
Beeswax	safe in the present practices of use and concentration	86,87
Bertholletia Excelsa Seed Oil	safe in the present practices of use and concentration	80
Borago Officinalis Seed Oil	safe in the present practices of use and concentration	80
Butyrospermum Parkii (Shea) Butter	safe in the present practices of use and concentration	80
Caprylic/Capric/Coco Glycerides	safe for use as a cosmetic ingredient	76
Carthamus Tinctorius (Safflower) Seed Oil	safe in the present practices of use and concentration	80
Citrullus Lanatus (Watermelon) Seed Oil	safe in the present practices of use and concentration	80
Cocos Nucifera (Coconut) Oil	safe for use as a cosmetic ingredient	76
Cocoglycerides		
Hydrogenated Coco-Glycerides		
Corylus Avellana (Hazelnut) Seed Oil	safe in the present practices of use and concentration	80
Cucurbita Pepo (Pumpkin) Seed Oil	safe in the present practices of use and concentration	80
Elaeis Guineensis (Palm) Oil	safe in the present practices of use and concentration	80
Elaeis Guineensis (Palm) Kernel Oil		
Euphorbia Cerifera (Candelilla) Wax	safe in the present practices of use and concentration	86,87
Glycine Soja (Soybean) Oil	safe in the present practices of use and concentration	80
Hydrogenated Soybean Oil		
Helianthus Annuus (Sunflower) Seed Oil	safe in the present practices of use and concentration	80
Helianthus Annuus (Sunflower) Seed Wax		
Linum Usitatissimum (Linseed) Seed Oil	safe in the present practices of use and concentration	80
Macadamia Integrifolia Seed Oil	safe in the present practices of use and concentration	80
Macadamia Ternifolia Seed Oil		
Olea Europaea (Olive) Fruit Oil	safe in the present practices of use and concentration	80
Orbignya Oleifera Seed Oil		
Oryza Sativa (Rice) Bran Oil	safe in the present practices of use and concentration	88
Oryza Sativa (Rice) Bran Wax		



**Table 4. Previously Reviewed Components and Related Ingredients**

<b>Component</b>	<b>Conclusion</b>	<b>Reference</b>
Persea Gratissima (Avocado) Oil	safe in the present practices of use and concentration	80
Prunus Amygdalus Dulcis (Sweet Almond) Oil	safe in the present practices of use and concentration	80
Prunus Armeniaca (Apricot) Kernel Oil	safe in the present practices of use and concentration	80
Ricinus Communis (Castor) Seed Oil	safe in the present practices of use and concentration	81
Hydrogenated Castor Oil		
Schinziophyton Rautanenii Kernel Oil	safe in the present practices of use and concentration	80
Sclerocarya Birrea Seed Oil	safe in the present practices of use and concentration	80
Simmondsia Chinensis (Jojoba) Seed Wax	safe in the present practices of use and concentration	89
Sesamum Indicum (Sesame) Seed Oil	safe in the present practices of use and concentration	80
Theobroma Cacao (Cocoa) Seed Butter	safe in the present practices of use and concentration	80
Theobroma Grandiflorum Seed Butter	safe in the present practices of use and concentration	80

**Table 5. Average fatty acid composition of polyglyceryl fatty acid esters (%)**

Fatty Acids	Adansonia Digitata Seed Oil Polyglyceryl- 6 Esters <sup>90</sup>	Apricot Kernel Oil Polyglyceryl-6 Esters <sup>91</sup>	Apricot Kernel Oil Polyglyceryl-10 Esters <sup>92</sup>	Argan Oil Polyglyceryl-6 Esters <sup>93,93</sup>	Babassu Oil Polyglyceryl-6 Esters <sup>94</sup>	Bertholletia Excelsa Seed Oil Polyglyceryl- 6 Esters <sup>95</sup>	Caprylic/Capric Glycerides Poly- glyceryl-10 Esters <sup>96</sup>
Caproic (C6)							<2
Caprylic (C8)					2-8		50-65
Capric (C10)					1-8		30-50
Lauric (C12)*					35-55		<3
Myristic (C14)					10-30		<1
Myristoleic (C14:1)							
Palmitic (C16)	18-30	3.0-9.0	4.6-7.6	10-15	5-15	10-20	
Palmitoleic (C16:1)		<1.5					
Heptadecanoic (C17:0)							
Stearic (C18)	2-9	0.5-4.0	0.2-1.3	4-7	1-8	5-15	
Oleic (C18:1)	30-45	55.0-75.0	60-74	40-55	9-20	25-40	
Linoleic (C18:2)	20-40	20.0-35.0	20-34	25-40	1-7	30-55	
Linolenic (C18:3)	1-3			<0.5		<1	
Arachidic (C20)	< 2	<1.0		<1		<1	
Eicosenoic (C20:1)		<1.0		<1			
Behenic (C22)							
Erucic (C22:1)							
Lignoceric (C24)							
Others							

	Cocoa Butter Polyglyceryl-6 Esters <sup>97</sup>	Coconut oil Polyglyceryl-6 Esters <sup>98</sup>	Hazelnut Seed Oil Polyglyceryl-6 Esters <sup>99</sup>	Macadamia Seed Oil Polyglyceryl 6 Esters <sup>100</sup>	Olive Oil Polyglyceryl-6 Esters <sup>101</sup>	Polyglyceryl-10 Decaoleate <sup>32</sup>	Safflower Seed Oil Polyglyceryl-6 Esters <sup>102</sup>
Caproic (C6)		<1					
Caprylic (C8)		4-10					
Capric (C10)		4-11					
Lauric (C12)*		42-52				4.2	
Myristic (C14)		13-21				2.6	
Myristoleic (C14:1)							
Palmitic (C16)	20-35	6-12	4.5-9.	7-11	7.5-20	16.6	6-7
Palmitoleic (C16:1)	<1			16-30	<3.5		
Heptadecanoic (C17:0)							
Stearic (C18)	25-40	1-4	1-4	2-7	0.5-5	14.4	0.9-9.7
Oleic (C18:1)	25-40	3-12	66-86.2	50-67	55-85	5.3	10-20
Linoleic (C18:2)	2-5	0.5-4	8-10.4	1-5	3.5-20	55.8	68-83
Linolenic (C18:3)	<0.5		<0.6		<1.5		<0.2
Arachidic (C20)	0.5-2			1-4	<1		
Eicosenoic (C20:1)				1-3	<1		
Behenic (C22)							
Erucic (C22:1)							
Lignoceric (C24)							
Others						Total fatty acids are 83.1%	

**Table 5. Average fatty acid composition of polyglyceryl fatty acid esters (%)**

	Schinziophyton Rautanenii Kernel Oil Polyglyceryl-6 Esters <sup>103</sup>	Sclerocarya Birrea Seed Oil Polyglyceryl- 6 Esters <sup>104</sup>	Sesame Oil Polyglyceryl-6 Esters <sup>105</sup>	Shea Butter Polyglyceryl-6 Esters <sup>106</sup>	Soybean Oil Polyglyceryl-6 Esters <sup>107</sup>	Sunflower Seed Oil Polyglyceryl-6 Esters (high oleic acid) <sup>108</sup>	Sunflower Seed Oil Polyglyceryl-10 Esters <sup>109</sup>
<b>Fatty Acids</b>							
Caproic (C6)							
Caprylic (C8)							
Capric (C10)							
Lauric (C12)*							
Myristic (C14)		<0.2					
Myristoleic (C14:1)							
Palmitic (C16)	6-10	9-13	5-15	3-7	8-13	2-6	3-5.5
Palmitoleic (C16:1)		<0.2					
Heptadecanoic (C17:0)							
Stearic (C18)	4-8	4-8	2-8	35-47	2-7	1-5	2-5
Oleic (C18:1)	10-20	70-80	35-55	33-50	17-28.5	70-90	74-82
Linoleic (C18:2)	30-54	4-9	34-55	3-8	46-62	5-20	8-15.5
Linolenic (C18:3)	30-32	<0.7	<1.1	<2	4-10	<1	<0.2
Arachidic (C20)		<1	<1.2	<2.5		<1	
Eicosenoic (C20:1)				<0.5		<0.5	
Behenic (C22)						<1	
Erucic (C22:1)							
Lignoceric (C24)						<1	
Others							
	Sweet Almond Oil Polyglyceryl-6 Esters <sup>110</sup>	Trichilia Emetica Seed Oil Polyglyceryl-6 Esters <sup>111</sup>					
Caproic (C6)							
Caprylic (C8)							
Capric (C10)							
Lauric (C12)*							
Myristic (C14)							
Myristoleic (C14:1)							
Palmitic (C16)	4-9	30-40					
Palmitoleic (C16:1)							
Heptadecanoic (C17:0)	<1						
Stearic (C18)	<3	1.5-4					
Oleic (C18:1)	62-86	45-55					
Linoleic (C18:2)		8-13					
Linolenic (C18:3)	20-30	<1.5					
Arachidic (C20)	<1						
Eicosenoic (C20:1)							
Behenic (C22)							
Erucic (C22:1)							
Lignoceric (C24)							
Others							

**Table 6. Physical and Chemical Properties**

<b>Property</b>	<b>Adansonia Digitata Seed Oil Polyglyceryl-6 Esters<sup>90</sup></b>	<b>Apricot Kernel Oil Polyglyceryl-6 Esters<sup>91</sup></b>	<b>Apricot Kernel Oil Polyglyceryl-10 Esters<sup>92</sup></b>	<b>Argan Oil Polyglyceryl-6 Esters<sup>93,93</sup></b>	<b>Babassu Oil Polyglyceryl-6 Esters<sup>94</sup></b>	<b>Bertholletia Excelsa Seed Oil Polyglyceryl-6 Esters<sup>95</sup></b>	<b>Borage Seed Oil Polyglyceryl-6 Esters<sup>112</sup></b>
physical characteristics	soft paste amber in color	amber liquid (20°C)	amber (physical state not specified)	amber liquid	soft paste with amber color	soft paste with amber color	oil
molecular wt							
solubility	water dispersible	water dispersible	water soluble	water dispersible	water dispersible	water dispersible	water dispersible
melting point (°C)							
density (g/ml)	<1	<1	>1		<1	<1	
specific gravity (g/ml)							
pH							
refractive index (20°C)	approx. 1.47	approx. 1.47	approx. 1.47	approx. 1.47	approx. 1.47	approx. 1.47	
saponification value	150 – 170	125-155		125-155	175-205	125-155	
acid value (mg KOH/g)	< 5	<5	<5	<5	<5	< 5	
hydroxyl value (mg KOH/g)							
peroxide value (meq of active oxygen/Kg)	<10	<10	<10	<10	<10	<10	
iodine value (gI <sub>2</sub> /100g)		75-90		75-90	10-25	75-90	
polarity	non-ionic, amphiphilic	non-ionic, amphiphilic	non-ionic, amphiphilic	non-ionic, amphiphilic	non-ionic, amphiphilic	non-ionic, amphiphilic	non-ionic, amphiphilic
HLB							
	<b>Caprylic/Capric Glycerides Polyglyceryl-10 Esters<sup>96</sup></b>	<b>Cocoa Butter Polyglyceryl-6 Esters<sup>97</sup></b>	<b>Coconut Oil Polyglyceryl-6 Esters<sup>98</sup></b>	<b>Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate</b>	<b>Hazelnut Seed Oil Polyglyceryl-6 Esters<sup>99</sup></b>	<b>Macadamia Seed Oil Polyglyceryl-6 Esters<sup>100</sup></b>	<b>Olive Oil Polyglyceryl-6 Esters<sup>101</sup></b>
physical characteristics	amber in color	beige solid	soft paste, with amber color	viscous liquid <sup>113</sup> yellow liquid <sup>114</sup> ~6000	amber	amber liquid	amber liquid
molecular wt							
solubility		water dispersible	water dispersible		water dispersible	water dispersible	water dispersible
melting point (°C)		40-50	40-50				
density (g/ml)	>1	<1	<1		<1	<1	<1
specific gravity (g/ml)							
pH							
refractive index (20°C)	approx. 1.47	approx. 1.47	approx. 1.47		approx.. 1.47	~1.47	~1.47
saponification value		145-165	180-220	140-160 <sup>113</sup>		140-160	125-155
acid value (mg KOH/g)	<5	< 5	< 5	10.0 max <sup>113</sup>	<5	<5	<5
hydroxyl value (mg KOH/g)							
peroxide value (meq of active oxygen/Kg)	<10	<10	<10		<10	<10	<10
iodine value (gI <sub>2</sub> /100g)		20-35	3-10	10.0 max <sup>113</sup>			60-75
polarity	non-ionic, amphiphilic	non-ionic, amphiphilic	non-ionic, amphiphilic	~5 <sup>114</sup>	non-ionic, amphiphilic	non-ionic, amphiphilic	non-ionic, amphiphilic
HLB							

**Table 6. Physical and Chemical Properties**

	<b>Palm Kernel Oil Poly- glyceryl-4 Esters<sup>115</sup></b>	<b>Polyglyceryl-3 Beeswax<sup>116</sup></b>	<b>Polyglyceryl-2 Caprate<sup>117</sup></b>	<b>Polyglyceryl-4 Caprate</b>	<b>Polyglyceryl-3 Caprylate<sup>118</sup></b>	<b>Polyglyceryl-10 Caprylate/Caprate<sup>24,119</sup></b>	<b>Polyglyceryl-10 Decaisostearate<sup>120</sup></b>
physical characteristics		white to off-white		transparent, pale, yellow liquid with faint odor <sup>121</sup> colorless to yellow, clear to slightly turbid, viscous liquid <sup>122</sup>	high viscosity liquid	amber, viscous liquid	faint yellow liquid
molecular wt			320.42				
solubility	water- and oil- soluble			soluble in water, ethanol, 1,2-propanediol, esters oil; insoluble in paraffin oi, isopropyl myristate, vegetable oil <sup>122</sup>			insoluble in water
melting point (°C)		63-73					
density (g/ml)			1.083 g/cm <sup>3</sup>				
specific gravity (g/ml)							0.956 (25°C)
pH							
refractive index (20°C)			1.481				
saponification value		80-94		50-70 <sup>121</sup>		85-105	
acid value (mg KOH/g)		2 max		5 max <sup>121</sup>		7.0 max	
hydroxyl value (mg KOH/g)							
peroxide value (meq of active oxygen/Kg)						5.0 max	
iodine value (gI <sub>2</sub> /100g)						2.0 max	
polarity							
HLB				14.5 <sup>121</sup> ; ~14 <sup>122</sup>		14	

**Table 6. Physical and Chemical Properties**

	<b>Polyglyceryl-10 Decaoleate</b>	<b>Polyglyceryl-3 Di- Hydroxystearate</b>	<b>Polyglyceryl-2 Diisostearate</b>	<b>Polyglyceryl-3 Diisostearate)<sup>34</sup></b>	<b>Polyglyceryl-6 Diisostearate<sup>123</sup></b>	<b>Polyglyceryl-3 Diolate<sup>26,124</sup></b>	<b>Polyglyceryl-6 Diolate<sup>125</sup></b>
physical characteristics		solid	clear pale yellow, homogenous liquid <sup>33</sup>	slightly yellowish, viscous liquid	pale yellow liquid	viscous yellow liquid	
molecular wt						766.13 <sup>126</sup>	991.38
solubility		slightly soluble in water		< 0.15 mg/L (water)		dispersible in water; soluble in many organic solvents	
melting point (°C)			-10 <sup>33</sup>				
density (g/ml)			0.941 g/cm <sup>3</sup> <sup>33</sup>				
specific gravity (g/ml)						0.99	
pH							
refractive index (20°C)				8.129 (predicted)			
saponification value	170.9 <sup>31</sup> ; 177.5 <sup>32</sup>						
acid value (mg KOH/g)	14.0 <sup>31</sup>						
hydroxyl value (mg KOH/g)	23.0 <sup>32</sup> ; 40.0 <sup>31</sup>						
peroxide value (meq of active oxygen/Kg)	3.4 <sup>32</sup>						
iodine value (gI <sub>2</sub> /100g)	66.2 <sup>32</sup>						
polarity							
HLB				1.4 (predicted)	8	3	

**Table 6. Physical and Chemical Properties**

	<b>Polyglyceryl-10 Dipalmitate</b> <sup>127,127</sup>	<b>Polyglyceryl-3 Distearate</b> <sup>128</sup>	<b>Polyglyceryl-6 Distearate</b>	<b>Polyglyceryl-10 Distearate</b> <sup>129</sup>	<b>Polyglyceryl-2 Iso- palmitate/Sebacate</b> <sup>130</sup>	<b>Polyglyceryl-2 Isostearate</b> <sup>131</sup>	<b>Polyglyceryl-4 Isostearate</b> <sup>132</sup>
physical characteristics	beads or waxy solids	white or slightly yellowish powder	waxy solid <sup>127</sup>	yellow waxy solid	liquid		yellow liquid
molecular wt			995.43 <sup>133</sup>			450.65	
solubility		at 20°C: forms liquid crystals in water, etha- nol, and glycerin; insol- uble in propylene gly- col; forms a solid wax with wheat germ, avo- cado, and paraffin oils, and squalene; at 65°C: dispersible in water, clearly soluble in ethanol, in wheat germ, avocado, and paraffin oils, and squalene; tur- bid solubility in glycer- in; insoluble in propyl- ene glycol			slightly soluble to soluble in water		
melting point (°C)				50-58			
density (g/ml)							
specific gravity (g/ml)							
pH							
refractive index (20°C)							
saponification value		140-180		105-125			
acid value (mg KOH/g)				2.0			
hydroxyl value (mg KOH/g)							
peroxide value (meq of active oxygen/Kg)		≤1.0					
iodine value (gI <sub>2</sub> /100g)		≤1.0		3.0			
polarity							
HLB	11		6 <sup>134</sup> ; 8 <sup>127</sup>	~11			~5

**Table 6. Physical and Chemical Properties**

	<b>Polyglyceryl-3 Laurate<sup>135</sup></b>	<b>Polyglyceryl-4 Laurate</b>	<b>Polyglyceryl-10 Laurate</b>	<b>Polyglyceryl-10 Myristate<sup>136</sup></b>	<b>Polyglyceryl-3 Oleate</b>	<b>Polyglyceryl-4 Oleate</b>	<b>Polyglyceryl-10 Oleate</b>
physical characteristics	viscous liquid	viscous liquid <sup>137</sup>	light yellow viscous liquid <sup>6</sup>		yellow liquid <sup>138</sup>	amber liquid with an ester-like odor <sup>139</sup>	waxy solid <sup>25</sup>
molecular weight	422 (average)		349.48 <sup>126</sup>			504.7 <sup>126</sup>	1203.41 <sup>140</sup>
solubility						dispersible in water <sup>139</sup>	
melting point (°C)							
density (g/ml)						0.99 g/cm <sup>3</sup> <sup>139</sup>	
specific gravity (g/ml)							
pH							
refractive index (20°C)							
saponification value	128-144		30-45; 63-83 <sup>6</sup>	60-70	115 <sup>31</sup>		92.1 <sup>31</sup>
acid value (mg KOH/g)	6 max			5 max	1.5 <sup>31</sup>		4.2 <sup>31</sup>
hydroxyl value (mg KOH/g)							337 <sup>31</sup>
peroxide value (meq of active oxygen/Kg)							
iodine value (gI <sub>2</sub> /100g)							
polarity		non-ionic <sup>137</sup>			lipophilic <sup>138</sup>		
HLB		~11			~5 <sup>138</sup>		13 <sup>141</sup>
	<b>Polyglyceryl-10 Palmitate<sup>142</sup></b>	<b>Polyglyceryl-6 Pentacaprylate<sup>143</sup></b>	<b>Polyglyceryl-3 Pentacaprylate/ Caprate<sup>144</sup></b>	<b>Polyglyceryl-3 Pentaoleate<sup>145</sup></b>	<b>Polyglyceryl-10 Pentaoleate<sup>146,147</sup></b>	<b>Polyglyceryl-4 Pentastearate<sup>148</sup></b>	<b>Polyglyceryl-6 Pentastearate<sup>149,150</sup></b>
physical characteristics	liquid	liquid	liquid	amber viscous liquid	pale yellow to red-yellow viscous liquid	white to pale yellow pellet	pale yellow waxy solid
molecular wt							
solubility	slightly soluble to soluble in water	slightly soluble in water					easy to soluble in oil and organic solvent, and disperse into hot water
melting point (°C)							53-60
density (g/ml)							
specific gravity (g/ml)							
pH							
refractive index (20°C)							
saponification value				170-200			125-140
acid value (mg KOH/g)				5.0 max			2.0
hydroxyl value (mg KOH/g)							
peroxide value (meq of active oxygen/Kg)							
iodine value (gI <sub>2</sub> /100g)							3.0
polarity				non-ionic <sup>145</sup>			
HLB			3.0		3.5		~7.0



**Table 6. Physical and Chemical Properties**

	<b>Polyglyceryl-10 Pentastearate<sup>151,152</sup></b>	<b>Polyglyceryl-3 Rice Branate<sup>153</sup></b>	<b>Polyglyceryl-3 Ricinoate<sup>154</sup></b>	<b>Polyglyceryl-2 Sesquicaprylate</b>	<b>Polyglyceryl-2 Sesquioleate<sup>155</sup></b>	<b>Polyglyceryl-3 Soyate/Shea Butterate<sup>156</sup></b>	<b>Polyglyceryl-3 Stearate<sup>127</sup></b>
physical characteristics	white to pale yellow solid	light ivory (waxy solid (flakes)		yellow, transparent liquid <sup>157</sup>	highly viscous liquid	liquid	granules
molecular wt	2091.15						
solubility		dispersible in water; miscible in oils		insoluble in water, soluble in castor oil, ethanol, mineral oil <sup>157</sup>		slightly soluble to soluble in water	
melting point (°C)							
density (g/ml)		>1 g/ml (25°C)					
specific gravity (g/ml)							0.89-0.92 (25°C)
pH							
refractive index (20°C)							
saponification value							
acid value (mg KOH/g)							
hydroxyl value (mg KOH/g)							
peroxide value (meq of active oxygen/Kg)							
iodine value (gI <sub>2</sub> /100g)							
polarity		non-ionic		hydrophobic; non-ionic <sup>157</sup>			
HLB	3.5		4		~4		
	<b>Polyglyceryl-4 Stearate</b>	<b>Polyglyceryl-10 Stearate<sup>126,158</sup></b>	<b>Polyglyceryl-2 Tetraisostearate<sup>157</sup></b>	<b>Polyglyceryl-10 Tetraoleate<sup>159</sup></b>	<b>Polyglyceryl-2 Tetrastearate<sup>160</sup></b>	<b>Polyglyceryl-10 Tricocoate<sup>161</sup></b>	<b>Polyglyceryl-10 Tridecanoate<sup>162</sup></b>
physical characteristics		pale yellow to light yellow liquid or solid	yellow liquid	viscous amber to brown liquid		pale yellow viscous liquid	liquid
molecular wt	580.79 <sup>126</sup>	432.64			1095.97		
solubility			soluble in low and high polar esters and in vegetable oil, castor oil, and mineral oil; insoluble in water and ethanol	insoluble in water		insoluble in water	slightly soluble in water
melting point (°C)							
density (g/ml)							
specific gravity (g/ml)			0.926	1.01			
pH							
refractive index (20°C)			1.466				
saponification value							
acid value (mg KOH/g)							
hydroxyl value (mg KOH/g)							
peroxide value (meq of active oxygen/Kg)							
iodine value (gI <sub>2</sub> /100g)							
polarity		hydrophilic					
HLB		12.0					

**Table 6. Physical and Chemical Properties**

	<b>Polyglyceryl-10 Triisostearate<sup>163,164</sup></b>	<b>Polyglyceryl-10 Trioleate<sup>165</sup></b>	<b>Polyglyceryl-10 Tristearate<sup>166</sup></b>	<b>Rice Brain Oil Polyglyceryl-3 Esters</b>	<b>Safflower Seed Oil Polyglyceryl-6 Esters<sup>102</sup></b>	<b>Schinziophyton Rautanenii Kernel Oil Polyglyceryl-6 Esters<sup>103</sup></b>	<b>Sclerocarya Birrea Seed Oil Polygly- ceryl-6 Esters<sup>104</sup></b>
physical characteristics	pale yellow liquid	light yellow to red- yellow viscous liquid	white to pale yellow waxy substance	oily limpid liquid <sup>167</sup> clear, oily, amber-colored liquid <sup>168</sup>	amber (physical state not specified)	brown liquid	amber liquid
molecular wt							
solubility	insoluble in water			dispersible in water; miscible in oils <sup>167</sup>	water dispersible	water dispersible	water dispersible
melting point (°C)							
density (g/ml)				>1	<1	<1	<1
specific gravity (g/ml)							
pH							
refractive index (20°C)					approx. 1.47	approx. 1.47	approx.. 1.47
saponification value						145-165	145-165
acid value (mg KOH/g)					< 5	< 5	<5
hydroxyl value (mg KOH/g)							
peroxide value (meq of active oxygen/Kg)					<10	<10	<10
iodine value (gI <sub>2</sub> /100g)						95-110	50-65
polarity				non-ionic		non-ionic, amphiphilic	non-ionic, amphiphilic
HLB	8	7.0	7.5				

	<b>Sesame Oil Polyglyceryl-6 Esters<sup>105</sup></b>	<b>Shea Butter Polyglyceryl-6 Esters<sup>106</sup></b>	<b>Soybean Oil Polyglyceryl-6 Esters<sup>107</sup></b>	<b>Sunflower Seed Oil Polyglyceryl-10 Esters<sup>109</sup></b>	<b>Sweet Almond Oil Polyglyceryl-6 Esters<sup>110</sup></b>	<b>Trichilia Emetica Seed Oil Polyglyceryl-6 Esters<sup>111</sup></b>	<b>Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate<sup>50,169,170</sup></b>
physical characteristics	amber liquid	beige solid	dark orange liquid	amber viscous liquid	amber liquid	dark brown soft paste	hazy, viscous liquid
molecular wt							>1000
solubility	water dispersible	water dispersible	water dispersible	water dispersible	water dispersible	water dispersible	
melting point (°C)		35-45					
density (g/ml)	<1	<1	<1	>1	<1	<1	
specific gravity (g/ml)							
pH							
refractive index (20°C)	approx.. 1.47	approx.. 1.47	approx. 1.47	approx. 1.47	approx.. 1.47	approx.. 1.47	
saponification value	140-160	135-165	145-165	115-135	130-160	140-160	160-180
acid value (mg KOH/g)	<5	<5		< 5	<5	<5	≤10
hydroxyl value (mg KOH/g)							
peroxide value (meq of active oxygen/Kg)	<10	<10		<10	<10	<10	
iodine value (gI <sub>2</sub> /100g)	75-90	45-60	90-105	50-60	70-85	50-65	≤10
polarity	non-ionic, amphiphilic	non-ionic, amphiphilic	non-ionic, amphiphilic	non-ionic, amphiphilic	non-ionic, amphiphilic	non-ionic, amphiphilic	
HLB							

Table 6. Physical and Chemical Properties

Ximenia Americana	
Seed Oil	
Polyglyceryl-6	
Esters <sup>171</sup>	
physical characteristics	oil
molecular wt	
solubility	hydrodispersible - water soluble
melting point (°C)	
density (g/ml)	
specific gravity (g/ml)	
pH	
refractive index (20°C)	
saponification value	
acid value (mg KOH/g)	
hydroxyl value (mg KOH/g)	
peroxide value (meq of active oxygen/Kg)	
iodine value (gI <sub>2</sub> /100g)	
polarity	
HLB	

**Table 7. Specifications, Impurities, and/or Constituents**

<b>Ingredient</b>	<b>Specifications/Impurities/Constituents</b>	<b>Reference</b>
Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate	PEG-free	114
Polyglyceryl-4 Caprate	PEG-free	121
Polyglyceryl-6 Distearate	100% vegetable-derived ; PEG-free	134,172
Polyglyceryl-10 Distearate	arsenic = 0.002; heavy metals = 0.005	129
Polyglyceryl-4 Laurate	PEG-free	137
Polyglyceryl-4 Oleate	100 ppm D,L-tocopherol; <1% volatiles	139
Polyglyceryl-10 Myristate	2 ppm arsenic; 20 ppm heavy metals	136

Abbreviations: BHT - butylated hydroxytoluene; EG – polyethylene glycol

**Table 8. Frequency and concentration of use according to duration and type of exposure**

	# of Uses <sup>9</sup>	Max Conc of Use (%) <sup>10-14</sup>	# of Uses <sup>9</sup>	Max Conc of Use (%) <sup>10-14</sup>	# of Uses <sup>9</sup>	Max Conc of Use (%) <sup>10-14</sup>
	Acacia Decurrens/Jojoba/Sunflower Seed Wax Polyglyceryl-3 Ester		Babassu Oil Polyglyceryl-4 Esters		Babassu Oil Polyglyceryl-6 Esters	
<b>Totals*</b>	<b>10</b>	<b>2</b>	<b>18</b>	<b>2.3</b>	<b>1</b>	<b>NR</b>
<b>Duration of Use</b>						
Leave-On	9	2	NR	NR	NR	NR
Rinse-Off	1	NR	18	2.3	1	NR
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR
<b>Exposure Type</b>						
Eye Area	1	NR	NR	NR	NR	NR
Incidental Ingestion	1	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	2 <sup>a</sup> ; 1 <sup>b</sup>	NR	NR	NR	NR	NR
Incidental Inhalation-Powder	1 <sup>b</sup>	NR	NR	NR	NR	NR
Dermal Contact	9	2	1	2.3	1	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	17	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	2	NR	NR	NR	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR
	Candelilla/Jojoba/Rice Bran Polyglyceryl-3 Esters		Coconut Oil Polyglyceryl-6 Esters		Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate	
<b>Totals*</b>	<b>16</b>	<b>0.5-2</b>	<b>2</b>	<b>NR</b>	<b>3</b>	<b>2-4</b>
<b>Duration of Use</b>						
Leave-On	16	0.5-2	NR	NR	3	2-4
Rinse Off	NR	NR	2	NR	NR	NR
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR
<b>Exposure Type</b>						
Eye Area	6	NR	NR	NR	1	NR
Incidental Ingestion	1	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	4 <sup>a</sup> ; 1 <sup>b</sup>	NR	NR	NR	2 <sup>a</sup>	NR
Incidental Inhalation-Powder	1 <sup>b</sup>	NR	NR	NR	NR	NR
Dermal Contact	15	0.5-2	2	NR	3	2-4
Deodorant (underarm)	NR	aerosol: 0.5	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	1	NR	1	NR	NR	NR
Baby Products	1	1.5	NR	NR	NR	NR
	Glyceryl/Polyglyceryl-6 Isostearate/Behenate Esters		Macadamia Seed Oil Polyglyceryl-6 Esters Behenate		Palm Oil Polyglyceryl-4 Esters	
<b>NR</b>	<b>10</b>	<b>2</b>	<b>4</b>	<b>2-25</b>	<b>1</b>	<b>NR</b>
<b>Duration of Use</b>						
Leave-On	10	2	4	2-25	1	NR
Rinse-Off	NR	NR	NR	NR	NR	NR
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR
<b>Exposure Type</b>						
Eye Area	2	NR	2	2-3	NR	NR
Incidental Ingestion	2	NR	NR	25	NR	NR
Incidental Inhalation-Spray	NR	NR	1 <sup>a</sup>	NR	1 <sup>b</sup>	NR
Incidental Inhalation-Powder	NR	NR	NR	NR	1 <sup>b</sup>	NR
Dermal Contact	8	2	3	2	1	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	2	NR	NR	25	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR

**Table 8. Frequency and concentration of use according to duration and type of exposure**

	# of Uses <sup>9</sup> Max Conc of Use (%) <sup>10-14</sup>		# of Uses <sup>9</sup> Max Conc of Use (%) <sup>10-14</sup>		# of Uses <sup>9</sup> Max Conc of Use (%) <sup>10-14</sup>	
	<b>Polyglyceryl-2 Caprate</b>		<b>Polyglyceryl-2 Diisostearate</b>		<b>Polyglyceryl-2 Isopalmitate</b>	
<b>Totals</b>	<b>5</b>	<b>NR</b>	<b>983</b>	<b>0.1-18.8</b>	<b>9</b>	<b>NR</b>
<b>Duration of Use</b>						
<i>Leave-On</i>	5	NR	81	0.1-18.8	9	NR
<i>Rinse Off</i>	NR	NR	2	0.88-5	NR	NR
<i>Diluted for (Bath) Use</i>	NR	NR	NR	NR	NR	NR
<b>Exposure Type</b>						
Eye Area	NR	NR	6	1.5-4	NR	NR
Incidental Ingestion	NR	NR	33	4-18.8	9	NR
Incidental Inhalation-Spray	4 <sup>b</sup>	NR	8 <sup>a</sup> ; 15 <sup>b</sup>	0.25-5; 0.48-4 <sup>a</sup>	NR	NR
Incidental Inhalation-Powder	4 <sup>b</sup>	NR	15 <sup>b</sup>	0.1; 0.14-2 <sup>c</sup>	NR	NR
Dermal Contact	5	NR	48	0.1-5	NR	NR
Deodorant (underarm)	NR	NR	NR	0.1 (not spray)	NR	NR
Hair - Non-Coloring	NR	NR	NR	0.25-15	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	33	4-18.8	9	NR
Baby Products	NR	NR	NR	NR	NR	NR
	<b>Polyglyceryl-2 Isostearate</b>		<b>Polyglyceryl-2 Laurate</b>		<b>Polyglyceryl-2 Oleate</b>	
<b>Totals*</b>	<b>7</b>	<b>1-19.3</b>	<b>9</b>	<b>2-4.6</b>	<b>3</b>	<b>0.009-2.4</b>
<b>Duration of Use</b>						
<i>Leave-On</i>	6	1.6-19.3	6	2	3	0.09-1.6
<i>Rinse-Off</i>	1	1	3	4.6	NR	2.4
<i>Diluted for (Bath) Use</i>	NR	NR	NR	NR	NR	NR
<b>Exposure Type</b>						
Eye Area	NR	NR	1	NR	NR	0.27-2.4
Incidental Ingestion	NR	2.3-19.3	NR	NR	NR	NR
Incidental Inhalation-Spray	NR	NR	3 <sup>a</sup> ; 1 <sup>b</sup>	NR	3 <sup>a</sup>	NR
Incidental Inhalation-Powder	2	2.1 <sup>c</sup>	1 <sup>b</sup>	NR	NR	0.09 <sup>c</sup>
Dermal Contact	7	1-2.5	8	NR	3	0.09-2.4
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	1	2-4.6	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	1	2.3-19.3	NR	NR	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR
	<b>Polyglyceryl-2 Sesquiisostearate</b>		<b>Polyglyceryl-2 Sesquisteate</b>		<b>Polyglyceryl-2 Stearate</b>	
<b>Totals*</b>	<b>11</b>	<b>1.1-7.6</b>	<b>NR</b>	<b>0.9</b>	<b>NR</b>	<b>0.16-2.2</b>
<b>Duration of Use</b>						
<i>Leave-On</i>	9	2.1-7.6	NR	NR	NR	0.16-2.2
<i>Rinse-Off</i>	2	1.1	NR	0.9	NR	0.2
<i>Diluted for (Bath) Use</i>	NR	NR	NR	NR	NR	NR
<b>Exposure Type</b>						
Eye Area	NR	2.1	NR	NR	NR	0.2-1
Incidental Ingestion	NR	7.6	NR	NR	NR	0.2
Incidental Inhalation-Spray	2 <sup>a</sup> ; 2 <sup>b</sup>	NR	NR	NR	NR	NR
Incidental Inhalation-Powder	2 <sup>b</sup>	4.4 <sup>c</sup>	NR	NR	NR	2.2 <sup>c</sup>
Dermal Contact	7	1.1-4.4	NR	0.9	NR	0.16-2.2
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	2	7.6	NR	NR	NR	0.2
Baby Products	NR	NR	NR	NR	NR	NR

**Table 8. Frequency and concentration of use according to duration and type of exposure**

	# of Uses <sup>9</sup> Max Conc of Use (%) <sup>10-14</sup>		# of Uses <sup>9</sup> Max Conc of Use (%) <sup>10-14</sup>		# of Uses <sup>9</sup> Max Conc of Use (%) <sup>10-14</sup>	
	<b>Polyglyceryl-2 Tetraistearate</b>		<b>Polyglyceryl-2 Triistearate</b>		<b>Polyglyceryl-3 Beeswax</b>	
<b>Totals</b>	<b>28</b>	<b>0.5-7</b>	<b>160</b>	<b>0.12-40</b>	<b>63</b>	<b>0.5-5.8</b>
<b>Duration of Use</b>						
<i>Leave-On</i>	28	0.5-7	155	0.12-40	55	0.5-5.8
<i>Rinse Off</i>	NR	NR	5	1-4	8	2.5
<i>Diluted for (Bath) Use</i>	NR	NR	NR	NR	NR	NR
<b>Exposure Type</b>						
Eye Area	NR	NR	20	0.12-20	10	0.8-3
Incidental Ingestion	25	7	88	4.1-40	8	3.8-5.8
Incidental Inhalation-Spray	NR	NR	8 <sup>a</sup> ; 2 <sup>b</sup>	NR	1; 12 <sup>a</sup> ; 7 <sup>c</sup>	NR
Incidental Inhalation-Powder	NR	0.96	2; 2 <sup>b</sup>	0.49-2; 1-5 <sup>c</sup>	7 <sup>c</sup>	3.4; 4 <sup>c</sup>
Dermal Contact	3	0.5-4.6	72	0.12-20	11	0.5-3.4
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	3	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	25	7	89	4.1-40	8	3.8-5.8
Baby Products	NR	NR	NR	NR	NR	NR
	<b>Polyglyceryl-3 Caprate</b>		<b>Polyglyceryl-3 Caprylate</b>		<b>Polyglyceryl-3 Dicitrate/Stearate</b>	
<b>Totals*</b>	<b>12</b>	<b>NR</b>	<b>11</b>	<b>0.05-1</b>	<b>4</b>	<b>2-4</b>
<b>Duration of Use</b>						
<i>Leave-On</i>	11	NR	8	0.05-1	4	2-4
<i>Rinse-Off</i>	1	NR	3	0.6	NR	NR
<i>Diluted for (Bath) Use</i>	NR	NR	NR	NR	NR	NR
<b>Exposure Type</b>						
Eye Area	NR	NR	NR	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	NR	NR	1 <sup>b</sup>	0.05	4 <sup>a</sup>	NR
Incidental Inhalation-Powder	NR	NR	NR	0.05 <sup>c</sup>	NR	2-4 <sup>c</sup>
Dermal Contact	12	NR	11	0.05-1	1	2-4
Deodorant (underarm)	11 <sup>a</sup>	NR	6 <sup>a</sup>	not spray: 0.5-1; aerosol: 0.6	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR	3	2.2
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	1	NR	2	0.6	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR
	<b>Polyglyceryl-3 Diisostearate</b>		<b>Polyglyceryl-3 Distearate</b>		<b>Polyglyceryl-3 Isostearate</b>	
<b>Totals*</b>	<b>356</b>	<b>0.00000015-39</b>	<b>8</b>	<b>0.02-3</b>	<b>11</b>	<b>NR</b>
<b>Duration of Use</b>						
<i>Leave-On</i>	350	0.00000015-39	5	0.02-3	9	NR
<i>Rinse-Off</i>	5	0.000025-29.7	3	NR	2	NR
<i>Diluted for (Bath) Use</i>	1	0.5	NR	NR	NR	NR
<b>Exposure Type</b>						
Eye Area	41	0.006-12.2	NR	0.02-0.066	1	NR
Incidental Ingestion	206	7.8-39	NR	NR	NR	NR
Incidental Inhalation-Spray	34 <sup>a</sup> ; 24 <sup>b</sup>	0.00000015-0.5	1 <sup>a</sup>	3	3 <sup>a</sup> ; 4 <sup>b</sup>	NR
Incidental Inhalation-Powder	24 <sup>b</sup>	0.25; 0.03-1 <sup>c</sup>	NR	0.29 <sup>c</sup>	4 <sup>b</sup>	NR
Dermal Contact	143	0.003-12.2	4	0.29-1.3	11	NR
Deodorant (underarm)	NR	0.003-0.3 (not spray)	NR	NR	NR	NR
Hair - Non-Coloring	NR	0.00000015-0.003	4	1	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	210	0.003-29.7	NR	NR	NR	NR
Baby Products	NR	2	NR	NR	NR	NR

**Table 8. Frequency and concentration of use according to duration and type of exposure**

	# of Uses <sup>9</sup> Max Conc of Use (%) <sup>10-14</sup>		# of Uses <sup>9</sup> Max Conc of Use (%) <sup>10-14</sup>		# of Uses <sup>9</sup> Max Conc of Use (%) <sup>10-14</sup>	
	<b>Polyglyceryl-3 Laurate</b>		<b>Polyglyceryl-3 Oleate</b>		<b>Polyglyceryl-3 Pentaricinoleate</b>	
<b>Totals</b>	<b>118</b>	<b>0.6-6</b>	<b>14</b>	<b>1.2-1.5</b>	<b>NR</b>	<b>0.15</b>
<b>Duration of Use</b>						
Leave-On	2	6	11	1.2-1.5	NR	0.15
Rinse Off	116	0.6-2	3	NR	NR	NR
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR
<b>Exposure Type</b>						
Eye Area	NR	6	2	1.5	NR	0.15
Incidental Ingestion	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	1 <sup>a</sup> ; 1 <sup>b</sup>	NR	6 <sup>a</sup> ; 2 <sup>b</sup>	NR	NR	NR
Incidental Inhalation-Powder	1 <sup>b</sup>	NR	2 <sup>b</sup>	NR	NR	NR
Dermal Contact	109	2-6	14	1.5	NR	0.15
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	9	0.6-2	NR	1.2	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	106	NR	NR	NR	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR
	<b>Polyglyceryl-3 Ricinoleate</b>		<b>Polyglyceryl-3 Stearate</b>		<b>Polyglyceryl-4 Caprate</b>	
<b>Totals*</b>	<b>62</b>	<b>0.25-2</b>	<b>15</b>	<b>0.5-0.61</b>	<b>15</b>	<b>0.5-1.5</b>
<b>Duration of Use</b>						
Leave-On	62	0.25-2	12	0.5-0.54	5	0.5-1.5
Rinse-Off	NR	NR	3	0.61	9	0.9-1.5
Diluted for (Bath) Use	NR	NR	NR	NR	1	NR
<b>Exposure Type</b>						
Eye Area	5	NR	NR	NR	2	NR
Incidental Ingestion	NR	NR	1	0.5	NR	NR
Incidental Inhalation-Spray	51 <sup>a</sup> ; 2 <sup>b</sup>	NR	2 <sup>a</sup> ; 8 <sup>b</sup>	NR	1 <sup>a</sup> ; 2 <sup>b</sup>	0.5 <sup>a</sup>
Incidental Inhalation-Powder	2 <sup>b</sup>	0.25	8 <sup>b</sup>	NR	2 <sup>b</sup>	0.72 <sup>c</sup>
Dermal Contact	57	0.25-2	14	0.54-0.61	14	0.72-1.5
Deodorant (underarm)	NR	NR	NR	NR	1 <sup>a</sup>	1.5 (not spray)
Hair - Non-Coloring	NR	NR	NR	NR	1	0.5-1.1
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	1	0.5	4	1-1.5
Baby Products	NR	NR	NR	NR	NR	NR
	<b>Polyglyceryl-4 Isostearate</b>		<b>Polyglyceryl-4 Laurate</b>		<b>Polyglyceryl-4 Oleate</b>	
<b>Totals*</b>	<b>269</b>	<b>0.067-24.1</b>	<b>10</b>	<b>0.47</b>	<b>7</b>	<b>1.8</b>
<b>Duration of Use</b>						
Leave-On	268	0.067-24.1	9	NR	7	1.8
Rinse-Off	1	0.16-1.7	1	0.47	NR	NR
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR
<b>Exposure Type</b>						
Eye Area	50	1.2-24.1	1	NR	2	NR
Incidental Ingestion	41	0.067-10.9	NR	NR	NR	NR
Incidental Inhalation-Spray	18 <sup>a</sup> ; 8 <sup>b</sup>	0.26; 1.1-2.1 <sup>a</sup>	4 <sup>a</sup>	NR	3 <sup>a</sup>	1.8
Incidental Inhalation-Powder	3; 8 <sup>b</sup> ; 1 <sup>c</sup>	0.17; 0.5-2.5 <sup>c</sup>	NR	NR	NR	NR
Dermal Contact	222	0.067-24.1	10	0.47	7	1.8
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	2	2.1	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	41	0.067-10.9	NR	NR	NR	NR
Baby Products	1	1	NR	NR	NR	NR



