Safety Assessment of Polyoxyalkylene Siloxane Copolymers, Alkyl-Polyoxyalkylene Siloxane Copolymers, and Related Ingredients as Used in Cosmetics

Status: Draft Report for Panel Review
Release Date: May 16, 2014
Panel Meeting Date: June 9-10, 2014

The 2014 Cosmetic Ingredient Review Expert Panel members are: Chairman, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; Ronald A Hill, 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 report was prepared by Lillian C. Becker, Scientific Analyst/Writer.

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MEMORANDOM

To: CIR Expert Panel and Liaisons

From: Lillian C. Becker, M.S.
Scientific Analyst and Writer

Date: May 16, 2014

Subject: Alkoxy Polysiloxanes as Used in Cosmetics

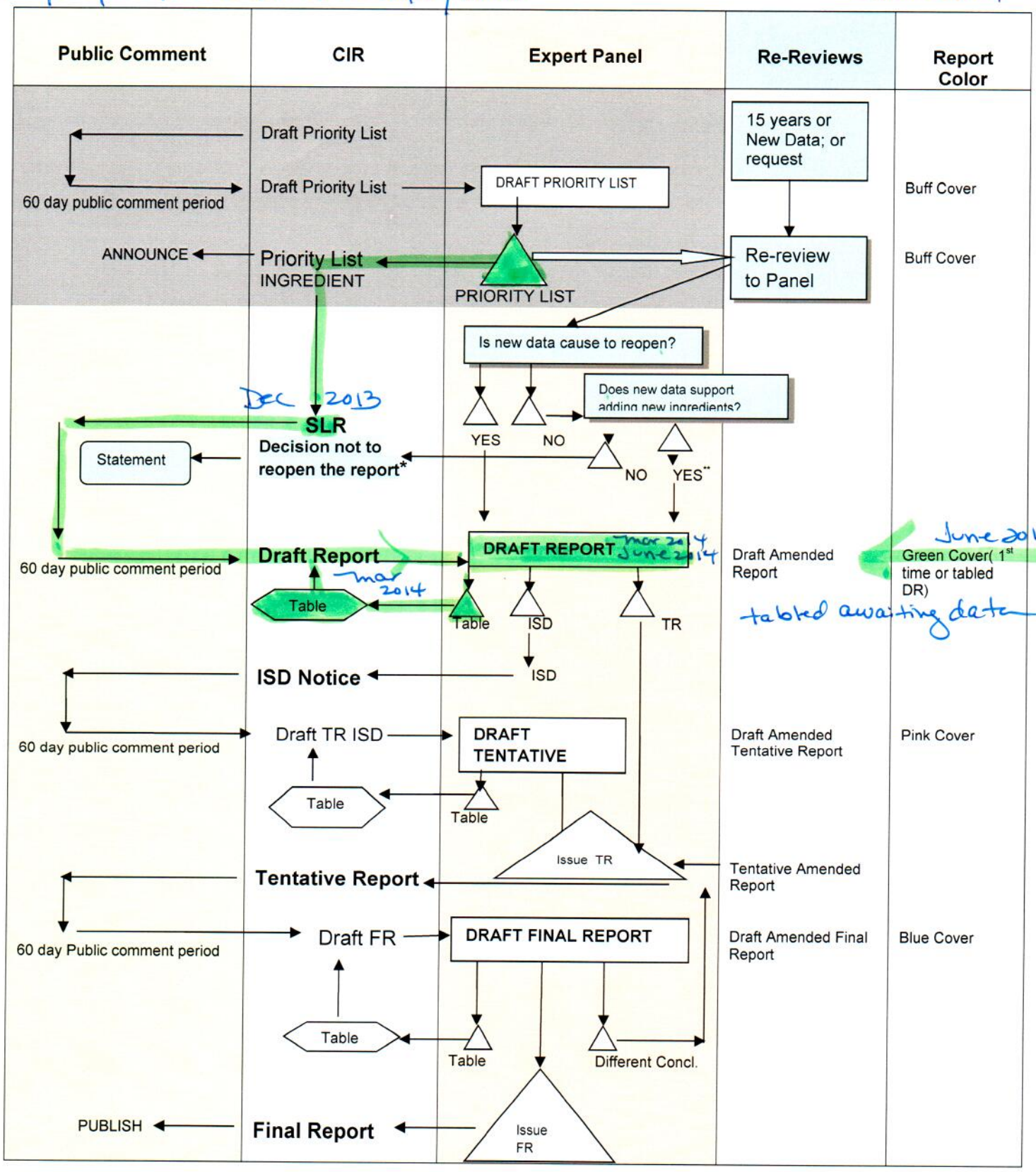
This is the Panel's second look at the draft report of Alkoxy Polysiloxanes as used in cosmetics. At the March, 2014 meeting the Panel decided to table the report to allow the Silicone Environmental, Health and Safety Center (SEHSC) to submit data on these ingredients. The SEHSC anticipates that they will be able to deliver that data before the June meeting. Some of the data has been submitted and incorporated into the report. The data memo outlines the submitted data, which is provided at the end of this report packet. More data from SEHSC is expected. If it arrives in time, it will be included in Wave 2. Updated concentration of use data have been incorporated into the report.