**Table 8. Frequency and concentration of use according to duration and type of exposure**

	# of Uses <sup>9</sup> Max Conc of Use (%) <sup>10-14</sup>		# of Uses <sup>9</sup> Max Conc of Use (%) <sup>10-14</sup>		# of Uses <sup>9</sup> Max Conc of Use (%) <sup>10-14</sup>	
	<b>Polyglyceryl-5 Dioleate</b>		<b>Polyglyceryl-5 Isostearate</b>		<b>Polyglyceryl-5 Laurate</b>	
<b>Totals</b>	<b>1</b>	<b>NR</b>	<b>2</b>	<b>NR</b>	<b>2</b>	<b>0.6</b>
<b>Duration of Use</b>						
<i>Leave-On</i>	NR	NR	2	NR	NR	0.6
<i>Rinse Off</i>	1	NR	NR	NR	1	0.6
<i>Diluted for (Bath) Use</i>	NR	NR	NR	NR	1	NR
<b>Exposure Type</b>						
Eye Area	NR	NR	1	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	NR	NR	1 <sup>b</sup>	NR	NR	NR
Incidental Inhalation-Powder	NR	NR	1 <sup>b</sup>	NR	NR	0.6 <sup>c</sup>
Dermal Contact	1	NR	2	NR	2	0.6
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	1	NR	NR	NR	2	NR
Baby Products	NR	NR	NR	NR	NR	NR
	<b>Polyglyceryl-5 Oleate</b>		<b>Polyglyceryl-5 Stearate</b>		<b>Polyglyceryl-5 Triisostearate</b>	
<b>Totals*</b>	<b>10</b>	<b>0.35</b>	<b>NR</b>	<b>1</b>	<b>NR</b>	<b>1-5</b>
<b>Duration of Use</b>						
<i>Leave-On</i>	8	0.35	NR	1	NR	1-5
<i>Rinse-Off</i>	2	NR	NR	NR	NR	NR
<i>Diluted for (Bath) Use</i>	NR	NR	NR	NR	NR	NR
<b>Exposure Type</b>						
Eye Area	NR	NR	NR	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR	NR	5
Incidental Inhalation-Spray	6 <sup>a</sup>	0.35 <sup>c</sup>	NR	NR	NR	NR
Incidental Inhalation-Powder	NR	NR	NR	1 <sup>c</sup>	NR	NR
Dermal Contact	10	0.35	NR	1	NR	1
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	1	NR	NR	NR	NR	5
Baby Products	NR	NR	NR	NR	NR	NR
	<b>Polyglyceryl-5 Trioleate</b>		<b>Polyglyceryl-6 Caprylate/Caprate</b>		<b>Polyglyceryl-6 Dioleate</b>	
<b>Totals*</b>	<b>6</b>	<b>2.8</b>	<b>NR</b>	<b>0.75</b>	<b>27</b>	<b>1.8-2.4</b>
<b>Duration of Use</b>						
<i>Leave-On</i>	6	NR	NR	NR	20	2.4
<i>Rinse-Off</i>	NR	2.8	NR	0.75	7	1.8
<i>Diluted for (Bath) Use</i>	NR	NR	NR	NR	NR	NR
<b>Exposure Type</b>						
Eye Area	NR	NR	NR	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR	2	NR
Incidental Inhalation-Spray	1 <sup>a</sup> ; 5 <sup>b</sup>	NR	NR	NR	2 <sup>a</sup> ; 7 <sup>b</sup>	NR
Incidental Inhalation-Powder	5 <sup>b</sup>	NR	NR	NR	7 <sup>b</sup>	2.4 <sup>c</sup>
Dermal Contact	6	NR	NR	NR	19	2.4
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	2.8	NR	0.75	6	1.8
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	NR	2	NR
Baby Products	NR	NR	NR	NR	NR	NR

**Table 8. Frequency and concentration of use according to duration and type of exposure**

	# of Uses <sup>9</sup> Max Conc of Use (%) <sup>10-14</sup>		# of Uses <sup>9</sup> Max Conc of Use (%) <sup>10-14</sup>		# of Uses <sup>9</sup> Max Conc of Use (%) <sup>10-14</sup>	
	<b>Polyglyceryl-6 Distearate</b>		<b>Polyglyceryl-6 Isostearate</b>		<b>Polyglyceryl-6 Octastearate</b>	
<b>Totals</b>	<b>22</b>	<b>4-22.4</b>	<b>14</b>	<b>NR</b>	<b>1</b>	<b>NR</b>
<b>Duration of Use</b>						
Leave-On	21	4-22.4	14	NR	1	NR
Rinse Off	1	NR	NR	NR	NR	NR
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR
<b>Exposure Type</b>						
Eye Area	4	4	NR	NR	NR	NR
Incidental Ingestion	1	22.4	1	NR	NR	NR
Incidental Inhalation-Spray	7 <sup>a</sup> ; 8 <sup>b</sup>	NR	4 <sup>a</sup> ; 8 <sup>b</sup>	NR	1 <sup>a</sup>	NR
Incidental Inhalation-Powder	8 <sup>b</sup> ; 1 <sup>c</sup>	NR	8 <sup>b</sup>	NR	NR	NR
Dermal Contact	19	4-10.5	13	NR	1	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	5	NR	NR	NR	NR
Mucous Membrane	2	22.4	1	NR	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR
	<b>Polyglyceryl-6 Oleate</b>		<b>Polyglyceryl-6 Pentastearate</b>		<b>Polyglyceryl-6 Ricinoleate</b>	
<b>Totals*</b>	<b>1</b>	<b>NR</b>	<b>NR</b>	<b>5</b>	<b>1</b>	<b>NR</b>
<b>Duration of Use</b>						
Leave-On	1	NR	NR	5	1	NR
Rinse-Off	NR	NR	NR	NR	NR	NR
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR
<b>Exposure Type</b>						
Eye Area	NR	NR	NR	5	NR	NR
Incidental Ingestion	NR	NR	NR	NR	1	NR
Incidental Inhalation-Spray	1 <sup>b</sup>	NR	NR	NR	NR	NR
Incidental Inhalation-Powder	1 <sup>b</sup>	NR	NR	NR	NR	NR
Dermal Contact	1	NR	NR	5	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	NR	1	NR
Baby Products	NR	NR	NR	NR	NR	NR
	<b>Polyglyceryl-6 Tricaprylate</b>		<b>Polyglyceryl-8 Decabehenate/Caprate</b>		<b>Polyglyceryl-8 Decaerucate/Decaiso-stearate/Decaricinoleate</b>	
<b>Totals*</b>	<b>NR</b>	<b>3.6</b>	<b>NR</b>	<b>9</b>	<b>1</b>	<b>NR</b>
<b>Duration of Use</b>						
Leave-On	NR	3.6	NR	9	1	NR
Rinse-Off	NR	NR	NR	NR	NR	NR
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR
<b>Exposure Type</b>						
Eye Area	NR	NR	NR	NR	NR	NR
Incidental Ingestion	NR	NR	NR	9	NR	NR
Incidental Inhalation-Spray	NR	NR	NR	NR	1 <sup>b</sup>	NR
Incidental Inhalation-Powder	NR	NR	NR	NR	1 <sup>b</sup>	NR
Dermal Contact	NR	3.6	NR	NR	1	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	9	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR

**Table 8. Frequency and concentration of use according to duration and type of exposure**

	# of Uses <sup>9</sup> Max Conc of Use (%) <sup>10-14</sup>		# of Uses <sup>9</sup> Max Conc of Use (%) <sup>10-14</sup>		# of Uses <sup>9</sup> Max Conc of Use (%) <sup>10-14</sup>	
	<b>Polyglyceryl-10 Behenate/Eicosadioate</b>		<b>Polyglyceryl-10 Decaisostearate</b>		<b>Polyglyceryl-10 Decaoleate</b>	
<b>Totals</b>	<b>2</b>	<b>2-5</b>	<b>NR</b>	<b>2.7</b>	<b>10</b>	<b>0.01-5</b>
<b>Duration of Use</b>						
<i>Leave-On</i>	1	2	NR	2.7	10	1-5
<i>Rinse Off</i>	1	5	NR	NR	NR	0.01
<i>Diluted for (Bath) Use</i>	NR	NR	NR	NR	NR	NR
<b>Exposure Type</b>						
Eye Area	NR	NR	NR	2.7	NR	NR
Incidental Ingestion	NR	2	NR	NR	3	5
Incidental Inhalation-Spray	NR	NR	NR	NR	4 <sup>a</sup>	NR
Incidental Inhalation-Powder	NR	NR	NR	NR	NR	NR
Dermal Contact	2	5	NR	2.7	7	1-5
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	2	NR	NR	3	0.01
Baby Products	NR	NR	NR	NR	NR	NR
	<b>Polyglyceryl-10 Diisostearate</b>		<b>Polyglyceryl-10 Dioleate</b>		<b>Polyglyceryl-10 Dipalmitate</b>	
<b>Totals*</b>	<b>9</b>	<b>0.8-17</b>	<b>NR</b>	<b>3.9</b>	<b>17</b>	<b>2-10</b>
<b>Duration of Use</b>						
<i>Leave-On</i>	8	0.8-2	NR	NR	3	10
<i>Rinse-Off</i>	1	1.6-17	NR	NR	12	2
<i>Diluted for (Bath) Use</i>	NR	NR	NR	NR	2	2
<b>Exposure Type</b>						
Eye Area	NR	NR	NR	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR	1	NR
Incidental Inhalation-Spray	3 <sup>a</sup> ; 4 <sup>b</sup>	2 <sup>a</sup>	NR	NR	1 <sup>b</sup>	NR
Incidental Inhalation-Powder	4 <sup>b</sup>	0.8 <sup>c</sup>	NR	NR	1 <sup>b</sup>	10 <sup>c</sup>
Dermal Contact	9	0.8-17	NR	3.9	16	2-10
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	2	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	NR	12	2
Baby Products	NR	NR	NR	NR	NR	NR
	<b>Polyglyceryl-10 Distearate</b>		<b>Polyglyceryl-10 Heptahydroxystearate</b>		<b>Polyglyceryl-10 Hydroxystearate/ Stearate/Eicosadioate</b>	
<b>Totals*</b>	<b>10</b>	<b>NR</b>	<b>NR</b>	<b>1-2</b>	<b>2</b>	<b>0.62-1.8</b>
<b>Duration of Use</b>						
<i>Leave-On</i>	9	NR	NR	1-2	1	0.62-1.2
<i>Rinse-Off</i>	1	NR	NR	NR	1	1.8
<i>Diluted for (Bath) Use</i>	NR	NR	NR	NR	NR	NR
<b>Exposure Type</b>						
Eye Area	NR	NR	NR	NR	NR	NR
Incidental Ingestion	NR	NR	NR	2	NR	0.62-1.2
Incidental Inhalation-Spray	9 <sup>a</sup>	NR	NR	NR	NR	NR
Incidental Inhalation-Powder	NR	NR	NR	NR	NR	NR
Dermal Contact	10	NR	NR	1	2	1.8
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	1	NR	NR	2	NR	0.62-1.2
Baby Products	NR	NR	NR	NR	NR	NR

**Table 8. Frequency and concentration of use according to duration and type of exposure**

	# of Uses <sup>9</sup> Max Conc of Use (%) <sup>10-14</sup>		# of Uses <sup>9</sup> Max Conc of Use (%) <sup>10-14</sup>		# of Uses <sup>9</sup> Max Conc of Use (%) <sup>10-14</sup>	
	<b>Polyglyceryl-10 Isostearate</b>		<b>Polyglyceryl-10 Laurate</b>		<b>Polyglyceryl-10 Myristate</b>	
<b>Totals</b>	<b>3</b>	<b>0.6</b>	<b>44</b>	<b>0.0009-6.5</b>	<b>18</b>	<b>0.0003-1.2</b>
<b>Duration of Use</b>						
Leave-On	NR	0.6	36	0.0009-6.5	11	0.0003-1.2
Rinse Off	NR	NR	8	0.2-5	7	0.0003-0.04
Diluted for (Bath) Use	NR	NR	NR	0.69-2	NR	NR
<b>Exposure Type</b>						
Eye Area	NR	NR	5	NR	1	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	3 <sup>a</sup>	0.6 (pump spray)	11 <sup>a</sup> ; 9 <sup>b</sup>	0.5; 6.5 <sup>a</sup>	6 <sup>a</sup> ; 3 <sup>b</sup>	NR
Incidental Inhalation-Powder	NR	NR	9 <sup>b</sup>	NR	3 <sup>b</sup>	0.8 <sup>c</sup>
Dermal Contact	3	0.6	39	0.0009-2	17	0.0003-1.2
Deodorant (underarm)	NR	NR	NR	NR	NR	not spray: 0.0003 aerosol: 0.1
Hair - Non-Coloring	NR	NR	5	0.5-6.5	1	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	2	NR	NR
Baby Products	NR	NR	6	1	1	NR
	<b>Polyglyceryl-10 Nonaisostearate</b>		<b>Polyglyceryl-10 Oleate</b>		<b>Polyglyceryl-10 Pentahydroxystearate</b>	
<b>Totals*</b>	<b>58</b>	<b>0.5</b>	<b>26</b>	<b>0.0000085-3</b>	<b>3</b>	<b>NR</b>
<b>Duration of Use</b>						
Leave-On	58	NR	19	0.21-3	2	NR
Rinse-Off	NR	0.5	7	0.0000085	1	NR
Diluted for (Bath) Use	NR	NR	NR	2	NR	NR
<b>Exposure Type</b>						
Eye Area	23	NR	NR	0.63	1	NR
Incidental Ingestion	26	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	NR	NR	10 <sup>a</sup> ; 7 <sup>b</sup>	1	1 <sup>a</sup>	NR
Incidental Inhalation-Powder	NR	NR	7 <sup>b</sup>	0.21-3 <sup>c</sup>	NR	NR
Dermal Contact	32	0.5	21	0.0000085-3	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	2	NR
Hair - Non-Coloring	NR	NR	5	0.0000085-1	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	26	NR	NR	2	NR	NR
Baby Products	NR	NR	1	NR	NR	NR
	<b>Polyglyceryl-10 Pentaistearate</b>		<b>Polyglyceryl-10 Pentaoleate</b>		<b>Polyglyceryl-10 Pentastearate</b>	
<b>Totals*</b>	<b>NR</b>	<b>2-4.8</b>	<b>5</b>	<b>1-2.6</b>	<b>13</b>	<b>0.0003-2.2</b>
<b>Duration of Use</b>						
Leave-On	NR	2-4.8	5	1-2.6	11	0.0003-2.2
Rinse-Off	NR	NR	NR	NR	2	0.0003-0.1
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR
<b>Exposure Type</b>						
Eye Area	NR	NR	1	NR	1	NR
Incidental Ingestion	NR	4.8	1	2.6	NR	0.0003-2
Incidental Inhalation-Spray	NR	NR	1; 1 <sup>a</sup>	1 <sup>a</sup>	6 <sup>a</sup> ; 3 <sup>b</sup>	NR
Incidental Inhalation-Powder	NR	2 <sup>c</sup>	NR	NR	3 <sup>b</sup>	1-2.2 <sup>c</sup>
Dermal Contact	NR	2	2	NR	12	0.0003-2.2
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	2	1	1	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	4.8	1	2.6	NR	0.0003-2
Baby Products	NR	NR	NR	NR	NR	NR

**Table 8. Frequency and concentration of use according to duration and type of exposure**

	# of Uses <sup>9</sup>	Max Conc of Use (%) <sup>10-14</sup>	# of Uses <sup>9</sup>	Max Conc of Use (%) <sup>10-14</sup>	# of Uses <sup>9</sup>	Max Conc of Use (%) <sup>10-14</sup>
	<b>Polyglyceryl-10 Stearate</b>		<b>Polyglyceryl-10 Tristearate</b>		<b>Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate</b>	
<b>Totals*</b>	<b>89</b>	<b>0.13-2</b>	<b>1</b>	<b>NR</b>	<b>19</b>	<b>1-11.2</b>
<b>Duration of Use</b>						
<i>Leave-On</i>	82	0.13-2	1	NR	19	1-11.2
<i>Rinse-Off</i>	7	1	NR	NR	NR	NR
<i>Diluted for (Bath) Use</i>	NR	NR	NR	NR	NR	NR
<b>Exposure Type</b>						
Eye Area	11	0.41-1.8	1	NR	1	1-1.2
Incidental Ingestion	NR	NR	NR	NR	17	9-11.2
Incidental Inhalation-Spray	28 <sup>a</sup> ; 30 <sup>b</sup>	0.25 <sup>a</sup>	NR	NR	NR	NR
Incidental Inhalation-Powder	30 <sup>b</sup>	0.13-2 <sup>c</sup>	NR	NR	NR	NR
Dermal Contact	88	0.13-2	1	NR	2	1-1.2
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	1	0.25	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	NR	17	9-11.2
Baby Products	NR	NR	NR	NR	NR	NR

\*Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure types may not equal the sum of total uses.

<sup>a</sup> Includes products that can be sprays, but it is not known whether the reported uses are sprays

<sup>b</sup> Not specified whether this product is a spray or a powder or neither, but it is possible it may be a spray or a powder, so this information is captured for both categories of incidental inhalation

<sup>c</sup> Includes products that can be powders, but it is not known whether the reported uses are powders

NR – no reported use

NS – survey results have not yet been received

**Table 9. Supplier Recommended Use Levels**

<b>Ingredient</b>	<b>Supplier-Recommended Concentration</b>	<b>Reference</b>
Acacia Decurrens/Jojoba/ Sunflower Seed Wax Polyglyceryl 3 Esters	1-5%	<sup>173</sup>
Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate	3.0%	<sup>114</sup>
Polyglyceryl-4 Caprate	2-10%	<sup>121</sup>
Polyglyceryl-3 Caprylate	0.2-2%	<sup>118</sup>
Polyglyceryl-10 Caprylate/Caprate	1-7%	<sup>119</sup>
Polyglyceryl-4 Cocoate	1-5%	<sup>174</sup>
Polyglyceryl-6 Distearate	1-3%	<sup>134</sup>
	4-6	<sup>172</sup>
Polyglyceryl-10 Eicosanedioate/Tetradecanedioate	1-10%	<sup>175</sup>
Polyglyceryl-4 Isostearate	2.5-4%	<sup>132</sup>
Polyglyceryl-4 Laurate (in o/w lotion wipes)	5.0 - 10.0 % in concentrates 0.5 - 1.0 % in impregnating liquids	<sup>137</sup>
Polyglyceryl-10 Laurate (~60% pure, with ~40% polyglycerin-10 and ~2% sodium laurate)	≤3%	<sup>20</sup>
Polyglyceryl-3 Oleate	2.5-4%	<sup>138</sup>
Polyglyceryl-10 Oleate	1-7%	<sup>141</sup>
Polyglyceryl-3 Ricinoleate	3.5-4% (w/o emulsions); 5-25% (anhydrous products)	<sup>154</sup>
Polyglyceryl-2 Sesquileate	2-3%	<sup>155</sup>

**Table 10.** Ingredients Not Reported to be Used <sup>9-14</sup>

Adansonia Digitata Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Rice Branate	Polyglyceryl-6 Pentaricinoleate	Polyglyceryl-10 Tetradecanedioate
Almond Oil/Polyglyceryl-10 Esters	Polyglyceryl-3 Soyate/Shea Butterate	Polyglyceryl-6 Schinzioophyton Rautanenii Kernelate	Polyglyceryl-10 Tetralaurate
Apricot Kernel Oil Polyglyceryl-3 Esters	Polyglyceryl-3 Stearate SE	Polyglyceryl-6 Sclerocarya Birrea Seedate	Polyglyceryl-10 Tetraoleate
Apricot Kernel Oil Polyglyceryl-4 Esters	Polyglyceryl-3 Triisostearate	Polyglyceryl-6 Sesquicaprylate	Polyglyceryl-10 Tricocoate
Apricot Kernel Oil Polyglyceryl-5 Esters	Polyglyceryl-3 Triolivate	Polyglyceryl-6 Sesquiosostearate	Polyglyceryl-10 Tridecanoate
Apricot Kernel Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Almondote/Shea Butterate	Polyglyceryl-6 Sesquisteate	Polyglyceryl-10 Trierucate
Apricot Kernel Oil Polyglyceryl-10 Esters	Polyglyceryl-4 Caprylate	Polyglyceryl-6 Stearate	Polyglyceryl-10 Triisostearate
Argan Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Caprylate/Caprata	Polyglyceryl-6 Terabehenate	Polyglyceryl-10 Trilaurate
Astrocaryum Vulgare Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Coccoate	Polyglyceryl-6 Tetracaprylate	Polyglyceryl-10 Trioleate
Avocado Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Dilaurate	Polyglyceryl-6 Tetraoleate	Polyglyceryl-10 Undecylenate
Bertholletia Excelsa Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Distearate	Polyglyceryl-6 Trichilia Emetica Seedate	Polyglyceryl-15 Diisostearate
Borage Seed Oil Polyglyceryl-4 Esters	Polyglyceryl-4 Hazelnutseedate	Polyglyceryl-6 Tristearate	Polyglyceryl-20 Docosabehenate/Isostearate
Borage Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Isostearate/Laurate	Polyglyceryl-6 Undecylenate	Polyglyceryl-20 Docosabehenate/Laurate
Caprylic/Capric Glycerides Polyglyceryl-10 Esters	Polyglyceryl-4 Laurate/Sebacate	Polyglyceryl-6 Ximenia Americana Seedate	Polyglyceryl-20 Docosabehenate/Oleate
Carapa Guaianensis Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Laurate/Succinate	Polyglyceryl-8 C12-20 Acid Ester	Polyglyceryl-20 Heptacaprylate
Castor Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Pentaoleate	Polyglyceryl-8 Oleate	Polyglyceryl-20 Heptadecabehenate/Laurate
Cocoa Butter Polyglyceryl-6 Esters	Polyglyceryl-4 Pentapalmitate/Stearate	Polyglyceryl-8 Stearate	Polyglyceryl-20 Hexacaprylate
Coffee Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Pentastearate	Polyglyceryl-10 Apricot Kernelate	Polyglyceryl-20 Octadecabehenate/Laurate
Hazelnut Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Punicate	Polyglyceryl-10 Caprate	Polyglyceryl-20 Octaisnonanoate
Linseed Oil Polyglyceryl-4 Esters	Polyglyceryl-4 Stearate	Polyglyceryl-10 Caprylate	Pumpkin Seed Oil Polyglyceryl-4 Esters
Macadamia Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Sweet Almondote	Polyglyceryl-10 Caprylate/Caprata	Pumpkin Seed Oil Polyglyceryl-4 Esters Succinate
Mauritia Flexuosa Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Tristearate	Polyglyceryl-10 Coccoate	Rice Bran Oil Polyglyceryl-3 Esters
Olive Oil Polyglyceryl-3 Esters	Polyglyceryl-5 Caprate	Polyglyceryl-10 Decaethylhexanoate	Rosa Rubiginosa Seed Oil Polyglyceryl-6 Esters
Olive Oil Polyglyceryl-4 Esters	Polyglyceryl-5 Dicaprylate	Polyglyceryl-10 Decahydroxystearate	Safflower Seed Oil Polyglyceryl-6 Esters
Olive Oil Polyglyceryl-6 Esters	Polyglyceryl-5 Dilaurate	Polyglyceryl-10 Decalinoleate	Schinzioophyton Rautanenii Kernel Oil Polyglyceryl-6 Esters
Palm Kernel Oil Polyglyceryl-4 Esters	Polyglyceryl-5 Hexastearate	Polyglyceryl-10 Decamacadamiate	Sclerocarya Birrea Seed Oil Polyglyceryl-6 Esters
Palm Oil Polyglyceryl-3 Esters	Polyglyceryl-5 Myristate	Polyglyceryl-10 Decastearate	Sclerocarya Birrea Seed Oil Polyglyceryl-10 Esters
Palm Oil Polyglyceryl-5 Esters	Polyglyceryl-5 Pentamyrystate	Polyglyceryl-10 Dicocoate	Sesame Oil Polyglyceryl-6 Esters
Palm Oil Polyglyceryl-6 Esters	Polyglyceryl-5 Ricinoleate	Polyglyceryl-10 Didecanoate	Shea Butter Polyglyceryl-3 Esters
Parinari Curatellifolia Oil Polyglyceryl-6 Esters	Polyglyceryl-5 Tribehenate	Polyglyceryl-10 Dilaurate	Shea Butter Polyglyceryl-4 Esters
Pinus Sibirica Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-5 Trimyrystate	Polyglyceryl-10 Dimyrystate	Shea Butter Polyglyceryl-6 Esters
Polyglyceryl-2 Caprylate	Polyglyceryl-5 Tristearate	Polyglyceryl-10 Dodecabehenate	Shea Butter Polyglyceryl-6 Esters
Polyglyceryl-2 Dioleate	Polyglyceryl-6 Adansonia Digitata Seedate	Polyglyceryl-10 Dodecacaprata	Soybean Oil Polyglyceryl-6 Esters
Polyglyceryl-2 Distearate	Polyglyceryl-6 Apricot Kernelate	Polyglyceryl-10 Dodecacaprylate	Sunflower Seed Oil Polyglyceryl-3 Esters
Polyglyceryl-2 Isopalmitate/Sebacate	Polyglyceryl-6 Argan Kernelate	Polyglyceryl-10 Dodeca-Caprylate/ Caprate	Sunflower Seed Oil Polyglyceryl-4 Esters
Polyglyceryl-2 Myristate	Polyglyceryl-6 Behenate	Polyglyceryl-10 Eicosanedioate/Tetradecanedioate	Sunflower Seed Oil Polyglyceryl-5 Esters
Polyglyceryl-2 Palmitate	Polyglyceryl-6 Caprate	Polyglyceryl-10 Hepta(Behenate/Stearate)	Sunflower Seed Oil Polyglyceryl-6 Esters
Polyglyceryl-2 Sesquicaprylate	Polyglyceryl-6 Caprylate	Polyglyceryl-10 Heptaoleate	Sunflower Seed Oil Polyglyceryl-10 Esters
Polyglyceryl-2 Sesquioleate	Polyglyceryl-6 Citrullus Lanatus Seedate	Polyglyceryl-10 Heptastearate	Sweet Almond Oil Polyglyceryl-4 Esters
Polyglyceryl-2 Tetrabehenate/ Macadamiate/Sebacate	Polyglyceryl-6 Dicaprate	Polyglyceryl-10 Hexaerucate	Sweet Almond Oil Polyglyceryl-6 Esters
Polyglyceryl-2 Tetraoleate	Polyglyceryl-6 Diisostearate	Polyglyceryl-10 Hexaisostearate	Theobroma Grandiflorum Seed Butter Polyglyceryl-6 Esters
Polyglyceryl-2 Tetraoleate	Polyglyceryl-6 Dipalmitate	Polyglyceryl-10 Hexaoleate	Trichilia Emetica Seed Oil Polyglyceryl-6 Esters
Polyglyceryl-3 Behenate	Polyglyceryl-6 Heptacaprylate	Polyglyceryl-10 Linoleate	Watermelon Seed Oil Polyglyceryl-6 Esters
Polyglyceryl-3 Coccoate	Polyglyceryl-6 Hexaoleate	Polyglyceryl-10 Mono/Dioleate	Watermelon Seed Oil Polyglyceryl-10 Esters
Polyglyceryl-3 Dicaprate	Polyglyceryl-6 Hexastearate	Polyglyceryl-10 Nonaerucate	Ximenia Americana Seed Oil Polyglyceryl-6 Esters
Polyglyceryl-3 Dicocoate	Polyglyceryl-6 Laurate	Polyglyceryl-10 Palmate	
Polyglyceryl-3 Di-Hydroxystearate	Polyglyceryl-6 Myristate	Polyglyceryl-10 Palmitate	
Polyglyceryl-3 Dioleate	Polyglyceryl-6 Octacaprylate	Polyglyceryl-10 Pentacaprylate	
Polyglyceryl-3 Myristate	Polyglyceryl-6 Palmitate	Polyglyceryl-10 Pentalaurate	
Polyglyceryl-3 Palmitate	Polyglyceryl-6 Palmitate/Succinate	Polyglyceryl-10 Pentalinoleate	
Polyglyceryl-3 Pentacaprylate/Caprata	Polyglyceryl-6 Pentacaprylate	Polyglyceryl-10 Pentaricinoleate	
Polyglyceryl-3 Pentaolivate	Polyglyceryl-6 Pentaoleate	Polyglyceryl-10 Sesquisteate	

**Table 11. Disposition of radioactivity in rats after a single oral dose**

<b>Catabolism Study<sup>31</sup></b>						
<b>Test Compound - Ingredients</b>	<b>% radioactivity recovered</b>					
	<b>CO<sub>2</sub></b>	<b>urine</b>	<b>Feces</b>	<b>GI contents</b>	<b>carcass</b>	
[ <sup>14</sup> C]Polyglyceryl-10 Oleate	2.1	36.8	9.5	46.5	5.3	
[ <sup>14</sup> C]Polyglyceryl-10 Decaoleate	3.5	33.5	15.5	44.6	3.0	
polyglyceryl-3 [ <sup>14</sup> C]oleate	68.2	1.3	0.1	2.8	27.7	
polyglyceryl-10 [ <sup>14</sup> C]oleate	68.5	2.2	0.6	4.0	24.7	
polyglyceryl-10 [ <sup>14</sup> C]decaoleate	66.0	1.7	0.9	2.8	28.7	
<b>For Comparison</b>						
glycerol-1,3- <sup>14</sup> C	73.3	5.2	0.7	1.3	19.5	
[ <sup>14</sup> C]polyglycerin-3	2.1	88.3	5.5	2.9	1.2	
[ <sup>14</sup> C]polyglycerin-10	4.2	34.1	23.9	35.2	2.5	
triglycerol [ <sup>14</sup> C]tetraoleate	70.4	1.4	1.5	3.0	23.6	
polyglycerin-10 [ <sup>14</sup> C]monoeicosanoate	55.5	1.6	9.9	12.2	20.8	
<b>Catabolism- Absorption Study<sup>31</sup></b>						
<b>Test Compound - Ingredients</b>	<b>% radioactivity recovered</b>					
	<b>CO<sub>2</sub></b>	<b>urine</b>	<b>feces</b>	<b>GI contents</b>	<b>carcass</b>	<b>lymph</b>
[ <sup>14</sup> C]Polyglyceryl-10 Oleate	1.5	42.4	45.6	3.5	5.1	1.9
[ <sup>14</sup> C]Polyglyceryl-10 Decaoleate	1.7	25.6	60.8	3.1	3.8	5.0
polyglyceryl-3 [ <sup>14</sup> C]oleate	13.7	0.9	3.4	0.4	3.1	78.5
polyglyceryl-10 [ <sup>14</sup> C]oleate	14.4	1.0	6.1	1.6	1.9	75.0
polyglyceryl-10 [ <sup>14</sup> C]decaoleate	13.3	1.4	8.4	2.3	7.1	67.5
<b>For Comparison</b>						
glycerol-1,3- <sup>14</sup> C	73.6	4.8	1.7	0.4	12.7	6.8
[ <sup>14</sup> C]polyglycerin-3	1.7	69.5	20.2	0.6	4.7	3.3
[ <sup>14</sup> C]polyglycerin-10	3.9	45.4	34.0	4.3	11.6	0.8
triglycerol [ <sup>14</sup> C]tetraoleate	12.7	0.9	6.2	1.7	2.6	76.0
polyglycerin-10 [ <sup>14</sup> C]monoeicosanoate	8.9					

### Table 12. Acute Toxicity Studies

[illegible]



Table 13. Genotoxicity studies

Test Article	Concentration/Vehicle	Test System	Procedure	Results	Reference
<b>IN VITRO</b>					
<b>Polyglyceryl Monoesters</b>					
Polyglyceryl-2 Oleate	333-5000 µg/plate in DMSO	<i>S. typhimurium</i> TA1535, TA1537, TA98 and TA100; <i>E. coli</i> WP2uvrA	Ames test, with and without metabolic activation (OECD Guideline 471)	not mutagenic cytotoxic at 5000 µg/plate in strain TA1537 without activation and TA1535 with activation positive and vehicle controls gave expected results	44
Polyglyceryl-2 Oleate	10-150 µg/ml, 4-h exposure with and without activation 5-75 µg/ml, 24-h exposure without activation in DMSO	mouse lymphoma L5178Y cells	mammalian cell gene mutation assay, with and without metabolic activation (OECD test guideline 476)	not genotoxic cytotoxic without activation at ≥30 µg/ml and with activation at ≥50 µg/ml positive and vehicle controls gave expected results	44
Polyglyceryl-2 Oleate	25-150 and 50-200 µg/ml, 4-h exposure without and with activation, respectively; 25-100 µg/ml, 22-h exposure without activation in DMSO	human peripheral blood lymphocytes	chromosomal aberration assay, with and without metabolic activation (OECD Guideline 473)	not genotoxic positive and vehicle controls gave expected results	44
Polyglyceryl-3 Caprate	not provided	not provided	Ames test; OECD 471	not evidence of mutagenic activity	39
Polyglyceryl-3 Caprylate	not provided	not provided	Ames test; OECD 471	not evidence of mutagenic activity	40
Polyglyceryl-3 Laurate	50-5000 µg/plate (vehicle not specified)	not provided	Ames test; details not provided	negative	50
Polyglyceryl-3 Isostearate	not provided	not provided	Ames test; details not provided	not evidence of mutagenic activity	41
Polyglyceryl-4 Caprate	not provided	not provided	Ames test; OECD 471	not evidence of mutagenic activity	43
Polyglyceryl-4 Isostearate	not provided	not provided	Ames test; details not provided	negative	42
Polyglyceryl-4 Laurate/Succinate	1.5-5000 µg/plate in distilled water	<i>S. typhimurium</i> TA1535, TA1537, TA98, TA100; <i>E. coli</i> WP2uvrA	Ames test, with and without metabolic activation	not mutagenic cytotoxicity was observed in <i>S. typhimurium</i> with several concentrations positive and vehicle controls gave expected results	51
Polyglyceryl-6 Caprylate/Caprate	0.15-5000 µg/plate in distilled water	<i>S. typhimurium</i> TA1535, TA1537, TA98, TA100; <i>E. coli</i> WP2uvrA	Ames test, with and without metabolic activation	not mutagenic cytotoxicity was observed with several concentrations positive and vehicle controls gave expected results	52
Polyglyceryl-10 Laurate (~60% pure, with ~40% polyglycerin-10 and ~2% sodium laurate)	0-125 µg/ml without activation 0-2250 µg/ml with activation	Chinese hamster V79 cells	chromosomal aberration assay; 20 h harvest time	equivocal without and positive with activation without activation, a slight increase of aberrant cells was seen with 50 and 70, but not 65, µg/ml with activation, the aberration rates with 1250 and 1500 µg/mL were significantly increased, and a dose relationship was observed	20

**Table 13. Genotoxicity studies**

Test Article	Concentration/Vehicle	Test System	Procedure	Results	Reference
Polyglyceryl-10 Laurate (~60% pure, with ~40% polyglycerin-10 and ~2% sodium laurate)	10-1000 µg/ml, 4-h exposure without and with activation 10-500 µg/ml, 20-h exposure without activation	human peripheral lymphocytes	chromosomal aberration assay; 20 h harvest time metaphase analysis was performed with cultures exposed to 50 - 250 µg/ml for 4 h and 50 - 300 µg/ml for 20 h without metabolic activation, and to 125 -500 µg/ml with metabolic activation	not clastogenic; no significant increases in chromosomal aberrant aberrations were observed in any treatment group at any dose level	<sup>20</sup>
<b>Polyglyceryl Multi-esters</b>					
Polyglyceryl-2 Diisostearate	4-5000µg/plate in acetone	<i>S. typhimurium</i> TA1535, TA1537, TA98, TA100	Ames test, with and without metabolic activation (OECD test guideline 471)	not mutagenic	<sup>33</sup>
Polyglyceryl-2 Diisostearate	3.16 - 5000 µg/ml, 4-h exposure without and with activation 10-5000 µg/ml, 20-h exposure without activation cell culture medium (MEM) served as the vehicle	Chinese hamster lung fibroblasts V79 cells	mammalian cell gene mutation assay, with and without metabolic activation (OECD test guideline 476); 20 h harvest time chromosomal aberrations were evaluated in cultures exposed to 1000-5000 µg/ml for 4 h and 50 - 5000 µg/ml for 20 h without metabolic activation, and to 100 -5000 µg/ml with metabolic activation	no evidence of a concentration-related positive response	<sup>33</sup>
Polyglyceryl-2 Diisostearate	3.16-5000µg/ml in cell culture medium (MEM)	Chinese hamster lung fibroblasts V79 cells	chromosomal aberration assay, with and without metabolic activation (OECD test guideline 473)	not clastogenic	<sup>33</sup>
1,2,3-propanetriol, homopolymer, diisooctadecanoate (n not defined; most likely Polyglyceryl-3 Diisostearate)	8-5000 µg/plate in Tween 80/bidistilled water	<i>S. typhimurium</i> TA1535, TA1537, TA1538, TA98 and TA100	Ames test, with and without metabolic activation (OECD Guideline 471)	not mutagenic positive and vehicle controls gave expected results	<sup>38</sup>
1,2,3-propanetriol, homopolymer, diisooctadecanoate (n not defined; most likely Polyglyceryl-3 Diisostearate)	3.13 - 200 µg/ml, 4-h exposure without activation 3.13 - 150 µg/ml, 4-h exposure with activation in DMSO	CHO cells	mammalian cell gene mutation assay, with and without metabolic activation (OECD test guideline 476); 4-h exposure	not genotoxic positive and negative controls gave expected results	<sup>38</sup>
1,2,3-propanetriol, homopolymer, diisooctadecanoate (n not defined; most likely Polyglyceryl-3 Diisostearate)	12.5-800µg/ml without and 3.13-800µg/ml with activation, in DMSO	Chinese hamster lung fibroblasts V79 cells	chromosomal aberration assay, with and without metabolic activation (OECD test guideline 473); 4 and 18-h exposure	not clastogenic	<sup>38</sup>
Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate	not provided	not provided	Ames test; OECD 471	negative	<sup>46</sup>

Abbreviations: CHO – Chinese hamster ovary; DMSO – dimethyl sulfoxide; MEM – minimum essential medium; OECD – Organisation for Economic Co-operation and Development

**Table 14. Dermal irritation and sensitization**

Test Article	Concentration/Dose	test system/# per Group	Procedure	Results	Reference
<b>ALTERNATIVE STUDIES</b>					
<b>Polyglyceryl Monoesters</b>					
Apricot Kernel Oil Polyglyceryl-4 Esters	16 ± 0.5 µl	reconstituted human epidermis	SkinEthic™ irritation test; test material was applied for 42 min; cell viability assessment by MTT method after 42 h	classified as non-irritant	48
Palm Oil Polyglyceryl-4 Esters	16 ± 0.5 µl	reconstituted human epidermis	SkinEthic™ irritation test; test material was applied for 42 min; cell viability assessment by MTT method after 42 h	classified as non-irritant	45
Polyglyceryl-4 Laurate/Sebacate	neat	reconstituted human epidermis	EpiSkin™ model; 15 min treatment period with a 42 h post-exposure incubation period; cell viability was measured by MTT reduction	considered to be non-irritant relative mean viability was 105.4%	53
Polyglyceryl-4 Laurate/Succinate	neat	reconstituted human epidermis	EpiSkin™ model; 15 min treatment period with a 42 h post-exposure incubation period; cell viability was measured by MTT reduction	considered to be non-irritant relative mean viability was 104.1%	54
Polyglyceryl-6 Caprylate/Caprates	neat	reconstituted human epidermis	EpiSkin™ model; 15 min treatment period with a 42 h post-exposure incubation period; cell viability was measured by MTT reduction	considered to be non-irritant relative mean viability was 105.7%	55
<b>ANIMAL</b>					
<b>Polyglyceryl Monoesters</b>					
Polyglyceryl-2 Isostearate	undiluted; 0.5 ml	3 NZW rabbits	OECD test guideline 404 4-h, 2 x 3 cm semi-occlusive patch applied to clipped skin	PII of 0.8 (mildly irritating); very slight erythema was observed in all 3 animals and resolved in 2-7 days	56
Polyglyceryl-3 Caprate	not provided	rabbit	OECD 404 (acute dermal irritation/corrosion)	not irritating	39
Polyglyceryl-3 Caprate	not provided	guinea pig	OECD 406 (sensitization)	no skin sensitization effect	39
a polyglyceryl mono/diester of capric acid (C10) (provided as read-across for Polyglyceryl-3 Caprylate)	not provided	rabbit	OECD 404 (acute dermal irritation/corrosion)	not irritating	40
Polyglyceryl-3 Caprylate	not provided	not stated	OECD 429; LLNA	not sensitizing	40
Polyglyceryl-3 Isostearate	not provided	rabbit	FHSA, 16 CFR 1500.41	moderately irritating	41
Polyglyceryl-3 Isostearate	not provided	guinea pig	OECD 406 (sensitization)	no skin sensitization effect	41
Polyglyceryl-3 Oleate	not provided	rabbit	FHSA, 16 CFR 1500.41	moderately irritating	42
Polyglyceryl-4 Caprate	not provided	rabbit	OECD 404 (acute dermal irritation/corrosion)	not irritating	43
Polyglyceryl-4 Caprate	not provided	guinea pig	OECD 406 (sensitization)	no skin sensitization effect	43
Polyglyceryl-4 Isostearate	not provided	guinea pig	OECD 406 (sensitization)	no sensitizing effect	42
<b>Polyglyceryl Multi-Esters</b>					
Polyglyceryl-2 Diisostearate	undiluted; 0.5 ml	3 NZW rabbits	OECD test guideline 404 4-h, 2.5 cm <sup>2</sup> semi-occlusive patch	non-irritating; 1 animal had well-defined erythema 24 h after patch removal	33
Polyglyceryl-2 Diisostearate	1 and 10% in saline, and undiluted; 0.5 ml	2 Albino-Himalayan-Kaninchen rabbits/gp	24-h, 2.5 cm <sup>2</sup> occlusive patch on intact and abraded skin	slightly irritating; with undiluted test substance, distinct erythema and slight to distinct edema was observed in both animals; with 10%, marked erythema was observed in 1 animal for a short time; with 1%, slight erythema in 1 animal	33

**Table 14. Dermal irritation and sensitization**

Test Article	Concentration/Dose	test system/# per Group	Procedure	Results	Reference
Polyglyceryl-2 Diisostearate	induction: 100% challenge: 20% in acetone	20 female Pirbright-White guinea pigs/gp	Buehler test using occlusive patches; 10 control animals were exposed to an ethanol-water (80:20) mixture	non-sensitizing	33
Polyglyceryl-3 Diisostearate	not specified	3 NZW rabbits	method was described as OECD Guideline 404, but study details were not provided; test sites were scored according to Draize	not irritating; slight erythema was seen on skin of all 3 animals tested starting 1 hour following application, and this effect was fully reversible within by 72 h	44,45
Polyglyceryl-3 Diisostearate	5-50% in paraffin perliquid DAB 8	3 Pirbright-White guinea pigs	in a range-finding study for a sensitization test, the test material was applied to the shaved flank for 6 h	not irritating after 24 h	44
1,2,3-propanetriol, homopolymer, diisooctadecanoate (n not defined; most likely Polyglyceryl-3 Diisostearate)	undiluted; 0.5 ml	4 male rabbits	OECD Guideline 404; 4-h occlusive patch to a shaved 6.25 cm <sup>2</sup> area	not irritating; very slight to slight erythema in 3/4 animals at 24 and 48 h; slight and moderate erythema in 2/4 animals at 72 h; the effects were reversible in all animals within 7 d	38
Polyglyceryl-3 Diisostearate	induction: 50% in paraffin perliquid DAB 8 (induction 1) or in petrolatum (inductions 2 and 3) challenge: 50% paraffin perliquid DAB 8 rechallenge: 25%	20 (test) or 19 (control) female Pirbright-White guinea pigs	test sites were pre-treated with 10% SDS in petrolatum, 24 h prior to each induction application <u>epicutaneous induction</u> : 6-h occlusive patches (0.2 ml) applied 1x/wk for 3 wks; half of the controls were pretreated with SDS 24 h prior to application of patches containing vehicle <u>challenge</u> : 6-h occlusive patch (0.1 ml) applied on day 28 <u>rechallenge</u> : 6-h occlusive patch (0.1 ml) applied on day 35	non-sensitizing very slight skin reactions (erythema and edema) were seen at 24-h following the challenge and rechallenge patches in test and control animals; these reactions were reversible in all animals within 48 h and were attributed to irritation	44
Polyglyceryl-3 Diisostearate	induction: 0.1% or 0.2% (intradermal) and 40% (epicutaneous) challenge: 10 and 15% rechallenge: 8 and 4% in paraffinum perliquidum DAB 8	20 (test) or 19 (control) female Pirbright-White guinea pigs	GPMT, with FCA; no positive control <u>intradermal induction</u> : 3 pairs of injections on day1 consisting of (1) 0.1 ml of a 1:1 mixture (v/v) FCA/physiological saline in water); (2) 0.1 ml test 0.1% substance in paraffin perliquid DAB 8; (3) 0.1 ml of a 1:1 mixture (v/v) of 0.2% test substance in paraffin perliquid DAB 8 and 50% FCA in physiological saline <u>epicutaneous induction</u> : 48-h occlusive patch (1 ml) on day 8 <u>challenge</u> : 24-h occlusive patches on day 22 (0.1 ml) <u>rechallenge</u> : 24 h occlusive patches on day 29 (0.1 ml)	results were inconclusive <u>intradermal induction</u> : 0.1 ml FCA (50% (v/v)), the test substance (0.1% (v/v)) and a 1:1 mixture of the test substance with FCA caused moderate to severe skin reactions; in the control group, 0.1 ml of the vehicle resulted in moderate skin reactions <u>epicutaneous induction</u> : after treatment with 40% of the test substance, the injection sites of the intradermal induction were bloody and purulent and at a later stage, this sites showed necrotic and scabby skin lesions <u>challenge with 15%</u> : at 24 h, erythema (1) was observed in 9 test and 2 control animals; edema (2) in 1 test animal, and edema (1) in 2 test and 2 control animals; at 48 h, erythema (2) in 1 test animal (that was 0 at 24 h), erythema (1) in 7 test animals, same edema scores as at 24 h for test animals, no edema in controls <u>challenge with 10%</u> : at 24 h, erythema (3) in 1 and erythema (1) in 5 test animals, edema (3) in 1 and edema (2) in 1 test animal; at 48 h, erythema (3) and edema (3) in 1 animal and erythema (1) and edema (1) in 1 test animal; no erythema or edema in controls at 24 or 48 h <u>rechallenge with 8%</u> : at 24 h, erythema (1) in 6 test and 4 control animals, no edema in test or controls; at 48-h, erythema (1) in 3 test and 1 control animals, no edema in test or controls <u>rechallenge with 4%</u> : no erythema or edema	44

**Table 14. Dermal irritation and sensitization**

Test Article	Concentration/Dose	test system/# per Group	Procedure	Results	Reference
Polyglyceryl-4 Diisostearate/ Polyhydroxystearate/Sebacate (provided as read-across for Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate)	not provided	guinea pig	OECD 406 (sensitization)	not sensitizing	46
<b>HUMAN</b>					
<b>Polyglyceryl Monoesters</b>					
Polyglyceryl-2 Isostearate	7% in ESTOL 1512 (i.e., isopropyl myristate); 0.4 ml	30 subjects	three 24-h occlusive patches, with 24 to 48-h between applications	elicited slight irritation; significantly less irritating than the positive control (0.3% sodium lauryl sulfate) and significantly more irritating than the negative control (deionized water) (p=0.05)	57
Polyglyceryl-3 Laurate	100%; 150 µl/patch	114 subjects	HRIPT	not an irritant or a sensitizer	50
Polyglyceryl-10 Myristate	10%	48 subjects	48-h occlusive patch test	negative	58
Polyglyceryl-10 Stearate	10%	48 subjects	48-h occlusive patch test	non-irritating	59
60% Polyglyceryl-10 Eicosanedi- oate/ Tetradecanedioate/40% gly- cerin mixture	undiluted	45 subjects	closed patch test; details not provided	negative	60
<b>Polyglyceryl Multi-Esters</b>					
Polyglyceryl-2 Sesquiosostearate	undiluted	50 subjects	24-h semi-occlusive patches	not irritating	33
1,2,3-propanetriol, homopolymer, diisooctadecanoate (n not defined; likely Polyglyceryl-3 Diisostearate)	20% “active substance” in “cosmetic alcohol”; 70 µl	20 subjects	24-h occlusive patches	not irritating slight erythema in 3 and slight scaling in 2 subjects	38
Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate	not provided	no provided	occlusive patch test; details not provided	“no concern”	46
Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate	100%; 150 µl/patch	103 subjects	HRIPT	not an irritant or a sensitizer	50
Polyglyceryl-10 Pentaistearate	50%	44 Japanese subjects	24-h occlusive patch	negative	61
Polyglyceryl-10 Decaoleate	neat	44 Japanese subjects	24-h occlusive patch	negative	62

Abbreviations: CFR – Code of Federal Regulations; CPSC – Consumer Product Safety Commission; FCA – Freund’s Complete Adjuvant; FHSA – Federal Hazardous Substances Act; GPMT – guinea pig maximization test; HET-CAM – hen’s egg test chorioallantoic membrane; HRIPT – human repeated insult patch test; LLNA – local lymph node assay; ME – microemulsion; OECD – Organisation for Economic Co-operation and Development; SDS – sodium dodecyl sulfate

**Table 15 Ocular irritation studies**

Test Article	Concentration/Dose	#/Animals/Grp	Method	Results	Reference
<b>ALTERNATIVE STUDIES</b>					
<b>Polyglyceryl Monoesters</b>					
Polyglyceryl-3 Laurate	10% in corn oil	---	EpiOcular™ tissue model	classified as non-irritating ET <sub>50</sub> was >256 min	63
ME containing 30% Polyglyceryl-4 Laurate	100 µl	6 replicates	HET-CAM assay; the test article also contained 1 or 2% linoleic acid, 4 or 5% isopropyl palmitate, and 65% water-1,2-pentanediol (1:9) or 63 or 65% water-1,2-pentanediol (1.5:8.5)	non-irritant	36
ME containing 40% Polyglyceryl-4 Laurate	100 µl	6 replicates	HET-CAM; this test article also contained 2% linoleic acid, 5% isopropyl palmitate, 53% water-1,2-pentanediol (1:9)	non-irritant	36
Apricot Kernel Oil Polyglyceryl-4 Esters	0.3 g	# of replicates not stated	HET-CAM; CAM was rinsed with 5 ml physiological saline after 240 s of contact	practically non-irritating	45
Palm Oil Polyglyceryl-4 Esters	0.3 g	# of replicates not stated	HET-CAM; CAM was rinsed with 5 ml physiological saline after 240 s of contact	practically non-irritating	45
Polyglyceryl-4 Laurate/Sebacate	30 µl	human corneal epithelial cells	SkinEthic™ reconstituted HCE model; 10 min treatment period, tissues were then rinsed; MTT was used to measure viability	considered to be non-irritant relative mean viability was 85.9%	64
Polyglyceryl-4 Laurate/Succinate	30 µl	human corneal epithelial cells	SkinEthic™ reconstituted HCE model; 10 min treatment period, tissues were then rinsed; MTT was used to measure viability	considered to be non-irritant relative mean viability was 70.0%	65
Polyglyceryl-6 Caprylate/Caprates	30 µl	human corneal epithelial cells	SkinEthic™ reconstituted HCE model; 10 min treatment period, tissues were then rinsed; MTT was used to measure viability	considered to be non-irritant relative mean viability was 88.4%	66
Polyglyceryl-10 Myristate	1000 mg/l (max)	rabbit corneal epithelial cells	SIRC-NR (not defined)	non-irritant	58
Polyglyceryl-10 Stearate	1000 mg/l (max)	rabbit corneal epithelial cells	SIRC-NR (not defined)	non-irritant	59
60% Polyglyceryl-10 Eicosanedioate/ Tetradecanedioate/40% glycerin mixture	undiluted	---	EpiOcular™ test	non-irritant	60
<b>Polyglyceryl Multi-Esters</b>					
Polyglyceryl-2 Dioleate	undiluted; 300 µl	6 eggs	HET-CAM assay	classified as non-irritating Q-score <1.2 (up to 300 s)	44
Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate	not stated	not stated	HET-CAM assay	minor irritation	46
Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate	10% in corn oil	---	EpiOcular™ tissue model	classified as non-irritating ET <sub>50</sub> was >256 min	47
Polyglyceryl-10 Diisostearate	1000 mg/l (max)	rabbit corneal epithelial cells	SIRC-NR (not defined)	non-irritant	67
<b>ANIMAL</b>					
<b>Polyglyceryl Monoesters</b>					
Polyglyceryl-3 Caprate	not provided	rabbits; # not stated	OECD 405 (acute eye irritation/corrosion)	not irritating	39
a polyglyceryl mono/diester of capric acid (C10) (provided as read-across for Polyglyceryl-3 Caprylate)	not provided	rabbits; # not stated	OECD 405 (acute eye irritation/corrosion)	not irritating	40

**Table 15 Ocular irritation studies**

<b>Test Article</b>	<b>Concentration/Dose</b>	<b>#/Animals/Grp</b>	<b>Method</b>	<b>Results</b>	<b>Reference</b>
Polyglyceryl-3 Isostearate	not provided	rabbits;# not stated	FHSA/CPSC 16 CFR 1500.42	mildly irritating	<sup>41</sup>
Polyglyceryl-3 Oleate	not provided	rabbits;# not stated	FHSA/CPSC 16 CFR 1500.42	mildly irritating	<sup>42</sup>
Polyglyceryl-4 Caprate	not provided	rabbits; # not stated	OECD 405 (acute eye irritation/corrosion)	not irritating	<sup>43</sup>
<b>Polyglyceryl Multi-Esters</b>					
Polyglyceryl-2 Diisostearate	undiluted, 0.1 ml	3 NZW rabbits	OECD test guideline 405 eyes were rinsed after 24 h and at all exams	not irritating; some observations were made at 24 h, but were fully reversible at 48 h	<sup>33</sup>
Polyglyceryl-2 Diisostearate	undiluted, 0.1 ml	6 NZW rabbits	rinsing not specified	not a primary eye irritant; at 24 h, 4 animals had injected vessels and 1 had swelling; at 48 h, 2 animals had erythema and 2 had swelling; no effects were seen at 72 h	<sup>33</sup>
Polyglyceryl-2 Diisostearate	0.1 and 10% in saline and undiluted; 0.1 ml	2 Albino-Himalayan-Kaninchen rabbits/gp	eyes were rinsed after 24 h	some ocular effects, including reddening were observed at all concentrations tested, but the results were not quantified	<sup>33</sup>
Polyglyceryl-2 Dioleate	undiluted	3 rabbits	rinsing not specified	not irritating; no signs of irritation were observed	<sup>44</sup>
Polyglyceryl-3 Diisostearate	not stated; assumed to be undiluted	3 New Zealand albino rabbits	OECD test guideline 405	non-irritating; at 1 h in animals, chemosis (score of 1) and redness (score of 2) were reported; at 72 h, chemosis was completely resolved and the redness score was 1	<sup>45</sup>
1,2,3-propanetriol, homopolymer, diisooctadecanoate (n not defined most likely Polyglyceryl-3 Diisostearate)	undiluted; 0.1 ml	4 male Kleinrusse rabbits	eyes were not rinsed	not irritating; at 24 h, very slight redness of the conjunctivae was observed in 1 animal, and the effect was reversible within 48 h	<sup>38</sup>
<b>HUMAN</b>					
<b>Polyglyceryl Monoesters</b>					
Polyglyceryl-10 Laurate (~60% pure, with ~40% polyglycerin-10 and ~2% sodium laurate)	not provided	not provided	not provided	possibly slightly irritating to the eyes	<sup>20</sup>

Abbreviations: HCE – human corneal epithelium; HET-CAM - Hen's Egg Test – Chorioallantoic Membrane; ME – microemulsion; NZW – New Zealand White; OECD – Organisation for Economic Co-operation and Development

## REFERENCES

1. Nikitakis J and Breslawec HP. International Cosmetic Ingredient Dictionary and Handbook. 15 *ed.* Washington, DC: Personal Care Products Council, 2014.
2. Johnson Jr W, Heldreth B, Bergfeld WF, Belsito DV, Klaassen CD, Hill RA, Liebler DC, Marks Jr JG, Shank RC, Slaga TJ, Snyder PW, and Andersen FA. Final Report of the Cosmetic Ingredient Review Expert Panel on the Safety Assessment of Pelargonic Acid (Nonanoic Acid) and Nonanoate Esters. *Int J Toxicol.* 2011;30(Suppl 3):228S-269S. <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr558.pdf>.
3. Fiume MM, Heldreth BA, Bergfeld WF, Belsito DV, Hill RA, Klaassen CD, Liebler DC, Marks Jr JG, Shank RC, Slaga TJ, Snyder PW, and Gill LJ. 2015. Final Amended Report of the Safety Assessment of Monoglyceryl Monoesters as Used in Cosmetics. Available on the Cosmetic Ingredient Review website.
4. European Chemical Agency (ECHA). Information on Chemicals. <http://echa.europa.eu/information-on-chemicals;jsessionid=A978100B4E4CC39C78C93A851EB3E3C7.live1>. Last Updated 2015. Date Accessed 4-23-2015.
5. Norn V. Polyglycerol esters. Emulsifiers Food Technol. 2004. CAPLUS AN 2004:1017707(Conference; General Review).
6. Dürr-Auster N. Doctor of Sciences. Formation and stability of a liquid foam prepared from a lamellar surfactant dispersion. 2008. Switzerland: Swiss Federal Institute of Technology Zurich. ETH Dissertation Number 18045. <http://e-collection.library.ethz.ch/eserv/eth:31101/eth-31101-02.pdf>Date Accessed 4-27-2015
7. Hasenhuettl GL. Synthesis and Commercial Preparation of Food Emulsifiers. Chapter: 2. Hasenhuettl GL and Hartel RW. In: *Food Emulsifiers and Their Applications*. New York: Springer; 2008:11-37.
8. Food and Agriculture Organization (FAO) of the United Nations. Polyglycerol Esters of Fatty Acids. <http://www.fao.org/ag/agn/jecfa-additives/specs/Monograph1/Additive-317.pdf>. Last Updated 2006. Date Accessed 4-20-2015.
9. Food and Drug Administration (FDA). Frequency of use of cosmetic ingredients. *FDA Database*. 2015.
10. Personal Care Products Council. 4-29-2014. Concentration of Use by FDA Product Category: Glyceryl Monoesters. Unpublished data submitted by Personal Care Products Council.
11. Personal Care Products Council. 1-6-2015. Concentration of Use by FDA Product Category: Polyglyceryl Esters. Unpublished data submitted by Personal Care Products Council. 1 pages.
12. Personal Care Products Council. 4-10-2015. Concentration of Use by FDA Product Category: Polyglyceryl Compounds included in the February 2015 Survey. Unpublished data submitted by Personal Care Products Council.
13. Personal Care Products Council. 2015. Concentration of use information: polyglyceryl-10 hydroxystearate/stearate/eicosodioate. Unpublished data submitted by the Personal Care Products Council.
14. Personal Care Products Council. 7-6-2015. Concentration of Use by FDA Product Category: Caprylic/Capric Glycerides Polyglyceryl-10 Esters and Pumpkin Seed Oil Polyglyceryl-4 Esters Succinate. Unpublished data submitted by Personal Care Products Council.
15. Johnsen MA. The influence of particle size. *Spray Technology and Marketing.* 2004;14(11):24-27.
16. Rothe H. Special Aspects of Cosmetic Spray Evaluation. 9-26-2011. Unpublished data presented at the 26 September CIR Expert Panel meeting. Washington, D.C.
17. Bremmer HJ, Prud'homme de Lodder LCH, and Engelen JGM. Cosmetics Fact Sheet: To assess the risks for the consumer; Updated version for ConsExpo 4. 2006. Report No. RIVM 320104001/2006. pp. 1-77.
18. Rothe H, Fautz R, Gerber E, Neumann L, Rettinger K, Schuh W, and Gronewold C. Special aspects of cosmetic spray safety evaluations: Principles on inhalation risk assessment. *Toxicol Lett.* 2011;205(2):97-104.



19. European Commission. CosIng database; following Cosmetic Regulation No. 1223/2009. <http://ec.europa.eu/consumers/cosmetics/cosing/>. Last Updated 2015. Date Accessed 2-27-2015.
20. National Industrial Chemicals Notification and Assessment Scheme (NICNAS). File No. STD/1453. Public report: 1,2,3-Propanetriol, homopolymer, dodecanoate (CAS No. 74504-64-6). 2013. [www.nicnas.gov.au/data/assets/word\\_doc/0003/6096/STD1453-FR-FINAL.docx](http://www.nicnas.gov.au/data/assets/word_doc/0003/6096/STD1453-FR-FINAL.docx). Date Accessed 4-23-2015. Report No. File No: STD/1453.
21. World Health Organization (WHO). Evaluation of certain food additives and contaminants. Thirty-fifth report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series (TRS) 789. [http://whqlibdoc.who.int/trs/WHO\\_TRS\\_789.pdf](http://whqlibdoc.who.int/trs/WHO_TRS_789.pdf). Last Updated 1990. Date Accessed 4-20-2015.
22. Food and Agriculture Organization (FAO) of the United Nations. Polyglycerol esters of interesterified ricinoleic acid. <http://www.fao.org/ag/agn/jecfa-additives/specs/Monograph1/Additive-318.pdf>. Last Updated 2000. Date Accessed 9-17-2015.
23. European Food Safety Authority (EFSA) Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel). Scientific Opinion on the safety assessment of the substance, polyglycerol, CAS No 25618-55-7, for use in food contact materials. *EFSA Journal*. 2015;11(10):3389-3396. <http://www.efsa.europa.eu/en/efsajournal/doc/3389.pdf>.
24. Lonza. Product data sheet: Polyaldo 10-1 CC KFG (Polyglyceryl-10 Caprylate/Caprates). [http://bio.lonza.com/uploads/tx\\_mwaxmarketingmaterial/Lonza\\_ProductDataSheets\\_Polyaldo\\_10-1-CC\\_KFG\\_NON\\_GMO\\_PDS.pdf](http://bio.lonza.com/uploads/tx_mwaxmarketingmaterial/Lonza_ProductDataSheets_Polyaldo_10-1-CC_KFG_NON_GMO_PDS.pdf). Last Updated 2010. Date Accessed 3-23-2015.
25. ChemicalBook. Polyglyceryl-10 Oleate. [http://www.chemicalbook.com/ChemicalProductProperty\\_EN\\_CB2966106.htm](http://www.chemicalbook.com/ChemicalProductProperty_EN_CB2966106.htm). Last Updated 2010. Date Accessed 10-30-2015.
26. Gattefossé. Plurol® Oleique CC 497 (Polyglyceryl-3 Dioleate). <http://www.gattefosse.com/en/applications/plurol-oleique-cc497.html>. Last Updated 2010. Date Accessed 12-1-2015.
27. World Health Organization (WHO). Toxicological evaluation of some antimicrobials, antioxidants, emulsifiers, stabilizers, flour-treatment agents, acids and bases. Polyglycerol esters of fatty acids. 1967. <http://www.inchem.org/documents/jecfa/jecmono/40abcj26.htm>. Date Accessed 4-20-2015. Report No. Report Series No. 40A, B, C; WHO/Food Add./67.29.
28. Bodansky M, Herrmann CL, and Campbell K. CCXLIX. Utilization of polyglycerol esters. *Biochem J*. 1938;32(11):1938-1942.
29. Babayan VK, Kaunitz H, and Slanetz CA. Nutritional studies of polyglycerol esters. *Journal of the American Oil Chemists' Society*. 1964;41(6):434-437.
30. World Health Organization (WHO). Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thickening agents. Polyglycerol esters of fatty acids. 1974. <http://www.inchem.org/documents/jecfa/jecmono/v05je45.htm>. Date Accessed 4-20-2015. Report No. WHO Food Additives Series No. 5.
31. Michael WR and Coots RH. Metabolism of polyglycerol and polyglycerol esters. *Toxicol Appl Pharmacol*. 1971;20(3):334-345.
32. King WR, Michael WR, and Coots RH. Subacute oral toxicity of polyglycerol ester. *Toxicol Appl Pharmacol*. 1971;20(3):327-333.
33. European Chemicals Agency (ECHA). Di(isooctadecanoic) acid, diester with oxydi(propanediol) (CAS No. 67938-21-0). <http://echa.europa.eu/en/registration-dossier/-/registered-dossier/12200>. Last Updated 4-13-2015. Date Accessed 6-5-2015.
34. Cornwell PA, Tubek J, van Gompel HAHP, Little CJ, and Wiechers JW. Glyceryl monocaprylate/caprates as a moderate skin penetration enhancer. *International Journal of Pharmaceutics*. 1998;171(2):243-255.
35. Sahle FF, Metz H, Wohrlab J, and Neubert RH. Polyglycerol fatty acid ester surfactant-based microemulsions for targeted delivery of ceramide AP into the stratum corneum: formulation, characterisation, in vitro release and penetration investigation. *Eur J Pharm Biopharm*. 2012;82(1):139-150.
36. Sahle FF, Wohrlab J, and Neubert RH. Controlled penetration of ceramides into and across the stratum corneum using various types of microemulsions and formulation associated toxicity studies. *Eur J Pharm Biopharm*. 2014;86(2):244-250.

37. Endo M, Yamamoto T, and Ijuin T. Effect of nonionic surfactants on the percutaneous absorption tenoxicam. *Chem Pharm Bull (Tokyo)*. 1996;44(4):865-867.
38. European Chemicals Agency (ECHA). 1,2,3-Propanetriol, homopolymer, diisooctadecanoate (CAS No. 63705-03-3). <http://echa.europa.eu/registration-dossier/-/registered-dossier/11209>. Last Updated 2014. Date Accessed 4-23-2015.
39. Anonymous. 2016. Polyglyceryl-3 Caprate: Summary of product data with reference to toxicology. Unpublished data submitted by Personal Care Products Council.
40. Anonymous. 2016. Polyglyceryl-3 Caprylate: Summary of product data with reference to toxicology. Unpublished data submitted by Personal Care Products Council.
41. Anonymous. 2016. Polyglyceryl-3 Isostearate: Summary of product data with reference to toxicology. Unpublished data submitted by Personal Care Products Council.
42. Anonymous. 2016. Polyglyceryl-3 Oleate: Summary of product data with reference to toxicology. Unpublished data submitted by Personal Care Products Council.
43. Anonymous. 2016. Polyglyceryl-4 Caprate: Summary of product data with reference to toxicology. Unpublished data submitted by Personal Care Products Council.
44. European Chemicals Agency (ECHA). Oleic acid, monoester with oxybis(propanediol (CAS No. 49553-76-6). <http://echa.europa.eu/registration-dossier/-/registered-dossier/12212>. Last Updated 2013. Date Accessed 4-21-2015.
45. Anonymous. 2016. Summary information Palm Oil Polyglyceryl-4 Esters, Apricot Kernel Oil Polyglyceryl-4 Esters and Polyglyceryl-3 Diisostearate. Unpublished data submitted by Personal Care Products Council.
46. Anonymous. 2016. Diisostearyl Polyglyceryl-3 Dimer Dilinoleate: Summary of product data with reference to toxicology. Unpublished data submitted by Personal Care Products Council.
47. Lubrizol. Toxicology & Microbiology Studies (TOX-104): Schercemol™ PTID Ester( Triisostearyl Polyglyceryl-3 Dimer Dilinoleate). <https://www.lubrizol.com/Personal-Care/Documents/Toxicological-and-Microbiological-Studies/TOX-104-Schercemol%E2%84%A2-PTID-Ester.pdf>. Last Updated 2007. Date Accessed 3-11-2015.
48. Lubrizol Advanced Materials. 2007. Schercemol™ PDD Ester (Diisostearyl Polyglyceryl-3 Dimer Dilinoleate) toxicology studies. Unpublished data submitted by Personal Care Products Council.
49. Baichwal MR and Lalla JK. Polyglycerol esters. III. Stability, toxicity, and compatibility of polyglycerol stearate with pharmaceutical adjuvants. *Indian Journal of Pharmacy*. 1973;35(5):140-145.
50. Lubrizol Advanced Materials. 2016. Summary information polyglyceryl fatty acid esters. Unpublished data submitted by Personal Care Products Council.
51. Harlan Laboratories, Ltd. 2010. Summary: Reverse mutation assay "Ames test" using *Salmonella typhimurium* and *Escherichia coli* (Polyglyceryl-4 Laurate/Succinate). Project No. 4100/3617. Unpublished data submitted by Personal Care Products Council.
52. Harlan Laboratories, Ltd. 2010. Summary: Reverse mutation assay "Ames test" using *Salmonella typhimurium* and *Escherichia coli* (Polyglyceryl-6 Caprylate/Caprate). Project No. 41003618. Unpublished data submitted by Personal Care Products Council.
53. Harlan Laboratories, Ltd. Summary: Determination of skin irritation potential using the Episkin™ reconstituted human epidermis model (Polyglyceryl-4 Laurate/Sebacate). Project No. 2724/0056. 2010. Unpublished data submitted by Personal Care Products Council.
54. Harlan Laboratories, Ltd. 2010. Summary: Determination of skin irritation potential using the Episkin™ reconstituted human epidermis model (Polyglyceryl-4 Laurate/Succinate). Project No. 2724/0055. Unpublished data submitted by Personal Care Products Council.
55. Harlan Laboratories, Ltd. 2010. Summary: Determination of skin irritation potential using the Episkin™ reconstituted human epidermis model (Polyglyceryl-6 Caprylate/Caprate). Project No. 2724/0057. Unpublished data submitted by Personal Care Products Council.

56. Notox BV. Primary skin irritation/corrosion study with Polyglyceryl-2 Isostearate in the rabbit. 1996. Report No. NOTOX Project 167996. Unpublished data submitted by Personal Care Products Council.
57. Globecrown Services Ltd. A three-application patch trial in healthy volunteers to investigate the skin irritation potential of Polyglyceryl-2 Isostearate following cutaneous patch applications. Globecrown Report No. 97/UNCPAT6. 1997. Unpublished data submitted by Personal Care Products Council.
58. Nikko Chemicals Co. Ltd. 2016. Safety information NIKKOL Decaglyn 1-M (Polyglyceryl-10 Myristate). Unpublished data submitted by Personal Care Products Council.
59. Nikko Chemicals Co. Ltd. 2016. Safety information NIKKOL Decaglyn 1-SV (Polyglyceryl-10 Stearate). Unpublished data submitted by Personal Care Products Council.
60. Anonymous. 2009. Material safety data sheet on a trade name mixture containing 60% Polyglyceryl-10 Eicosanedioate/Tetradecanedioate. Unpublished data submitted by Personal Care Products Council.
61. Nikko Chemicals Co. Ltd. 2016. Safety information NIKKOL Decaglyn 5-IS (Polyglyceryl-10 Pentaisostearate). Unpublished data submitted by Personal Care Products Council.
62. Nikko Chemicals Co. Ltd. 2016. Safety information NIKKOL Decaglyn 10-O (Polyglyceryl-10 Decaoleate). Unpublished data submitted by Personal Care Products Council.
63. Lubrizol. Toxicology studies (TOX-094): Hydramol™ TGL Ester (Polyglyceryl-3 Laurate). <https://www.lubrizol.com/Personal-Care/Documents/Toxicological-and-Microbiological-Studies/TOX-094-Hydramol%E2%84%A2-TGL-Ester.pdf>. Last Updated 2007. Date Accessed 3-31-2015.
64. Harlan Laboratories, Ltd. 2010. Summary: Assessment of ocular irritation potential using the Skinethic™ reconstituted human corneal epithelium model (Polyglyceryl-4 Laurate/Sebacate). Project No. 2724/0059. Unpublished data submitted by Personal Care Products Council.
65. Harlan Laboratories, Ltd. 2010. Summary: Assessment of ocular irritation potential using the Skinethic™ reconstituted human corneal epithelium model (Polyglyceryl-4 Laurate/Succinate). Project No. 2724/0058. Unpublished data submitted by Personal Care Products Council.
66. Harlan Laboratories, Ltd. 2010. Summary: Assessment of ocular irritation potential using the Skinethic reconstituted human corneal epithelium model. Project no. 2724/0060. Unpublished data submitted by Personal Care Products Council.
67. Nikko Chemicals Co. Ltd. 2016. Safety information NIKKOL Decaglyn 2-ISV (Polyglyceryl-10 Diisostearate). Unpublished data submitted by Personal Care Products Council.
68. Washizaki K, Kanto H, Yazaki S, and Ito M. A case of allergic contact dermatitis to polyglyceryl laurate. *Contact Dermatitis*. 2008;58(3):187-188.
69. Becker LC, Bergfeld WF, Belsito DV, Hill RA, Klaassen CD, Liebler DC, Marks JG Jr, Shank RC, Slaga TJ, Snyder PW, and Gill LJ. Safety assessment of glycerin as used in cosmetics. 2015. <http://www.cir-safety.org/ingredients>. Date Accessed 8-23-2015. Available on the CIR website.
70. Elder RL (ed). Final Reprt on the Safety Assessment of Butylene Glycol, Hexylene Glycol, Ethoxydiglycol, and Dipropylene Glycol. *J Am Coll Toxicol*. 1985;4(5):223-248.
71. Andersen FA (ed). Annual Review of Cosmetic Ingredient Safety Assessments - 2004/2005. *Int J Toxicol*. 2006;25(Suppl 2):10-18.
72. Fiume MM, Heldreth BA, Bergfeld WF, Belsito DV, Hill RA, Klaassen CD, Liebler DC, Marks JG Jr, Shank RC, Slaga TJ, Snyder PW, and Andersen FA. Safety Assessment of Propylene Glycol, Tripropylene Glycol, and PPGs as Used in Cosmetics. *Int J Toxicol*. 2012;31(Suppl 2):245S-260S.
73. Johnson WJ Jr, Heldreth BA, Bergfeld WF, Belsito DV, Hill RA, Klaassen CD, Liebler DC, Marks JG Jr, Shank RC, Slaga TJ, Snyder PW, and Gill LJ. 2015. Final Report on the Safety Assessment of Polysaccharide Gums as Used in Cosmetics. Available on the CIR website.

74. Becker LC, Bergfeld WF, Belsito DV, Hill RA, Klaassen CD, Marks JG Jr, Shank RC, Slaga TJ, Snyder PW, and Andersen FA. Final Report on the Amended Safety Assessment of Myristic Acid and Its Salts and Esters as Used in Cosmetics. *Int J Toxicol.* 2010;29(Suppl 3):162S-186S.
75. Fiume MM, Heldreth BA, Bergfeld WF, Belsito DV, Hill RA, Klaassen CD, Liebler DC, Marks JG Jr, Shank RC, Slaga TJ, Snyder PW, and Andersen FA. Safety assessment of citric acid, inorganic citrate salts, and alkyl citrate esters as used in cosmetics. *Int J Toxicol.* 2014;33(Suppl 2):16S-46S. <http://www.cir-safety.org/ingredients>.
76. Burnett CL, Bergfeld WF, Belsito DV, Klaassen CD, Marks JG Jr, Shank RC, Slaga TJ, Snyder PW, and Andersen FA. Final report on the safety assessment of *Cocos nucifera* (coconut) oil and related ingredients. *Int J Toxicol.* 2011;30(Suppl 1):5S-16S. <http://www.cir-safety.org/ingredients>.
77. Andersen FA (ed). Amended final report on the safety assessment of hydroxystearic acid. *Int J Toxicol.* 1999;18(Suppl 1):1-10. <http://www.cir-safety.org/ingredients>.
78. Elder RL (ed). Final report on the safety assessment of isostearic acid. *J Am Coll Toxicol.* 1983;2(7):61-74. <http://www.cir-safety.org/ingredients>.
79. Elder RL (ed). Final report on the safety assessment of oleic acid, lauric acid, palmitic acid, myristic acid, and stearic acid. *J Am Coll Toxicol.* 1987;6(3):321-401. <http://www.cir-safety.org/ingredients>.
80. Burnett CL, Fiume MM, Bergfeld WF, Belsito DV, Hill RA, Klaassen CD, Liebler DC, Marks JG Jr, Shank RC, Slaga TJ, Snyder PW, and Andersen FA. 2011. Final report on the safety assessment of plant-derived fatty acid oils as used in cosmetics. Available on the CIR website.
81. Andersen FA (ed). Final Report on the Safety Assessment of Ricinus Communis (Castor) Seed Oil, Hydrogenated Castor Oil, Glyceryl Ricinoleate, Glyceryl Ricinoleate SE, Ricinoleic Acid, Potassium Ricinoleate, Sodium Ricinoleate, Zinc Ricinoleate, Cetyl Ricinoleate, Ethyl Ricinoleate, Glycol Ricinoleate, Isopropyl Ricinoleate, Methyl Ricinoleate, and Octyldodecyl Ricinoleate. *Int J Toxicol.* 2007;26(Suppl 3):31-77. <http://www.cir-safety.org/ingredients>.
82. Fiume MM, Heldreth BA, Bergfeld WF, Belsito DV, Hill RA, Klaassen CD, Liebler DC, Marks JG Jr, Shank RC, Slaga TJ, Snyder PW, and Andersen FA. Final report of the Cosmetic Ingredient Review Expert Panel on the safety assessment of dicarboxylic acids, salts, and esters. *Int J Toxicol.* 2012;31(Suppl 1):5S-76S. <http://www.cir-safety.org/ingredients>.
83. Elder RL (ed). Final Report of the Safety Assessment of Lithium Stearate, Aluminum Distearate, Aluminum Stearate, Aluminum Tristearate, Ammonium Stearate, Calcium Stearate, Magnesium Stearate, Potassium Stearate, Sodium Stearate, and Zinc Stearate. *J Am Coll Toxicol.* 2016;1(2):143-177.
84. Andersen FA (ed). Annual Review of Cosmetic Ingredient Safety Assessments - 2001/2002. *Int J Toxicol.* 2003;22(Suppl 1):19-28.
85. Andersen FA (ed). Final report on the safety assessment of Acacia Catechu Gum, Acacia Concinna Fruit Extract, Acacia Dealbata Leaf Extract, Acacia Dealbata Leaf Wax, Acacia Decurrens Extract, Acacia Farnesiana Extract, Acacia Farnesiana Flower Wax, Acacia Farnesiana Gum, Acacia Senegal Extract, Acacia Senegal Gum, and Acacia Senegal Gum Extract. *Int J Toxicol.* 2005;24(Suppl 3):75-118.
86. Elder RL (ed). Final Report on the safety assessment of Candelilla Wax, Carnauba Wax, Japan Wax, and Beeswax. *J Am Coll Toxicol.* 1984;3(3):1-41.
87. Andersen FA (ed). Annual Review of Cosmetic Ingredient Safety Assessments - 2002/2003. *Int J Toxicol.* 2005;24(Suppl 1):48-52.
88. Andersen FA (ed). Amended Final Report on the Safety Assessment of Oryza Sativa (Rice) Bran Oil, Oryza Sativa (Rice) Germ Oil, Rice Bran Acid, Oryza Sativa (Rice) Bran Wax, Hydrogenated Rice Bran Wax, Oryza Sativa (Rice) Bran Extract, Oryza Sativa (Rice) Extract, Oryza Sativa (Rice) Germ Powder, Oryza Sativa (Rice) Starch, Oryza Sativa (Rice) Bran, Hydrolyzed Rice Bran Extract, Hydrolyzed Rice Bran Protein, Hydrolyzed Rice Extract, and Hydrolyzed Rice Protein. *Int J Toxicol.* 2006;25(Suppl 2):91-120.
89. Becker LC, Bergfeld WF, Belsito DV, Klaassen CD, Marks JG Jr, Shank RC, Slaga TJ, Snyder PW, and Andersen FA. 2008. Safety Assessment of Simmondsia Chinensis (Jojoba) Seed Oil, Simmondsia Chinensis (Jojoba) Seed Wax, Hydrogenated Jojoba Oil, Hydrolyzed Jojoba Esters, Isomerized Jojoba Oil, Jojoba Esters, Simmondsia Chinensis (Jojoba) Butter, Jojoba Alcohol, and Synthetic Jojoba Oil. Available on the Cosmetic Ingredient Review website.

90. Aldivia. Technical Data Sheet: VIATENZA® Baobab PO6 (Adansonia Digitata Seed Oil Polyglyceryl-6 Esters). <http://glenncorp.com/wp-content/uploads/2014/06/TDS-Viatenza%C2%AE-Baobab-PO6-Amphiphilic-200608.pdf>. Last Updated 2008. Date Accessed 2-27-2015.
91. Aldivia. Data sheet: VIATENZA® Apricot PO6 (Apricot Kernel Oil Polyglyceryl-6 Esters ). <http://glenncorp.com/wp-content/uploads/2014/06/TDS-Viatenza-Apricot-PO6-Amphiphile-V9-05-03-2013.pdf>. Last Updated 2013. Date Accessed 4-10-2015.
92. Aldivia. Data Sheet: VIATENZA® Apricot PO10 (Apricot Kernel Oil Polyglyceryl-10 Esters). <http://glenncorp.com/wp-content/uploads/2014/06/TDS-Viatenza%C2%AE-Apricot-PO10-Amphiphilic-160608.pdf>. Last Updated 2008. Date Accessed 3-3-2015.
93. Aldivia. Technical Data Sheet: VIATENZA® Argan PO6 (Argan Oil Polyglyceryl-6 Esters). <http://glenncorp.com/wp-content/uploads/2014/06/Viatenza%C2%AE-Argan-PO6-Amphiphilic.-TDS.-05.03.13.pdf>. Last Updated 2013. Date Accessed 3-3-2015.
94. Aldivia. Technical Data Sheet: VIATENZA® Babassu PO6 (Babassu Oil Polyglyceryl-6 Esters). [http://glenncorp.com/wp-content/uploads/2014/06/Glenn.TDS\\_.Viatenza-Babassu-PO6-Amphiphilic.05.03.13.pdf](http://glenncorp.com/wp-content/uploads/2014/06/Glenn.TDS_.Viatenza-Babassu-PO6-Amphiphilic.05.03.13.pdf). Last Updated 2013. Date Accessed 3-3-2015.
95. Aldivia. Technical data sheet: VIATENZA® Brazil Nut PO6 (Bertholletia Excelsa Seed Oil Polyglyceryl-6 Esters). <http://glenncorp.com/wp-content/uploads/2014/07/TDS-Viatenza-Brazil-Nut-PO6-Amphiphilic-V7-05-03-2013.pdf>. Last Updated 2012. Date Accessed 3-3-2015.
96. Aldivia. Data Sheet: VIATENZA® Caprylic/Capric PO10 (Caprylic/Capric Glycerides Polyglycerin-10 Esters). [http://glenncorp.com/wp-content/uploads/2014/06/Viatenza-Caprylic-Capric-PO10.TDS\\_.06.16.08.pdf](http://glenncorp.com/wp-content/uploads/2014/06/Viatenza-Caprylic-Capric-PO10.TDS_.06.16.08.pdf). Last Updated 2008. Date Accessed 4-14-2015.
97. Abitec. Technical Data Sheet: VIATENZA® Cocoa PO6 (Cocoa butter Polyglyceryl-6 Esters). <http://glenncorp.com/wp-content/uploads/2014/07/TDS-Viatenza-Cocoa-PO6-Amphiphilic-V7-05-03-2013.pdf>. Last Updated 2013. Date Accessed 3-3-2015.
98. Aldivia. Technical Data Sheet: VIATENZA® Coco PO6 (Coconut Oil Polyglyceryl-6 Esters). <http://glenncorp.com/wp-content/uploads/2014/07/TDS-Viatenza-Coco-PO6-Amphiphilic-V5-05-03-2013.pdf>. Last Updated 2013. Date Accessed 3-3-2015.
99. Aldivia. Technical data sheet: VIATENZA® Hazel PO6 (Hazel Seed Oil Polyglyceryl-6 Esters). <http://glenncorp.com/wp-content/uploads/2014/07/TDS-Viatenza%C2%AE-Hazel-PO6-Amphiphilic-2006081.pdf>. Last Updated 2008. Date Accessed 3-4-2015.
100. Aldivia. Technical data sheet: VIATENZA® Macadamia PO6 (Macadamia Seed Oil Polyglyceryl-6 Esters). <http://glenncorp.com/wp-content/uploads/2014/07/TDS-Viatenza%C2%AE-Macadamia-PO6-Amphiphilic-29112010.pdf>. Last Updated 2010. Date Accessed 3-4-2015.
101. Aldivia. Technical data sheet: VIATENZA® Olive PO6 (Olive Oil Polyglyceryl-6 Esters). <http://glenncorp.com/wp-content/uploads/2014/06/Viatenza-Olive-PO6-Amphiphilic.-TDS.-05.03.13.pdf>. Last Updated 2013. Date Accessed 3-4-2015.
102. Aldivia. Technical data sheet: VIATENZA® Safflower PO6 (Safflower Oil Polyglyceryl-6 Esters). <http://glenncorp.com/wp-content/uploads/2014/06/Viatenza%C2%AE-Safflower-PO6-Cx-Amphiphilic.-TDS.-06.16.08.pdf>. Last Updated 2008. Date Accessed 3-5-2015.
103. Aldivia. Technical data sheet: VIATENZA® Mongongo PO6 (Schinziophyton Rautanenii Kernel Oil Polyglyceryl-6 Esters). <http://glenncorp.com/wp-content/uploads/2014/06/Viatenza%C2%AE-Mongongo-PO6-Amphiphilic.-TDS.-07.15.08.pdf>. Last Updated 2008. Date Accessed 3-5-2015.
104. Aldivia. Technical data sheet: VIATENZA® Marula PO6 (Sclerocarya Birrea Seed Oil Polyglyceryl-6 Esters). <http://glenncorp.com/wp-content/uploads/2014/07/TDS-Viatenza%C2%AE-Marula-PO6-Amphiphilic-130608.pdf>. Last Updated 2008. Date Accessed 3-5-2015.
105. Aldivia. Technical data sheet: VIATENZA® Sesame PO6 (Sesame Oil Polyglyceryl-6 Esters). <http://glenncorp.com/wp-content/uploads/2014/07/TDS-Viatenza%C2%AE-Sesame-PO6-Amphiphilic-160608.pdf>. Last Updated 2008. Date Accessed 3-5-2015.



106. Aldivia. Technical data sheet: VIATENZA<sup>®</sup> Shea PO6 (Shea Butter Polyglyceryl-6 Esters). <http://glenncorp.com/wp-content/uploads/2014/07/TDS-Viatenza%C2%AE-Shea-PO6-Amphiphilic-V7-05-03-2013.pdf>. Last Updated 2013. Date Accessed 3-9-2015.
107. Aldivia. Technical data sheet: VIATENZA<sup>®</sup> Soybean P06 (Soybean Oil Polyglyceryl-6 Esters). <http://glenncorp.com/wp-content/uploads/2014/07/TDS-Viatenza%C2%AE-Soybean-PO6-Amphiphilic-160608.pdf>. Last Updated 2008. Date Accessed 3-9-2015.
108. Aldivia. Technical data sheet: VIATENZA<sup>®</sup> Oleic Sunflower PO6 (Sunflower Seed Oil Polyglyceryl-6 Esters). <http://glenncorp.com/wp-content/uploads/2014/06/TDS-Viatenza-Oleic-Sunflower-PO6-Amphiphilic-V3-26-12-2012.pdf>. Last Updated 2012. Date Accessed 3-5-2015.
109. Aldivia. Technical data sheet: VIATENZA<sup>®</sup> Oleic Sunflower PO10 (Sunflower Seed Oil Polyglyceryl-10 Esters ). [http://glenncorp.com/wp-content/uploads/2014/06/Viatenza-Oleic-Sunflower-PO10.TDS\\_10.06.08.pdf](http://glenncorp.com/wp-content/uploads/2014/06/Viatenza-Oleic-Sunflower-PO10.TDS_10.06.08.pdf). Last Updated 2008. Date Accessed 3-9-2015.
110. Aldivia. Technical data sheet: VIATENZA<sup>®</sup> Almond PO6 (Sweet Almond Oil Polyglyceryl-6 Esters ). <http://glenncorp.com/wp-content/uploads/2014/07/TDS-Viatenza-Almond-PO6-Amphiphilic-V9-05-03-2013.pdf>. Last Updated 2013. Date Accessed 3-10-2015.
111. Aldivia. Technical data sheet: VIATENZA<sup>®</sup> Mafura PO6 (Trichilia Emetica Seed Oil Polyglyceryl-6 Esters). <http://glenncorp.com/wp-content/uploads/2014/07/TDS-Viatenza%C2%AE-Mafura-PO6-Amphiphilic-160608.pdf>. Last Updated 2008. Date Accessed 3-10-2015.
112. AVG Pharma. PO6 Viatenza<sup>®</sup> Borage (Borage Seed Oil Polyglyceryl-6 Esters). <http://www.avgpharma.it/Attivo.aspx?ActiveID=106&FunctionID=26&ProductID=228&CategoryID=61>. Last Updated 2015. Date Accessed 3-3-2015.
113. Lubrizol. Technical data sheet (TDS-399): Schercemol<sup>™</sup> PDD Ester (Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate). <https://www.lubrizol.com/Personal-Care/Documents/Technical-Data-Sheets/TDS-399-Schercemol%E2%84%A2-PDD-Ester.pdf>. Last Updated 2009.
114. Evonik Industries. Technical Data Sheet: Isolan<sup>®</sup> PDI (Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate). [http://glenn.wpengine.com/wp-content/uploads/2013/11/DS\\_ISOLAN\\_PDI.pdf](http://glenn.wpengine.com/wp-content/uploads/2013/11/DS_ISOLAN_PDI.pdf). Last Updated 2013. Date Accessed 4-10-2015.
115. Stephenson Personal Care. Durosoft. <http://www.stephensonpersonalcare.com/products/durosoft/>. Last Updated 2015. Date Accessed 3-4-2015.
116. Koster Keunen. Technical data sheet: Cera Bellina (Polyglyceryl-3 Beeswax). [http://www.brenntagsspecialties.com/en/downloads/Products/Personal\\_care/Koster\\_Keunen/Cera\\_Bellina\\_106\\_TDS.pdf](http://www.brenntagsspecialties.com/en/downloads/Products/Personal_care/Koster_Keunen/Cera_Bellina_106_TDS.pdf). Last Updated 2015. Date Accessed 4-14-2015.
117. ChemNet. 156153-06-9; Polyglyceryl-2 Caprate. <http://www.chemnet.com/cas/en/156153-06-9/POLYGLYCERYL-2-CAPRATE.html>. Last Updated 2015. Date Accessed 9-14-2015.
118. Evonik Industries. TEGO<sup>®</sup> Cosmo P 813 (Polyglyceryl-3 Caprylate). [http://www.finecon.sk/admin/pdf/DS\\_TEGO\\_Cosmo\\_P\\_813\\_e.pdf](http://www.finecon.sk/admin/pdf/DS_TEGO_Cosmo_P_813_e.pdf). Last Updated 2008. Date Accessed 4-10-2015.
119. Lonza. Product information: Polyaldo<sup>™</sup> 10-1-CC KFG (Polyglyceryl-10 Caprylate/Caprate) [pamphlet]. 2014.
120. Nikko Chemicals co., Ltd. Material Safety Data Sheet: NIKKOL Decaglyn 10-ISV (Polyglyceryl-10 Decaisostearate). <http://www.barnetproducts.com/pdfs/msds/DEC10-ISV.pdf>. Last Updated 2004. Date Accessed 4-14-2015.
121. AIC. Specification Sheet: Polyglyceryl-4 Caprate (SOLDOP PG 410<sup>®</sup>). <http://www.aicma.com/products/Polyglyceryl-4%20Caprate%20SOLDOP%20PG%20410%20PG410L.pdf>. Last Updated 2014. Date Accessed 9-17-2015.
122. Evonik Industries. TEGOSOFT<sup>®</sup> PC 41 (Polyglyceryl-4 Caprate). [http://glenn.wpengine.com/wp-content/uploads/2013/11/DS\\_TEGOSOFT\\_PC41\\_e.pdf](http://glenn.wpengine.com/wp-content/uploads/2013/11/DS_TEGOSOFT_PC41_e.pdf). Last Updated 2013. Date Accessed 9-18-2015.
123. Nihoh Emulsion Co., Ltd. Product information: Emalex DISG-6 (Polyglyceryl-6 Diisostearate). <https://www.nihon-emulsion.co.jp/products/detail/EMALEX%20DISG-6>. Last Updated 2015. Date Accessed 12-3-2015.