The Panel is to examine the provided data and decide if it is sufficient to come to a conclusion on the safety of these cosmetic ingredients. If not, then the Panel is to issue an insufficient data announcement and create a list of data needs. If there is enough data to come to a conclusion, the Panel is to develop the basis for the Abstract and Discussion and issue a tentative report.

SAFETY ASSESSMENT FLOW CHART

Polyoxyalkylene Siloxane Copolymers

June 2014



*The CIR Staff notifies of the public of the decision not to re-open the report and prepares a draft statement for review by the Panel. After Panel review, the statement is issued to the Public.

**If Draft Amended Report (DAR) is available, the Panel may choose to review; if not, CIR staff prepares DAR for Panel Review.

△

History – Polyoxyalkylene Siloxane Copolymers, Alkyl-Polyoxyalkylene Siloxane Copolymers, and Related Ingredients

1982 - A safety assessment of dimethicone copolyol with a safe as used conclusion. "Dimethicone copolyol" was an umbrella term of polymers of dimethylsioxane with polyoxyethylene and/or polypropylene side chains. These polymers included straight-chain dimethicone polymers (up to 10000 repeating units of dimethyl polysiloxanes); cyclinized dimethicones; silica-activated dimethicones; and cyclinized dimethicone copolyol forms.

2005 – The conclusion was confirmed. The Panel noted that the INCI naming conventions had changed for these ingredients and listed ingredients that would be included under the term "dimethicone copolyol".

November, 2013 – SLR was issued for Alkoxy Polysiloxanes that include the "dimethicone copolyols".

March, 2014 – The Panel tabled the report to allow the Silicones Environmental Health and Safety Center to assemble data and submit it to CIR. At the request of SEHSC, the name of the group of ingredients was changed to "Polyoxyalkylene Siloxane Copolymers, Alkyl-Polyoxyalkylene Siloxane Copolymers, and Related Ingredients".

June, 2014 -

Search History –

SciFinder – Compound search by identifier - 31 hit, One useful.
Search for sub-structures – 7550 hits. Removed patents – 18 hits, 0 useful.
Compound class search – 14691 hits. Narrowed for "toxicity" – 171 hits, 1 useful.

ECHA – Ingredient names, "dimethicone", Alkoxy Polysiloxanes, Alkoxylated Polysiloxanes, Alkoxylated Dimethicone, Alkoxylated Methicone – no hits.

HPVIS – "Dimethicone", "Methicone", "siloxane", "polysiloxane", "copolyol" and CAS Nos. No hits.

PubMed – "alkoxy polysiloxane", alkox* polysiloxane", "alkox* dimethicone", "alkox* methicone", "PEG dimethicone", PPG dimethicone", PEG methicone", PPG methicone", "Dimethicone Copolyol", "copolyol" - ~70 total hits, 0 useful.