124. United States Pharmacopeial Convention. Material Safety Data Sheet: Polyglyceryl-3 Dioleate. <http://static.usp.org/pdf/EN/referenceStandards/msds/1546933.pdf>. Last Updated 2010. Date Accessed 12-1-2015.
125. Sigma-Aldrich. Polyglyceryl-6 Dioleate. <http://www.sigmaaldrich.com/catalog/search?term=76009-37-5&interface=CAS%20No.&N=0+&mode=partialmax&lang=en&region=US&focus=product>. Last Updated 2015. Date Accessed 12-3-2015.
126. U.S. National Library of Medicine (NLM). ChemID Plus. <http://chem.sis.nlm.nih.gov/chemidplus/>. Last Updated 2015. Date Accessed 9-14-2015.
127. Lonza. Information brochure: Aldo™ and Polyaldo™ Specific Emulsifier Solution for All Types of Formulations [pamphlet]. 2014.
128. BASF. Technical Information: Cremophor® GS 32 (Polyglyceryl-3 Distearate). <http://dewolfchem.com/wp-content/uploads/2013/08/Cremophor-GS-32.pdf>. Last Updated 2006. Date Accessed 12-1-2015.
129. Parchem. Data sheet. Polyglyceryl-10 Distearate. [www.parchem.com/Polyglyceryl-10-Distearate-getpdf-012393.aspx](http://www.parchem.com/Polyglyceryl-10-Distearate-getpdf-012393.aspx). Last Updated 1993. Date Accessed 9-11-2015.
130. FTA Global. Polyglyceryl isopalmitate/sebacate. <http://www.ftaglobal.com/data/show-4449.html>. Last Updated 2013. Date Accessed 9-15-2015.
131. ChemNet. 73296-86-3; Isooctadecanoic acid, ester with oxybis[propanediol] (polyglyceryl-2 isostearate). <http://www.chemnet.com/cas/en/73296-86-3/Dermol-DGMIS-1.html>. Last Updated 2015. Date Accessed 9-15-2015.
132. Goldschmidt AG. ISOLAN® GI 34 (Polyglyceryl-4 Isostearate). [http://www.quetzalquimica.com/images/DS\\_ISOLAN\\_GI\\_34\\_e10-08-2007.pdf](http://www.quetzalquimica.com/images/DS_ISOLAN_GI_34_e10-08-2007.pdf). Last Updated 2007. Date Accessed 9-18-2015.
133. The Good Scents Company. Polyglyceryl-6 Distearate. <http://www.thegoodscentscompany.com/data/rw1300381.html>. Last Updated 2015. Date Accessed 12-3-2015.
134. Lonza. Information pamphlet: Polyaldo™ HGDS KFG (6-2-S) (Polyglyceryl-6 Distearate) [pamphlet]. 2015.
135. Lubrizol. Technical data sheet (TDS-371): Hydramol™ TGL Ester (Polyglyceryl-3 Laurate). <https://www.lubrizol.com/Personal-Care/Documents/Technical-Data-Sheets/TDS-371-Hydramol%E2%84%A2-TGL-Ester.pdf>. Last Updated 2014. Date Accessed 3-31-2015.
136. Barnet Products Corporation. Product specifications: Decaglyn 1-M (polyglyceryl-10 myristate; CAS No. 87390-32-7). <http://www.barnetproducts.com/pdfs/specs/Decaglyn%201M.pdf>. Last Updated 2002. Date Accessed 9-14-2015.
137. Evonik Industries. TEGO® Care PL 4 (Polyglyceryl-4 Laurate). [http://glennncorp.com/wp-content/uploads/2013/11/DS\\_TEGO\\_Care\\_PL\\_4\\_e-1.pdf](http://glennncorp.com/wp-content/uploads/2013/11/DS_TEGO_Care_PL_4_e-1.pdf). Last Updated 2009. Date Accessed 4-10-2015.
138. Evonik Industries. ISOLAN® GO 33 (Polyglyceryl-3 Oleate). [http://www.finecon.sk/admin/pdf/DS\\_ISOLAN\\_GO\\_33\\_e.pdf](http://www.finecon.sk/admin/pdf/DS_ISOLAN_GO_33_e.pdf). Last Updated 1999. Date Accessed 4-10-2015.
139. Anonymous. 2016. Composition and physical and chemical properties Polyglyceryl-4 Oleate. Unpublished data submitted by Personal Care Products Council.
140. The Good Scents Company. Polyglyceryl-10 Oleate. <http://www.thegoodscentscompany.com/data/rw1366941.html>. Last Updated 2015. Date Accessed 10-30-2015.
141. Lonza. Information brochure: Polyaldo™ 10-1-O KFG (NON GMO) (Polyglyceryl-10 Oleate) [pamphlet]. 2014.
142. SAAPedia. Polyglyceryl palmate. <http://www.saapedia.org/en/saa/?type=detail&id=4420>. Last Updated 2013. Date Accessed 11-17-2015.
143. SAAPedia. Polyglyceryl pentacaprylate. <http://www.saapedia.org/en/saa/?type=detail&id=4481>. Last Updated 2013. Date Accessed 12-3-2015.
144. Stepan. NEOBEE® Medium Chain Triglycerides, WECOBEE® Triglycerides, DREWPOL® Polyglycerol Esters, and DREWMULSE® Mono and Diglycerides.

<http://webcache.googleusercontent.com/search?q=cache:kIZTsQtW7KsJ:www.stepan.com/workarea/downloadasset.aspx%3Fid%3D1459+&cd=6&hl=en&ct=clnk&gl=us>. Last Updated 2008. Date Accessed 12-12-0015.

145. Medolla. Technical datasheet: Olivatis 12 (Polyglyceryl-3 Pentaolive). [http://www.coastsouthwest.com/wp-content/uploads/2014/05/medolla\\_olivatis\\_12.pdf](http://www.coastsouthwest.com/wp-content/uploads/2014/05/medolla_olivatis_12.pdf). Last Updated 2014. Date Accessed 3-30-2015.
146. Nikko Chemicals Co. Ltd. Safety Data Sheet: NIKKOL Decaglyn 5-OV (Polyglyceryl-10 Pentaoleate). [https://www.chemical-navi.com/english/product\\_search/view126.html](https://www.chemical-navi.com/english/product_search/view126.html). Last Updated 2014. Date Accessed 12-1-2015.
147. Nikko Chemicals Co. Ltd. Product Details: NIKKOL Decaglyn 5-OV (Polyglyceryl-10 Pentaoleate). [https://www.chemical-navi.com/english/product\\_search/detail66.html](https://www.chemical-navi.com/english/product_search/detail66.html). Last Updated 2010. Date Accessed 12-1-2015.
148. Nikko Chemicals Co. Ltd. Product Details: NIKKOL Tetraglyn 5-S (Polyglyceryl-4 Pentastearate). [https://www.chemical-navi.com/english/product\\_search/detail356.html](https://www.chemical-navi.com/english/product_search/detail356.html). Last Updated 2010. Date Accessed 12-1-2015.
149. Parchem. Specifications: Polyglyceryl-6 Pentastearate. [www.parchem.com/Polyglyceryl-6-Pentastearate-getpdf-012391.aspx](http://www.parchem.com/Polyglyceryl-6-Pentastearate-getpdf-012391.aspx). Last Updated 1991. Date Accessed 12-3-2015.
150. Dowin Chemical. Polyglyceryl-6 Pentastearate (99734-30-2 ). <http://dowinchem.trustexporter.com/product/detail/99/666577.htm>. Last Updated 2015. Date Accessed 12-3-2015.
151. Nikko Chemicals Co. Ltd. Product Details: NIKKOL Decaglyn 5-SV (Polyglyceryl-10 Pentastearate). [https://www.chemical-navi.com/english/product\\_search/detail67.html](https://www.chemical-navi.com/english/product_search/detail67.html). Last Updated 2010. Date Accessed 12-1-2015.
152. The Good Scents Company. Polyglyceryl-10 Pentastearate. <http://www.thegoodscentscompany.com/data/rw1480771.html>. Last Updated 2015. Date Accessed 12-1-2015.
153. Progressus s.r.l. 2015. Material safety data sheet PROLIX RB (Polyglyceryl-3 Rice Branate). Unpublished data submitted by Personal Care Products Council.
154. AAK. Product information: Akoline PGPR (Polyglyceryl-3 Ricinoleate). [http://aak.com/Global/Products/Beauty%20and%20personal%20care/Emulsifiers/aak-lfc\\_akoline\\_pgpr\\_0808.pdf](http://aak.com/Global/Products/Beauty%20and%20personal%20care/Emulsifiers/aak-lfc_akoline_pgpr_0808.pdf). Last Updated 2008. Date Accessed 4-1-2015.
155. Dr. Straetmans Chemische Produkte GmbH. Product information: dermofeel® GO (Polyglyceryl-2 Sesquioleate). <http://www.lucasmeyercosmetics.com/mailling/pdf/DermofeelGOsoft-ProductInformation.pdf>. Last Updated 2012. Date Accessed 12-1-2015.
156. SAAPedia. Polyglyceryl soyate/shear butterate. <http://www.saapedia.org/en/saa/?type=detail&id=4432>. Last Updated 2013. Date Accessed 9-17-2015.
157. Nisshin Oillio Group Ltd. Raw materials for the cosmetics industry. <http://www.nisshin-oillio.com/english/products/pdf/finechemicals.pdf>. Last Updated 2013. Date Accessed 11-17-2015.
158. Nikko Chemicals Co. Ltd. Product Details: Nikkol Decaglyn 1-SV (Polyglyceryl-10 Stearate). [https://www.chemical-navi.com/english/product\\_search/detail60.html](https://www.chemical-navi.com/english/product_search/detail60.html). Last Updated 2010. Date Accessed 10-30-2015.
159. Abitec. Material Safety Data Sheet: Caprol 10G40 (Polyglyceryl-10 Tetraoleate; CAS No. 34424-98-1). [http://www.abiteccorp.com/wp-content/files\\_mf/1343830278Caprol10G40.pdf](http://www.abiteccorp.com/wp-content/files_mf/1343830278Caprol10G40.pdf). Last Updated 2005. Date Accessed 12-1-2015.
160. U.S. Environmental Protection Agency (EPA). Substance Details - Octadecanoic acid, tetraester with oxybis[propanediol]. [http://iaspub.epa.gov/sor\\_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p\\_type=CAS\\_NO&p\\_value=72347-89-8](http://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=CAS_NO&p_value=72347-89-8). Last Updated 2015. Date Accessed 12-1-2015.
161. Nihoh Emulsion Co., Ltd. Material Safety Data Sheet: Emalex TCCG-10 (Polyglyceryl-10 Tricocoate). [https://www.nihon-emulsion.co.jp/pdf/msds/TCCG-10\\_E\\_MSDS.pdf](https://www.nihon-emulsion.co.jp/pdf/msds/TCCG-10_E_MSDS.pdf). Last Updated 2013. Date Accessed 12-1-2015.
162. SAAPedia. Polyglyceryl tridecanoate. <http://www.saapedia.org/en/saa/?type=detail&id=4501>. Last Updated 2013. Date Accessed 12-1-2015.
163. Nihoh Emulsion Co., Ltd. Material Safety Data Sheet: Emalex TISG-10 (Polyglyceryl-10 Triisostearate). [https://www.nihon-emulsion.co.jp/pdf/msds/TISG-10\\_E\\_MSDS.pdf](https://www.nihon-emulsion.co.jp/pdf/msds/TISG-10_E_MSDS.pdf). Last Updated 2014. Date Accessed 12-1-2015.



164. Nihoh Emulsion Co., Ltd. Product info: Emalex TISG-10 (Polyglyceryl-10 Triisostearate). <https://translate.google.com/translate?hl=en&sl=ja&u=https://www.nihon-emulsion.co.jp/products/detail/EMALEX%2520TISG-10&prev=search>. Last Updated 2015. Date Accessed 12-1-2015.
165. Nikko Chemicals Co. Ltd. Product Details: NIKKOL Decaglyn 3-OV (Polyglyceryl-10 Trioleate). [https://www.chemical-navi.com/english/product\\_search/detail63.html](https://www.chemical-navi.com/english/product_search/detail63.html). Last Updated 2010. Date Accessed 12-1-2015.
166. Nikko Chemicals Co. Ltd. Product Details: NIKKOL Decaglyn 3-SV (Polyglyceryl-10 Tristearate). Last Updated 2010. Date Accessed 12-1-2015.
167. Progressus s.r.l. 2015. Material safety data sheet PROLIX RO (Rice Brain Oil Polyglyceryl-3 Esters). Unpublished data submitted by Personal Care Products Council.
168. Progressus. Prolix RO (Rice Bran Oil Polyglyceryl-3 Ester). <http://www.progressus.it/en/products-2/>. Last Updated 2015. Date Accessed 12-3-2015.
169. Lubrizol. Product Specifications: Schercemol™ PTID Ester (Triisostearoyl Polyglycerol-3 Dimer Dilinoleate). <https://www.lubrizol.com/Personal-Care/Documents/Specifications/Schercemol%E2%84%A2-PTID-Ester.pdf>. Last Updated 2008. Date Accessed 3-10-2015.
170. Lubrizol. Technical data sheet (TDS-403): Schercemol™ PTID Ester (Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate). <https://www.lubrizol.com/Personal-Care/Documents/Technical-Data-Sheets/TDS-403-Schercemol%E2%84%A2-PTID-Ester.pdf>. Last Updated 2009. Date Accessed 3-11-2015.
171. AVG Personal Care. Viatenza® Ximenia PO6 (Ximenia Americana Seed Oil Polyglyceryl-6 Esters). [http://translate.google.com/translate?hl=en&sl=it&u=http://www.avgpersonalcare.it/%28A%28mOMli\\_fDygEkAAAA%28YTY1NjUyZDUtZDgwMS00NzhjLWJiOTYtZTM3NTAxOGZiZDlmb58x4ypbPeRWwGO0KtXbz4s8jaQ1%29S%28gxx5te45ank1x045cte4xt2b%29%29/Attivo.aspx%3FActiveID%3D117%26FunctionID%3D123%26ProductID%3D20%26CategoryID%3D10&prev=search](http://translate.google.com/translate?hl=en&sl=it&u=http://www.avgpersonalcare.it/%28A%28mOMli_fDygEkAAAA%28YTY1NjUyZDUtZDgwMS00NzhjLWJiOTYtZTM3NTAxOGZiZDlmb58x4ypbPeRWwGO0KtXbz4s8jaQ1%29S%28gxx5te45ank1x045cte4xt2b%29%29/Attivo.aspx%3FActiveID%3D117%26FunctionID%3D123%26ProductID%3D20%26CategoryID%3D10&prev=search). Last Updated 2014. Date Accessed 3-11-2015.
172. Gattefossé. Plurol® Stearique WL 1009 (Polyglyceryl-6 Distearate). <http://www.gattefosse.com/en/products/plurol-stearique-wl-1009.html>. Last Updated 2015. Date Accessed 4-10-2015.
173. Gattefossé. Hydracire S. <http://dir.cosmeticsandtoiletries.com/detail/tradeName.html?id=20543>. Last Updated 2016. Date Accessed 1-14-2016.
174. CREMER OLEO GmbH & Co. KG. CremerCOOR® PG4 Coccoate (Polyglyceryl-4 Coccoate). <http://www.cremeroleo.de/en/produktbereiche/cremer-care/produkte/CremerCOOR-PG4-Coccoate-Solubilizers.php>. Last Updated 2015. Date Accessed 10-15-2015.
175. Vantage Specialty Ingredients. Neosolue® -Aqua (Polyglyceryl-10 Eicosanedioate/Tetradecanedioate). <http://www.lipochemicals.com/products/neosolue-aqua>. Last Updated 2015. Date Accessed 11-17-2015.

Distributed for Comment Only -- Do Not Cite or Quote  
**Polyglyceryl Fatty Acid Esters - 2015 FDA VCRP**

ACACIA DECURRENS/JOJOBA/SUNFLOWER SEED WAX/POLYGLYCERYL-3 ESTERS	03B - Eyeliner	1
ACACIA DECURRENS/JOJOBA/SUNFLOWER SEED WAX/POLYGLYCERYL-3 ESTERS	07A - Blushers (all types)	2
ACACIA DECURRENS/JOJOBA/SUNFLOWER SEED WAX/POLYGLYCERYL-3 ESTERS	07E - Lipstick	1
ACACIA DECURRENS/JOJOBA/SUNFLOWER SEED WAX/POLYGLYCERYL-3 ESTERS	07I - Other Makeup Preparations	1
ACACIA DECURRENS/JOJOBA/SUNFLOWER SEED WAX/POLYGLYCERYL-3 ESTERS	10E - Other Personal Cleanliness Products	1
ACACIA DECURRENS/JOJOBA/SUNFLOWER SEED WAX/POLYGLYCERYL-3 ESTERS	12C - Face and Neck (exc shave)	1
ACACIA DECURRENS/JOJOBA/SUNFLOWER SEED WAX/POLYGLYCERYL-3 ESTERS	12D - Body and Hand (exc shave)	1
ACACIA DECURRENS/JOJOBA/SUNFLOWER SEED WAX/POLYGLYCERYL-3 ESTERS	12F - Moisturizing	2
BABASSU OIL POLYGLYCERYL-4 ESTERS	05F - Shampoos (non-coloring)	17
BABASSU OIL POLYGLYCERYL-4 ESTERS	12A - Cleansing	1
BABASSU OIL POLYGLYCERYL-6 ESTERS	12A - Cleansing	1
CANDELILLA/JOJOBA/RICE BRAN POLYGLYCERYL-3 ESTERS	01B - Baby Lotions, Oils, Powders, and Creams	1
CANDELILLA/JOJOBA/RICE BRAN POLYGLYCERYL-3 ESTERS	03D - Eye Lotion	2
CANDELILLA/JOJOBA/RICE BRAN POLYGLYCERYL-3 ESTERS	03G - Other Eye Makeup Preparations	4
CANDELILLA/JOJOBA/RICE BRAN POLYGLYCERYL-3 ESTERS	07C - Foundations	1
CANDELILLA/JOJOBA/RICE BRAN POLYGLYCERYL-3 ESTERS	07E - Lipstick	1
CANDELILLA/JOJOBA/RICE BRAN POLYGLYCERYL-3 ESTERS	12C - Face and Neck (exc shave)	2
CANDELILLA/JOJOBA/RICE BRAN POLYGLYCERYL-3 ESTERS	12D - Body and Hand (exc shave)	1
CANDELILLA/JOJOBA/RICE BRAN POLYGLYCERYL-3 ESTERS	12F - Moisturizing	2
CANDELILLA/JOJOBA/RICE BRAN POLYGLYCERYL-3 ESTERS	12G - Night	2
COCONUT OIL POLYGLYCERYL-6 ESTERS	10E - Other Personal Cleanliness Products	1
COCONUT OIL POLYGLYCERYL-6 ESTERS	12A - Cleansing	1
DIISOSTEAROYL POLYGLYCERYL-3 DIMER DILINOLEATE	03C - Eye Shadow	1
DIISOSTEAROYL POLYGLYCERYL-3 DIMER DILINOLEATE	12G - Night	2
GLYCERYL/POLYGLYCERYL-6 ISOSTEARATE/BEHENATE ESTERS	03B - Eyeliner	1
GLYCERYL/POLYGLYCERYL-6 ISOSTEARATE/BEHENATE ESTERS	03C - Eye Shadow	1
GLYCERYL/POLYGLYCERYL-6 ISOSTEARATE/BEHENATE ESTERS	07A - Blushers (all types)	1
GLYCERYL/POLYGLYCERYL-6 ISOSTEARATE/BEHENATE ESTERS	07C - Foundations	2
GLYCERYL/POLYGLYCERYL-6 ISOSTEARATE/BEHENATE ESTERS	07E - Lipstick	2
GLYCERYL/POLYGLYCERYL-6 ISOSTEARATE/BEHENATE ESTERS	12D - Body and Hand (exc shave)	1
GLYCERYL/POLYGLYCERYL-6 ISOSTEARATE/BEHENATE ESTERS	12J - Other Skin Care Preps	2
MACADAMIA SEED OIL POLYGLYCERYL-6 ESTERS BEHENATE	03C - Eye Shadow	1
MACADAMIA SEED OIL POLYGLYCERYL-6 ESTERS BEHENATE	03F - Mascara	1
MACADAMIA SEED OIL POLYGLYCERYL-6 ESTERS BEHENATE	03G - Other Eye Makeup Preparations	1
MACADAMIA SEED OIL POLYGLYCERYL-6 ESTERS BEHENATE	13A - Suntan Gels, Creams, and Liquids	1
PALM OIL POLYGLYCERYL-4 ESTERS	12D - Body and Hand (exc shave)	1
POLYGLYCERYL-10 BEHENATE/EICOSADIOATE	12A - Cleansing	1
POLYGLYCERYL-10 BEHENATE/EICOSADIOATE	12J - Other Skin Care Preps	1
POLYGLYCERYL-10 DECAOLEATE	07C - Foundations	1
POLYGLYCERYL-10 DECAOLEATE	07E - Lipstick	3
POLYGLYCERYL-10 DECAOLEATE	07F - Makeup Bases	1
POLYGLYCERYL-10 DECAOLEATE	12F - Moisturizing	4
POLYGLYCERYL-10 DECAOLEATE	12J - Other Skin Care Preps	1

POLYGLYCERYL-10 DIISOSTEARATE	07F - Makeup Bases	1
POLYGLYCERYL-10 DIISOSTEARATE	12A - Cleansing	1
POLYGLYCERYL-10 DIISOSTEARATE	12C - Face and Neck (exc shave)	4
POLYGLYCERYL-10 DIISOSTEARATE	12F - Moisturizing	3
POLYGLYCERYL-10 DIPALMITATE	02A - Bath Oils, Tablets, and Salts	2
POLYGLYCERYL-10 DIPALMITATE	07E - Lipstick	1
POLYGLYCERYL-10 DIPALMITATE	10E - Other Personal Cleanliness Products	9
POLYGLYCERYL-10 DIPALMITATE	12A - Cleansing	2
POLYGLYCERYL-10 DIPALMITATE	12C - Face and Neck (exc shave)	1
POLYGLYCERYL-10 DIPALMITATE	12H - Paste Masks (mud packs)	1
POLYGLYCERYL-10 DIPALMITATE	12J - Other Skin Care Preps	1
POLYGLYCERYL-10 DISTEARATE	10E - Other Personal Cleanliness Products	1
POLYGLYCERYL-10 DISTEARATE	12F - Moisturizing	9
POLYGLYCERYL-10 HYDROXYSTEARATE/STEARATE/EICOSADIOATE	07I - Other Makeup Preparations	1
POLYGLYCERYL-10 HYDROXYSTEARATE/STEARATE/EICOSADIOATE	12A - Cleansing	1
POLYGLYCERYL-10 ISOSTEARATE	12F - Moisturizing	3
POLYGLYCERYL-10 LAURATE	01A - Baby Shampoos	2
POLYGLYCERYL-10 LAURATE	01C - Other Baby Products	4
POLYGLYCERYL-10 LAURATE	03B - Eyeliner	1
POLYGLYCERYL-10 LAURATE	03D - Eye Lotion	2
POLYGLYCERYL-10 LAURATE	03G - Other Eye Makeup Preparations	2
POLYGLYCERYL-10 LAURATE	05A - Hair Conditioner	2
POLYGLYCERYL-10 LAURATE	05I - Other Hair Preparations	1
POLYGLYCERYL-10 LAURATE	07I - Other Makeup Preparations	2
POLYGLYCERYL-10 LAURATE	12A - Cleansing	4
POLYGLYCERYL-10 LAURATE	12C - Face and Neck (exc shave)	9
POLYGLYCERYL-10 LAURATE	12F - Moisturizing	8
POLYGLYCERYL-10 LAURATE	12G - Night	2
POLYGLYCERYL-10 LAURATE	12I - Skin Fresheners	1
POLYGLYCERYL-10 LAURATE	12J - Other Skin Care Preps	4
POLYGLYCERYL-10 MYRISTATE	01A - Baby Shampoos	1
POLYGLYCERYL-10 MYRISTATE	03C - Eye Shadow	1
POLYGLYCERYL-10 MYRISTATE	07I - Other Makeup Preparations	1
POLYGLYCERYL-10 MYRISTATE	12A - Cleansing	6
POLYGLYCERYL-10 MYRISTATE	12C - Face and Neck (exc shave)	3
POLYGLYCERYL-10 MYRISTATE	12F - Moisturizing	2
POLYGLYCERYL-10 MYRISTATE	13A - Suntan Gels, Creams, and Liquids	3
POLYGLYCERYL-10 MYRISTATE	13B - Indoor Tanning Preparations	1
POLYGLYCERYL-10 NONAISOSTEARATE	03C - Eye Shadow	18
POLYGLYCERYL-10 NONAISOSTEARATE	03G - Other Eye Makeup Preparations	5
POLYGLYCERYL-10 NONAISOSTEARATE	07C - Foundations	2
POLYGLYCERYL-10 NONAISOSTEARATE	07E - Lipstick	26
POLYGLYCERYL-10 NONAISOSTEARATE	07I - Other Makeup Preparations	7
POLYGLYCERYL-10 OLEATE	01A - Baby Shampoos	1
POLYGLYCERYL-10 OLEATE	05A - Hair Conditioner	2
POLYGLYCERYL-10 OLEATE	05F - Shampoos (non-coloring)	1
POLYGLYCERYL-10 OLEATE	05G - Tonics, Dressings, and Other Hair Groc	1

POLYGLYCERYL-10 OLEATE	11G - Other Shaving Preparation Products	1
POLYGLYCERYL-10 OLEATE	12C - Face and Neck (exc shave)	5
POLYGLYCERYL-10 OLEATE	12D - Body and Hand (exc shave)	2
POLYGLYCERYL-10 OLEATE	12F - Moisturizing	6
POLYGLYCERYL-10 OLEATE	12H - Paste Masks (mud packs)	2
POLYGLYCERYL-10 OLEATE	12J - Other Skin Care Preps	2
POLYGLYCERYL-10 OLEATE	13A - Suntan Gels, Creams, and Liquids	3
POLYGLYCERYL-10 PENTAHYDROXYSTEARATE	03F - Mascara	1
POLYGLYCERYL-10 PENTAHYDROXYSTEARATE	12G - Night	1
POLYGLYCERYL-10 PENTAHYDROXYSTEARATE	12H - Paste Masks (mud packs)	1
POLYGLYCERYL-10 PENTAOLEATE	03G - Other Eye Makeup Preparations	1
POLYGLYCERYL-10 PENTAOLEATE	05B - Hair Spray (aerosol fixatives)	1
POLYGLYCERYL-10 PENTAOLEATE	05G - Tonics, Dressings, and Other Hair Groc	1
POLYGLYCERYL-10 PENTAOLEATE	07E - Lipstick	1
POLYGLYCERYL-10 PENTAOLEATE	12G - Night	1
POLYGLYCERYL-10 PENTASTEARATE	03D - Eye Lotion	1
POLYGLYCERYL-10 PENTASTEARATE	05A - Hair Conditioner	1
POLYGLYCERYL-10 PENTASTEARATE	07C - Foundations	1
POLYGLYCERYL-10 PENTASTEARATE	12A - Cleansing	1
POLYGLYCERYL-10 PENTASTEARATE	12C - Face and Neck (exc shave)	3
POLYGLYCERYL-10 PENTASTEARATE	12F - Moisturizing	4
POLYGLYCERYL-10 PENTASTEARATE	12G - Night	2
POLYGLYCERYL-10 STEARATE	03C - Eye Shadow	2
POLYGLYCERYL-10 STEARATE	03D - Eye Lotion	1
POLYGLYCERYL-10 STEARATE	03G - Other Eye Makeup Preparations	8
POLYGLYCERYL-10 STEARATE	05G - Tonics, Dressings, and Other Hair Groc	1
POLYGLYCERYL-10 STEARATE	07C - Foundations	2
POLYGLYCERYL-10 STEARATE	07F - Makeup Bases	1
POLYGLYCERYL-10 STEARATE	12A - Cleansing	5
POLYGLYCERYL-10 STEARATE	12C - Face and Neck (exc shave)	15
POLYGLYCERYL-10 STEARATE	12D - Body and Hand (exc shave)	14
POLYGLYCERYL-10 STEARATE	12E - Foot Powders and Sprays	1
POLYGLYCERYL-10 STEARATE	12F - Moisturizing	21
POLYGLYCERYL-10 STEARATE	12G - Night	2
POLYGLYCERYL-10 STEARATE	12H - Paste Masks (mud packs)	2
POLYGLYCERYL-10 STEARATE	12I - Skin Fresheners	1
POLYGLYCERYL-10 STEARATE	12J - Other Skin Care Preps	10
POLYGLYCERYL-10 STEARATE	13A - Suntan Gels, Creams, and Liquids	3
POLYGLYCERYL-10 TRISTEARATE	03D - Eye Lotion	1
POLYGLYCERYL-2 CAPRATE	12D - Body and Hand (exc shave)	4
POLYGLYCERYL-2 CAPRATE	12F - Moisturizing	1
POLYGLYCERYL-2 DIISOSTEARATE	03C - Eye Shadow	1
POLYGLYCERYL-2 DIISOSTEARATE	03D - Eye Lotion	3
POLYGLYCERYL-2 DIISOSTEARATE	03F - Mascara	2
POLYGLYCERYL-2 DIISOSTEARATE	07A - Blushers (all types)	1
POLYGLYCERYL-2 DIISOSTEARATE	07C - Foundations	1
POLYGLYCERYL-2 DIISOSTEARATE	07E - Lipstick	32
POLYGLYCERYL-2 DIISOSTEARATE	07F - Makeup Bases	2
POLYGLYCERYL-2 DIISOSTEARATE	07G - Rouges	7
POLYGLYCERYL-2 DIISOSTEARATE	07H - Makeup Fixatives	3

POLYGLYCERYL-2 DIISOSTEARATE	07I - Other Makeup Preparations	3
POLYGLYCERYL-2 DIISOSTEARATE	12A - Cleansing	1
POLYGLYCERYL-2 DIISOSTEARATE	12C - Face and Neck (exc shave)	10
POLYGLYCERYL-2 DIISOSTEARATE	12D - Body and Hand (exc shave)	3
POLYGLYCERYL-2 DIISOSTEARATE	12F - Moisturizing	5
POLYGLYCERYL-2 DIISOSTEARATE	12H - Paste Masks (mud packs)	1
POLYGLYCERYL-2 DIISOSTEARATE	13A - Suntan Gels, Creams, and Liquids	1
DIGLYCERYL DIISOSTEARATE	07E - Lipstick	1
DIGLYCERYL DIISOSTEARATE	07F - Makeup Bases	1
DIGLYCERYL DIISOSTEARATE	12C - Face and Neck (exc shave)	2
DIGLYCERYL DIISOSTEARATE	12F - Moisturizing	2
DIGLYCERYL DIISOSTEARATE	12J - Other Skin Care Preps	1
POLYGLYCERYL-2 ISOPALMITATE	07E - Lipstick	9
POLYGLYCERYL-2 ISOSTEARATE	07B - Face Powders	2
POLYGLYCERYL-2 ISOSTEARATE	07C - Foundations	2
POLYGLYCERYL-2 ISOSTEARATE	07I - Other Makeup Preparations	1
POLYGLYCERYL-2 ISOSTEARATE	10E - Other Personal Cleanliness Products	1
POLYGLYCERYL-2 ISOSTEARATE	12J - Other Skin Care Preps	1
POLYGLYCERYL-2 LAURATE	03D - Eye Lotion	1
POLYGLYCERYL-2 LAURATE	05F - Shampoos (non-coloring)	1
POLYGLYCERYL-2 LAURATE	12A - Cleansing	2
POLYGLYCERYL-2 LAURATE	12C - Face and Neck (exc shave)	1
POLYGLYCERYL-2 LAURATE	12F - Moisturizing	1
POLYGLYCERYL-2 LAURATE	12G - Night	1
POLYGLYCERYL-2 LAURATE	12I - Skin Fresheners	1
POLYGLYCERYL-2 LAURATE	12J - Other Skin Care Preps	1
POLYGLYCERYL-2 OLEATE	07C - Foundations	1
POLYGLYCERYL-2 OLEATE	12F - Moisturizing	2
POLYGLYCERYL-2 SESQUIISOSTEARATE	07C - Foundations	1
POLYGLYCERYL-2 SESQUIISOSTEARATE	07E - Lipstick	2
POLYGLYCERYL-2 SESQUIISOSTEARATE	07I - Other Makeup Preparations	1
POLYGLYCERYL-2 SESQUIISOSTEARATE	08G - Other Manicuring Preparations	1
POLYGLYCERYL-2 SESQUIISOSTEARATE	12A - Cleansing	2
POLYGLYCERYL-2 SESQUIISOSTEARATE	12C - Face and Neck (exc shave)	2
POLYGLYCERYL-2 SESQUIISOSTEARATE	12F - Moisturizing	2
POLYGLYCERYL-2 TETRAISOSTEARATE	07C - Foundations	2
POLYGLYCERYL-2 TETRAISOSTEARATE	07E - Lipstick	25
POLYGLYCERYL-2 TETRAISOSTEARATE	07I - Other Makeup Preparations	1
POLYGLYCERYL-2 TRIISOSTEARATE	03A - Eyebrow Pencil	5
POLYGLYCERYL-2 TRIISOSTEARATE	03B - Eyeliner	3
POLYGLYCERYL-2 TRIISOSTEARATE	03C - Eye Shadow	10
POLYGLYCERYL-2 TRIISOSTEARATE	03E - Eye Makeup Remover	2
POLYGLYCERYL-2 TRIISOSTEARATE	07A - Blushers (all types)	6
POLYGLYCERYL-2 TRIISOSTEARATE	07B - Face Powders	2
POLYGLYCERYL-2 TRIISOSTEARATE	07C - Foundations	7
POLYGLYCERYL-2 TRIISOSTEARATE	07E - Lipstick	88
POLYGLYCERYL-2 TRIISOSTEARATE	07F - Makeup Bases	2
POLYGLYCERYL-2 TRIISOSTEARATE	07G - Rouges	8

POLYGLYCERYL-2 TRIISOSTEARATE	07I - Other Makeup Preparations	13
POLYGLYCERYL-2 TRIISOSTEARATE	10E - Other Personal Cleanliness Products	1
POLYGLYCERYL-2 TRIISOSTEARATE	12C - Face and Neck (exc shave)	1
POLYGLYCERYL-2 TRIISOSTEARATE	12D - Body and Hand (exc shave)	2
POLYGLYCERYL-2 TRIISOSTEARATE	12F - Moisturizing	4
POLYGLYCERYL-2 TRIISOSTEARATE	12G - Night	2
POLYGLYCERYL-2 TRIISOSTEARATE	12J - Other Skin Care Preps	2
POLYGLYCERYL-2 TRIISOSTEARATE	13A - Suntan Gels, Creams, and Liquids	2
POLYGLYCERYL-3 BEESWAX	03C - Eye Shadow	1
POLYGLYCERYL-3 BEESWAX	03D - Eye Lotion	5
POLYGLYCERYL-3 BEESWAX	03F - Mascara	3
POLYGLYCERYL-3 BEESWAX	03G - Other Eye Makeup Preparations	1
POLYGLYCERYL-3 BEESWAX	04E - Other Fragrance Preparation	1
POLYGLYCERYL-3 BEESWAX	07C - Foundations	11
POLYGLYCERYL-3 BEESWAX	07E - Lipstick	8
POLYGLYCERYL-3 BEESWAX	07F - Makeup Bases	1
POLYGLYCERYL-3 BEESWAX	07I - Other Makeup Preparations	2
POLYGLYCERYL-3 BEESWAX	11E - Shaving Cream	3
POLYGLYCERYL-3 BEESWAX	12C - Face and Neck (exc shave)	5
POLYGLYCERYL-3 BEESWAX	12D - Body and Hand (exc shave)	2
POLYGLYCERYL-3 BEESWAX	12F - Moisturizing	9
POLYGLYCERYL-3 BEESWAX	12G - Night	3
POLYGLYCERYL-3 BEESWAX	12H - Paste Masks (mud packs)	5
POLYGLYCERYL-3 BEESWAX	12J - Other Skin Care Preps	3
POLYGLYCERYL-3 CAPRATE	10A - Bath Soaps and Detergents	1
POLYGLYCERYL-3 CAPRATE	10B - Deodorants (underarm)	11
POLYGLYCERYL-3 CAPRYLATE	10A - Bath Soaps and Detergents	2
POLYGLYCERYL-3 CAPRYLATE	10B - Deodorants (underarm)	6
POLYGLYCERYL-3 CAPRYLATE	12A - Cleansing	1
POLYGLYCERYL-3 CAPRYLATE	12C - Face and Neck (exc shave)	1
POLYGLYCERYL-3 CAPRYLATE	12J - Other Skin Care Preps	1
POLYGLYCERYL-3 DICITRATE/STEARATE	05G - Tonics, Dressings, and Other Hair Groc	3
POLYGLYCERYL-3 DICITRATE/STEARATE	12F - Moisturizing	1
POLYGLYCERYL-3 DIISOSTEARATE	02A - Bath Oils, Tablets, and Salts	1
POLYGLYCERYL-3 DIISOSTEARATE	03B - Eyeliner	8
POLYGLYCERYL-3 DIISOSTEARATE	03C - Eye Shadow	18
POLYGLYCERYL-3 DIISOSTEARATE	03D - Eye Lotion	2
POLYGLYCERYL-3 DIISOSTEARATE	03F - Mascara	7
POLYGLYCERYL-3 DIISOSTEARATE	03G - Other Eye Makeup Preparations	6
POLYGLYCERYL-3 DIISOSTEARATE	07A - Blushers (all types)	5
POLYGLYCERYL-3 DIISOSTEARATE	07B - Face Powders	4
POLYGLYCERYL-3 DIISOSTEARATE	07C - Foundations	20
POLYGLYCERYL-3 DIISOSTEARATE	07E - Lipstick	206
POLYGLYCERYL-3 DIISOSTEARATE	07F - Makeup Bases	2
POLYGLYCERYL-3 DIISOSTEARATE	07H - Makeup Fixatives	1
POLYGLYCERYL-3 DIISOSTEARATE	07I - Other Makeup Preparations	9
POLYGLYCERYL-3 DIISOSTEARATE	10A - Bath Soaps and Detergents	1
POLYGLYCERYL-3 DIISOSTEARATE	10E - Other Personal Cleanliness Products	2
POLYGLYCERYL-3 DIISOSTEARATE	11E - Shaving Cream	1
POLYGLYCERYL-3 DIISOSTEARATE	12A - Cleansing	1
POLYGLYCERYL-3 DIISOSTEARATE	12C - Face and Neck (exc shave)	13
POLYGLYCERYL-3 DIISOSTEARATE	12D - Body and Hand (exc shave)	11
POLYGLYCERYL-3 DIISOSTEARATE	12F - Moisturizing	23
POLYGLYCERYL-3 DIISOSTEARATE	12G - Night	4

POLYGLYCERYL-3 DIISOSTEARATE	12J - Other Skin Care Preps	4
POLYGLYCERYL-3 DIISOSTEARATE	13A - Suntan Gels, Creams, and Liquids	5
POLYGLYCERYL-3 DIISOSTEARATE	13B - Indoor Tanning Preparations	1
POLYGLYCERYL-3 DIISOSTEARATE	13C - Other Suntan Preparations	1
POLYGLYCERYL-3 DISTEARATE	05A - Hair Conditioner	1
POLYGLYCERYL-3 DISTEARATE	05F - Shampoos (non-coloring)	2
POLYGLYCERYL-3 DISTEARATE	05G - Tonics, Dressings, and Other Hair Groc	1
POLYGLYCERYL-3 DISTEARATE	12F - Moisturizing	4
POLYGLYCERYL-3 ISOSTEARATE	03D - Eye Lotion	1
POLYGLYCERYL-3 ISOSTEARATE	07F - Makeup Bases	1
POLYGLYCERYL-3 ISOSTEARATE	12A - Cleansing	2
POLYGLYCERYL-3 ISOSTEARATE	12C - Face and Neck (exc shave)	2
POLYGLYCERYL-3 ISOSTEARATE	12D - Body and Hand (exc shave)	2
POLYGLYCERYL-3 ISOSTEARATE	12F - Moisturizing	3
POLYGLYCERYL-3 LAURATE	05F - Shampoos (non-coloring)	8
POLYGLYCERYL-3 LAURATE	05G - Tonics, Dressings, and Other Hair Groc	1
POLYGLYCERYL-3 LAURATE	10A - Bath Soaps and Detergents	106
POLYGLYCERYL-3 LAURATE	12A - Cleansing	1
POLYGLYCERYL-3 LAURATE	12D - Body and Hand (exc shave)	1
POLYGLYCERYL-3 LAURATE	12H - Paste Masks (mud packs)	1
POLYGLYCERYL-3 OLEATE	03G - Other Eye Makeup Preparations	2
POLYGLYCERYL-3 OLEATE	12A - Cleansing	1
POLYGLYCERYL-3 OLEATE	12C - Face and Neck (exc shave)	1
POLYGLYCERYL-3 OLEATE	12D - Body and Hand (exc shave)	1
POLYGLYCERYL-3 OLEATE	12F - Moisturizing	3
POLYGLYCERYL-3 OLEATE	12H - Paste Masks (mud packs)	2
POLYGLYCERYL-3 OLEATE	12I - Skin Fresheners	1
POLYGLYCERYL-3 OLEATE	12J - Other Skin Care Preps	1
POLYGLYCERYL-3 OLEATE	13A - Suntan Gels, Creams, and Liquids	2
POLYGLYCERYL-3 RICINOLEATE	03F - Mascara	2
POLYGLYCERYL-3 RICINOLEATE	03G - Other Eye Makeup Preparations	3
POLYGLYCERYL-3 RICINOLEATE	07C - Foundations	3
POLYGLYCERYL-3 RICINOLEATE	07I - Other Makeup Preparations	1
POLYGLYCERYL-3 RICINOLEATE	12D - Body and Hand (exc shave)	2
POLYGLYCERYL-3 RICINOLEATE	12F - Moisturizing	50
POLYGLYCERYL-3 RICINOLEATE	13B - Indoor Tanning Preparations	1
POLYGLYCERYL-3 STEARATE	07A - Blushers (all types)	1
POLYGLYCERYL-3 STEARATE	07E - Lipstick	1
POLYGLYCERYL-3 STEARATE	12A - Cleansing	3
POLYGLYCERYL-3 STEARATE	12C - Face and Neck (exc shave)	4
POLYGLYCERYL-3 STEARATE	12D - Body and Hand (exc shave)	4
POLYGLYCERYL-3 STEARATE	12G - Night	2
POLYGLYCERYL-4 CAPRATE	02A - Bath Oils, Tablets, and Salts	1
POLYGLYCERYL-4 CAPRATE	03E - Eye Makeup Remover	2
POLYGLYCERYL-4 CAPRATE	05G - Tonics, Dressings, and Other Hair Groc	1
POLYGLYCERYL-4 CAPRATE	07I - Other Makeup Preparations	1
POLYGLYCERYL-4 CAPRATE	10A - Bath Soaps and Detergents	3
POLYGLYCERYL-4 CAPRATE	10B - Deodorants (underarm)	1
POLYGLYCERYL-4 CAPRATE	12A - Cleansing	4
POLYGLYCERYL-4 CAPRATE	12C - Face and Neck (exc shave)	2

POLYGLYCERYL-4 ISOSTEARATE	01B - Baby Lotions, Oils, Powders, and Creams	1
POLYGLYCERYL-4 ISOSTEARATE	03A - Eyebrow Pencil	1
POLYGLYCERYL-4 ISOSTEARATE	03B - Eyeliner	3
POLYGLYCERYL-4 ISOSTEARATE	03C - Eye Shadow	23
POLYGLYCERYL-4 ISOSTEARATE	03D - Eye Lotion	2
POLYGLYCERYL-4 ISOSTEARATE	03F - Mascara	4
POLYGLYCERYL-4 ISOSTEARATE	03G - Other Eye Makeup Preparations	17
POLYGLYCERYL-4 ISOSTEARATE	05G - Tonics, Dressings, and Other Hair Grooming Products	2
POLYGLYCERYL-4 ISOSTEARATE	07A - Blushers (all types)	3
POLYGLYCERYL-4 ISOSTEARATE	07B - Face Powders	3
POLYGLYCERYL-4 ISOSTEARATE	07C - Foundations	86
POLYGLYCERYL-4 ISOSTEARATE	07D - Leg and Body Paints	3
POLYGLYCERYL-4 ISOSTEARATE	07E - Lipstick	41
POLYGLYCERYL-4 ISOSTEARATE	07F - Makeup Bases	13
POLYGLYCERYL-4 ISOSTEARATE	07G - Rouges	1
POLYGLYCERYL-4 ISOSTEARATE	07H - Makeup Fixatives	2
POLYGLYCERYL-4 ISOSTEARATE	07I - Other Makeup Preparations	28
POLYGLYCERYL-4 ISOSTEARATE	08G - Other Manicuring Preparations	1
POLYGLYCERYL-4 ISOSTEARATE	12C - Face and Neck (exc shave)	7
POLYGLYCERYL-4 ISOSTEARATE	12D - Body and Hand (exc shave)	1
POLYGLYCERYL-4 ISOSTEARATE	12F - Moisturizing	12
POLYGLYCERYL-4 ISOSTEARATE	12G - Night	1
POLYGLYCERYL-4 ISOSTEARATE	12H - Paste Masks (mud packs)	1
POLYGLYCERYL-4 ISOSTEARATE	12J - Other Skin Care Preps	11
POLYGLYCERYL-4 ISOSTEARATE	13B - Indoor Tanning Preparations	3
POLYGLYCERYL-4 LAURATE	03D - Eye Lotion	1
POLYGLYCERYL-4 LAURATE	07C - Foundations	2
POLYGLYCERYL-4 LAURATE	07I - Other Makeup Preparations	2
POLYGLYCERYL-4 LAURATE	12A - Cleansing	1
POLYGLYCERYL-4 LAURATE	12F - Moisturizing	3
POLYGLYCERYL-4 LAURATE	13B - Indoor Tanning Preparations	1
POLYGLYCERYL-4 OLEATE	03D - Eye Lotion	2
POLYGLYCERYL-4 OLEATE	07C - Foundations	1
POLYGLYCERYL-4 OLEATE	07D - Leg and Body Paints	1
POLYGLYCERYL-4 OLEATE	12F - Moisturizing	3
POLYGLYCERYL-5 DIOLEATE	10E - Other Personal Cleanliness Products	1
POLYGLYCERYL-5 ISOSTEARATE	03G - Other Eye Makeup Preparations	1
POLYGLYCERYL-5 ISOSTEARATE	12D - Body and Hand (exc shave)	1
POLYGLYCERYL-5 LAURATE	02B - Bubble Baths	1
POLYGLYCERYL-5 LAURATE	10A - Bath Soaps and Detergents	1
POLYGLYCERYL-5 OLEATE	10E - Other Personal Cleanliness Products	1
POLYGLYCERYL-5 OLEATE	12A - Cleansing	1
POLYGLYCERYL-5 OLEATE	12F - Moisturizing	2
POLYGLYCERYL-5 OLEATE	12I - Skin Fresheners	4
POLYGLYCERYL-5 OLEATE	12J - Other Skin Care Preps	2
POLYGLYCERYL-5 TRIOLEATE	12C - Face and Neck (exc shave)	5
POLYGLYCERYL-5 TRIOLEATE	12F - Moisturizing	1



POLYGLYCERYL-6 DIOLEATE	05A - Hair Conditioner	6
POLYGLYCERYL-6 DIOLEATE	07E - Lipstick	2
POLYGLYCERYL-6 DIOLEATE	07I - Other Makeup Preparations	7
POLYGLYCERYL-6 DIOLEATE	12A - Cleansing	1
POLYGLYCERYL-6 DIOLEATE	12C - Face and Neck (exc shave)	1
POLYGLYCERYL-6 DIOLEATE	12D - Body and Hand (exc shave)	6
POLYGLYCERYL-6 DIOLEATE	12F - Moisturizing	2
POLYGLYCERYL-6 DIOLEATE	12J - Other Skin Care Preps	2
POLYGLYCERYL-6 DISTEARATE	01B - Baby Lotions, Oils, Powders, and Creams	1
POLYGLYCERYL-6 DISTEARATE	03C - Eye Shadow	1
POLYGLYCERYL-6 DISTEARATE	03D - Eye Lotion	1
POLYGLYCERYL-6 DISTEARATE	03F - Mascara	2
POLYGLYCERYL-6 DISTEARATE	07C - Foundations	1
POLYGLYCERYL-6 DISTEARATE	07E - Lipstick	1
POLYGLYCERYL-6 DISTEARATE	10E - Other Personal Cleanliness Products	1
POLYGLYCERYL-6 DISTEARATE	12C - Face and Neck (exc shave)	7
POLYGLYCERYL-6 DISTEARATE	12D - Body and Hand (exc shave)	1
POLYGLYCERYL-6 DISTEARATE	12F - Moisturizing	3
POLYGLYCERYL-6 DISTEARATE	12G - Night	2
POLYGLYCERYL-6 DISTEARATE	13B - Indoor Tanning Preparations	1
POLYGLYCERYL-6 ISOSTEARATE	07E - Lipstick	1
POLYGLYCERYL-6 ISOSTEARATE	12C - Face and Neck (exc shave)	7
POLYGLYCERYL-6 ISOSTEARATE	12D - Body and Hand (exc shave)	1
POLYGLYCERYL-6 ISOSTEARATE	12F - Moisturizing	3
POLYGLYCERYL-6 ISOSTEARATE	12J - Other Skin Care Preps	1
POLYGLYCERYL-6 ISOSTEARATE	13A - Suntan Gels, Creams, and Liquids	1
POLYGLYCERYL-6 OCTASTEARATE	12F - Moisturizing	1
POLYGLYCERYL-6 OLEATE	12C - Face and Neck (exc shave)	1
POLYGLYCERYL-6 RICINOLEATE	07E - Lipstick	1
POLYGLYCERYL-8 DECAERUCATE/DECAISOSTEARATE/DECARICINOLEATE	12C - Face and Neck (exc shave)	1
TRISOSTEAROYL POLYGLYCERYL-3 DIMER DILINOLEATE	03C - Eye Shadow	1
TRISOSTEAROYL POLYGLYCERYL-3 DIMER DILINOLEATE	07E - Lipstick	17
TRISOSTEAROYL POLYGLYCERYL-3 DIMER DILINOLEATE	07I - Other Makeup Preparations	1

**Concentration of Use by FDA Product Category – Polyglyceryl Esters\***

Acacia Decurrens/Jojoba/ Sunflower Seed Wax	Polyglyceryl-6 Caprate
Polyglyceryl-3 Esters	Polyglyceryl-10 Caprate
Adansonia Digitata Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-2 Caprylate
Almond Oil/Polyglyceryl-10 Esters	Polyglyceryl-3 Caprylate
Apricot Kernel Oil Polyglyceryl-3 Esters	Polyglyceryl-4 Caprylate
Apricot Kernel Oil Polyglyceryl-4 Esters	Polyglyceryl-6 Caprylate
Apricot Kernel Oil Polyglyceryl-5 Esters	Polyglyceryl-10 Caprylate
Apricot Kernel Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Caprylate/Caprate
Apricot Kernel Oil Polyglyceryl-10 Esters	Polyglyceryl-6 Caprylate/Caprate
Argan Oil Polyglyceryl-6 Esters	Polyglyceryl-10 Caprylate/Caprate
Astrocaryum Vulgare Oil Polyglyceryl-6 Esters	Polyglyceryl-6 Citrullus Lanatus Seedate
Avocado Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Cocoate
Babassu Oil Polyglyceryl-4 Esters	Polyglyceryl-4 Cocoate
Babassu Oil Polyglyceryl-6 Esters	Polyglyceryl-10 Cocoate
Bertholletia Excelsa Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-2 Isopalmitate/Sebacate
Borage Seed Oil Polyglyceryl-4 Esters	Polyglyceryl-2 Isostearate
Borage Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Isostearate
Candelilla/Jojoba/Rice Bran Polyglyceryl-3 Esters	Polyglyceryl-4 Isostearate
Carapa Guaianensis Oil Polyglyceryl-6 Esters	Polyglyceryl-5 Isostearate
Castor Oil Polyglyceryl-6 Esters	Polyglyceryl-6 Isostearate
Cocoa Butter Polyglyceryl-6 Esters	Polyglyceryl-10 Isostearate
Coconut Oil Polyglyceryl-6 Esters	Polyglyceryl-10 Eicosanedioate/Tetradecanedioate
Coffee Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Hazelnutseedate
Hazelnut Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-2 Isopalmitate
Linseed Oil Polyglyceryl-4 Esters	Polyglyceryl-4 Isostearate/Laurate
Macadamia Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-2 Laurate
Mauritia Flexuosa Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Laurate
Olive Oil Polyglyceryl-3 Esters	Polyglyceryl-4 Laurate
Olive Oil Polyglyceryl-4 Esters	Polyglyceryl-5 Laurate
Olive Oil Polyglyceryl-6 Esters	Polyglyceryl-6 Laurate
Palm Kernel Oil Polyglyceryl-4 Esters	Polyglyceryl-10 Laurate
Palm Oil Polyglyceryl-3 Esters	Polyglyceryl-10 Linoleate
Palm Oil Polyglyceryl-4 Esters	Polyglyceryl-2 Myristate
Palm Oil Polyglyceryl-5 Esters	Polyglyceryl-3 Myristate
Palm Oil Polyglyceryl-6 Esters	Polyglyceryl-5 Myristate
Parinari Curatellifolia Oil Polyglyceryl-6 Esters	Polyglyceryl-6 Myristate
Pinus Sibirica Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-10 Myristate
Polyglyceryl-6 Adansonia Digitata Seedate	Polyglyceryl-2 Oleate
Polyglyceryl-4 Almond/Shea Butterate	Polyglyceryl-3 Oleate
Polyglyceryl-6 Apricot Kernelate	Polyglyceryl-4 Oleate
Polyglyceryl-10 Apricot Kernelate	Polyglyceryl-5 Oleate
Polyglyceryl-6 Argan Kernelate	Polyglyceryl-6 Oleate
Polyglyceryl-3 Beeswax	Polyglyceryl-8 Oleate
Polyglyceryl-3 Behenate	Polyglyceryl-10 Oleate
Polyglyceryl-6 Behenate	Polyglyceryl-10 Palmate
Polyglyceryl-10 Behenate/Eicosadioate	Polyglyceryl-2 Palmitate
Polyglyceryl-8 C12-20 Acid Ester	Polyglyceryl-3 Palmitate
Polyglyceryl-2 Caprate	Polyglyceryl-6 Palmitate
Polyglyceryl-3 Caprate	Polyglyceryl-10 Palmitate
Polyglyceryl-4 Caprate	Polyglyceryl-6 Palmitate/Succinate
Polyglyceryl-5 Caprate	Polyglyceryl-4 Punicate

Polyglyceryl-3 Rice Branate	Polyglyceryl-10 Decalinoleate
Polyglyceryl-3 Ricinoleate	Polyglyceryl-10 Decamacadamiate
Polyglyceryl-5 Ricinoleate	Polyglyceryl-10 Decaoleate
Polyglyceryl-6 Ricinoleate	Polyglyceryl-10 Decastearate
Polyglyceryl-6 Schinziophyton Rautanenii Kernelate	Polyglyceryl-3 Dicaprate
Polyglyceryl-6 Sclerocarya Birrea Seedate	Polyglyceryl-6 Dicaprate
Polyglyceryl-3 Soyate/Shea Butterate	Polyglyceryl-5 Dicaprylate
Polyglyceryl-2 Stearate	Polyglyceryl-3 Dicitrate/Stearate
Polyglyceryl-3 Stearate	Polyglyceryl-3 Dicocoate
Polyglyceryl-4 Stearate	Polyglyceryl-10 Dicocoate
Polyglyceryl-5 Stearate	Polyglyceryl-10 Didecanoate
Polyglyceryl-6 Stearate	Polyglyceryl-3 Di-Hydroxystearate
Polyglyceryl-8 Stearate	Polyglyceryl-2 Diisostearate
Polyglyceryl-10 Stearate	Polyglyceryl-3 Diisostearate
Polyglyceryl-3 Stearate SE	Polyglyceryl-6 Diisostearate
Polyglyceryl-4 Sweet Almondate	Polyglyceryl-10 Diisostearate
Polyglyceryl-6 Trichilia Emetica Seedate	Polyglyceryl-15 Diisostearate
Polyglyceryl-6 Undecylenate	Polyglyceryl-4 Dilaurate
Polyglyceryl-10 Undecylenate	Polyglyceryl-5 Dilaurate
Polyglyceryl-6 Ximenia Americana Seedate	Polyglyceryl-10 Dilaurate
Pumpkin Seed Oil Polyglyceryl-4 Esters	Polyglyceryl-10 Dimyristate
Rice Bran Oil Polyglyceryl-3 Esters	Polyglyceryl-2 Dioleate
Rosa Rubiginosa Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Dioleate
Safflower Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-5 Dioleate
Schinziophyton Rautanenii Kernel Oil Polyglyceryl-6 Esters	Polyglyceryl-6 Dioleate
Sclerocarya Birrea Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-10 Dioleate
Sclerocarya Birrea Seed Oil Polyglyceryl-10 Esters	Polyglyceryl-6 Dipalmitate
Sesame Oil Polyglyceryl-6 Esters	Polyglyceryl-10 Dipalmitate
Shea Butter Polyglyceryl-3 Esters	Polyglyceryl-2 Distearate
Shea Butter Polyglyceryl-6 Esters	Polyglyceryl-3 Distearate
Soybean Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Distearate
Sunflower Seed Oil Polyglyceryl-3 Esters	Polyglyceryl-6 Distearate
Sunflower Seed Oil Polyglyceryl-4 Esters	Polyglyceryl-10 Distearate
Sunflower Seed Oil Polyglyceryl-5 Esters	Polyglyceryl-20 Docosabehenate/Isostearate
Sunflower Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-20 Docosabehenate/Laurate
Sunflower Seed Oil Polyglyceryl-10 Esters	Polyglyceryl-20 Docosabehenate/Oleate
Sweet Almond Oil Polyglyceryl-4 Esters	Polyglyceryl-10 Dodecabehenate
Sweet Almond Oil Polyglyceryl-6 Esters	Polyglyceryl-10 Dodecacaprate
Theobroma Grandiflorum Seed Butter Polyglyceryl-6 Esters	Polyglyceryl-10 Dodecacaprylate
Trichilia Emetica Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-10 Dodeca-Caprylate/Caprate
Watermelon Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-10 Hepta(Behenate/Stearate)
Watermelon Seed Oil Polyglyceryl-10 Esters	Polyglyceryl-6 Heptacaprylate
Ximenia Americana Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-20 Heptacaprylate
Macadamia Seed Oil Polyglyceryl-6 Esters Behenate	Polyglyceryl-20 Heptadecabehenate/Laurate
Polyglyceryl-8 Decabehenate/Caprate	Polyglyceryl-10 Heptahydroxystearate
Polyglyceryl-8 Decaerucate/Decaisostearate/Decaricinoleate	Polyglyceryl-10 Heptaoleate
Polyglyceryl-10 Decaethylhexanoate	Polyglyceryl-10 Heptastearate
Polyglyceryl-10 Decahydroxystearate	Polyglyceryl-20 Hexacaprylate
Polyglyceryl-10 Decaisostearate	Polyglyceryl-10 Hexaerucate
	Polyglyceryl-10 Hexaisostearate
	Polyglyceryl-6 Hexaoleate
	Polyglyceryl-10 Hexaoleate

Polyglyceryl-5 Hexastearate	Polyglyceryl-2 Sesquistearate
Polyglyceryl-6 Hexastearate	Polyglyceryl-6 Sesquistearate
Polyglyceryl-10 Mono/Dioleate	Polyglyceryl-10 Sesquistearate
Polyglyceryl-10 Nonaerucate	Polyglyceryl-6 Tetrabehenate
Polyglyceryl-10 Nonaisostearate	Polyglyceryl-2 Tetrabehenate/Macadamate/Sebacate
Polyglyceryl-6 Octacaprylate	Polyglyceryl-6 Tetracaprylate
Polyglyceryl-20 Octadecabehenate/Laurate	Polyglyceryl-10 Tetradecanedioate
Polyglyceryl-20 Octaisnonanoate	Polyglyceryl-2 Tetraisostearate
Polyglyceryl-6 Octastearate	Polyglyceryl-10 Tetralaurate
Polyglyceryl-6 Pentacaprylate	Polyglyceryl-2 Tetraoleate
Polyglyceryl-10 Pentacaprylate	Polyglyceryl-6 Tetraoleate
Polyglyceryl-3 Pentacaprylate/Caprates	Polyglyceryl-10 Tetraoleate
Polyglyceryl-10 Pentahydroxystearate	Polyglyceryl-2 Tetrastearate
Polyglyceryl-10 Pentaistearate	Polyglyceryl-5 Tribehenate
Polyglyceryl-10 Pentalaurate	Polyglyceryl-6 Tricaprylate
Polyglyceryl-10 Pentalinoleate	Polyglyceryl-10 Tricocoate
Polyglyceryl-5 Pentamyrystate	Polyglyceryl-10 Tridecanoate
Polyglyceryl-4 Pentaoleate	Polyglyceryl-10 Trierucate
Polyglyceryl-6 Pentaoleate	Polyglyceryl-2 Triisostearate
Polyglyceryl-10 Pentaoleate	Polyglyceryl-3 Triisostearate
Polyglyceryl-3 Pentaolive	Polyglyceryl-5 Triisostearate
Polyglyceryl-4 Pentapalmitate/Stearate	Polyglyceryl-10 Triisostearate
Polyglyceryl-3 Pentaricinoleate	Polyglyceryl-10 Trilaurate
Polyglyceryl-6 Pentaricinoleate	Polyglyceryl-5 Trimyrystate
Polyglyceryl-10 Pentaricinoleate	Polyglyceryl-5 Trioleate
Polyglyceryl-4 Pentastearate	Polyglyceryl-10 Trioleate
Polyglyceryl-6 Pentastearate	Polyglyceryl-3 Triolive
Polyglyceryl-10 Pentastearate	Polyglyceryl-4 Tristearate
Polyglyceryl-2 Sesquicaprylate	Polyglyceryl-5 Tristearate
Polyglyceryl-6 Sesquicaprylate	Polyglyceryl-6 Tristearate
Polyglyceryl-2 Sesquiisostearate	Polyglyceryl-10 Tristearate
Polyglyceryl-6 Sesquiisostearate	Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate
Polyglyceryl-2 Sesquioleate	

<b>Ingredient</b>	<b>Product Category</b>	<b>Maximum Concentration of Use</b>
Acacia Decurrens/Jojoba/Sunflower Seed Wax Polyglyceryl-3 Esters	Face and neck products not spray, not powder	2%
Babassu Oil Polyglyceryl-6 Esters	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	2.3%
Candelilla/Jojoba/Rice Bran Polyglyceryl-6 Esters	Baby lotions, oils and creams not powder	1.5%
Candelilla/Jojoba/Rice Bran Polyglyceryl-6 Esters	Deodorants aerosol	0.5%
Candelilla/Jojoba/Rice Bran Polyglyceryl-6 Esters	Face and neck products not spray	1%
Candelilla/Jojoba/Rice Bran Polyglyceryl-6 Esters	Night products not spray	2%
Polyglyceryl-3 Beeswax	Eye shadow	0.8-2.8%
Polyglyceryl-3 Beeswax	Eye lotion	2.2-3%
Polyglyceryl-3 Beeswax	Face powder	3.4%
Polyglyceryl-3 Beeswax	Foundation	0.5-2.8%
Polyglyceryl-3 Beeswax	Lipstick	3.8-5.8%
Polyglyceryl-3 Beeswax	Makeup fixatives	2.5%
Polyglyceryl-3 Beeswax	Shaving cream	0.75%
Polyglyceryl-3 Beeswax	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	2.5%
Polyglyceryl-3 Beeswax	Face and neck products not spray	4%
Polyglyceryl-3 Beeswax	Suntan products not spray	0.5%
Polyglyceryl-10 Behenate/Eicosadioate	Lipstick	2%
Polyglyceryl-10 Behenate/Eicosadioate	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	5%
Polyglyceryl-4 Caprate	Shampoos (noncoloring)	1.1%
Polyglyceryl-4 Caprate	Tonics, dressings and other hair grooming aids	0.5%
Polyglyceryl-4 Caprate	Bath soaps and detergents	1-1.5%
Polyglyceryl-4 Caprate	Deodorants not spray	1.5%
Polyglyceryl-4 Caprate	Skin cleansing (cold creams cleansing lotions, liquids and pads)	0.9-1%
Polyglyceryl-4 Caprate	Face and neck products not spray	0.72%
Polyglyceryl-3 Caprylate	Colognes and toilet water	0.05%
Polyglyceryl-3 Caprylate	Deodorants not spray aerosol	0.5-1% 0.6%
Polyglyceryl-3 Caprylate	Other personal cleanliness products	0.6%
Polyglyceryl-3 Caprylate	Body and hand products not spray	0.05%
Polyglyceryl-6 Caprylate/Caprate	Shampoos (noncoloring)	0.75%
Polyglyceryl-2 Isostearate	Lipstick	2.3-19.3%
Polyglyceryl-2 Isostearate	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	1%
Polyglyceryl-2 Isostearate	Body and hand products not spray	2.1%
Polyglyceryl-2 Isostearate	Moisturizing products not spray	1.6-2.5%

Polyglyceryl-4 Isostearate	Baby lotions oils and creams not powder	1%
Polyglyceryl-4 Isostearate	Eyebrow pencil	13.2%
Polyglyceryl-4 Isostearate	Eyeliner	1.3-21.2%
Polyglyceryl-4 Isostearate	Eye shadow	13.4-14.8%
Polyglyceryl-4 Isostearate	Eye lotion	1.2-2.3%
Polyglyceryl-4 Isostearate	Mascara	2.8%
Polyglyceryl-4 Isostearate	Other eye makeup preparations	0.51-24.1%
Polyglyceryl-4 Isostearate	Tonics, dressings and other hair grooming aids	2.1%
Polyglyceryl-4 Isostearate	Face powders	0.17%
Polyglyceryl-4 Isostearate	Foundations	0.067-4%
Polyglyceryl-4 Isostearate	Leg and body paint	0.26%
Polyglyceryl-4 Isostearate	Lipstick	0.067-10.9%
Polyglyceryl-4 Isostearate	Makeup bases	0.067%
Polyglyceryl-4 Isostearate	Makeup fixatives	1.4-3%
Polyglyceryl-4 Isostearate	Other makeup preparations	0.067-1.5%
Polyglyceryl-4 Isostearate	Other oral hygiene products	0.16%
Polyglyceryl-4 Isostearate	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	1.7%
Polyglyceryl-4 Isostearate	Face and neck products not spray	1.2-1.7%
Polyglyceryl-4 Isostearate	Body and hand products not spray	0.5-2.5%
Polyglyceryl-4 Isostearate	Moisturizing products not spray	2%
Polyglyceryl-4 Isostearate	Night products not spray	1-1.3%
Polyglyceryl-4 Isostearate	Suntan products not spray aerosol	1.5-4.6% 0.26%
Polyglyceryl-4 Isostearate	Indoor tanning preparations	1.1%
Polyglyceryl-10 Isostearate	Face and neck products pump spray	0.6%
Polyglyceryl-10 Isostearate	Moisturizing products not spray	0.6%
Polyglyceryl-2 Laurate	Hair conditioners	4.6%
Polyglyceryl-2 Laurate	Tonics, dressings and other hair grooming aids	2%
Polyglyceryl-3 Laurate	Eye shadow	6%
Polyglyceryl-3 Laurate	Hair conditioner	2%
Polyglyceryl-3 Laurate	Shampoos (noncoloring)	0.6-1.5%
Polyglyceryl-3 Laurate	Depilatories	2%
Polyglyceryl-4 Laurate	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.47%
Polyglyceryl-5 Laurate	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.6%
Polyglyceryl-5 Laurate	Face and neck products not spray	0.6%
Polyglyceryl-5 Laurate	Other skin care preparations	0.6%
Polyglyceryl-10 Laurate	Baby shampoo	1%
Polyglyceryl-10 Laurate	Other baby products	1%
Polyglyceryl-10 Laurate	Bubble bath	2%
Polyglyceryl-10 Laurate	Other bath preparations	0.69%
Polyglyceryl-10 Laurate	Perfumes	0.5%
Polyglyceryl-10 Laurate	Shampoos (noncoloring)	0.4-5%
Polyglyceryl-10 Laurate	Tonics, dressings and other hair grooming aids	6.5%

Polyglyceryl-10 Laurate	Other hair preparations (noncoloring)	5%
Polyglyceryl-10 Laurate	Foundations	0.0009%
Polyglyceryl-10 Laurate	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.2-1%
Polyglyceryl-10 Myristate	Deodorants not spray aerosol	0.0003% 0.1%
Polyglyceryl-10 Myristate	Shaving cream	0.0003%
Polyglyceryl-10 Myristate	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.003-0.04%
Polyglyceryl-10 Myristate	Body and hand products not spray	0.8%
Polyglyceryl-10 Myristate	Moisturizing products not spray	0.08-1.2%
Polyglyceryl-2 Oleate	Eye lotions	0.27%
Polyglyceryl-2 Oleate	Eye makeup removers	2.4%
Polyglyceryl-2 Oleate	Other eye makeup preparations	1.6%
Polyglyceryl-2 Oleate	Foundations	1-1.6%
Polyglyceryl-2 Oleate	Lipstick	2.4%
Polyglyceryl-2 Oleate	Face and neck products not spray	0.09%
Polyglyceryl-2 Oleate	Moisturizing products not spray	0.09%
Polyglyceryl-2 Oleate	Night products not spray	0.09%
Polyglyceryl-3 Oleate	Eye lotion	1.5%
Polyglyceryl-3 Oleate	Tonics, dressings and other hair grooming aids not spray	1.2%
Polyglyceryl-4 Oleate	Leg and body paints	1.8%
Polyglyceryl-4 Oleate	Suntan products aerosol	1.8%
Polyglyceryl-5 Oleate	Face and neck products not spray	0.35%
Polyglyceryl-10 Oleate	Bath oils, tablets and salts	2%
Polyglyceryl-10 Oleate	Eye lotion	0.63%
Polyglyceryl-10 Oleate	Hair conditioners	0.0000085%
Polyglyceryl-10 Oleate	Hair spray pump spray	1%
Polyglyceryl-10 Oleate	Shampoos (noncoloring)	0.0000085%
Polyglyceryl-10 Oleate	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.0000085%
Polyglyceryl-10 Oleate	Face and neck products not spray	0.21-3%
Polyglyceryl-10 Oleate	Body and hand products not spray	3%
Polyglyceryl-10 Oleate	Moisturizing products not spray	0.21%
Polyglyceryl-10 Oleate	Night products not spray	0.21%
Polyglyceryl-10 Oleate	Other skin care preparations	3%
Polyglyceryl-3 Ricinoleate	Foundations	2%
Polyglyceryl-3 Ricinoleate	Body and hand products not spray	0.25%
Polyglyceryl-2 Stearate	Eye lotion	1%
Polyglyceryl-2 Stearate	Eye makeup remover	0.2%
Polyglyceryl-2 Stearate	Lipstick	0.2%

Polyglyceryl-2 Stearate	Face and neck products not spray	2.2%
Polyglyceryl-2 Stearate	Moisturizing products not spray	0.16%
Polyglyceryl-3 Stearate	Blushers	0.54%
Polyglyceryl-3 Stearate	Lipstick	0.5%
Polyglyceryl-3 Stearate	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.61%
Polyglyceryl-5 Stearate	Body and hand products not spray	1%
Polyglyceryl-10 Stearate	Eyeliners	1.8%
Polyglyceryl-10 Stearate	Eye shadow	0.41%
Polyglyceryl-10 Stearate	Tonics, dressings and other hair grooming aids	0.25%
Polyglyceryl-10 Stearate	Foundations	0.36%
Polyglyceryl-10 Stearate	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	1%
Polyglyceryl-10 Stearate	Face and neck products not spray	0.2-2%
Polyglyceryl-10 Stearate	Body and hand products not spray	0.13%
Polyglyceryl-10 Stearate	Moisturizing products not spray	0.2-0.3%
Polyglyceryl-10 Stearate	Night products not spray	1.2%
Macadamia Seed Oil Polyglyceryl-6 Esters Behenate	Eye shadow	2%
Macadamia Seed Oil Polyglyceryl-6 Esters Behenate	Mascara	3%
Macadamia Seed Oil Polyglyceryl-6 Esters Behenate	Foundation	2%
Macadamia Seed Oil Polyglyceryl-6 Esters Behenate	Lipstick	25%
Polyglyceryl-8 Decabehenate/Caprates	Lipstick	9%
Polyglyceryl-10 Decaisostearate	Eye shadow	2.7%
Polyglyceryl-10 Decaoleate	Foundation	5%
Polyglyceryl-10 Decaoleate	Lipstick	5%
Polyglyceryl-10 Decaoleate	Other oral hygiene products	0.01%
Polyglyceryl-10 Decaoleate	Face and neck products not spray or powder	1%
Polyglyceryl-3 Dicitrate/Stearate	Tonics, dressings and other hair grooming aids	2.2%
Polyglyceryl-3 Dicitrate/Stearate	Face and neck products not spray	3-4%
Polyglyceryl-3 Dicitrate/Stearate	Body and hand products not spray	2%
Polyglyceryl-2 Diisostearate	Eye shadow	2-2.3%
Polyglyceryl-2 Diisostearate	Eye lotion	1.5-4%
Polyglyceryl-2 Diisostearate	Mascara	4%
Polyglyceryl-2 Diisostearate	Perfume	0.5%
Polyglyceryl-2 Diisostearate	Powders (dusting and talcum)	0.1%
Polyglyceryl-2 Diisostearate	Hair conditioners	0.88%
Polyglyceryl-2 Diisostearate	Hair spray pump spray	0.25%
Polyglyceryl-2 Diisostearate	Tonics, dressings and other hair grooming aids	15%
Polyglyceryl-2 Diisostearate	Foundation	2%
Polyglyceryl-2 Diisostearate	Lipstick	4-18.8%



Polyglyceryl-2 Diisostearate	Makeup bases	2%
Polyglyceryl-2 Diisostearate	Deodorant not spray	0.1%
Polyglyceryl-2 Diisostearate	Aftershave lotion	1%
Polyglyceryl-2 Diisostearate	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	5%
Polyglyceryl-2 Diisostearate	Face and neck products not spray	0.14-2%
Polyglyceryl-2 Diisostearate	Body and hand products not spray	0.5-2%
Polyglyceryl-2 Diisostearate	Moisturizing products not spray	0.48-4%
Polyglyceryl-2 Diisostearate	Other skin care preparations	1.2%
Polyglyceryl-3 Diisostearate	Baby lotions, oils and creams not powder	2%
Polyglyceryl-3 Diisostearate	Other bath preparations	0.5%
Polyglyceryl-3 Diisostearate	Eye brow pencil	8.6-12.2%
Polyglyceryl-3 Diisostearate	Eye liner	3.8-8%
Polyglyceryl-3 Diisostearate	Eye shadow	0.71-8%
Polyglyceryl-3 Diisostearate	Eye lotion	0.006-1%
Polyglyceryl-3 Diisostearate	Mascara	1.5%
Polyglyceryl-3 Diisostearate	Other eye makeup preparations	1%
Polyglyceryl-3 Diisostearate	Hair conditioners	0.000025-0.003%
Polyglyceryl-3 Diisostearate	Hair spray aerosol pump spray	0.00000015% 0.000025%
Polyglyceryl-3 Diisostearate	Shampoos (noncoloring)	0.003%
Polyglyceryl-3 Diisostearate	Tonics, dressings and other hair grooming aids aerosol	0.00000023%
Polyglyceryl-3 Diisostearate	Blushers	0.2-2.5%
Polyglyceryl-3 Diisostearate	Face powder	0.25%
Polyglyceryl-3 Diisostearate	Foundations	0.3-12.2%
Polyglyceryl-3 Diisostearate	Lipstick	7.8-39%
Polyglyceryl-3 Diisostearate	Rouge	3%
Polyglyceryl-3 Diisostearate	Makeup fixatives	4.6%
Polyglyceryl-3 Diisostearate	Other oral hygiene products	29.7%
Polyglyceryl-3 Diisostearate	Deodorant not spray	0.003-0.3%
Polyglyceryl-3 Diisostearate	Other personal cleanliness products	0.003%
Polyglyceryl-3 Diisostearate	Other shaving preparations	0.5%
Polyglyceryl-3 Diisostearate	Skin cleansing (cold creams, cleansing lotions liquids and pads)	4.8%
Polyglyceryl-3 Diisostearate	Face and neck products not spray	0.03-1%
Polyglyceryl-3 Diisostearate	Body and hand products not spray spray	0.25-1% 0.5%
Polyglyceryl-3 Diisostearate	Moisturizing products not spray	1-2%
Polyglyceryl-3 Diisostearate	Night products not spray	0.5-1%
Polyglyceryl-3 Diisostearate	Paste masks and mud packs	0.006%
Polyglyceryl-3 Diisostearate	Suntan products not spray	10%

Polyglyceryl-10 Diisostearate	Tonics, dressings and other hair grooming aids	2%
Polyglyceryl-10 Diisostearate	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	1.6-17%
Polyglyceryl-10 Diisostearate	Face and neck products not spray	0.8%
Polyglyceryl-6 Dioleate	Hair conditioners	1.8%
Polyglyceryl-6 Dioleate	Body and hand products not spray	2.4%
Polyglyceryl-10 Dioleate	Other makeup preparations	3.9%
Polyglyceryl-10 Dipalmitate	Other bath preparations	2%
Polyglyceryl-10 Dipalmitate	Other personal cleanliness products	2%
Polyglyceryl-10 Dipalmitate	Face and neck products not spray	10%
Polyglycery-3 Distearate	Mascara	0.02-0.066%
Polyglycery-3 Distearate	Tonics, dressings and other hair grooming aids	1%
Polyglycery-3 Distearate	Body and hand creams not spray spray	0.29% 3%
Polyglycery-3 Distearate	Suntan products not spray	1.3%
Polyglyceryl-6 Distearate	Mascara	4%
Polyglyceryl-6 Distearate	Foundation	4%
Polyglyceryl-6 Distearate	Lipstick	22.4%
Polyglyceryl-6 Distearate	Rouge	10.5%
Polyglyceryl-6 Distearate	Cuticle softener	5%
Polyglyceryl-10 Heptahydroxystearate	Foundation	1%
Polyglyceryl-10 Heptahydroxystearate	Lipstick	2%
Polyglyceryl-10 Nonaisostearate	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.5%
Polyglyceryl-10 Pentaisostearate	Lipstick	4.8%
Polyglyceryl-10 Pentaisostearate	Body and hand products not spray	2%
Polyglyceryl-10 Pentaoleate	Tonics, dressings and other hair grooming aids	1%
Polyglyceryl-10 Pentaoleate	Lipstick	2.6%
Polyglyceryl-6 Pentastearate	Eyeliners	5%
Polyglyceryl-3 Pentaricinoleate	Eyeliners	0.15%
Polyglyceryl-10 Pentastearate	Foundation	0.069-2%
Polyglyceryl-10 Pentastearate	Lipstick	0.0003-2%
Polyglyceryl-10 Pentastearate	Other makeup preparations	0.0003%
Polyglyceryl-10 Pentastearate	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.0003-0.1%
Polyglyceryl-10 Pentastearate	Face and neck products not spray	2-2.2%
Polyglyceryl-10 Pentastearate	Body and hand products not spray	1%
Polyglyceryl-10 Pentastearate	Moisturizing products not spray	1.3%
Polyglyceryl-10 Pentastearate	Night products not spray	0.38%
Polyglyceryl-10 Pentastearate	Suntan products not spray	1.3%
Polyglyceryl-2 Sesquiosostearate	Eye lotion	2.1%
Polyglyceryl-2 Sesquiosostearate	Foundation	3%
Polyglyceryl-2 Sesquiosostearate	Lipstick	7.6%

Polyglyceryl-2 Sesquiosostearate	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	1.1%
Polyglyceryl-2 Sesquiosostearate	Face and neck products not spray	4.4%
Polyglyceryl-2 Sesquiosostearate	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.9%
Polyglyceryl-2 Tetraisostearate	Face powder	0.96%
Polyglyceryl-2 Tetraisostearate	Foundation	0.5-4.6%
Polyglyceryl-2 Tetraisostearate	Lipstick	7%
Polyglyceryl-6 Tricaprylate	Other makeup preparations	3.6%
Polyglyceryl-2 Triisostearate	Eyebrow pencil	2.2-3%
Polyglyceryl-2 Triisostearate	Eyeliners	0.12-20%
Polyglyceryl-2 Triisostearate	Eye shadow	2.6-3%
Polyglyceryl-2 Triisostearate	Hair tints	3%
Polyglyceryl-2 Triisostearate	Blushers	17%
Polyglyceryl-2 Triisostearate	Face powder	0.49-2%
Polyglyceryl-2 Triisostearate	Foundation	0.2-4%
Polyglyceryl-2 Triisostearate	Lipstick	4.1-40%
Polyglyceryl-2 Triisostearate	Other makeup preparations	3.6%
Polyglyceryl-2 Triisostearate	Skin cleansing (cold creams, cleansing lotions, liquids and pads)	1-4%
Polyglyceryl-2 Triisostearate	Face and neck products not spray	5%
Polyglyceryl-2 Triisostearate	Body and hand products not spray	1%
Polyglyceryl-2 Triisostearate	Suntan products not spray	3%
Polyglyceryl-5 Triisostearate	Foundation	1%
Polyglyceryl-5 Triisostearate	Lipstick	5%
Polyglyceryl-5 Trioleate	Hair conditioners	2.8%
Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate	Eyeliners	1%
Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate	Eye shadow	1.2%
Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate	Mascara	1.2%
Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate	Lipstick	9-11.2%

\*Ingredients included in the title of the table but not found in the table were included in the survey, but no uses were reported.

Information collected in 2014  
Table prepared December 24, 2014

**Concentration of Use by FDA Product Category – Polyglyceryl Additions\***

Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate

Polyglyceryl-2 Cocoate/Shea Butterate

Shea Butter Polyglyceryl-4 Esters

<b>Ingredient</b>	<b>Product Category</b>	<b>Maximum Concentration of Use</b>
Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate	Foundations	4%
Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate	Body and hand products Not spray	2%

\*Ingredients included in the title of the table but not found in the table were included in a concentration of use survey, but no uses were reported.

Information collected in 2015  
Table prepared April 10, 2015



### **Memorandum**

**TO:** Lillian Gill, D.P.A.  
Director - COSMETIC INGREDIENT REVIEW (CIR)

**FROM:** Beth A. Lange, Ph.D.  
Industry Liaison to the CIR Expert Panel

**DATE:** July 6, 2015

**SUBJECT:** Concentration of Use by FDA Product Category: Caprylic/Capric Glycerides  
Polyglyceryl-10 Esters and Pumpkin Seed Oil Polyglyceryl-4 Esters Succinate

Caprylic/Capric Glycerides Polyglyceryl-10 Esters and Pumpkin Seed Oil Polyglyceryl-4 Esters Succinate were included in a concentration of use survey. No uses were reported.

**Concentration of Use by FDA Product Category - Polyglyceryl-10  
Hydroxystearate/Stearate/Eicosadioate**

<b>Product Category</b>	<b>Maximum Concentration of Use</b>
Lipstick	0.62-1.2%
Skin cleansing (cold creams, cleansing lotions, liquids and pads)	1.8%

Information collected in 2015  
Table prepared October 8, 2015



## Memorandum

**TO:** Lillian Gill, D.P.A.  
Director - COSMETIC INGREDIENT REVIEW (CIR)

**FROM:** Beth A. Lange, Ph.D.  
Industry Liaison to the CIR Expert Panel

**DATE:** February 1, 2016

**SUBJECT:** Polyglyceryl-4 Oleate

Anonymous. 2016. Composition and physical and chemical properties Polyglyceryl-4 Oleate.

February 2016

### **Composition and Physical and Chemical Properties Polyglyceryl-4 Oleate**

Concentration of Polyglyceryl-4 Oleate	99.0-100%
D,L-alpha-tocopherol	100 ppm


Form:	Liquid
Odor:	Ester-like
Color:	Amber
Boiling point:	>149 Degrees C (1,013 hPa)
Vapor pressure:	<1.3 hPa (25 Degrees C)
Density:	0.99 g/cm <sup>3</sup> (25 Degrees C)
% volatiles:	<1%
Solubility in water:	Dispersible





**Memorandum**

**TO:** Lillian Gill, D.P.A.  
Director - COSMETIC INGREDIENT REVIEW (CIR)

**FROM:** Beth A. Lange, Ph.D.  
Industry Liaison to the CIR Expert Panel 

**DATE:** February 10, 2016

**SUBJECT:** Palm Oil Polyglyceryl-4 Esters, Apricot Kernel Oil Polyglyceryl-4 Esters and Polyglyceryl-3 Diisostearate

Anonymous. 2016. Summary information Palm Oil Polyglyceryl-4 Esters, Apricot Kernel Oil Polyglyceryl-4 Esters and Polyglyceryl-3 Diisostearate.

February 10, 2016

### **Summary Information**

#### **Palm Oil Polyglyceryl-4 Esters, Apricot Kernel Oil Polyglyceryl-4 Esters, Polyglyceryl-3 Diisostearate**

##### Palm Oil Polyglyceryl-4 Esters

###### **1. HET CAM Test completed in 2010**

In this test, fertilized eggs incubated for 9 days are opened to expose the chorion-allonothoid membrane (CAM). 0.3 g of the test material is applied to the surface of the CAM and, after a contact period of 240 seconds, CAM is rinsed with 5 ml of physiological solution.

Possible alterations of blood vessels and albumen are recorded after 30 seconds from product application. In particular, hyperemia, hemorrhage and coagulation are observed.

In this model, Palm Oil Polyglyceryl-4 Esters was practically non-irritating.

###### **2. SkinEthic skin tolerance assay completed in 2010**

The purpose of the study is the evaluation of skin tolerance of Palm Oil Polyglyceryl-4 Esters by using the SkinEthic Skin Irritation Test - 42a assay.

Study performed on reconstituted human epidermis SkinEthic (RHE/S/17)

Deposit  $16 \mu\text{L} \pm 0.5 \mu\text{L}$  (or  $16 \text{ mg} \pm 2 \text{ mg}$ ) of the test material on the surface of the epidermis for 42 minutes.

Post-incubation for 42 hours.

Assessment of cell viability by MTT method after 42 hours incubation. Validation of the test by with negative and positive control (SDS 5%)

Following observations performed during this study and the results of cell viability obtained after incubation (94.93%), Palm Oil Polyglyceryl-4 Ester was classified as NON-IRRITANT.

##### Apricot Kernel Oil Polyglyceryl-4- Esters

###### **1. HET CAM Test completed in 2010**

In this test, fertilized eggs incubated for 9 days are opened to expose the chorion-allonothoid membrane (CAM). 0.3 ml of the test material is applied to the surface of the CAM and, after a contact period of 300 seconds, CAM is rinsed with 5 ml of physiological solution.

Possible alterations of blood vessels and albumen are recorded after 0.5, 3 and 5 minutes from product application. In particular, hyperemia, hemorrhage and coagulation are observed.

In this model, Apricot Kernel Oil Polyglyceryl-4 Esters was practically non-irritating.

###### **2. SkinEthic skin tolerance assay completed in 2010**

The purpose of the study is the evaluation of skin tolerance of Apricot Kernel Oil Polyglyceryl-4 Esters by using the SkinEthic Skin Irritation Test - 42a assay.

Study performed on reconstituted human epidermis SkinEthic (RHE/S/17)

Deposit  $16 \mu\text{L} \pm 0.5 \mu\text{L}$  (or  $16 \text{ mg} \pm 2 \text{ mg}$ ) of the test material on the surface of the epidermis for 42 minutes.

Post-incubation for 42 hours.

Assessment of cell viability by MTT method after 42 hours incubation. Validation of the test by with negative and positive control (SDS 5%)

Following observations performed during this study and the results of cell viability obtained after incubation (71.99%), Apricot Kernel Oil Polyglyceryl-4 Ester was classified as NON-IRRITANT.