Scifinder Search Terms

Alkoxy Polysiloxanes
Alkoxylated Polysiloxanes
Alkoxylated Dimethicone
Alkoxylated Methicone
Behenoxy Dimethicone
Behenoxy PEG-10 Dimethicone
1136947-78-8
Bis-Cetyl/PEG-8 Cetyl PEG-8 Dimethicone
Bis-Hydroxyethoxypropyl Dimethicone
1136947-78-8
Bis-Isobutyl PEG/PPG-10/7/ Dimethicone Copolymer
158451-77-5
Bis-Isobutyl PEG-13/Dimethicone Copolymer
197980-52-2
Bis-Isobutyl PEG-24/PPG-7/ Dimethicone Copolymer
Bis-PEG-1 Dimethicone
Bis-PEG-4 Dimethicone
Bis-PEG-8 Dimethicone
Bis-PEG-10 Dimethicone
Bis-PEG-12 Dimethicone
Bis-PEG-12 Dimethicone Beeswax
Bis-PEG-12 Dimethicone Candelillate
Bis-PEG-15 Methyl Ether Dimethicone
Bis-PEG-20 Dimethicone
Bis-PEG-8 PEG-8 Dimethicone
Bis-PEG/PPG-14/14 Dimethicone
151662-01-0
Bis-PEG/PPG-15/5 Dimethicone
Bis-PEG/PPG-16/16 PEG/PPG-16/16 Dimethicone
Bis-PEG/PPG-18/6 Dimethicone
Bis-PEG/PPG-20/20 Dimethicone
Bis-PEG/PPG-20/5 PEG/PPG-20/5 Dimethicone
Bis-Stearoxyethyl Dimethicone
128446-57-1
Cetyl PEG/PPG-10/1 Dimethicone
191044-49-2
Cetyl PEG/PPG-10/1 Dimethicone
Cetyl PEG/PPG-15/15 Butyl Ether Dimethicone
Cetyl PEG/PPG-7/3 Dimethicone
Cetyl PEG-8 Dimethicone
Lauryl Isopentyl-PEG/PPG-18/18 Methicone
1112315-26-0
Lauryl PEG/PPG-18/18 Methicone
Lauryl PEG-10 Methyl Ether Dimethicone
Lauryl PEG-10 Tris(Trimethylsiloxy)silylethyl Dimethicone
Lauryl PEG-8 Dimethicone
Lauryl PEG-8 PPG-8 Dimethicone
Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone
Lauryl Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone
Methoxy PEG-11 Methoxy PPG-24 Dimethicone
472975-82-9
Methoxy PEG/PPG-25/4 Dimethicone
Methoxy PEG-13 Ethyl Polysilsesquioxane
PEG/PPG-10/2 Dimethicone
PEG/PPG-10/3 Oleyl Ether Dimethicone
PEG/PPG-12/16 Dimethicone

PEG/PPG-12/18 Dimethicone
PEG/PPG-14/4 Dimethicone
PEG/PPG-15/15 Dimethicone
PEG/PPG-15/5 Dimethicone
PEG/PPG-16/2 Dimethicone
PEG/PPG-16/8 Dimethicone
PEG/PPG-17/18 Dimethicone
PEG/PPG-18/12 Dimethicone
PEG/PPG-18/18 Dimethicone
PEG/PPG-18/6 Dimethicone
PEG/PPG-19/19 Dimethicone
PEG/PPG-20/15 Dimethicone
PEG/PPG-20/20 Dimethicone
PEG/PPG-20/22 Butyl Ether Dimethicone
67762-87-2
PEG/PPG-20/22 Methyl Ether Dimethicone
125857-75-2
PEG/PPG-20/23 Dimethicone
PEG/PPG-20/29 Dimethicone
PEG/PPG-20/6 Dimethicone
PEG/PPG-22/22 Butyl Ether Dimethicone
PEG/PPG-22/23 Dimethicone
PEG/PPG-22/24 Dimethicone
PEG/PPG-23/23 Butyl Ether Dimethicone
PEG/PPG-23/6 Dimethicone
PEG/PPG-24/18 Butyl Ether Dimethicone
67762-87-2
PEG/PPG-25/25 Dimethicone
PEG/PPG-27/27 Dimethicone
PEG/PPG-27/9 Butyl Ether Dimethicone
PEG/PPG-3/10 Dimethicone
PEG/PPG-30/10 Dimethicone
PEG/PPG-4/12 Dimethicone
PEG/PPG-6/4 Dimethicone
PEG/PPG-6/11 Dimethicone
PEG/PPG-8/14 Dimethicone
PEG/PPG-8/26 Dimethicone
PEG-10 Dimethicone
68937-54-2
PEG-10 Methyl Ether Dimethicone
68938-54-5
PEG-10 Polydimethylsiloxyethyl Dimethicone/Bis-Vinyl Dimethicone Crosspolymer
PEG-11 Methyl Ether Dimethicone
PEG-12 Dimethicone
PEG-14 Dimethicone
PEG-17 Dimethicone
PEG-3 Dimethicone
PEG-32 Methyl Ether Dimethicone
PEG-4 PEG-12 Dimethicone
PEG-6 Dimethicone
PEG-6 Methyl Ether Dimethicone
PEG-7 Dimethicone
PEG-7 Methyl Ether Dimethicone
PEG-8 Cetyl Dimethicone
PEG-8 Dimethicone
PEG-8 Dimethicone Dimer Dilinoleate
PEG-8 Dimethicone/Dimer Dilinoleic Acid Copolymer
PEG-8 Methicone
PEG-8 Methyl Ether Dimethicone
PEG-8 PEG-4 Dimethicone
PEG-8 PPG-8 Dimethicone
PEG-9 Dimethicone
PEG-9 Methyl Ether Dimethicone
PEG-9 Polydimethylsiloxyethyl Dimethicone
Polysilicone-13
158451-77-5
197980-52-2
PPG-12 Butyl Ether Dimethicone
PPG-12 Dimethicone
PPG-2 Dimethicone
68440-66-4
68554-64-3
PPG-25 Dimethicone
68957-00-6
PPG-27 Dimethicone
PPG-4 Oleth-10 Dimethicone
Stearoxy Dimethicone
68554-53-0
Stearoxymethicone/Dimethicone Copolymer
Dimethicone Copolyol