Polyglyceryl-3 Diisostearate - studies completed in 1997

1. Acute Oral Toxicity

5 female NMRI mice were give a single oral dose of 2000 mg/kg Polyglyceryl-3 Diisostearate and observed for 6 days after treatment. No deaths occurred. The lethal dose is greater than 2000 mg/kg

2. Acute dermal irritation/corrosion (OECD 404)

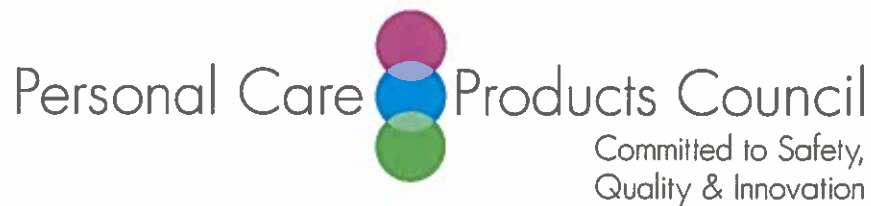
3 New Zealand albino rabbits

No edema was observed at the 1, 24, 48 and 72 hour observations. Erythema scores were 1 for all 3 rabbits a 1, 24 and 48 hours. Erythema resolved completely by 72 hours. Polyglyceryl-3 Diisostearate was considered non-irritating to the skin.

3. Acute eye irritation/corrosion (OECD 405)

3 New Zealand albino rabbits

No effects on the iris or cornea were observed at the 1, 24, 48 and 72 hour observations. Chemosis scores were 1 (maximum 4) for all animals at 1 hour and completely resolved by 72 hours. Scores of 2 for redness (maximum 3) were observed in all three rabbits at 1 hour and were reduced to 1 by 72 hours. Polyglyceryl-3 Diisostearate was considered non-irritating to the eyes.



## Memorandum

**TO:** Lillian Gill, D.P.A.  
Director - COSMETIC INGREDIENT REVIEW (CIR)

**FROM:** Beth A. Lange, Ph.D.  
Industry Liaison to the CIR Expert Panel

**DATE:** February 18, 2016

**SUBJECT:** Polyglyceryl-3 Rice Branate and Rice Bran Oil Polyglyceryl-3 Esters

Progressus s.r.l. 2015. Material safety data sheet PROLIX RB (Polyglyceryl-3 Rice Branate).

Progressus s.r.l. 2015. Material safety data sheet PROLIX RO (Rice Bran Oil Polyglyceryl-3 Esters).

Code: GH/085

Date of issue: 03/09/2015 Revision Date: 03/08/2015

[www.progressus.it](http://www.progressus.it)**1. IDENTIFICATION OF SUBSTANCE AND COMPANY**

- 1.1 Trade Name: **PROLIX RB**
- INCI Name Polyglyceryl-3 Rice Branate  
 Cas No. 1166833-04-0, 1166833-52-8  
 EC No. polymer  
 REACH number: all the ingredients of this product in the scope of Regulation 1907/2006/EC (REACH), if not exempted, have been (pre-)registered.
- 1.2 Relevant uses identified: Non-ionic Emulsifier for the cosmetics industry.
- 1.3 Information on data sheet provider: PROGRESSUS Srl - Via B. Ubaldi - 06024 Gubbio (PG)  
 Tel. +39.075.9277974 - E-mail: [info@progressus.it](mailto:info@progressus.it)
- 1.4 Emergency telephone: +39.0759276749

**2. IDENTIFICATION OF DANGERS**

- 2.1 Substance classification: Derivative of polyglycerol and plant fatty acids.  
 Classification according to Regulation (EC) No. 1272/2008 [CLP] Not classified
- 2.2 Label elements: Labelling according to Regulation (EC) No. 1272/2008 [CLP] No labelling applicable
- 2.3 Other dangers: No danger found in normal use. Not listed among the substances considered dangerous to health according to directive 67/548/EEC and successive adjustments, nor among substances with recognized exposure limits.

**3. COMPOSITION / INFORMATION OF INGREDIENTS**

- 3.1 Chemical Identity: Monoester of triglycerol rice fatty acids
- 3.2 Concentration: 100%
- 3.3 INCI name: POLYGLYCERYL-3 RICE BRANATE
- 3.4 CAS number: 1166833-04-4; 1166833-52-8
- 3.5 Origin (12<sup>th</sup> Dir.): Synthesis of raw materials of plant origin

**4. FIRST AID MEASURES**

- 4.1 Contact with skin: Remove contaminated clothing and rinse thoroughly with running water. And subsequently wash with soap the parts of the body which have come into contact with the product.
- 4.2 Contact with the eyes: with eyelids open, wash eyes immediately and thoroughly with running water. If irritation persists, consult a specialist; do not use eyedrops or ointments of any sort prior to consulting an optician

Progressus s.r.l



Administrative Office Via Beniamino Ubaldi - 06024 Gubbio (PG) - Tel. 075 9277974  
 Chemical Division PRO+ Loc. Semonte - 06024 Gubbio (PG) - Tel. 075.9276749

Code: GH/085

Date of issue: 03/09/2015 Revision Date: 03/08/2015

[www.progressus.it](http://www.progressus.it)

- |                 |   |
|-----------------|---|
| 4.3 Ingestion:  | Do not induce Vomiting. Consult a doctor who will decide the best course of action to take, if necessary.                                       |
| 4.4 Inhalation: | Effects of this kind are not expected. Should inhalation occur, ventilate the room, move the injured person to a well-ventilated place to rest. |

**5. FIRE SAFETY**

- |   |   |
|---|---|
| 5.1 Extinction method::                         | Water, CO <sub>2</sub> , foam and chemical powders depending on materials involved in the fire..              |
| Prohibited extinguishers:                       | None in particular  |
| 5.2 Special hazards arising from the substance: | If the product is involved in a fire, toxic gases and can be aggressive.                                      |
| 5.3 Recommendations for fire fighters:          | Breathing apparatus and adequate clothing. Follow necessary precautions in fires involving chemical products. |

**6. PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES.**

- |  |   |
|--|---|
| 6.1 Handling precautions:                            | Wear protective gear that is appropriate for the emergency. Block the leak at source if safe to do so.  |
| 6.2 Environmental precautions:                       | Control leak with soil or sand. Prevent leak from penetrating sources of water or sewerage systems and from contaminating soil or vegetation. If this should occur, contact the relevant authorities. |
| 6.3 Methods and materials for control and clearance: | Soak up the product with inert material. After clearing, wash the area and relative materials with water.   |
| 6.4 References and other sections:                   | Not necessary.  |

**7. HANDLING AND STORAGE**

- |   |   |
|---|---|
| 7.1 Precautions for safe handling:                            | <ul style="list-style-type: none"> <li>• Use protective rubber or PVC gloves</li> <li>• Use protective glasses</li> <li>• Do not eat, drink or smoke in work areas;</li> <li>• Wash hands after use</li> <li>• Remove contaminated clothing and protective equipment before accessing areas where food is eaten.</li> </ul> |
| 7.2 Conditions for safe storage and possible incompatibility: | <ul style="list-style-type: none"> <li>• Store the product in original containers or in plastic or stainless steel containers;</li> <li>• Avoid basic or easily oxidisable materials;</li> </ul>  |

Progressus s.r.l.



Administrative Office: Via Beniamino Ubaldi - 06024 Gubbio (PG) - Tel. 075 9277974  
 Chemical Division PRO+: Loc. Semonte - 06024 Gubbio (PG) - Tel. 075 9276749

Code: GH/085

Date of issue: 03/09/2015 Revision Date: 03/08/2015

[www.progressus.it](http://www.progressus.it)

- Keep the product at a temperature between 5° and 35°. Never exceed 50°.
- No particular environmental conditions are required.

7.3 Specific End use: Emulsifier for cosmetic use.

**8. EXPOSURE CONTROL / INDIVIDUAL PROTECTION**

8.1 Control parameters: Results of clinical experiments carried out on substances of the same chemical classification, imply an acute oral toxicity (DL50) >2000 mg/Kg.

The product does not contain any substances subject to environmental exposure limits in the workplace (DPR 303 – 19/03/56).

Evaluation: There is no known evidence of effects of carcinogenesis, mutagenesis or teratogenesis..

8.2 Measures and equipment for personal protection

- Protective glasses
- Protective PVC or rubber gloves
- Follow the usual precautional measures for handling chemical products.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

Form:	Waxy solid, in flakes
Colour:	Light ivory
Odour:	Light, characteristic
Density at 25°C:	>1 g/ml
Ph, dispersion. Aqueous 5%:	7 approx.
Pour point:	60° approx.
Boiling point:	>200°C
Flash point:	>250 °C
Solubility:	Dispersible in water, miscible in oils
Auto-ignition temperature:	Not determined
Decomposition point:	>300°
Explosive properties:	Not relevant
Oxidizing properties:	Not relevant

**10. STABILITY AND REACTIVITY**

10.1 Reactivity: No potential danger known at present.

10.2 Chemical stability: Stable in conditions previously mentioned (see 7.2)

10.3 Possibility of dangerous reactions: None known at present.

Progressus s.r.l.



Administrative Office: Via Beniamino Ubaldi - 06024 Gubbio (PG) - Tel. 075 9277974  
 Chemical Division PRO+: Loc. Semonte - 06024 Gubbio (PG) - Tel. 075.9276749

Code: GH/085

Date of issue: 03/09/2015 Revision Date: 03/08/2015

[www.progressus.it](http://www.progressus.it)

10.4 Conditions to avoid:	None in particular, except for those previously indicated. (see 7.2)
10.5 Incompatible materials:	None in particular
10.6 Reactivity:	No potential dangers known at present.
10.7 Dangerous decomposition products:	If the product is involved in a fire, toxic and aggressive fumes may develop.

**11. INFORMATION ON TOXICOLOGICAL EFFECTS**

Skin Irritation:	Product not irritating. In Vitro test on reconstructed epidermis, model Epi-200 EpiDerm™
Eye Irritation:	Product not irritating. In Vitro test on model of reconstructed epidermis EpiOcular™

**12. ECOLOGICAL INFORMATION**

12.1 Ichtyo-toxicity:	>1-10 mg/l
12.2 Persistence and degradability:	Product is over 95% biodegradable (OECD) in accordance with the requirements of detergent regulation 648/2004/EC
12.3 Bioaccumulation potential	None, in normal conditions of use.
12.4 Mobility in soil:	Not available
12.5 PBT and PvB Evaluation:	Not prescribed
12.6 Other adverse effects:	Data not available

**13. DISPOSAL**

13.1 Methods of Refuse treatment:	Product to be used according to common industrial practices in order to protect the environment. Send to authorized establishments or incinerate under controlled conditions
Classification:	EEC Directive 88/379, EEC Directive 67/548, EEC Directive 99/45 and reference formulations

**14. TRANSPORTATION INFORMATION**

14.1 ONU number:	Not available
14.2 RID/ADR:	Product not considered dangerous



Progressus s.r.l.

 Administrative Office: Via Beniamino Ubaldi - 06024 Gubbio (PG) - Tel. 075 9277974  
 Chemical Division PRO+: Loc. Semonte - 06024 Gubbio (PG) - Tel. 075 9276749



Code: GH/085

Date of issue: 03/09/2015 Revision Date: 03/08/2015

[www.progressus.it](http://www.progressus.it)

14.3 IMDG: Product not considered dangerous

14.4 ICAO/IATA: Product not considered dangerous

**15 INFORMATION ON REGULATIONS****15.1 Standards and Legislation**

NIOSH - Registry of Toxic Effects of Chemical Substances (1983).

N.Irving Sax, R.J. Lewis Sr. - Dangerous Properties of industrial Materials - ED. Van Nostrand, Reinhold- 1989, 7<sup>th</sup> edition.

CESIO - Classification and Labelling of Anionic, Nonionic Surfactants (1990).

CID (SSOG- [test centre for oils and fats industries]) - Contribution to the compilation of safety data sheets of surfactants, 2<sup>nd</sup> edition.

ACGIH, Threshold Limit Values for Chemical Substances and Physical Agents - 1993/ 1994

SINTALEX- Version 7.0

D.M. [Ministerial Decree]- 16 February 1993 (classification of dangers of substances).

CCNL - Attached 1 "TLV FOR 1989/90"

EINECS- European Inventory of Existing Commercial Chemical Substances

**15.2 Chemical safety evaluation:** The product is not mentioned in the attachments and is not required to fulfill any requirements of regulations (relevant incident risks D.P.R 175/88 and subsequent modifications).

Where applicable, with respect to the type of product and / or use, reference is made to the following regulations:

D.M. 28/01/92. Classification, packaging and labeling of dangerous products.

D.P.R 547/56. General regulations for work hygiene.

D.P.R 203/88. Emissions in the atmosphere.

D.L. 277/91. Exposure to chemical agents.

Law 136/83. Biodegradability of detergents.

D.L. 98/92. Biodegradability of surfactants contained in detergents.

D.P.R. 250/89 Labeling of detergents.

D.P.R. 175/88. (Seveso Directive), 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup> attachment .

Law 319/76 (water drainage) and D.L. 133/92 (Water drainage).

Ministerial Circulars 46 and 61. Aromatic amines.

**16. OTHER INFORMATION**

**16.1** The information provided in this safety data sheet is based on our current knowledge and on community regulations. The product must not be used for reasons other than those specified in section 1, unless handling instructions have been received in writing. It is the responsibility of the user to take all necessary measures in compliance with local and national regulations.

Progressus s.r.l.



Administrative Office Via Beniamino Ubaldi - 06024 Gubbio (PG) - Tel. 075 9277974

Chemical Division PRO+ Loc. Semonte - 06024 Gubbio (PG) - Tel. 075 9276749

Code: GH/061

Date of issue: 03/09/2015 Revision Date: 03/08/2015

[www.progressus.it](http://www.progressus.it)**1. IDENTIFICATION OF SUBSTANCE AND COMPANY**

- 1.1 Trade Name:** **PROLIX RO**
- INCI Name** Rice Bran Oil Polyglyceryl-3 Esters  
**Cas No.** 1436849-14-7  
**EC No.** polymer  
**REACH number:** all the ingredients of this product in the scope of Regulation 1907/2006/EC (REACH), if not exempted, have been (pre-)registered.
- 1.2 Relevant uses identified:** Non-ionic Emulsifier for the cosmetics industry.
- 1.3 Information on data sheet provider:** PROGRESSUS Srl - Via B. Ubaldi - 06024 Gubbio (PG)  
 Tel. +39.075.9277974 - E-mail: [info@progressus.it](mailto:info@progressus.it)
- 1.4 Emergency telephone:** +39.0759276749

**2. IDENTIFICATION OF DANGERS**

- 2.1 Substance classification:** Derivative of polyglycerol and rice oil.  
 Classification according to Regulation (EC) No. 1272/2008 [CLP] Not classified
- 2.2 Label elements:** Labelling according to Regulation (EC) No. 1272/2008 [CLP] No labelling applicable
- 2.3 Other dangers:** No danger found in normal use. Not listed among the substances considered dangerous to health according to directive 67/548/EEC and successive adjustments, nor among substances with recognized exposure limits.

**3. COMPOSITION / INFORMATION OF INGREDIENTS**

- 3.1 Chemical Identity:** Ester of triglycerol with rice oil.
- 3.2 Concentration:** 100%
- 3.3 INCI name:** Rice Bran Oil Polyglyceryl-3 Esters
- 3.4 CAS number:** 1436849-14-7
- 3.5 Origin (12<sup>th</sup> Dir.):** Synthesis of raw materials of plant origin

**4. FIRST AID MEASURES**

- 4.1 Contact with skin:** Remove contaminated clothing and rinse thoroughly with running water. And subsequently wash with soap the parts of the body which have come into contact with the product.
- 4.2 Contact with the eyes:** with eyelids open, wash eyes immediately and thoroughly with running water. If irritation persists, consult a specialist; do not use eyedrops or ointments of any sort prior to consulting an optician

Progressus s.r.l.


 Administrative Office: Via Beniamino Ubaldi - 06024 Gubbio (PG) - Tel. 075 9277974  
 Chemical Division PRO+: Loc. Semonte - 06024 Gubbio (PG) - Tel. 075.9276749

Code: **GH/061**

Date of issue: 03/09/2015 Revision Date: 03/08/2015

[www.progressus.it](http://www.progressus.it)

- |                 |   |
|-----------------|---|
| 4.3 Ingestion:  | Do not induce Vomiting. Consult a doctor who will decide the best course of action to take, if necessary.                                       |
| 4.4 Inhalation: | Effects of this kind are not expected. Should inhalation occur, ventilate the room, move the injured person to a well-ventilated place to rest. |

**5. FIRE SAFETY**

- |   |   |
|---|---|
| 5.1 Extinction method::                         | Water, CO2, foam and chemical powders depending on materials involved in the fire..                           |
| Prohibited extinguishers:                       | None in particular  |
| 5.2 Special hazards arising from the substance: | If the product is involved in a fire, toxic gases and can be aggressive.                                      |
| 5.3 Recommendations for fire fighters:          | Breathing apparatus and adequate clothing. Follow necessary precautions in fires involving chemical products. |

**6. PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES.**

- |  |   |
|--|---|
| 6.1 Handling precautions:                            | Wear protective gear that is appropriate for the emergency. Block the leak at source if safe to do so.  |
| 6.2 Environmental precautions:                       | Control leak with soil or sand. Prevent leak from penetrating sources of water or sewerage systems and from contaminating soil or vegetation. If this should occur, contact the relevant authorities. |
| 6.3 Methods and materials for control and clearance: | Soak up the product with inert material. After clearing, wash the area and relative materials with water.   |
| 6.4 References and other sections:                   | Not necessary.  |

**7. HANDLING AND STORAGE**

- |   |   |
|---|---|
| 7.1 Precautions for safe handling:                            | <ul style="list-style-type: none"> <li>• Use protective rubber or PVC gloves</li> <li>• Use protective glasses</li> <li>• Do not eat, drink or smoke in work areas;</li> <li>• Wash hands after use</li> <li>• Remove contaminated clothing and protective equipment before accessing areas where food is eaten.</li> </ul> |
| 7.2 Conditions for safe storage and possible incompatibility: | <ul style="list-style-type: none"> <li>• Store the product in original containers or in plastic or stainless steel containers;</li> <li>• Avoid basic or easily oxidisable materials;</li> </ul>  |



Progressus s.r.l.

 Administrative Office: Via Beniamino Ubaldi - 06024 Gubbio (PG) - Tel. 075 9277974  
 Chemical Division PRO+: Loc. Semonte - 06024 Gubbio (PG) - Tel. 075.9276749

Code: GH/061

Date of issue: 03/09/2015 Revision Date: 03/08/2015

[www.progressus.it](http://www.progressus.it)

- Keep the product at a temperature between 5° and 35°. Never exceed 50°.
- No particular environmental conditions are required.

7.3 Specific End use: Emulsifier for cosmetic use.

## 8. EXPOSURE CONTROL / INDIVIDUAL PROTECTION

8.1 Control parameters: Results of clinical experiments carried out on substances of the same chemical classification, imply an acute oral toxicity (DL50) >2000 mg/Kg.

The product does not contain any substances subject to environmental exposure limits in the workplace (DPR 303 – 19/03/56).

Evaluation: There is no known evidence of effects of carcinogenesis, mutagenesis or teratogenesis..

8.2 Measures and equipment for personal protection

- Protective glasses
- Protective PVC or rubber gloves
- Follow the usual precautional measures for handling chemical products.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Form:	Oily limpid liquid
Colour:	Amber
Odour:	Light, characteristic
Density at 25°C:	>1 g/ml
Pour point:	60° approx.
Boiling point:	>200°C
Flash point:	>250 °C
Solubility:	Dispersible in water, miscible in oils
Auto-ignition temperature:	Not determined
Decomposition point:	>300°
Explosive properties:	Not relevant
Oxidizing properties:	Not relevant

## 10. STABILITY AND REACTIVITY

10.1 Reactivity: No potential danger known at present.

10.2 Chemical stability: Stable in conditions previously mentioned (see 7.2)

10.3 Possibility of dangerous reactions: None known at present.

Progressus s.r.l



Administrative Office Via Beniamino Ubaldi - 06024 Gubbio (PG) - Tel. 075 9277974  
Chemical Division PRO+ Loc. Semonte - 06024 Gubbio (PG) - Tel. 075.9276749

Code: **GH/061**

Date of issue: 03/09/2015 Revision Date: 03/08/2015

[www.progressus.it](http://www.progressus.it)

10.4 Conditions to avoid:	None In particular, except for those previously indicated. (see 7.2)
10.5 Incompatible materials:	None in particular
10.6 Reactivity:	No potential dangers known at present.
10.7 Dangerous decomposition products:	If the product is involved in a fire, toxic and aggressive fumes may develop.

**11. INFORMATION ON TOXICOLOGICAL EFFECTS**

Skin Irritation:	Product not irritating. In Vitro test on reconstructed epidermis, model Epi-200 EpiDerm™
Eye Irritation:	Product not irritating. In Vitro test on model of reconstructed epidermis EpiOcular™

**12. ECOLOGICAL INFORMATION**

12.1 Ichtyo-toxicity:	>1-10 mg/l
12.2 Persistence and degradability:	Product is over 95% biodegradable (OECD) in accordance with the requirements of detergent regulation 648/2004/EC
12.3 Bioaccumulation potential	None, in normal conditions of use.
12.4 Mobility in soil:	Not available
12.5 PBT and PvB Evaluation:	Not prescribed
12.6 Other adverse effects:	Data not available

**13. DISPOSAL**

13.1 Methods of Refuse treatment:	Product to be used according to common industrial practices in order to protect the environment. Send to authorized establishments or incinerate under controlled conditions
Classification:	EEC Directive 88/379, EEC Directive 67/548, EEC Directive 99/45 and reference formulations

**14. TRANSPORTATION INFORMATION**

14.1 ONU number:	Not available
14.2 RID/ADR:	Product not considered dangerous

Progressus s.r.l.


 Administrative Office Via Beniamino Ubaldi - 06024 Gubbio (PG) - Tel. 075 9277974  
 Chemical Division PRO+, Loc. Semonte - 06024 Gubbio (PG) - Tel. 075 9276749

Code: GH/061

Date of issue: 03/09/2015 Revision Date: 03/08/2015

[www.progressus.it](http://www.progressus.it)

14.3 IMDG: Product not considered dangerous

14.4 ICAO/IATA: Product not considered dangerous

**15 INFORMATION ON REGULATIONS****15.1 Standards and Legislation**

NIOSH – Registry of Toxic Effects of Chemical Substances (1983).

N.Irving Sax, R.J. Lewis Sr. – Dangerous Properties of industrial Materials – ED. Van Nostrand, Reinhold- 1989, 7<sup>th</sup> edition.

CESIO – Classification and Labelling of Anionic, Nonionic Surfactants (1990).

CID (SSOG- [test centre for oils and fats industries]) – Contribution to the compilation of safety data sheets of surfactants, 2<sup>nd</sup> edition.

ACGIH, Threshold Limit Values for Chemical Substances and Physical Agents – 1993/ 1994

SINTALEX- Version 7.0

D.M. [Ministerial Decree]– 16 February 1993 (classification of dangers of substances).

CCNL – Attached 1 "TLV FOR 1989/90"

EINECS- European Inventory of Existing Commercial Chemical Substances

**15.2 Chemical safety evaluation:** The product is not mentioned in the attachments and is not required to fulfill any requirements of regulations (relevant incident risks D.P.R 175/88 and subsequent modifications).

Where applicable, with respect to the type of product and / or use, reference is made to the following regulations:

D.M. 28/01/92. Classification, packaging and labeling of dangerous products.

D.P.R 547/56. General regulations for work hygiene.

D.P.R 203/88. Emissions in the atmosphere.

D.L. 277/91. Exposure to chemical agents.

Law 136/83. Biodegradability of detergents.

D.L. 98/92. Biodegradability of surfactants contained in detergents.

D.P.R. 250/89 Labeling of detergents.

D.P.R. 175/88. (Seveso Directive), 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup> attachment .

Law 319/76 (water drainage) and D.L. 133/92 (Water drainage).

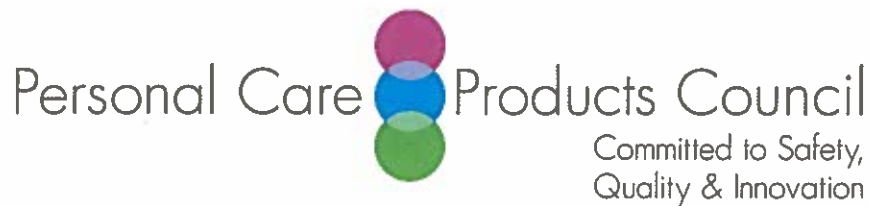
Ministerial Circulars 46 and 61. Aromatic amines.

**16. OTHER INFORMATION**

**16.1** The information provided in this safety data sheet is based on our current knowledge and on community regulations. The product must not be used for reasons other than those specified in section 1, unless handling instructions have been received in writing. It is the responsibility of the user to take all necessary measures in compliance with local and national regulations.

Progressus s.r.l.


 Administrative Office: Via Beniamino Ubaldi - 06024 Gubbio (PG) - Tel. 075 9277974  
 Chemical Division PRO+ Loc. Semonte - 06024 Gubbio (PG) - Tel. 075.9276749



**Memorandum**

**TO:** Lillian Gill, D.P.A.  
Director - COSMETIC INGREDIENT REVIEW (CIR)

**FROM:** Beth A. Lange, Ph.D.  
Industry Liaison to the CIR Expert Panel

A handwritten signature in blue ink that reads "Beth A. Lange".

**DATE:** February 19, 2016

**SUBJECT:** Polyglyceryl-10 Eicosanedioate/Tetradecanedioate

Anonymous. 2009. Material safety data sheet on a trade name mixture containing 60%  
Polyglyceryl-10 Eicosanedioate/Tetradecanedioate.

# MATERIAL SAFETY DATA SHEET

In accordance with Directive 93/112/EC

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY

**Product name:**

**Company:**

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

**Chemical characterization  
of the substance:**

Name	Concentration	CAS No
Polyglyceryl Eicosanedioate/ Tetradecanedioate	60%	875112-30-4
Glycerin	40%	56-81-5

## 3. HAZARDS IDENTIFICATION

Not classified according to pertinent EC regulation.

## 4. FIRST-AID MEASURES

**Skin contact:**

Wash off with plenty of water and soap.

**Eye contact:**

Wash out with water. Get medical attention if any sensations persist.

**Ingestion:**

Give a plenty of water and call medical care. If fallen unconscious or convulsion, get medical attention immediately.

**Inhalation:**

Bring person to fresh air after inhalation. Symptomatic treatment. In case of indisposition, seek immediately medical advice.

**General information:**

There is no antidote known.



**Product name:**

## **5. FIRE-FIGHTING MEASURES**

**Suitable extinguishing media:**

Powder fire extinguisher, CO2 foaming fire extinguisher, water extinguishing media appropriate to surrounding materials.

**Special exposure hazards arising from combustion products, resulting gases:**

Carbonoxides, Nitrogenoxides and other gases.

**Special fire fighting procedures:**

Cool down the containers with water spray. Untrained personnel should be removed to a safe place.

**Special protective equipment for fire-fighters:**

Wear full protective clothing and self-contained breathing apparatus.

## **6. ACCIDENTAL RELEASE MEASURES**

**Personal precautions:**

Wear proper protective equipment (suitable gloves and safety goggles).

**Environmental precautions:**

Avoid the release to aquatic systems.

**Methods for cleaning up:**

Transfer product to suitably labelled containers for disposal at an approved site. Absorb liquid spillage onto inert material (e.g. sand). Residues and small spillages may be washed away with water and detergent

## **7. HANDLING AND STORAGE**

### **7.1 Handling**

**Technical measures:**

Good local ventilation is recommended.

**Precautions for handling:**

The usual precautions for safe handling of chemicals have to be followed. Avoid skin and eye contact.

### **7.2 Storage**

**Technical measures / conditions for safe storage:**

Stored in closed containers in appropriate storage rooms. Avoid substance residues on the containers.

**Incompatible materials:**

None known.

**Other information:**

For quality reasons, to be stored under cool, dry and dark conditions.

**Product name:**

## **8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Technical measures:**

Good local ventilation is recommended.

**Personal protection:**

**Hand protection:**

Wear suitable gloves.

**Eye protection:**

Safety glasses

**Hygiene measures:**

Wash hands with soap and water after handling

## **9. PHYSICAL AND CHEMICAL PROPERTIES**

<b>Appearance:</b>	Waxy paste(20°C)
<b>Colour:</b>	White~Pale Yellow
<b>Odour:</b>	A faint characteristic odor
<b>pH-Value:</b>	pH 5~6(5%aq)
<b>Bolling point:</b>	>200°C
<b>Melting point:</b>	about 50°C
<b>Relative density:</b>	1.23 (20°C)
<b>Vapor pressure:</b>	no data available
<b>Solubility in water:</b>	soluble
<b>Partition coefficient:</b>	no data available
<b>Flammability:</b>	Not applicable
<b>Flash point:</b>	242°C
<b>Self-ignition temperature:</b>	no data available
<b>Explosive properties:</b>	Not to be expected

## **10. STABILITY AND REACTIVITY**

**Stability:**

Stable at 25°C under storage conditions.

**Conditions to avoid:**

Direct sunbeams

**Substances to avoid:**

Strong oxidizers

**Hazardous materials produced upon decomposition:**

Thermal decomposition will evolve irritant vapors and COx.

**Product name:**

<b>11. TOXICOLOGICAL INFORMATION</b>
--------------------------------------

**Skin-irritation:**

Negative (Human closed Patch Test) (mixture tested at 100% in 45 volunteers)

**Eye-irritation:**

Non irritant. (EpiOcular™ test) (mixture tested undiluted)

**Sensitization:**

no data available

**Mutagenicity/carcinogenicity:**

Ames test: Negative

<b>12. ECOLOGICAL INFORMATION</b>
-----------------------------------

**Degradability:**

Ready Biodegradability:

no data available

Inhibition of Microbial Activity (3h):

IC<sub>50</sub>: no data available

NOEC: no data available

**Ecotoxicity:**

Acute fish toxicity (Rainbow trout):

EC<sub>50</sub> (96 h): > no data available

Acute daphnia toxicity (Daphnia magna):

EC<sub>50</sub> (48 h): > no data available

Acute algal toxicity:

- with *Scenedesmus subspicatus*:

EC<sub>50</sub> (72 h): > no data available

**Product name:**

### 13. DISPOSAL CONSIDERATIONS

**Product:**

Incinerate solid waste in a controlled and accepted incinerator (Code EEC 660) and treat waste water by controlled discharge to a waste water treatment plant (Code EEC 641). Local legislation has to be observed.

**Empty Packaging:**

Recycling is highly recommended.

### 14. TRANSPORT INFORMATION

**Land - Road/Railway:**

This product is not classified according to ADR/RID.

**Sea:**

This product is not classified according to IMDG.

**Air:**

This product is not classified according to ICAO/IATA.

This product is not classified as dangerous goods.

### 15. REGULATORY INFORMATION

**Label name:**

**Hazard symbols:**

Non-relevant

**Risk phrases:**

Non-relevant

**Safety phrases:**

Non-relevant

EU Classification: Not classified according to pertinent EC regulation.

### 16. OTHER INFORMATION

----

The information of this Material- Safety- Data- Sheet has been established based on the available data which are believed to be correct. These information should serve as basis to ensure the safety in handling, storing, transporting and disposal of this product. No guarantee or warranty of any kind expressed or implied is made with respect to the information contained herein.



**Memorandum**

**TO:** Lillian Gill, D.P.A.  
Director - COSMETIC INGREDIENT REVIEW (CIR)

**FROM:** Beth A. Lange, Ph.D.  
Industry Liaison to the CIR Expert Panel

A handwritten signature in black ink, appearing to read "Beth A. Lange", is written over the printed name.

**DATE:** February 25, 2016

**SUBJECT:** Polyglyceryl Esters

Nikko Chemicals Co., Ltd. 2016. Safety information NIKKOL Decaglyn 1-L (Polyglyceryl-10 Laurate).

Nikko Chemicals Co., Ltd. 2016. Safety information NIKKOL Decaglyn 1-M (Polyglyceryl-10 Myristate).

Nikko Chemicals Co., Ltd. 2016. Safety information NIKKOL Decaglyn 1-SV (Polyglyceryl-10 Stearate).

Nikko Chemicals Co., Ltd. 2016. Safety information NIKKOL Decaglyn 2-ISV (Polyglyceryl-10 Diisostearate).

Nikko Chemicals Co., Ltd. 2016. Safety information NIKKOL Decaglyn 5-IS (Polyglyceryl-10 Pentaisostearate).

Nikko Chemicals Co., Ltd. 2016. Safety information NIKKOL Decaglyn 10-O (Polyglyceryl-10 Decaoleate).

Nikko Chemicals Co., Ltd. 2016. Safety information NIKKOL Decaglyn PR-20 (Polyglyceryl-10 Polyricinoleate).

Nikko Chemicals Co., Ltd. 2016. Safety information NIKKOL Hexaglyn PR-15 (Polyglyceryl-6 Polyricinoleate).

Nikko Chemicals Co., Ltd.  
1-4-8, Nihonbashi-Bakurocho, Chuoku, Tokyo  
TEL +81-3-3661-1677

Safety Information of NIKKOL Decaglyn 1-L Polylactate

Category	Test Name	Alternative	Model/Cell	Method	Concentration	Result	Remarks
Irritation	Cell toxicity	Alternative	Balb/c 3T3	NR assay	Max. 1,000mg/L	The irritation level is lower than sucrose laurate, SDS.	TC50 = 752.0mg/L

※These test results may not be representative of the safety of the final formulated product.

Nikko Chemicals Co., Ltd.

1-4-8, Nihonbashi-Bakurocho, Chuoku, Tokyo

TEL +81-3-3661-1677

## Safety Information of NIKKOL Decaglyn 1-M Polyglyceryl-10 Myristate

Category	Test Name	Alternative	Model/Cell	Method	Concentration	Result	Remarks
Irritation	Human patch	—	Human skin	48h closed, n=48	10% Negative	10% Negative	—
Irritation	Ocular irritation	Alternative	Corneal epithelial cells, rabbit	SIRC-NR	Max. 1,000mg/L	Non irritant	NRS0 > 1,000mg/L

\*These test results may not be representative of the safety of the final formulated product.

Nikko Chemicals Co., Ltd.

1-4-8, Nihonbashi-Bakurocho, Chuoku, Tokyo

TEL +81-3-3661-1677

Safety Information of NIKKOL Decaglyn 1-SV *Polyglyceryl-10 stearate*

Category	Test Name	Alternative	Model/Cell	Method	Concentration	Result	Remarks
Irritation	Ocular irritation	Alternative	Corneal epithelial cells, rabbit	SIRC-NR	Max. 1,000mg/L	Non irritant	NR50 > 1,000mg/L
Irritation	Human patch	—	Human skin	48h closed, n=48	10%	Non irritant	—

※ These test results may not be representative of the safety of the final formulated product.



Nikko Chemicals Co., Ltd.  
1-4-8, Nihonbashi-Bakurocho, Chuoku, Tokyo  
TEL +81-3-3661-1677

Safety Information of NIKKOL Decaglyn 2-ISV *polyglyceryl-10 Disostearate*

Category	Test Name	Alternative	Model/Cell	Method	Concentration	Result	Remarks
Irritation	Ocular Irritation	Alternative	Corneal epithelial cells, rabbit	SIRC-NR	Max. 1,000mg/L	Non irritant	NR50 > 1,000mg/L

※These test results may not be representative of the safety of the final formulated product.

Nikko Chemicals Co., Ltd.  
1-4-8, Nihonbashi-Bakurocho, Chuoku, Tokyo  
TEL +81-3-3661-1677

Safety Information of NIKKOL Decaglyn 5-IS Polysilyceryl-10 Pentaistearate

Category	Test Name	Alternative	Model/Cell	Method	Concentration	Result	Remarks
Irritation	Human patch	--	Japanese Skin	24h closed, n=44	50%	Negative	--

\* These test results may not be representative of the safety of the final formulated product.

Nikko Chemicals Co., Ltd.  
1-4-8, Nihonbashi-Bakurocho, Chuoku, Tokyo  
TEL +81-3-3661-1677

Safety Information of NIKKOL Decaglyn 10-O Polyglyceryl-10 Decooleate

Category	Test Name	Alternative	Model/Cell	Method	Concentration	Result	Remarks
Irritation	Human patch	—	Japanese Skin	24h closed, n=44	as is	Negative	—

※ These test results may not be representative of the safety of the final formulated product.

Nikko Chemicals Co., Ltd.  
1-4-8, Nihonbashi-Bakurocho, Chuoku, Tokyo  
TEL +81-3-3661-1677

Safety Information of NIKKOL Decaglyn PR-20 Polysilyceryl-10 Polyricinoleate

Category	Test Name	Alternative	Model/Cell	Method	Concentration	Result	Remarks
Irritation	Human patch	—	Japanese Skin	24h closed, n=44	50% Negative	—	

※These test results may not be representative of the safety of the final formulated product.

Nikko Chemicals Co., Ltd.  
1-4-8, Nihonbashi-Bakurocho, Chuoku, Tokyo  
TEL +81-3-3661-1677

Safety Information of NIKKOL HEXAGLYN PR-15 Polyglyceryl-6 polyricinoleate

Category	Test Name	Alternative	Model/Cell	Method	Concentration	Result	Remarks
Irritation	Human patch	—	Japanese Skin	24h closed, n=44	50%	Negative	PII: 0.0
Irritation	Ocular irritation	Alternative	Corneal epithelial cells, rabbit	SIRC-NR	Max. 1,000mg/L	Non irritant	TC50 > 1,000mg/L

※These test results may not be representative of the safety of the final formulated product.



## Memorandum

**TO:** Lillian Gill, D.P.A.  
Director - COSMETIC INGREDIENT REVIEW (CIR)

**FROM:** Beth A. Lange, Ph.D.  
Industry Liaison to the CIR Expert Panel

**DATE:** February 29, 2016

**SUBJECT:** Polyglyceryl-3 Laurate, Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate,  
Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate

Lubrizol Advanced Materials, Inc. 2016. Summary information polyglyceryl fatty acid esters.

Lubrizol Advanced Materials, Inc. 2007. Hydramol™ TGL Ester (Polyglyceryl-3 Laurate) toxicology studies.

Lubrizol Advanced Materials, Inc. 2007. Schercemol™ PTID Ester (Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate) toxicology studies.

Lubrizol Advanced Materials, Inc. 2007. Schercemol™ PDD Ester (Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate) toxicology studies.

Lubrizol Advanced Materials, Inc.

February 2016

**Summary Information Polyglyceryl Fatty Acid Esters**

<b>Data Request</b>	<b>Polyglyceryl-3-Laurate (Hydramol TGL Ester)</b>	<b>Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate (Schercemol PTID Ester)</b>	<b>Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate (Schercemol PDD Esters)</b>
<b>dermal absorption data</b>	No data; ester based on glycerin and lauric acid which have been previously reviewed by CIR	MW >1000; not expected to be bioavailable and penetrate the skin	MW >1000; not expected to be bioavailable and penetrate the skin
<b>dermal toxicity</b>	No data; ester based on glycerin and lauric acid which have been previously reviewed by CIR	MW >1000; not expected to be bioavailable and penetrate the skin	MW >1000; not expected to be bioavailable and penetrate the skin
<b>inhalation toxicity</b>	no data	no data	no data
<b>genotoxicity</b>	Ames negative: tested from 50-5000 µg/plate	MW >1000; not expected to be bioavailable or genotoxic	MW >1000; not expected to be bioavailable or genotoxic
<b>dermal irritation and sensitization</b>	Non-irritating and non-sensitizing in human repeat insult patch test (HRIPT): 114 subjects completed testing; dosage was 150 µl per patch; product was tested as supplied (~100% Polyglyceryl-3 Laurate)	Non-irritating and non-sensitizing in HRIPT: 103 subjects completed the test; dosage was 150 µl/patch; product tested as supplied (~100% Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate)	Expected to be non-irritating and non-sensitizing based on read across from HRIPT on tetraisostearoyl polyglyceryl-3 dimer dilinoleate
<b>any other relevant data</b>	EpiOcular: non-irritating	EpiOcular: non-irritating LD <sub>50</sub> >5 g/kg for related material tetraisostearoyl polyglyceryl-3 dimer dilinoleate	LD <sub>50</sub> >5 g/kg and EpiOcular non-irritating for related material: tetraisostearoyl polyglyceryl-3 dimer dilinoleate



## TOXICOLOGY & MICROBIOLOGY STUDIES

TOX-094

Edition: October 26, 2007

Previous Edition: November 10, 2006

# Hydramol™ TGL Ester

## Toxicology Studies

**INCI NAME:** POLYGLYCERYL-3 LAURATE

### TEST

EpiOcular Tissue Model (In-Vitro) -  
(10% in corn oil)

Skin Irritation and sensitization – Human  
*(see summary table for more details)*

Genotoxicity –AMES  
*(see summary table for doses tested)*

### CONCLUSION

ET50: > 256 minutes  
Zero Draize score (estimated)  
Non-Irritating

Non-Irritating, Non-Sensitizing

Negative

Lubrizon Advanced Materials, Inc. / 9911 Brecksville Road, Cleveland, Ohio 44141-3247 / TEL: 800.379.5389 or 216.447.5000

The information contained herein is being furnished for informational purposes only, upon the express condition that the User makes its own assessment of the appropriate use of such information. While the information contained herein is believed to be reliable, no representations, guarantees or warranties of any kind are made as to its accuracy, suitability for a particular application or the results to be obtained herefrom. Lubrizon Advanced Materials, Inc. ("Lubrizon") cannot guarantee how any products associated with this information will perform in

combination with other substances or in the User's process. Due to variations in methods, conditions and equipment used commercially in processing these materials, no warranties or guarantees are made as to the suitability of the information or products for the applications disclosed. Lubrizon shall not be liable and the User assumes all risk and responsibility for any use or handling of any material beyond Lubrizon's direct control. LUBRIZOL MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO,

THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. It is the User's sole responsibility to determine if there are any issues relating to patent infringement of any component or combination of components relating to the supplied information. Nothing contained herein is to be considered as permission, recommendation, nor as an inducement to practice any patented invention without permission of the patent owner.

For further information, please visit: [www.lubrizon.com/personalcare](http://www.lubrizon.com/personalcare)





## TOXICOLOGY & MICROBIOLOGY STUDIES

TOX-104

Edition: February 8, 2007

Previous Edition: November 10, 2006

# Schercemol™ PTID Ester

## Toxicology Studies

**INCI NAME:** TRIISOSTEAROYL POLYGLYCERYL-3 DIMER DILINOLEATE

### TEST

Oral Toxicity - Rats<sup>1</sup>

EpiOcular Tissue Model (In-Vitro) -  
(10% in corn oil)

Skin Irritation -  
Human Repeat Insult Patch Test

Skin Sensitization -  
Human Repeat Insult Patch Test

(see summary table for more details)

### CONCLUSION

LD<sub>50</sub> > 5 g/kg

ET50: > 256 minutes  
Zero Draize score (estimated)  
Non-Irritating

Non-Irritating

Non-Sensitizing

<sup>1</sup> Data on a structurally and chemically similar material - tetraisoostearyl polyglyceryl-3  
dimer dilinoleate

Lubrizol Advanced Materials, Inc. / 9911 Brecksville Road, Cleveland, Ohio 44141-3247 / TEL: 800.379.5389 or 216.447.5000

The information contained herein is being furnished for informational purposes only, upon the express condition that the User makes its own assessment of the appropriate use of such information. While the information contained herein is believed to be reliable, no representations, guarantees or warranties of any kind are made as to its accuracy, suitability for a particular application or the results to be obtained herefrom. Lubrizol Advanced Materials, Inc. ("Lubrizol") cannot guarantee how any products associated with this information will perform in

combination with other substances or in the User's process. Due to variations in methods, conditions and equipment used commercially in processing these materials, no warranties or guarantees are made as to the suitability of the information or products for the applications disclosed. Lubrizol shall not be liable and the User assumes all risk and responsibility for any use or handling of any material beyond Lubrizol's direct control. LUBRIZOL MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO,

THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. It is the User's sole responsibility to determine if there are any issues relating to patent infringement of any component or combination of components relating to the supplied information. Nothing contained herein is to be considered as permission, recommendation, nor as an inducement to practice any patented invention without permission of the patent owner.

For further information, please visit: [www.lubrizol.com/personalcare](http://www.lubrizol.com/personalcare)



## TOXICOLOGY & MICROBIOLOGY STUDIES

TOX-103

Edition: May 2, 2007

Previous Edition: November 10, 2006

# Schercemol™ PDD Ester

## Toxicology Studies

**INCI NAME:** DIISOSTEAROYL POLYGLYCERYL-3 DIMER DILINOLEATE

### TEST

Oral Toxicity - Rats<sup>1</sup>

EpiOcular Tissue Model (In-Vitro) -  
(10% in corn oil)<sup>2</sup>

Skin Irritation -  
Human Repeat Insult Patch Test<sup>3</sup>

Skin Sensitization -  
Human Repeat Insult Patch Test<sup>4</sup>

### CONCLUSION

LD<sub>50</sub> > 5 g/kg

ET50: > 256 minutes  
Zero Draize score (estimated)  
Non-Irritating

Non-Irritating

Non-Sensitizing

<sup>1</sup> Data on a structurally and chemically similar material

<sup>2</sup> Data on a structurally and chemically similar material

<sup>3</sup> Data on a structurally and chemically similar material

<sup>4</sup> Data on a structurally and chemically similar material

tetraisostearoyl polyglyceryl-3  
dimer dilinoleate

Lubrizol Advanced Materials, Inc. / 9911 Brecksville Road, Cleveland, Ohio 44141-3247 / TEL: 800.379.5389 or 216.447.5000

The Information contained herein is being furnished for informational purposes only, upon the express condition that the User makes its own assessment of the appropriate use of such information. While the information contained herein is believed to be reliable, no representations, guarantees or warranties of any kind are made as to its accuracy, suitability for a particular application or the results to be obtained herefrom. Lubrizol Advanced Materials, Inc. ("Lubrizol") cannot guarantee how any products associated with this information will perform in

combination with other substances or in the User's process. Due to variations in methods, conditions and equipment used commercially in processing these materials, no warranties or guarantees are made as to the suitability of the information or products for the applications disclosed. Lubrizol shall not be liable and the User assumes all risk and responsibility for any use or handling of any material beyond Lubrizol's direct control. LUBRIZOL MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO,

THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. It is the User's sole responsibility to determine if there are any issues relating to patent infringement of any component or combination of components relating to the supplied information. Nothing contained herein is to be considered as permission, recommendation, nor as an inducement to practice any patented invention without permission of the patent owner.

For further information, please visit: [www.lubrizol.com/personalcare](http://www.lubrizol.com/personalcare)



## Memorandum

**TO:** Lillian Gill, D.P.A.  
Director - COSMETIC INGREDIENT REVIEW (CIR)

**FROM:** Beth A. Lange, Ph.D.  
Industry Liaison to the CIR Expert Panel

**DATE:** March 2, 2016

**SUBJECT:** Summary Information Polyglyceryl-3 Isostearate, Polyglyceryl-3 Caprate, Polyglyceryl-3 Caprylate, Polyglyceryl-3 Oleate, Polyglyceryl-4 Caprate and Diisostearyl Polyglyceryl-3 Dimer Dilinoleate

Anonymous. 2016. Polyglyceryl-3 Isostearate: Summary of product data with reference to toxicology.

Anonymous. 2016. Polyglyceryl-3 Caprate: Summary of product data with reference to toxicology.

Anonymous. 2016. Polyglyceryl-3 Caprylate: Summary of product data with reference to toxicology.

Anonymous. 2016. Polyglyceryl-3 Oleate: Summary of product data with reference to toxicology.

Anonymous. 2016. Polyglyceryl-4 Caprate: Summary of product data with reference to toxicology.

Anonymous. 2016. Diisostearyl Polyglyceryl-3 Dimer Dilinoleate: Summary of product data with reference to toxicology.

**Polyglyceryl-3 Isostearate****Summary of Product Data with Reference to Toxicology**

Test	Method	Result	Date
Acute Oral Toxicity (rat)	Federal Hazardous Substances Control Act, 16 CFR 1500.3	LD50 > 5,000 mg/kg	03/1993
Acute Dermal Irritation/Corrosion (rabbit)	FHSA (Federal Hazardous Substances Control Act), 16 CFR 1500.41	moderately irritating	05/1993
Acute Eye Irritation/Corrosion (rabbit)	FHSA/CPSC: Federal Hazardous Substances Control Act, 16 CFR 1500.42	mildly irritating	04/1993
Skin Sensitization (guinea pig)	OECD 406	no skin sensitisation effect	04/1996
Gene Toxicity (Ames)	Ames test	no evidence of mutagenic activity	02/1996

March 2016

**Polyglyceryl-3 Caprate**  
**Summary of Product Data with Reference to Toxicology**

Test	Method	Result	Date
Acute Oral Toxicity (rat)	OECD 401	LD50: > 2,000 mg/kg	05/1996
Acute Dermal Irritation/Corrosion (rabbit)	OECD 404	not irritating	10/1992
Acute Eye Irritation/Corrosion (rabbit)	OECD 405	not irritating	11/1992
Skin Sensitization (guinea pig)	OECD 406	no skin sensitisation effect	02/1998
Gene Toxicity (Ames)	OECD 471	no evidence of mutagenic activity	09/1996

March 2016

**Polyglyceryl-3 Caprylate****Summary of Product Data with Reference to Toxicology**

Test	Method	Result	Date	Comment
Acute Oral Toxicity (rat)	OECD 423	LD50 > 2,000 mg/kg	10/2001	
Acute Dermal Irritation/Corrosion (rabbit)	OECD 404	not irritating		These data have been collected with a structural-analogous product, a Polyglyceryl-mono/di-ester of Capric Acid (C10). They may be used for the toxicological evaluation of a Polyglyceryl monoester of Caprylic Acid (C8) until further notice.
Acute Eye Irritation/Corrosion (rabbit)	OECD 405	not irritating		
Skin Sensitisation (LLNA)	OECD 429	not sensitising	06/2002	
Gene Toxicity (Ames)	OECD 471	not mutagenic	10/2005	

March 2016

**Polyglyceryl-3 Oleate****Summary of Product Data with Reference to Toxicology**

Test	Method	Result	Date	Comments
Acute Oral Toxicity (rat)	Federal Hazardous Substances Control Act / FHSA, 16 CFR 1500.3	LD50 > 5,000 mg/kg	05/1993	
Acute Dermal Irritation/Corrosion (rabbit)	Federal Hazardous Substances Control Act / FHSA, 16 CFR 1500.41	moderately irritant	05/1993	
Acute Eye Irritation/Corrosion (rabbit)	Federal Hazardous Substances Control Act / FHSA, 16 CFR 1500.42	mildly irritant	04/1993	
Skin Sensitization (guinea pig)	OECD 406, July 17, 1992	no sensitizing effect	04/1996	Read across from Polyglyceryl-4 Isostearate
Gene Toxicity (Ames)	Ames, B.N., McCann, J., Yamasaki, E., Mutation Res. 31, 347-364 (1975)	negative	02/1996	

**Polyglyceryl-4 Caprate****Summary of Product Data with Reference to Toxicology**

Test	Method	Result	Date
Acute Oral Toxicity (rat)	OECD 401	LD50: > 2000 mg/kg	05/1996
Acute Dermal Irritation/Corrosion (rabbit)	OECD 404	not irritating	07/1992
Acute Eye Irritation/Corrosion (rabbit)	OECD 405	not irritating	08/1996
Skin Sensitization (guinea pig)	OECD 406	no skin sensitisation effect	02/1998
Gene Toxicity (Ames)	OECD 471	no evidence of mutagenic activity	09/1996



March 2016

**Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate**  
**Summary of Product Data with Reference to Toxicology**

Test	Method	Result	Date	Comment
Acute Oral Toxicity (rat)	OECD 423	LD50 >2.000 mg/kg b.w.	01/2007	
Acute Dermal Irritation/Corrosion (human)	Occlusive Patch Test Human Patch Test	no concern	01/1997	
Acute Eye Irritation/Corrosion (in-vitro)	Evaluated in-vitro alternative methodology, Hen's Egg Test on the Chorioallantois Membrane, HET-CAM	minor irritating	01/1997	
Skin Sensitization (guinea pig)	OECD 406	not sensitising	unknown	Read across from Polyglyceryl-4 Diisostearate/Polyhydroxystearate/Sebacate, which is very similar with regard to its molecular weight and chemical character
Gene Toxicity (Ames)	OECD 471	negative	05/1997	



## Memorandum

**TO:** Lillian Gill, D.P.A.  
Director - COSMETIC INGREDIENT REVIEW (CIR)

**FROM:** Beth A. Lange, Ph.D.  
Industry Liaison to the CIR Expert Panel

**DATE:** March 2, 2016

**SUBJECT:** Polyglyceryl-2 Isostearate, Polyglyceryl-4 Laurate/Sebacate, Polyglyceryl-4 Laurate/Succinate and Polyglyceryl-6 Caprylate/Caprates

Notox BV. 1996. Primary skin irritation/corrosion study with Polyglyceryl-2 Isostearate in the rabbit.

Globecrown Services Ltd. 1997. A three-application patch trial in healthy volunteers to investigate the skin irritation potential of Polyglyceryl-2 Isostearate following cutaneous patch applications.

Harlan Laboratories, Ltd. 2010. Summary: Determination of skin irritation potential using the Episkin™ reconstituted human epidermis model (Polyglyceryl-4 Laurate/Sebacate).

Harlan Laboratories, Ltd. 2010. Summary: Assessment of ocular irritation potential using the Skinethic reconstituted human corneal epithelium model (Polyglyceryl-4 Laurate/Sebacate).

Harlan Laboratories, Ltd. 2010. Summary: Reverse mutation assay "Ames Test" using *Salmonella typhimurim* and *Escherichia coli* (Polyglyceryl-4 Laurate/Succinate).

Harlan Laboratories, Ltd. 2010. Summary: Determination of skin irritation potential using the Episkin™ reconstituted human epidermis model (Polyglyceryl-4 Laurate/Succinate).

Harlan Laboratories, Ltd. 2010. Summary: Assessment of ocular irritation potential using the Skinethic reconstituted human corneal epithelium model (Polyglyceryl-4 Laurate/Succinate).

Harlan Laboratories, Ltd. 2010. Summary: Reverse mutation assay “Ames Test” using *Salmonella typhimurim* and *Escherichia coli* (Polyglyceryl-6 Caprylate/Caprata).

Harlan Laboratories, Ltd. 2010. Summary: Determination of skin irritation potential using the Episkin™ reconstituted human epidermis model (Polyglyceryl-6 Caprylate/Caprata).

Harlan Laboratories, Ltd. 2010. Summary: Assessment of ocular irritation potential using the Skinethic reconstituted human corneal epithelium model (Polyglyceryl-6 Caprylate/Caprata).

## REPORT

PRIMARY SKIN IRRITATION/CORROSION STUDY WITH

*Polyglyceryl-2 Isosorbate*

IN THE RABBIT

(4-HOUR SEMI-OCCLUSIVE APPLICATION)

NOTOX Project 167996  
NOTOX Substance 59283

- page 1 of 11 -

NOTOX Project 167996

STATEMENT OF GLP COMPLIANCE

---

NOTOX B.V., 's-Hertogenbosch, The Netherlands

The study described in this report was conducted in compliance with the most recent edition of:

The OECD Principles of Good Laboratory Practice

which are essentially in conformity with:

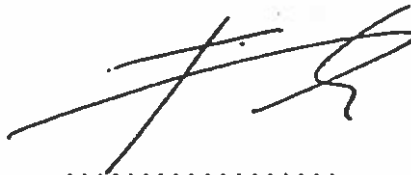
The United States Environmental Protection Agency, (FIFRA). Title 40 Code of Federal Regulations Part 160.

The United States Environmental Protection Agency, (TSCA). Title 40 Code of Federal Regulations Part 792.

The United States Food and Drug Administration. Title 21 Code of Federal Regulations Part 58.

Study Director

Dr.Ir. W.R. Pels Rijcken



.....

Date: 8 May 1996

NOTOX Project 167996

## QUALITY ASSURANCE STATEMENT

NOTOX B.V., 's-Hertogenbosch, The Netherlands

Study procedures were subject to periodic inspections and general non study specific processes were also inspected at periodic intervals.

This report was audited by the Quality Assurance Unit and the methods and results accurately reflect the raw data.

Dates of Q.A.U. Inspections/Audits	Reporting Date
20 February 1996	20 February 1996
5 March 1996	5 March 1996
6 May 1996	6 May 1996

Manager, Quality Assurance Unit

C.J. Mitchell B.Sc.



Date: 8-5-96

NOTOX Project 167996

## REPORT APPROVAL

---

STUDY DIRECTOR :

Dr.Ir. W.R. Pels Rijcken



.....

Date: 8 May 1996

MANAGEMENT :

Dr. I.C. Enninga  
Technical Director



.....

Date: 08/05/1996

## SUMMARY

Primary skin irritation/corrosion study with  
hour semi-occlusive application).

in the rabbit (4-

The study was carried out in accordance with the OECD guideline No. 404, 'Acute Dermal Irritation/Corrosion' and the EEC Directive 92/69/EEC, B.4, 'Acute Toxicity - Skin irritation.

Three rabbits were exposed to 0.5 ml of , applied onto clipped skin for 4 hours using a semi-occlusive dressing. Observations were made 1, 24, 48 and 72 hours and 7 days after exposure.

Exposure to resulted in very slight erythema in the treated skin-areas of the rabbits, which had resolved within 3 - 7 days in the animals. No signs of systemic intoxication were observed during the study period.

Dermal application of resulted in a primary irritation index of 0.8 (mildly irritating) when applied to the intact rabbit skin.



PREFACE

---

## Sponsor

Study Monitor	Drs. A. Hinze
Testing Facility	NOTOX B.V. Hambakenwetering 3 5231 DD 's-Hertogenbosch The Netherlands
Study Director	Dr.Ir. W.R. Pels Rijcken
Study Plan	Start        5 March 1996 End         12 March 1996

TEST SUBSTANCE

---

The sponsor is responsible for the completeness and GLP Compliance of all test substance data.

Identification	
Description	Yellow liquid
Batch	9666
Purity	Not indicated by sponsor; treated as 100% pure
Test substance storage	At room temperature in the dark
Stability under storage conditions	Not indicated
Expiry date	Not indicated
Preparation	The test substance was applied undiluted as delivered by the sponsor.

PURPOSE AND RATIONALE

---

The purpose of this primary skin irritation study was to assess the possible irritation or corrosion potential of a single dose of \_\_\_\_\_ when placed on the skin of rabbits.

This study should provide part of a rational basis for risk assessment in man. The absence of skin pigmentation in the albino rabbit facilitates the evaluation of induced skin reactions. The dermal route was selected because \_\_\_\_\_ may accidentally come into contact with the skin during manufacture, handling and/or use.

## GUIDELINES

---

Study procedures described in this report are in accordance with the following guidelines:

Organisation for Economic Co-operation and Development (OECD), OECD Guidelines for Testing of Chemicals, Guideline No. 404: "Acute Dermal Irritation/Corrosion", Paris Cedex, July 17, 1992.

European Economic Community (EEC), Directive 92/69/EEC, Annex V of the EEC Directive 67/548/EEC, Part B: Methods for the Determination of Toxicity; B.4: "Acute Toxicity - Skin Irritation", EEC Publication No. L 383, December 1992.

## ARCHIVING

---

NOTOX B.V. will archive the following data for at least 10 years: raw data, protocol, report and test substance reference sample.

## TEST SYSTEM

---

Species	Albino Rabbit, New Zealand White, (SPF-Quality) Source: Broekman Institute, Someren, The Netherlands.
Number of animals	3 male rabbits
Age at start of treatment	Approx. 8 weeks
Body weight at start of treatment	1492 - 1729 grams
Identification	Ear tag.

## ANIMAL HUSBANDRY

---

### Conditions

Air-conditioned room with approximately 15 air changes per hour and the environment controlled with optimal conditions considered as being a temperature of 21°C and a relative humidity of 50%. Fluctuations from these optimal conditions were noted, but were considered not to have affected study integrity. Lighting was 12 hours artificial fluorescent light and 12 hours dark per day.

### Accommodation

Individually in labelled cages with perforated floors (Scanbur Denmark) and equipped with an automatic drinking system (ITL, Bergen, The Netherlands). Acclimatisation period was at least 5 days before start of treatment under laboratory conditions.

### Diet

Standard laboratory rabbit diet (LKK-20, pellet diameter 4mm, Hope Farms, Woerden, The Netherlands) approx. 100 gram per day. Certificates of analysis were examined and retained in the NOTOX archives. In addition, hay (BMI, Helmond, The Netherlands) was provided once a week.

### Water

Free access to tap-water diluted with decalcified water. Certificates of analysis were examined and retained in the NOTOX archives.

## TREATMENT

---

Approximately 24 hours before treatment, the dorsal fur was clipped with electric clippers, exposing an area of approximately 150 square centimeters (10x15 cm<sup>2</sup>).

A health inspection was performed prior to the commencement of treatment, to ensure that the animals were in a good state of health. Special attention was paid to the skin to be treated, which was intact and free from abnormalities.

On test day 1, 0.5 ml of the test substance was applied to the skin of one flank, using a surgical gauze patch of 2x3 cm. The patch was mounted on Micropore tape\*, which was wrapped around the abdomen and secured with Coban elastic bandage\*.

Four hours after the application, the dressing was removed and the remaining test substance removed using a tissue moistened with tap-water and subsequently a dry tissue.

Whenever considered necessary the treated skin areas were re-clipped at least 3 hours before the observations, to facilitate the scoring.

\*. Supplier, 3M, St. Paul, U.S.A..

## OBSERVATIONS

---

Mortality/Viability	Twice daily
Toxicity	At least once daily.
Body Weight	Day of treatment (prior to application).
Irritation	The skin reactions were assessed at approximately 1, 24, 48 and 72 hours and 7 days after the removal of the dressings and test substance. The irritation scores and a description of all other (local) effects were recorded.

The skin reactions were graded according to the following numerical scoring system:

### ERYTHEMA AND ESCHAR FORMATION

No erythema .....	0
Very slight erythema (barely perceptible) .....	1
Well defined erythema .....	2
Moderate to severe erythema .....	3
Severe erythema (beet redness) .....	4

\*. If signs of necrosis or corrosion (injuries in depth) prevent erythema scoring, the maximum grade for erythema (= 4) is given.

### OEDEMA FORMATION

No oedema .....	0
Very slight oedema (barely perceptible) .....	1
Slight oedema (edges of area well defined by definite raising) .....	2
Moderate oedema (raised approximately 1 mm) .....	3
Severe oedema (raised more than 1 mm and extending beyond area of exposure) .....	4

NOTDX Project 167996

## INTERPRETATION OF RESULTS

---

A primary irritation index was calculated (the sum of the irritation scores for erythema and oedema obtained at 24 and 72 hours after exposure, divided by 2 times the number of animals used in the study). With the primary irritation index a degree of irritation was obtained, using the table described below (based on Oraize et.al. (1944) J.Pharmacol.Exp. 82, 377):

Primary irritation index	Degree of irritation
0	non-irritating
> 0 - 0.4	negligibly irritating
>0.4 - 2.0	mildly irritating
>2.0 - 5.0	moderately irritating
>5.0 - 8.0	severely irritating

Note: Where the scoring procedure and the clinical judgement were not in agreement, the assessment of irritancy was based on the latter.

## RESULTS

### IRRITATION

---

Four hours exposure to 0.5 ml of                      resulted in very slight erythema in the treated skin-areas of all animals. The erythema had resolved within 48 hours in one animal and within 7 days after exposure in the other two animals.

### CORROSION

---

There was no evidence of a corrosive effect on the skin.

### COLOURATION

---

No staining of the treated skin by the test substance was observed.

### TOXICITY SYMPTOMS / MORTALITY

---

No symptoms of systemic toxicity were observed in the animals during the test period and no mortality occurred.

## CONCLUSION

Dermal application of                      resulted in a primary irritation index of 0.8 (mildly irritating) when applied to the intact rabbit skin.

According to the EEC criteria for classification and labelling requirements, the mean value of the scores for erythema and oedema, calculated for each animal separately, is the following:

Animal no.	Mean 24 - 72 hours	
	Erythema	Oedema
1796	0.3	0
1800	0.7	0
1804	1.0	0

## INDIVIDUAL SKIN IRRITATION

hours/days after exposure

1 Hour

Rabbit	Erythema	Oedema	Comments
1796	1	0	-
1800	1	0	-
1804	1	0	-

24 Hours

Rabbit	Erythema	Oedema	Comments
1796	1	0	-
1800	1	0	-
1804	1	0	-

48 Hours

Rabbit	Erythema	Oedema	Comments
1796	0	0	-
1800	0	0	-
1804	1	0	-

72 Hours

Rabbit	Erythema	Oedema	Comments
1796	0	0	-
1800	1	0	-
1804	1	0	-

7 Days

Rabbit	Erythema	Oedema	Comments
1796	0	0	-
1800	0	0	-
1804	0	0	-

97/0000010

T

**A THREE-APPLICATION PATCH TRIAL IN HEALTHY VOLUNTEERS  
TO INVESTIGATE THE SKIN IRRITATION POTENTIAL OF PRODUCTS  
FOLLOWING CUTANEOUS PATCH APPLICATIONS**

*Polyglyceryl -2 Isostearate*

To:

From:  
Globecrown Services Ltd  
Globecrown House  
32 High Street  
Maldon  
Essex CM9 5PN  
England

Draft: 15 May 1997  
Final: 30 July 1997

97/UNCPAT6

**A THREE-APPLICATION PATCH TEST IN HEALTHY VOLUNTEERS  
TO INVESTIGATE THE SKIN IRRITATION POTENTIAL OF PRODUCTS  
FOLLOWING CUTANEOUS PATCH APPLICATIONS**

Globecrown Report No 97/UNCPAT6

I declare that the following report constitutes a true and faithful account of the procedures adopted and the results obtained in the performance of this study. The aspects of the study conducted by Globecrown Services Ltd were performed, where relevant, in accordance with the principles of Good Clinical Research Practice.

A Barlow, BSc (Hons)  
(Study Director)

  
Date 8/3/97

I have reviewed this report and concur with its contents.

D B Galloway, MB, ChB, DRCOG, FRCP, FRCPE, FFPM  
(Medical Advisor)

  
Date 13 Aug. 1997

This report has been audited and is considered to be an accurate description of the methods used and an accurate presentation of the data obtained during the conduct of the study.

A Waterman, BSc (Hons)  
(Quality Assurance Manager)

  
Date 10<sup>th</sup> September 1997



LIST OF PERSONNEL INVOLVED IN STUDY

1. Study Director : A Barlow BSc (Hons)
2. Medical Advisor : D B Galloway MB, ChB,  
DRCOG, FRCP, FRCPE,  
FFPM
3. Study Supervisor : E Armstrong
4. Responsible technicians  
  
Formulation and  
Test article accountability : J Statham  
  
Grading : J Sowerbutts  
  
Patching : J Sowerbutts  
S Stacey
5. Sponsor contact : Dr J Wiechers

CONTENTS

SUMMARY .....	5
INTRODUCTION AND OBJECTIVE .....	6
MATERIALS AND METHODS .....	7
RESULTS .....	14
CONCLUSIONS .....	15

FIGURE

1. Age and sex composition of the panel who completed the study .....	16
---	----

TABLE

1. Mean responses elicited by three applications of each test article (standard deviations in parentheses) .....	17
--	----

APPENDICES

1. Consent form .....	18
2. Subject information sheet .....	19
3. Pre-treatment questionnaire .....	21
4. Irritancy grading scale and key to symbols used .....	23
5. Ethics committee approval .....	24
* 6. Individual responses to applications of Polyglyceryl-3 Isostearate .....	25
7. Individual responses to applications of .....	26
8. Individual responses to applications of .....	27
9. Individual responses to applications of .....	28
10. Individual responses to applications of .....	29
11. Individual responses to applications of .....	30
12. Individual responses to applications of .....	31
13. Individual responses to applications of .....	32
14. Individual responses to applications of Water .....	33
15. Individual responses to applications of 0.3% Sodium lauryl sulphate .....	34
16. Results of statistical analysis .....	35

Addendum

## SUMMARY

1. This was a single-blind within subject comparison study conducted in 30 healthy volunteers of either sex to evaluate the skin irritation potential of products following three cutaneous patch applications.
2. Patches consisted of two sets of five Webril<sup>R</sup> squares (Kendall Corporation, USA) fixed along the midline of 5cm wide strips of occlusive Blendederm<sup>R</sup> (3M Co) tape.
3. Patches were applied for three 24 hour periods with assessments 24 hours after removal of the first and second patches and 48 hours after removal of the third patch.
4. Individual scores, mean scores and standard deviations for each study day are presented in this report for the 30 subjects who completed the study.
5. From the original data it can be seen that UNC 95.192 and elicited no more than minimal irritation. Whilst Polyglyceryl-2-Isostearate and elicited slight irritation, where as and elicited definite irritation.

The statistical analysis revealed that and were not significantly different in irritancy from the negative control (de-ionised water) whilst being significantly less irritant than the positive control (0.3% SLS solution) at the  $p=0.05$  level, on all study days.

were significantly less irritant than the positive control at the  $p=0.05$  level on all study days, they were significantly more irritant than the negative control on day 8 at the  $p=0.05$  level.

Whilst Polyglyceryl-2-Isostearate were significantly less irritant than the positive control at the  $p=0.05$  level on all study days, they were also significantly more irritant than the negative control on all study days at the  $p=0.05$  level.

was significantly more irritant than the negative control at the  $p=0.05$  level and was also not significantly different in irritancy from the positive control at the  $p=0.05$  level, on all study days.

97/UNCPAT6

## INTRODUCTION AND OBJECTIVE

The objective of this study was to determine the human skin irritation potential of following three cutaneous patch applications.

products

## MATERIALS AND METHODS

### 1. Study Design

The study was conducted single-blind.

A total of 30 subjects received three 24 hour occlusive patch applications.

### 2. Selection of subjects

#### 2.1 Screening

Thirty subjects were recruited into the study who satisfied the following inclusion and exclusion criteria, who were prepared to accept the prohibitions and restrictions and who gave witnessed, written informed consent (Appendices 1 and 2).

The suitability of each potential subject was confirmed before their acceptance by review of a study specific pre-treatment questionnaire (Appendix 3).

Volunteers received remuneration based on an estimate of time and inconvenience.

#### 2.2 Inclusion criteria

- Healthy volunteers of either sex aged 18 to 65.
- Completed witnessed written informed consent.

#### 2.3 Exclusion criteria

- Pregnancy or lactation.
- Inadequate or non-existent contraception (women of child bearing potential only).
- A current skin disease of any type apart from mild acne.
- History of skin tumours.
- Heavy alcohol consumption (ie more than 21 units per week or 8 units per day for men; more than 14 units per week or 4 units per day for women).
- A febrile illness lasting more than 24 hours in the six days prior to the first patch application.
- A significant past medical history of hepatic, renal, cardiac, pulmonary, digestive, haematological, neurological, locomotor or psychiatric disease.

- Organ transplant that required the use of immunosuppressive drugs (cornea or lens transplants were not included).
- Immune deficiency disease.
- History of malignant disease.
- Insulin dependent diabetes.
- A history of asthma requiring regular medication or hayfever that required prescription treatment in two or more of the previous three years.
- A history of multiple drug hypersensitivity.
- Concurrent medication likely to have affected the response to the test articles or confuse the results of the study.
- Known sensitivity to the test articles or their constituents including patch materials.
- Current treatment by a physician for allergy unless physician consulted by Investigator and participation approved.
- Participation in a repeat insult patch test (RIPT) or follow-up work within the last month.
- Sensitization or questionable sensitization in a repeat insult patch test (RIPT).
- Recent immunisation (less than ten days prior to test patch application).

2.4 Prohibitions and restrictions-for the duration of the study

- No use of aspirin, or other non-steroidal anti-inflammatory drugs.
- No use of sunbeds or sunlamps.
- No deliberate exposure of the test sites to natural sunlight or to other sources of UV light during the study.

### 3. Method

#### 3.1 Test articles

The test articles were supplied by the Sponsor and were received at Globecrown on 11, 14 and 21 of March 1997 coded as follows:

\* ..... (Polyglycerol-2 Isostearate)

In addition to:  
0.3% Sodium lauryl sulphate.  
Water.

and ..... were diluted to 25% w/w in ..... 2, Isopropyl  
myristate (IPM). *Polyglycerol-2 Isostearate* ..... were  
diluted to 7% w/w in ESTOL 1512, Isopropyl myristate (IPM)  
were diluted to 10% w/w and ..... was diluted to 20% w/w in Dipropylenc  
glycol (DPG).

Safety data sheets for the test articles are presented as an addendum to protocol. Safety data sheets for the test articles are presented as an addendum to this report. The following were provided by Globecrown Services Ltd, as a positive and negative control respectively:

0.3% Sodium lauryl sulphate  
Water

The identity and stability of the test articles were the responsibility of the Sponsor.

After the use of the test articles, a reserve sample of each was stored by Globecrown Services Ltd under appropriate conditions (as defined by the Sponsor) in the Sample Archives at Globecrown House, 32 High Street, Maldon, Essex, England and will be held for a minimum period of five years.

#### 3.2 Test patches

Patches consisted of a 5 cm wide strip of occlusive Blendederm<sup>R</sup> (3M Co.) tape to which Webril<sup>R</sup> (Kendall Corporation) squares (approximately 1cm x 1cm) were fixed along the midline. Two patch strips, left (L) and right (R), were applied to the upper left arm.

Each test article was applied to each square of each patch. Dots of crystal violet were applied on either side of the top square and below the bottom square of each patch to mark the skin to enable exact location of subsequent patches. Each subject was asked to avoid the dye marks during washing and to keep the patches dry.

Where reinforcement of patch adhesion became necessary, strips of porous tape (Micropore<sup>R</sup> (3M Co.)) were applied.

### 3.3 Dose regime

Subjects each received patches containing each of the ten test articles which were applied as 0.4 ml samples in one of five randomly assigned orders. The sample order for each subject was documented and maintained throughout the study in the form of a colour-coded identification card.

Subjects were instructed to keep the patches dry and in place for 24 hours then to remove and discard them. Patches were applied on Days 1, 3 and 5. Patches were applied to the same site each day unless a reaction stronger than a mild erythema (ie greater than a score of 1.5 (Appendix 5)) was present in which case the patch strip would have been cut and the relevant square/s not re-applied. Assessment of patch sites was immediately before application of the next patch on Days 3 and 5 and on Day 8.

### 3.4 Assessment of patch sites

J Sowerbutts assessed all patch sites for the duration of the study according to the scoring scale in Appendix 5.

Illumination of the patch sites was by a 60 watt pearl bulb approximately 30 cm from the site. All examinations were conducted with the subject's arm in a relaxed position at the side.

## 4. Evaluation of results

Irritation from the repeated application of test articles to the same site would have been evidenced by increasing levels of erythema.

For statistical analysis, if a subject was not repatched at any site (due to a score in excess of 1.5) then the scores for all sites were carried forward from that assessment for the remainder of the study. Both the original and adapted versions of the data were kept.

The adapted data was then analysed statistically by the sponsor using the mixed procedure in the SAS software, which computes models containing both fixed and random effects. The subjects were defined as random effects. The analysis was repeated three times for each test day (day 3, 5, 8) separately.

The mildness of the products was tested against the positive and negative control. The zero hypothesis ( $H_0$ ) for the test product and the controls were respectively defined as:

- Product under test is as mild as de-ionised water (negative control);
- Product under test is as harsh as 0.3% SLS in water (positive control).

The data analysis consisted of two steps. First the F-test was performed for the significance of the fixed effect (product). Finally each product was compared against both positive and negative control by a one tailed t-test. The significance was adjusted according to the Dunnett's procedure. The comparison was based on the difference between the least squares means.



## 5. Adverse events

An adverse event would have been anything untoward which happened to one of the subjects during the study, whether or not it was related to the administration of one of the test articles.

An adverse reaction to a test article would have been an adverse event occurring after the administration of the test article which was or may have been causally related to that of administration.

Every adverse event would have been recorded and then classified as Serious or Non-Serious.

### 5.1 Classification

An adverse event is NON-SERIOUS (sub-classified as Mild, Moderate or Severe) unless it fell into one or more of the following categories when it would be classified as SERIOUS.

The event:

- was fatal, life threatening, permanently disabling or incapacitating.
- required prolonged in-patient hospitalisation.
- was a congenital anomaly, cancer or overdose of the test article.
- required the withdrawal of the subject from the study in circumstances not foreseen in the protocol.
- was clinically significant, thought to be related to the test article and was not explained by the known pharmacology.

Maximum intensity of SERIOUS adverse events are assigned to one of the following categories:

- Mild: For example, an adverse event which was easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.
- Moderate: For example, an adverse event which was sufficiently discomforting to interfere with normal everyday activities.
- Severe: For example, an adverse event which prevented normal everyday activities.

### 5.2 Reporting of adverse events

In the event of a SERIOUS adverse event, the type, onset, severity, duration and outcome would have been recorded on an Adverse Event Form and the Sponsor notified within one working day with a written report following immediately. The significance of the event would have been discussed between the Medical Advisor and the Sponsor but the Medical Advisor would have reserved the right to withhold further administration pending further information and discussion. The subject's general practitioner would also have been informed as soon as was reasonably practicable.

The Ethics Committee would have been informed of any Serious Adverse Events in due course.

All adverse events would have been listed in the results section of this report.

### 5.3 Withdrawals

The participation of a subject in this study may have been discontinued for any of the following reasons:

- the subject wished to withdraw.
- if, in the opinion of the Study Director/Medical Advisor, it was in the best interests of the subject.
- adverse effects from the test article.
- intercurrent illness.
- violation of the prohibitions and restrictions (see 2.4)
- development of an exclusion criterion.

Subjects were free to withdraw from the study at any time and need not have given a reason, but every reasonable attempt would have been made to ascertain such reasons. The data for any subjects who had withdrawn from the study would have been included in this report.

## 6. Archives

All data relating to this study and a copy of the signed final report will be stored in Globecrown's Archives located at Arkheion, 13b Ouse Road, Bicton Industrial Park, Kimbolton, Huntingdon, Cambridgeshire, PE18 0LP, England for a minimum period of fifteen years.

## 7. Ethics review

Written approval of the study protocol, informed consent and Subject Information Sheets was obtained from an independent Ethics Committee for Globecrown prior to the commencement of the study (Appendix 6). The study was conducted in accordance with the Declaration of Helsinki (1964) and subsequent amendments.

8. References

EC: Good Clinical Practice for Trials on Medicinal Products in the European Community  
111/3976/88-EN. 1 July 1991.

Recommendations guiding physicians in biomedical research involving human subjects (Declaration of Helsinki). Amended by 41st World Medical Assembly, Hong Kong, September 1989.

## RESULTS

### 1. Location and dates of the study

The study was performed at The Royal British Legion Hall, Great Baddow, Chelmsford, Essex, England, between 7 April 1997 and 14 April 1997.

### 2. Subjects (Figure 1)

Thirty subjects of both sexes were recruited into and completed the study. The age and sex composition of these subjects is presented in Figure 1.

### 3. Adverse events, adverse reactions and subjects not completing the study

No adverse events or reactions were reported and the study was completed by all subjects.

### 4. Assessments (Table 1, Appendices 6-15)

Mean assessment scores and their standard deviations are presented in Table 1. Individual reactions to test articles are presented in Appendices 6 to 15.

From the original data it can be seen that *Isostearyl Isostearate* and *Polyglyceryl-2 Isostearate* elicited no more than minimal irritation. *Polyglyceryl-2 Isostearate* elicited some irritation in the panel, whilst *Isostearyl Isostearate* elicited irritation in a large proportion of the panel.

### 5. Statistical analysis (Appendices 6-16)

Individual data adapted for statistical analysis is presented with the original data in Appendices 5-15, the results of the statistical analysis are presented in Appendix 16.

The statistical analysis revealed that *Isostearyl Isostearate* and *Polyglyceryl-2 Isostearate* were not significantly different in irritancy from the negative control (de-ionised water) whilst being significantly less irritant than the positive control (0.3% SLS solution) at the  $p=0.05$  level, on all study days.

*Isostearyl Isostearate* were significantly less irritant than the positive control at the  $p=0.05$  level on all study days, however, they were significantly more irritant than the negative control on day 8 at the  $p=0.05$  level.

*Polyglyceryl-2 Isostearate* were significantly less irritant than the positive control at the  $p=0.05$  level, however, they were also significantly more irritant than the negative control on all study days at the  $p=0.05$  level.

*Isostearyl Isostearate* was significantly more irritant than the negative control at the  $p=0.05$  level and was also not significantly different in irritancy from the positive control at the  $p=0.05$  level, on all study days.

97/UNCPAT6

### CONCLUSIONS

It can be concluded from the results that whilst ~~the results~~ *Polyglyceryl-2 Isostearate* elicited no more than minimal irritation. Where as *Polyglyceryl-2 Isostearate* elicited slight irritation, whilst *Polyglyceryl-2 Isostearate* elicited definite irritation.

PAGE 1 OF 19 PAGES



*Polyglyceryl-4 Laurate Sebacate*  
**DETERMINATION OF SKIN IRRITATION POTENTIAL USING  
THE EPIKIN™ RECONSTITUTED HUMAN EPIDERMIS MODEL**

**PROJECT NUMBER: 2724/0056**

**AUTHOR:** N Warren

**STUDY SPONSOR:**

**TEST FACILITY:**

Harlan Laboratories Ltd  
Shardlow Business Park  
Shardlow  
Derbyshire  
DE72 2GD  
UK

Telephone: +44 (0) 1332 792896

Facsimile: +44 (0) 1332 799018

2724-0056.doc/JS

## QUALITY ASSURANCE REPORT

This study type is classed as short-term. The standard test method for this study type ("General Study Plan" in OECD terminology) was reviewed for compliance once only on initial production. Inspection of the routine and repetitive procedures that constitute the study is carried out as a continuous process designed to encompass the major phases at or about the time this study was in progress. In addition, inspection of general facilities not specifically related to this study are done monthly or annually in accordance with QA Standard Procedure.

This report has been audited by the Quality Assurance Unit, and is considered to be an accurate account of the data generated and of the procedures followed.

In each case, the outcome of QA evaluation is reported to the Study Director and Management on the day of evaluation. Audits of study documentation, and process inspections appropriate to the type and schedule of this study were as follows:

19 November 2008	Standard Test Method Compliance Audit
03 June 2010	Test Material Preparation
02 June 2010	Test System Preparation
03 June 2010	Exposure
11 June 2010	Assessment of Response
§ 26 July 2010	Draft Report Audit
§ Date of QA Signature	Final Report Audit
§ Evaluation specific to this study	



For the Quality Assurance Unit\*

DATE: 13 AUG 2010

---

**\*Authorised QA Signatures:**

Senior Audit Staff:

J G Riley BSc (Hons) MRQA, J M Crowther MScT MRQA,  
G Wren ONC MRQA, S Bevan BSc (Hons) MRQA, L Blaney MRQA

**GLP COMPLIANCE STATEMENT**

The work described was performed in compliance with UK GLP standards (Schedule 1, Good Laboratory Practice Regulations 1999 (SI 1999/3106 as amended by SI 2004/0994)). These Regulations are in accordance with GLP standards published as OECD Principles on Good Laboratory Practice (revised 1997, ENV/MC/CHEM(98)17); and are in accordance with, and implement, the requirements of Directives 2004/9/EC and 2004/10/EC.

This report fully and accurately reflects the procedures used and data generated.

.....*N. Warren*..... DATE: .....*12/8/2010*.....  
N Warren MIAT  
Study Director

This report may be presented in final form as a digital (pdf) document. Such documents are prepared by scanning the paper original, and are considered of equivalent integrity and authenticity to versions produced by optical photocopy. However, in all cases the hand-signed paper original, held in secure archives, is the definitive document.



## DETERMINATION OF SKIN IRRITATION POTENTIAL USING THE EPISKIN™ RECONSTITUTED HUMAN EPIDERMIS MODEL

### SUMMARY

**Introduction:** The purpose of this test was to evaluate the skin irritation potential of the test material using the EPISKIN™ reconstituted human epidermis model after a treatment period of 15 minutes followed by a post-exposure incubation period of 42 hours. The principle of the assay was based on the measurement of cytotoxicity in reconstituted human epidermal cultures following topical exposure to the test material by means of the colourimetric MTT reduction assay. Cell viability is measured by enzymatic reduction of the yellow MTT tetrazolium salt (3-[4,5-dimethylthiazol-2-yl]-2,5-diphenyl-tetrazolium bromide) to a blue formazan salt (within the mitochondria of viable cells) in the test material treated tissues relative to the negative controls. The concentration of the inflammatory mediator IL-1 $\alpha$  in the culture medium retained following the 42-Hour post-exposure incubation period is also determined for test materials which are found to be borderline non-irritant based upon the MTT reduction endpoint. This complimentary end-point will be used to either confirm a non-irritant result or will be used to override the non-irritant result.

**Method:** Triplicate tissues were treated with the test material for an exposure period of 15 minutes. At the end of the exposure period each tissue was rinsed before incubating for approximately 42 hours. At the end of the post-exposure incubation period each tissue was taken for MTT-loading. The maintenance medium from beneath each tissue was transferred to pre-labelled micro tubes and stored in a freezer for possible inflammatory mediator determination. After MTT loading a total biopsy of each epidermis was made and placed into micro tubes containing acidified isopropanol for extraction of formazan crystals out of the MTT-loaded tissues.

At the end of the formazan extraction period each tube was mixed thoroughly and duplicate 200  $\mu$ l samples were transferred to the appropriate wells of a pre-labelled 96-well plate. The optical density was measured at 540 nm.

Data are presented in the form of percentage viability (MTT reduction in the test material treated tissues relative to negative control tissues).

**Results:** The relative mean viability of the test material treated tissues was 105.4% after the 15-Minute exposure period.

**Quality criteria:** The quality criteria required for acceptance of results in the test were satisfied.

**Conclusion:** The test material was considered to be Non-Irritant (NI).

PAGE 1 OF 19 PAGES



*Polyglyceryl-4 Laurate Sebacate*  
**ASSESSMENT OF OCULAR IRRITATION POTENTIAL USING THE  
SKINETHIC RECONSTITUTED HUMAN CORNEAL EPITHELIUM MODEL**

**PROJECT NUMBER: 2724/0059**

**AUTHOR:** N Warren

**STUDY SPONSOR:**

**TEST FACILITY:**

Harlan Laboratories Ltd  
Shardlow Business Park  
Shardlow  
Derbyshire  
DE72 2GD  
UK

Telephone: +44 (0) 1332 792896

Facsimile: +44 (0) 1332 799018

## QUALITY ASSURANCE REPORT

This study type is classed as short-term. The standard test method for this study type ("General Study Plan" in OECD terminology) was reviewed for compliance once only on initial production. Inspection of the routine and repetitive procedures that constitute the study is carried out as a continuous process designed to encompass the major phases at or about the time this study was in progress. In addition, inspection of general facilities not specifically related to this study are done monthly or annually in accordance with QA Standard Procedure.

This report has been audited by the Quality Assurance Unit, and is considered to be an accurate account of the data generated and of the procedures followed.

In each case, the outcome of QA evaluation is reported to the Study Director and Management on the day of evaluation. Audits of study documentation, and process inspections appropriate to the type and schedule of this study were as follows:

19 November 2008	Standard Test Method Compliance Audit
15 July 2010	Test Material Preparation
06 July 2010	Test System Preparation
15 July 2010	Exposure
16 July 2010	Assessment of Response
§ 03 September 2010	Draft Report Audit
§ Date of QA Signature	Final Report Audit
§ Evaluation specific to this study	


 DATE: 22 SEP 2010  
 For the Quality Assurance Unit\*

\*Authorised QA Signatures:  
Senior Audit Staff:

J G Riley BSc (Hons) MRQA, J M Crowther MScT MRQA,  
G Wren ONC MRQA, S Bevan BSc (Hons) MRQA, L Blaney MRQA

### GLP COMPLIANCE STATEMENT

The work described was performed in compliance with UK GLP standards (Schedule 1, Good Laboratory Practice Regulations 1999 (SI 1999/3106 as amended by SI 2004/0994)). These Regulations are in accordance with GLP standards published as OECD Principles on Good Laboratory Practice (revised 1997, ENV/MC/CHEM(98)17); and are in accordance with, and implement, the requirements of Directives 2004/9/EC and 2004/10/EC.

This report fully and accurately reflects the procedures used and data generated.

.....*N Warren*..... DATE: .....*21/9/2010*.....

N Warren MIAT  
Study Director

This report may be presented in final form as a digital (pdf) document. Such documents are prepared by scanning the paper original, and are considered of equivalent integrity and authenticity to versions produced by optical photocopy. However, in all cases the hand-signed paper original, held in secure archives, is the definitive document.

## ASSESSMENT OF OCULAR IRRITATION POTENTIAL USING THE SKINETHIC RECONSTITUTED HUMAN CORNEAL EPITHELIUM MODEL

### SUMMARY

**Introduction.** The purpose of this study was to determine the eye irritation potential of the test material using the SkinEthic Reconstituted Human Corneal model (HCE, SkinEthic Laboratories, Nice, France) after a treatment period of 10 minutes. The test is based on the hypothesis that irritant chemicals are able to penetrate the corneal epithelial tissue and are sufficiently cytotoxic to cause cell death.

**Methods.** The experimental design of the study consists of a test for direct reduction of MTT (3-[4,5-dimethylthiazol-2-yl]-2,5-diphenyl-tetrazolium bromide) by the test material followed by the main test.

For the main test, triplicate SkinEthic tissues were treated with 30 µl of the test material for 10 minutes. Triplicate tissues treated with 30 µl of Solution A served as the negative control and triplicate tissues treated with 30 µl of 1% w/v Sodium Dodecyl Sulphate served as the positive control.

At the end of the exposure period each SkinEthic tissue was rinsed. The rinsed tissues (two per group) were taken for MTT loading. The remaining tissues were retained for possible histopathology. Following MTT loading the reduced MTT was extracted from the tissues.

After extraction the absorbency of triplicate aliquots of the extracted MTT solution for each SkinEthic tissue was measured. The optical density was measured at 540 nm (OD<sub>540</sub>). Data are presented in the form of percentage viability (MTT conversion relative to negative controls).

The test material was classified according to the following criteria:

- i) If the percentage relative mean tissue viability was  $\geq 60\%$  the test material was considered to be non-irritant (NI).
- ii) If the percentage relative mean tissue viability was  $< 60\%$  the test material was considered to be an irritant (I).

**Results.** The relative mean viability of the test material treated tissues after a 10 minute exposure was 85.9%.

It was considered unnecessary to proceed with tissue histopathology.

**Quality criteria.** The quality criteria required for acceptance of results in the test were satisfied.

**Conclusion.** According to the protocol followed the test material was considered to be a Non-Irritant (NI).

PAGE 1 OF 25 PAGES



---  
*Polyglyceryl-4 Laurate Succinate*  
**REVERSE MUTATION ASSAY "AMES TEST"**  
**USING *SALMONELLA* TYPHIMURIUM AND**  
***ESCHERICHIA COLI***

**PROJECT NUMBER: 41003617**

**AUTHOR:** P W Thompson

**STUDY SPONSOR:**

Green Europe Ltd

101  
101 101

**TEST FACILITY:**

Harlan Laboratories Ltd  
Shardlow Business Park  
Shardlow  
Derbyshire  
DE72 2GD  
UK

Telephone: +44 (0) 1332 792896

Facsimile: +44 (0) 1332 799018



## QUALITY ASSURANCE REPORT

This study type is classed as short-term. The General Study Plan for this study type was reviewed for compliance once only on initial production. Inspection of the routine and repetitive procedures that constitute the study is carried out as a continuous process designed to encompass the major phases at or about the time this study was in progress. In addition, inspection of general facilities not specifically related to this study are done monthly or annually in accordance with QA Standard Procedure.

This report has been audited by the Quality Assurance Unit, and is considered to be an accurate account of the data generated and of the procedures followed.

In each case, the outcome of QA evaluation is reported to the Study Director and Management on the day of evaluation. Audits of study documentation, and process inspections appropriate to the type and schedule of this study were as follows:

28 May 2010	General Study Plan Compliance Audit
28 September 2010	Test Item Preparation
07 September 2010	Test System Preparation
24 September 2010	Exposure
24 September 2010	Assessment of Response
§ 08 November 2010	Draft Report Audit
§ Date of QA Signature	Final Report Audit

§ Evaluation specific to this study



For the Quality Assurance Unit\*

DATE: 24 NOV 2010

### \*Authorised QA Signatures:

Senior Audit Staff:

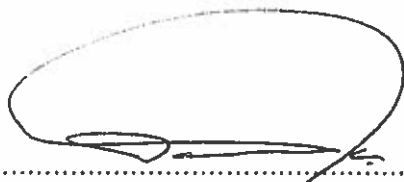
J G Riley BSc (Hons) MRQA, J M Crowther MIScT MRQA,  
G Wren ONC MRQA, S Bevan BSc (Hons) MRQA, L Blaney MRQA

### GLP COMPLIANCE STATEMENT

With the exception noted below the work described was performed in compliance with UK GLP standards (Schedule 1, Good Laboratory Practice Regulations 1999 (SI 1999/3106 as amended by SI 2004/0994)). These Regulations are in accordance with GLP standards published as OECD Principles on Good Laboratory Practice (revised 1997, ENV/MC/CHEM(98)17); and are in accordance with, and implement, the requirements of Directives 2004/9/EC and 2004/10/EC.

No analysis was carried out to determine the homogeneity, concentration or stability of the test item formulation. The test item was formulated within four hours of it being applied to the test system. It is assumed that the formulation was stable for this duration. This exception is considered not to affect the purpose or integrity of the study.

This report fully and accurately reflects the procedures used and data generated.



DATE: 24 NOV 2010

P W Thompson HNC  
Study Director

**REVERSE MUTATION ASSAY "AMES TEST"  
USING *SALMONELLA* TYPHIMURIUM AND  
*ESCHERICHIA COLI***

**SUMMARY**

**Introduction.** The test method was designed to be compatible with the guidelines for bacterial mutagenicity testing published by the major Japanese Regulatory Authorities including METI, MHLW and MAFF, the OECD Guidelines for Testing of Chemicals No. 471 "Bacterial Reverse Mutation Test", Method B13/14 of Commission Regulation (EC) number 440/2008 of 30 May 2008 and the USA, EPA (TSCA) OPPTS harmonised guidelines.

**Methods.** *Salmonella typhimurium* strains TA1535, TA1537, TA98, TA100 and *Escherichia coli* strain WP2uvrA were treated with the test item using both the Ames plate incorporation and pre-incubation methods at up to seven dose levels, in triplicate, both with and without the addition of a rat liver homogenate metabolising system (10% liver S9 in standard co-factors). The dose range was determined in a preliminary toxicity assay and was 15 to 5000 µg/plate in the first experiment. The experiment was repeated on a separate day (pre-incubation method) using fresh cultures of the bacterial strains and fresh test item formulations. Following the results of Experiment 1 and the change in test methodology for Experiment 2, the test item dose range was amended slightly and ranged between 1.5 and 5000 µg/plate, depending on bacterial strain type and presence or absence of S9-mix.

Additional dose levels and an expanded dose range were selected in both experiments in order to achieve both four non-toxic dose levels and the toxic limit of the test item.

**Results.** The vehicle (sterile distilled water) control plates gave counts of revertant colonies within the normal range. All of the positive control reference items used in the test induced marked increases in the frequency of revertant colonies, both with or without metabolic activation. Thus, the sensitivity of the assay and the efficacy of the S9-mix were validated.

In the first experiment (plate incorporation method) the test item caused a visible reduction in the growth of the bacterial background lawns and/or a substantial reduction in the revertant colony frequency of all of the *Salmonella* strains at 5000 µg/plate in both the presence and absence of S9-mix. In the second experiment (pre-incubation method) the test item induced a slightly stronger toxic response with weakened bacterial

background lawns initially noted to TA100 and TA1537 (absence of S9-mix) at 500 µg/plate and either weakened bacterial lawns or reductions in colony frequency noted at 1500 µg/plate to TA1535 (absence and presence of S9-mix) and TA100 (presence of S9-mix). No toxicity was noted to *Escherichia coli* strain WP2uvrA with either exposure method (plate incorporation or pre-incubation) at any test item dose level in either the presence or absence of S9-mix. The test item was tested up to either the maximum recommended dose level of 5000 µg/plate or the toxic limit, depending on bacterial strain type, presence or absence of S9-mix and experiment number. A test item precipitate (oily in appearance) was noted at 5000 µg/plate, this observation did not prevent the scoring of revertant colonies.

No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test item, either with or without metabolic activation or exposure method.

**Conclusion.** The test item was considered to be non-mutagenic under the conditions of this test.

PAGE 1 OF 19 PAGES



*Polyglyceryl-4 Laurate Succinate*  
**DETERMINATION OF SKIN IRRITATION POTENTIAL USING  
THE EPIKIN™ RECONSTITUTED HUMAN EPIDERMIS MODEL**

**PROJECT NUMBER: 2724/0055**

**AUTHOR:** N Warren

**STUDY SPONSOR:**

**TEST FACILITY:**

Harlan Laboratories Ltd  
Shardlow Business Park  
Shardlow  
Derbyshire  
DE72 2GD  
UK

Telephone: +44 (0) 1332 792896

Facsimile: +44 (0) 1332 799018

2724-0055.doc/JS

## QUALITY ASSURANCE REPORT


This study type is classed as short-term. The standard test method for this study type ("General Study Plan" in OECD terminology) was reviewed for compliance once only on initial production. Inspection of the routine and repetitive procedures that constitute the study is carried out as a continuous process designed to encompass the major phases at or about the time this study was in progress. In addition, inspection of general facilities not specifically related to this study are done monthly or annually in accordance with QA Standard Procedure.

This report has been audited by the Quality Assurance Unit, and is considered to be an accurate account of the data generated and of the procedures followed.

In each case, the outcome of QA evaluation is reported to the Study Director and Management on the day of evaluation. Audits of study documentation, and process inspections appropriate to the type and schedule of this study were as follows:

19 November 2008	Standard Test Method Compliance Audit
03 June 2010	Test Material Preparation
02 June 2010	Test System Preparation
03 June 2010	Exposure
11 June 2010	Assessment of Response
§ 26 July 2010	Draft Report Audit
§ Date of QA Signature	Final Report Audit

§ Evaluation specific to this study



For the Quality Assurance Unit\*

DATE: 13 AUG 2010

### \*Authorised QA Signatures:

Senior Audit Staff:

J G Riley BSc (Hons) MRQA, J M Crowther MSc MRQA,  
G Wren ONC MRQA, S Bevan BSc (Hons) MRQA, L Blaney MRQA

### GLP COMPLIANCE STATEMENT

The work described was performed in compliance with UK GLP standards (Schedule 1, Good Laboratory Practice Regulations 1999 (SI 1999/3106 as amended by SI 2004/0994)). These Regulations are in accordance with GLP standards published as OECD Principles on Good Laboratory Practice (revised 1997, ENV/MC/CHEM(98)17); and are in accordance with, and implement, the requirements of Directives 2004/9/EC and 2004/10/EC.

This report fully and accurately reflects the procedures used and data generated.

..... *N. Warren* ..... DATE: ..... *12/8/2010* .....  
N Warren MIAT  
Study Director

This report may be presented in final form as a digital (pdf) document. Such documents are prepared by scanning the paper original, and are considered of equivalent integrity and authenticity to versions produced by optical photocopy. However, in all cases the hand-signed paper original, held in secure archives, is the definitive document.

## DETERMINATION OF SKIN IRRITATION POTENTIAL USING THE EPISKIN™ RECONSTITUTED HUMAN EPIDERMIS MODEL

### SUMMARY

**Introduction:** The purpose of this test was to evaluate the skin irritation potential of the test material using the EPISKIN™ reconstituted human epidermis model after a treatment period of 15 minutes followed by a post-exposure incubation period of 42 hours. The principle of the assay was based on the measurement of cytotoxicity in reconstituted human epidermal cultures following topical exposure to the test material by means of the colourimetric MTT reduction assay. Cell viability is measured by enzymatic reduction of the yellow MTT tetrazolium salt (3-[4,5-dimethylthiazol-2-yl]-2,5-diphenyl-tetrazolium bromide) to a blue formazan salt (within the mitochondria of viable cells) in the test material treated tissues relative to the negative controls. The concentration of the inflammatory mediator IL-1 $\alpha$  in the culture medium retained following the 42-Hour post-exposure incubation period is also determined for test materials which are found to be borderline non-irritant based upon the MTT reduction endpoint. This complimentary end-point will be used to either confirm a non-irritant result or will be used to override the non-irritant result.

**Method:** Triplicate tissues were treated with the test material for an exposure period of 15 minutes. At the end of the exposure period each tissue was rinsed before incubating for approximately 42 hours. At the end of the post-exposure incubation period each tissue was taken for MTT-loading. The maintenance medium from beneath each tissue was transferred to pre-labelled micro tubes and stored in a freezer for possible inflammatory mediator determination. After MTT loading a total biopsy of each epidermis was made and placed into micro tubes containing acidified isopropanol for extraction of formazan crystals out of the MTT-loaded tissues.

At the end of the formazan extraction period each tube was mixed thoroughly and duplicate 200  $\mu$ l samples were transferred to the appropriate wells of a pre-labelled 96-well plate. The optical density was measured at 540 nm.

Data are presented in the form of percentage viability (MTT reduction in the test material treated tissues relative to negative control tissues).



**Results:** The relative mean viability of the test material treated tissues was 104.1% after the 15-Minute exposure period.

**Quality criteria:** The quality criteria required for acceptance of results in the test were satisfied.

**Conclusion:** The test material was considered to be Non-Irritant (NI).

PAGE 1 OF 19 PAGES



*Polyglyceryl-4 Laurate Succinate*  
**ASSESSMENT OF OCULAR IRRITATION POTENTIAL USING THE  
SKINETHIC RECONSTITUTED HUMAN CORNEAL EPITHELIUM MODEL**

**PROJECT NUMBER: 2724/0058**

**AUTHOR:** N Warren

**STUDY SPONSOR:**

...

**TEST FACILITY:**

Harlan Laboratories Ltd  
Shardlow Business Park  
Shardlow  
Derbyshire  
DE72 2GD  
UK

Telephone: +44 (0) 1332 792896

Facsimile: +44 (0) 1332 799018

## QUALITY ASSURANCE REPORT

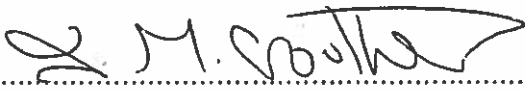
This study type is classed as short-term. The standard test method for this study type ("General Study Plan" in OECD terminology) was reviewed for compliance once only on initial production. Inspection of the routine and repetitive procedures that constitute the study is carried out as a continuous process designed to encompass the major phases at or about the time this study was in progress. In addition, inspection of general facilities not specifically related to this study are done monthly or annually in accordance with QA Standard Procedure.

This report has been audited by the Quality Assurance Unit, and is considered to be an accurate account of the data generated and of the procedures followed.

In each case, the outcome of QA evaluation is reported to the Study Director and Management on the day of evaluation. Audits of study documentation, and process inspections appropriate to the type and schedule of this study were as follows:

19 November 2008	Standard Test Method Compliance Audit
15 July 2010	Test Material Preparation
06 July 2010	Test System Preparation
15 July 2010	Exposure
16 July 2010	Assessment of Response
§ 03 September 2010	Draft Report Audit
§ Date of QA Signature	Final Report Audit

§ Evaluation specific to this study

 DATE: 22 SEP 2010  
For the Quality Assurance Unit\*

\*Authorised QA Signatures:  
Senior Audit Staff:

J G Riley BSc (Hons) MRQA, J M Crowther MScT MRQA,  
G Wren ONC MRQA, S Bevan BSc (Hons) MRQA, L Blaney MRQA

### GLP COMPLIANCE STATEMENT

The work described was performed in compliance with UK GLP standards (Schedule 1, Good Laboratory Practice Regulations 1999 (SI 1999/3106 as amended by SI 2004/0994)). These Regulations are in accordance with GLP standards published as OECD Principles on Good Laboratory Practice (revised 1997, ENV/MC/CHEM(98)17); and are in accordance with, and implement, the requirements of Directives 2004/9/EC and 2004/10/EC.

This report fully and accurately reflects the procedures used and data generated.

.....*N. Warren*..... DATE: .....*21/9/2010*.....

N Warren MIAT  
Study Director

This report may be presented in final form as a digital (pdf) document. Such documents are prepared by scanning the paper original, and are considered of equivalent integrity and authenticity to versions produced by optical photocopy. However, in all cases the hand-signed paper original, held in secure archives, is the definitive document.

## ASSESSMENT OF OCULAR IRRITATION POTENTIAL USING THE SKINETHIC RECONSTITUTED HUMAN CORNEAL EPITHELIUM MODEL

### SUMMARY

**Introduction.** The purpose of this study was to determine the eye irritation potential of the test material using the SkinEthic Reconstituted Human Corneal model (HCE, SkinEthic Laboratories, Nice, France) after a treatment period of 10 minutes. The test is based on the hypothesis that irritant chemicals are able to penetrate the corneal epithelial tissue and are sufficiently cytotoxic to cause cell death.

**Methods.** The experimental design of the study consists of a test for direct reduction of MTT (3-[4,5-dimethylthiazol-2-yl]-2,5-diphenyl-tetrazolium bromide) by the test material followed by the main test.

For the main test, triplicate SkinEthic tissues were treated with 30 µl of the test material for 10 minutes. Triplicate tissues treated with 30 µl of Solution A served as the negative control and triplicate tissues treated with 30 µl of 1% w/v Sodium Dodecyl Sulphate served as the positive control.

At the end of the exposure period each SkinEthic tissue was rinsed. The rinsed tissues (two per group) were taken for MTT loading. The remaining tissues were retained for possible histopathology. Following MTT loading the reduced MTT was extracted from the tissues.

After extraction the absorbency of triplicate aliquots of the extracted MTT solution for each SkinEthic tissue was measured. The optical density was measured at 540 nm (OD<sub>540</sub>). Data are presented in the form of percentage viability (MTT conversion relative to negative controls).

The test material was classified according to the following criteria:

- i) If the percentage relative mean tissue viability was  $\geq 60\%$  the test material was considered to be non-irritant (NI).
- ii) If the percentage relative mean tissue viability was  $< 60\%$  the test material was considered to be an irritant (I).

**Results.** The relative mean viability of the test material treated tissues after a 10 minute exposure was 70.0%.

It was considered unnecessary to proceed with tissue histopathology.

**Quality criteria.** The quality criteria required for acceptance of results in the test were satisfied.

**Conclusion.** According to the protocol followed the test material was considered to be a Non-Irritant (NI).

PAGE 1 OF 25 PAGES



*Polyglyceryl-6 Caprylate Caprate*  
**REVERSE MUTATION ASSAY "AMES TEST"**  
**USING *SALMONELLA* TYPHIMURIUM AND**  
***ESCHERICHIA COLI***

**PROJECT NUMBER: 41003618**

**AUTHOR:** P W Thompson

**STUDY SPONSOR:**

**TEST FACILITY:**

Harlan Laboratories Ltd  
Shardlow Business Park  
Shardlow  
Derbyshire  
DE72 2GD  
UK

Telephone: +44 (0) 1332 792896

Facsimile: +44 (0) 1332 799018

41003618.doc/MsOffice

## QUALITY ASSURANCE REPORT

This study type is classed as short-term. The General Study Plan for this study type was reviewed for compliance once only on initial production. Inspection of the routine and repetitive procedures that constitute the study is carried out as a continuous process designed to encompass the major phases at or about the time this study was in progress. In addition, inspection of general facilities not specifically related to this study are done monthly or annually in accordance with QA Standard Procedure.

This report has been audited by the Quality Assurance Unit, and is considered to be an accurate account of the data generated and of the procedures followed.

In each case, the outcome of QA evaluation is reported to the Study Director and Management on the day of evaluation. Audits of study documentation, and process inspections appropriate to the type and schedule of this study were as follows:

28 May 2010	General Study Plan Compliance Audit
28 September 2010	Test Item Preparation
07 September 2010	Test System Preparation
24 September 2010	Exposure
24 September 2010	Assessment of Response
§ 08 November 2010	Draft Report Audit
§ Date of QA Signature	Final Report Audit

§ Evaluation specific to this study



For the Quality Assurance Unit\*

DATE: 24 NOV 2010

\*Authorised QA Signatures:  
Senior Audit Staff:

J G Riley BSc (Hons) MRQA, J M Crowther MScT MRQA,  
G Wren ONC MRQA, S Bevan BSc (Hons) MRQA, L Blaney MRQA

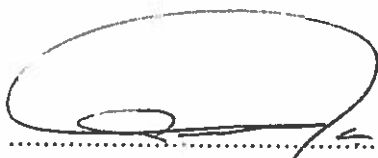


### GLP COMPLIANCE STATEMENT

With the exception noted below the work described was performed in compliance with UK GLP standards (Schedule 1, Good Laboratory Practice Regulations 1999 (SI 1999/3106 as amended by SI 2004/0994)). These Regulations are in accordance with GLP standards published as OECD Principles on Good Laboratory Practice (revised 1997, ENV/MC/CHEM(98)17); and are in accordance with, and implement, the requirements of Directives 2004/9/EC and 2004/10/EC.

No analysis was carried out to determine the homogeneity, concentration or stability of the test item formulation. The test item was formulated within four hours of it being applied to the test system. It is assumed that the formulation was stable for this duration. This exception is considered not to affect the purpose or integrity of the study.

This report fully and accurately reflects the procedures used and data generated.



P W Thompson HNC  
Study Director

DATE: 24 NOV 2010

This report may be presented in final form as a digital (pdf) document. Such documents are prepared by scanning the paper original, and are considered of equivalent integrity and authenticity to versions produced by optical photocopy. However, in all cases the hand-signed paper original, held in secure archives, is the definitive document.

**REVERSE MUTATION ASSAY "AMES TEST"  
USING *SALMONELLA TYPHIMURIUM* AND  
*ESCHERICHIA COLI***

**SUMMARY**

**Introduction.** The test method was designed to be compatible with the guidelines for bacterial mutagenicity testing published by the major Japanese Regulatory Authorities including METI, MHLW and MAFF, the OECD Guidelines for Testing of Chemicals No. 471 "Bacterial Reverse Mutation Test", Method B13/14 of Commission Regulation (EC) number 440/2008 of 30 May 2008 and the USA, EPA (TSCA) OPPTS harmonised guidelines.

**Methods.** *Salmonella typhimurium* strains TA1535, TA1537, TA98, TA100 and *Escherichia coli* strain WP2uvrA were treated with the test item using both the Ames plate incorporation and pre-incubation methods at up to seven dose levels, in triplicate, both with and without the addition of a rat liver homogenate metabolising system (10% liver S9 in standard co-factors). The dose range was determined in a preliminary toxicity assay and was 15 to 5000 µg/plate in the first experiment. The experiment was repeated on a separate day (pre-incubation method) using fresh cultures of the bacterial strains and fresh test item formulations. Following the results of Experiment 1 and the change in test methodology for Experiment 2, the test item dose range was amended slightly and ranged between 0.15 and 5000 µg/plate, depending on bacterial strain type and presence or absence of S9-mix.

Additional dose levels and an expanded dose range were selected in both experiments in order to achieve both four non-toxic dose levels and the toxic limit of the test item.

**Results.** The vehicle (sterile distilled water) control plates gave counts of revertant colonies within the normal range. All of the positive control reference items used in the test induced marked increases in the frequency of revertant colonies, both with or without metabolic activation. Thus, the sensitivity of the assay and the efficacy of the S9-mix were validated.

In the first experiment (plate incorporation method) the test item caused a visible reduction in the growth of the bacterial background lawns of all of the *Salmonella* strains at and above 1500 µg/plate in the absence of S9-mix only. In the second experiment (pre-incubation method) the test item induced a much stronger toxic response with weakened bacterial background lawns initially noted at 50 and 1500 µg/plate (TA100 in

the absence and presence of S9-mix, respectively). The sensitivity of the tester strains to the toxicity of the test item varied between strain type, exposures with or without S9-mix and experimental methodology. The test item was tested up to either the maximum recommended dose level of 5000 µg/plate or the toxic limit, depending on bacterial strain type, presence or absence of S9-mix and experiment number. A test item precipitate (oily in appearance) was noted at and above 1500 µg/plate, this observation did not prevent the scoring of revertant colonies.

No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test item, either with or without metabolic activation or exposure method.

**Conclusion.** The test item was considered to be non-mutagenic under the conditions of this test.

PAGE 1 OF 19 PAGES



*Polyglyceryl-6 Caprylate Caprate*  
**DETERMINATION OF SKIN IRRITATION POTENTIAL USING  
THE EPIKIN™ RECONSTITUTED HUMAN EPIDERMIS MODEL**

**PROJECT NUMBER: 2724/0057**

**AUTHOR:** N Warren

**STUDY SPONSOR:**

**TEST FACILITY:**

Harlan Laboratories Ltd  
Shardlow Business Park  
Shardlow  
Derbyshire  
DE72 2GD  
UK

Telephone: +44 (0) 1332 792896

Facsimile: +44 (0) 1332 799018

2724-0057.doc/JS

## QUALITY ASSURANCE REPORT

This study type is classed as short-term. The standard test method for this study type ("General Study Plan" in OECD terminology) was reviewed for compliance once only on initial production. Inspection of the routine and repetitive procedures that constitute the study is carried out as a continuous process designed to encompass the major phases at or about the time this study was in progress. In addition, inspection of general facilities not specifically related to this study are done monthly or annually in accordance with QA Standard Procedure.

This report has been audited by the Quality Assurance Unit, and is considered to be an accurate account of the data generated and of the procedures followed.

In each case, the outcome of QA evaluation is reported to the Study Director and Management on the day of evaluation. Audits of study documentation, and process inspections appropriate to the type and schedule of this study were as follows:

19 November 2008	Standard Test Method Compliance Audit
03 June 2010	Test Material Preparation
02 June 2010	Test System Preparation
03 June 2010	Exposure
11 June 2010	Assessment of Response
§ 26 July 2010	Draft Report Audit
§ Date of QA Signature	Final Report Audit

§ Evaluation specific to this study


 DATE: 13 AUG 2010  
 For the Quality Assurance Unit\*

**\*Authorised QA Signatures:**  
Senior Audit Staff:

J G Riley BSc (Hons) MRQA, J M Crowther MIScT MRQA,  
G Wren ONC MRQA, S Bevan BSc (Hons) MRQA, L Blaney MRQA

**GLP COMPLIANCE STATEMENT**

The work described was performed in compliance with UK GLP standards (Schedule 1, Good Laboratory Practice Regulations 1999 (SI 1999/3106 as amended by SI 2004/0994)). These Regulations are in accordance with GLP standards published as OECD Principles on Good Laboratory Practice (revised 1997, ENV/MC/CHEM(98)17); and are in accordance with, and implement, the requirements of Directives 2004/9/EC and 2004/10/EC.

This report fully and accurately reflects the procedures used and data generated.

.....*N. Warren*..... DATE: .....*12/8/2010*.....  
N Warren MIAT  
Study Director

This report may be presented in final form as a digital (pdf) document. Such documents are prepared by scanning the paper original, and are considered of equivalent integrity and authenticity to versions produced by optical photocopy. However, in all cases the hand-signed paper original, held in secure archives, is the definitive document.

## DETERMINATION OF SKIN IRRITATION POTENTIAL USING THE EPISKIN™ RECONSTITUTED HUMAN EPIDERMIS MODEL

### SUMMARY

**Introduction:** The purpose of this test was to evaluate the skin irritation potential of the test material using the EPISKIN™ reconstituted human epidermis model after a treatment period of 15 minutes followed by a post-exposure incubation period of 42 hours. The principle of the assay was based on the measurement of cytotoxicity in reconstituted human epidermal cultures following topical exposure to the test material by means of the colourimetric MTT reduction assay. Cell viability is measured by enzymatic reduction of the yellow MTT tetrazolium salt (3-[4,5-dimethylthiazol-2-yl]-2,5-diphenyl-tetrazolium bromide) to a blue formazan salt (within the mitochondria of viable cells) in the test material treated tissues relative to the negative controls. The concentration of the inflammatory mediator IL-1 $\alpha$  in the culture medium retained following the 42-Hour post-exposure incubation period is also determined for test materials which are found to be borderline non-irritant based upon the MTT reduction endpoint. This complimentary end-point will be used to either confirm a non-irritant result or will be used to override the non-irritant result.

**Method:** Triplicate tissues were treated with the test material for an exposure period of 15 minutes. At the end of the exposure period each tissue was rinsed before incubating for approximately 42 hours. At the end of the post-exposure incubation period each tissue was taken for MTT-loading. The maintenance medium from beneath each tissue was transferred to pre-labelled micro tubes and stored in a freezer for possible inflammatory mediator determination. After MTT loading a total biopsy of each epidermis was made and placed into micro tubes containing acidified isopropanol for extraction of formazan crystals out of the MTT-loaded tissues.

At the end of the formazan extraction period each tube was mixed thoroughly and duplicate 200  $\mu$ l samples were transferred to the appropriate wells of a pre-labelled 96-well plate. The optical density was measured at 540 nm.

Data are presented in the form of percentage viability (MTT reduction in the test material treated tissues relative to negative control tissues).

**Results:** The relative mean viability of the test material treated tissues was 105.7% after the 15-Minute exposure period.

**Quality criteria:** The quality criteria required for acceptance of results in the test were satisfied.

**Conclusion:** The test material was considered to be Non-Irritant (NI).



*Polyglyceryl-6 Caprylate-Caprate*  
**ASSESSMENT OF OCULAR IRRITATION POTENTIAL USING THE  
SKINETHIC RECONSTITUTED HUMAN CORNEAL EPITHELIUM MODEL**

**PROJECT NUMBER: 2724/0060**

**AUTHOR:** N Warren

**STUDY SPONSOR:**

**TEST FACILITY:**

Harlan Laboratories Ltd  
Shardlow Business Park  
Shardlow  
Derbyshire  
DE72 2GD  
UK

Telephone: +44 (0) 1332 792896

Facsimile: +44 (0) 1332 799018

## QUALITY ASSURANCE REPORT

This study type is classed as short-term. The standard test method for this study type ("General Study Plan" in OECD terminology) was reviewed for compliance once only on initial production. Inspection of the routine and repetitive procedures that constitute the study is carried out as a continuous process designed to encompass the major phases at or about the time this study was in progress. In addition, inspection of general facilities not specifically related to this study are done monthly or annually in accordance with QA Standard Procedure.

This report has been audited by the Quality Assurance Unit, and is considered to be an accurate account of the data generated and of the procedures followed.

In each case, the outcome of QA evaluation is reported to the Study Director and Management on the day of evaluation. Audits of study documentation, and process inspections appropriate to the type and schedule of this study were as follows:

19 November 2008	Standard Test Method Compliance Audit
15 July 2010	Test Material Preparation
06 July 2010	Test System Preparation
15 July 2010	Exposure
16 July 2010	Assessment of Response
§ 03 September 2010	Draft Report Audit
§ Date of QA Signature	Final Report Audit
§ Evaluation specific to this study	


 DATE: 22 SEP 2010  
 For the Quality Assurance Unit\*

\*Authorised QA Signatures:  
Senior Audit Staff:

J G Riley BSc (Hons) MRQA, J M Crowther MScT MRQA,  
G Wren ONC MRQA, S Bevan BSc (Hons) MRQA, L Blaney MRQA

**GLP COMPLIANCE STATEMENT**

The work described was performed in compliance with UK GLP standards (Schedule 1, Good Laboratory Practice Regulations 1999 (SI 1999/3106 as amended by SI 2004/0994)). These Regulations are in accordance with GLP standards published as OECD Principles on Good Laboratory Practice (revised 1997, ENV/MC/CHEM(98)17); and are in accordance with, and implement, the requirements of Directives 2004/9/EC and 2004/10/EC.

This report fully and accurately reflects the procedures used and data generated.

.....*N. Warren*..... DATE: .....*21/9/2010*.....

N Warren MIAT  
Study Director

This report may be presented in final form as a digital (pdf) document. Such documents are prepared by scanning the paper original, and are considered of equivalent integrity and authenticity to versions produced by optical photocopy. However, in all cases the hand-signed paper original, held in secure archives, is the definitive document.

## ASSESSMENT OF OCULAR IRRITATION POTENTIAL USING THE SKINETHIC RECONSTITUTED HUMAN CORNEAL EPITHELIUM MODEL

### SUMMARY

**Introduction.** The purpose of this study was to determine the eye irritation potential of the test material using the SkinEthic Reconstituted Human Corneal model (HCE, SkinEthic Laboratories, Nice, France) after a treatment period of 10 minutes. The test is based on the hypothesis that irritant chemicals are able to penetrate the corneal epithelial tissue and are sufficiently cytotoxic to cause cell death.

**Methods.** The experimental design of the study consists of a test for direct reduction of MTT (3-[4,5-dimethylthiazol-2-yl]-2,5-diphenyl-tetrazolium bromide) by the test material followed by the main test.

For the main test, triplicate SkinEthic tissues were treated with 30 µl of the test material for 10 minutes. Triplicate tissues treated with 30 µl of Solution A served as the negative control and triplicate tissues treated with 30 µl of 1% w/v Sodium Dodecyl Sulphate served as the positive control.

At the end of the exposure period each SkinEthic tissue was rinsed. The rinsed tissues (two per group) were taken for MTT loading. The remaining tissues were retained for possible histopathology. Following MTT loading the reduced MTT was extracted from the tissues.

After extraction the absorbency of triplicate aliquots of the extracted MTT solution for each SkinEthic tissue was measured. The optical density was measured at 540 nm (OD<sub>540</sub>). Data are presented in the form of percentage viability (MTT conversion relative to negative controls).

The test material was classified according to the following criteria:

- i) If the percentage relative mean tissue viability was  $\geq 60\%$  the test material was considered to be non-irritant (NI).
- ii) If the percentage relative mean tissue viability was  $< 60\%$  the test material was considered to be an irritant (I).

**Results.** The relative mean viability of the test material treated tissues after a 10 minute exposure was 88.4%.

It was considered unnecessary to proceed with tissue histopathology.

**Quality criteria.** The quality criteria required for acceptance of results in the test were satisfied.

**Conclusion.** According to the protocol followed the test material was considered to be a Non-Irritant (NI).



**Polyglycerol  
esterification for highly  
effective and natural-  
based ingredients.**



**EVONIK**  
INDUSTRIES

# Polyglycerol esters in cosmetics

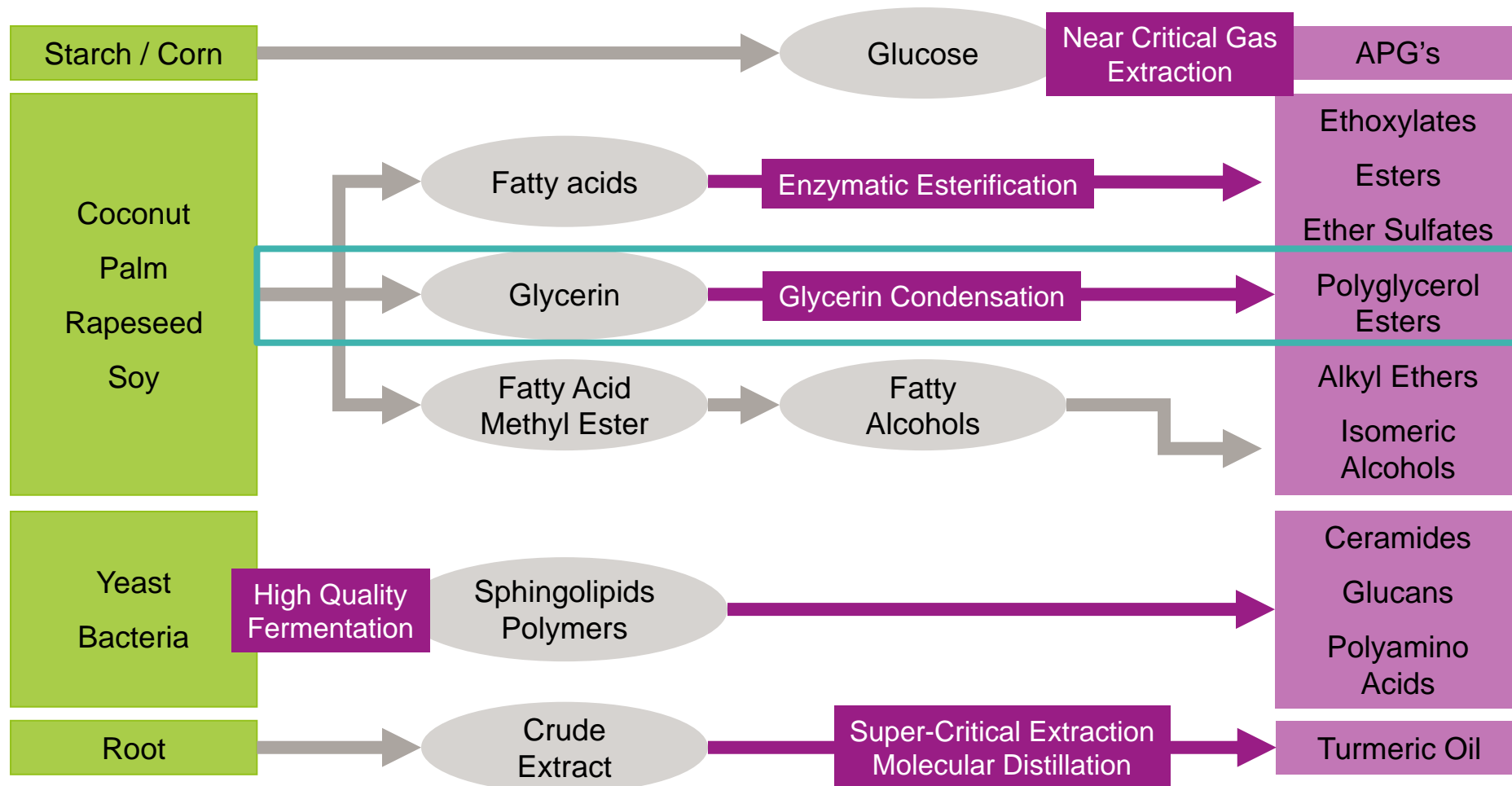


**Surface-active polyglycerol ester-based ingredients meet both criteria of the cosmetic market: Performance and eco-efficiency:**

- Very mild, non-irritating, non sensitizing
- Moisturizing and skin smoothing
- High biodegradability and low aquatic toxicity
- Use of renewable raw materials
- PEG-free
- Broad range of HLB values possible
- Also used in food industry
- Highly versatile

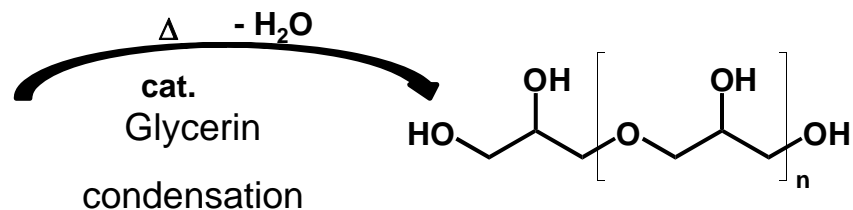


# Polyglycerol esterification – one key technology for sustainable processing at Evonik

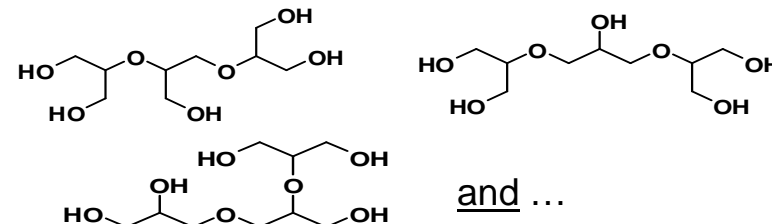




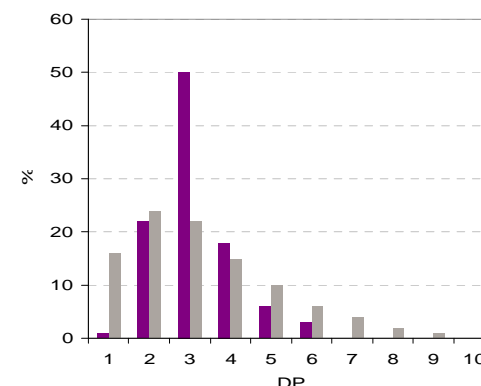
# The route to natural derived polyglycerol esters in cosmetics



and

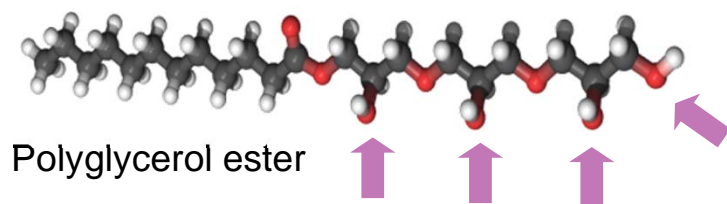


In addition: variation of degree of PG polymerisation:



Fatty acids

esterification



Polyglycerol ester

↑ ↑ ↑  
additional modifications possible

By variation of condensation degree, polyglycerol esters can be tailored to specific applications.

# Innovation with polyglycerol esters over the last decade



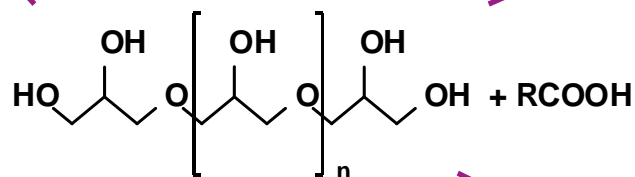
## W/O emulsifier for lotions with a light skin feel

Polyglyceryl-4 Diisostearate/  
Polyhydroxystearate/ Sebacate



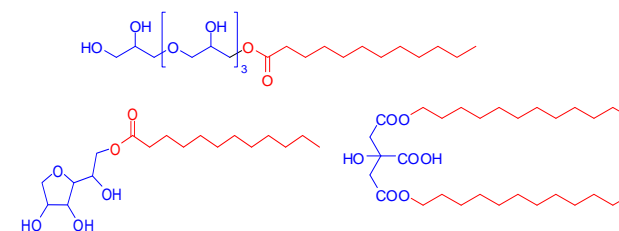
## Nanoemulsions for wipes by simple dilution with water based on Polyglyceryl-4 Laurate

based on Polyglyceryl-4 Laurate



## Cold processable, cost-efficient O/W emulsifier

Sorbitan Laurate; Polyglyceryl-4 Laurate; Dilauryl Citrate



## Solubilizers for essential & perfume oils

Polyglyceryl-6 Caprylate;  
Polyglyceryl-4 Caprate;  
Propylene Glycol

## Solubilizers for lipophilic oils

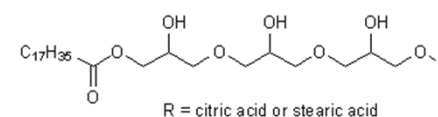
Polyglyceryl-6 Caprylate;  
Polyglyceryl-4 Caprate;  
Polyglyceryl-4 Cocoate,  
Polyglyceryl-6 Ricinoleate

## Robust O/W emulsifier for sprays and lotions

Polyglyceryl-6 Stearate;  
Polyglyceryl-6 Behenate

## Versatile, cost-efficient O/W emulsifier for creams and lotions

Polyglyceryl-3 Dicitrate/Stearate





**EVONIK**  
**INDUSTRIES**



## Memorandum

**TO:** Lillian Gill, D.P.A.  
Director - COSMETIC INGREDIENT REVIEW (CIR)

**FROM:** Beth A. Lange, Ph.D.  
Industry Liaison to the CIR Expert Panel

**DATE:** February 1, 2016

**SUBJECT:** Comments on the Scientific Literature Review: Safety Assessment of Polyglyceryl Fatty Acid Esters as Used in Cosmetics (SLR posted on the CIR website January 28, 2016)

The Council has no suppliers listed for the following ingredients:

Apricot Kernel Oil Polyglyceryl-3 Esters	Polyglyceryl-6 Dicaprate
Apricot Kernel Oil Polyglyceryl-5 Esters	Polyglyceryl-3 Dicocoate
Palm Oil Polyglyceryl-3 Esters	Polyglyceryl-3 Di-Hydroxystearate
Palm Oil Polyglyceryl-5 Esters	Polyglyceryl-4 Dilaurate
Palm Oil Polyglyceryl-6 Esters	Polyglyceryl-6 Dipalmitate
Polyglyceryl-2 Caprylate	Polyglyceryl-2 Distearate
Polyglyceryl-3 Cocoate	Polyglyceryl-6 Heptacaprylate
Polyglyceryl-3 Isostearate	Polyglyceryl-6 Hexaoleate
Polyglyceryl-2 Isopalmitate	Polyglyceryl-6 Pentaricinoleate
Polyglyceryl-8 Oleate	Polyglyceryl-6 Sesquiisostearate
Polyglyceryl-6 Palmitate	Polyglyceryl-2
Polyglyceryl-3 Soyate/Shea Butterate	Tetrabeheenate/Macadamate/Sebacate
Sunflower Seed Oil Polyglyceryl-3 Esters	Polyglyceryl-6 Tetraoleate
Sunflower Seed Oil Polyglyceryl-5 Esters	Polyglyceryl-3 Triisostearate
Polyglyceryl-3 Dicaprate	

Please use either "polyglycerol esters" or "polyglyceryl esters" throughout the report, rather than both terms as used in the Chemistry section.

Cosmetic Use - Please state the FDA product category with the highest leave-on concentration (lipstick).

Shea Butter Polyglyceryl-4 Esters is now listed in Cosing. Unless a newly named ingredient is in Annex II, ingredients getting INCI names are added to Cosing as soon as Joanne Nikitakis of the Council provides Europe with the data and they update their database.

Absorption, Distribution, Metabolism and Excretion - Unless the authors actually used the word "catabolism", please use "metabolism". Catabolism generally means the breakdown of compounds to produce energy. From the description in the report, it is not clear if the production of energy was also studied.

The following is included twice in the first paragraph under the heading Polyglyceryl Oleate and Decaoleate: "The study also included 2 polyglyceryl esters that are not cosmetic ingredients, but are similar to ingredients reviewed in this report:....."

Please correct: "at close to the same rats as that from glycerol" (rats should be rates)

Repeated Dose - It would be helpful if this section was organized by duration, with the shorter studies first and the longest study last.

Please change "ground nut oil" to "peanut oil" (this occurs in several places in the report)

It would be helpful to state where the study was presented, rather than saying "study described previously"

Summary - Please state the FDA leave-on product category in which the highest use concentrations were found.

Please state the species in which the carcinogenicity study was completed.

Table 4 - It is not clear why the use concentrations are presented for Glycerin but not the other ingredients.

Table 7 - As the methods listed are the same, this table does not seem necessary for the final report, although it may be helpful for keeping track of the information as the report is developed.

Table 10 - It should be stated that the recommended use levels for Polyglyceryl-4 Laurate (reference 112) are for "O/W lotion wipes".

Table 12 - If the study authors used "metabolism", "metabolism" should be used instead of "catabolism" in the headings of this table.

Table 14 - Although MEM may not have been defined in reference 33, it is a common abbreviation for "minimum essential medium". This can be added with the rest of the abbreviations at the end of the table.

Table 15 - As vaseline is a trade name, it would be better to use petrolatum or petroleum jelly.