ALKOXY POLYSILOXANE Data Profile for March, 2014. Writer - Lillian Becker

	ADME			Acute toxicity			Repeated dose toxicity			Irritation			Sensitization					
	Dermal Penetration	Log K_{ow}	Use	Oral	Dermal	Inhale	Oral	Dermal	Inhale	Ocular Irritation	Dermal Irr. Animal	Dermal Irr Human	Sensitization Animal	Sensitization Human	Repro/Devel toxicity	Genotoxicity	Carcinogenicity	Phototoxicity
Behenoxy Dimethicone																		
Behenoxy PEG-10 Dimethicone																		
Bis-Cetyl/PEG-8 Cetyl PEG-8 Dimethicone																		
Bis-Hydroxyethoxypropyl Dimethicone																		
Bis-Isobutyl PEG/PPG-10/7/Dimethicone Copolymer																		
Bis-Isobutyl PEG-13/Dimethicone Copolymer																		
Bis-Isobutyl PEG-24/PPG-7/Dimethicone Copolymer													X					
Bis-PEG-1 Dimethicone																		
Bis-PEG-4 Dimethicone																		
Bis-PEG-8 Dimethicone																		
Bis-PEG-10 Dimethicone																		
Bis-PEG-12 Dimethicone																		
Bis-PEG-12 Dimethicone Beeswax																		
Bis-PEG-12 Dimethicone Candelillate																		
Bis-PEG-15 Methyl Ether Dimethicone	X			X			X						X		X	X		
Bis-PEG-20 Dimethicone																		
Bis-PEG-8 PEG-8 Dimethicone																		
Bis-PEG/PPG-14/14 Dimethicone																		
Bis-PEG/PPG-15/5 Dimethicone																		
Bis-PEG/PPG-16/16 PEG/PPG-16/16 Dimethicone																		
Bis-PEG/PPG-18/6 Dimethicone																		
Bis-PEG/PPG-20/20 Dimethicone																		
Bis-PEG/PPG-20/5 PEG/PPG-																		

ALKOXY POLYSILOXANE Data Profile for March, 2014. Writer - Lillian Becker

	ADME			Acute toxicity			Repeated dose toxicity			Irritation			Sensitization					
	Dermal Penetration	Log K_{ow}	Use	Oral	Dermal	Inhale	Oral	Dermal	Inhale	Ocular Irritation	Dermal Irr. Animal	Dermal Irr Human	Sensitization Animal	Sensitization Human	Repro/Devel toxicity	Genotoxicity	Carcinogenicity	Phototoxicity
20/5 Dimethicone																		
Bis-Stearoxy Dimethicone																		
Bis-Stearoxyethyl Dimethicone																		
Cetyl PEG/PPG-10/1 Dimethicone																		
Cetyl PEG/PPG-15/15 Butyl Ether Dimethicone																		
Cetyl PEG/PPG-7/3 Dimethicone																		
Cetyl PEG-8 Dimethicone																		
Lauryl Isopentyl-PEG/PPG-18/18 Methicone																		
Lauryl PEG/PPG-18/18 Methicone														X		X		
Lauryl PEG-10 Methyl Ether Dimethicone																		
Lauryl PEG-10 Tris(Trimethylsiloxy)silylethyl Dimethicone																		
Lauryl PEG-8 Dimethicone																		
Lauryl PEG-8 PPG-8 Dimethicone																		
Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone																		
Lauryl Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone																		
Methoxy PEG-11 Methoxy PPG-24 Dimethicone																		
Methoxy PEG/PPG-25/4 Dimethicone																		
Methoxy PEG-13 Ethyl Polysilsesquioxane																		
PEG/PPG-10/2 Dimethicone																		
PEG/PPG-10/3 Oleyl Ether Dimethicone																		
PEG/PPG-12/16 Dimethicone																		
PEG/PPG-12/18 Dimethicone																		
PEG/PPG-14/4																		

ALKOXY POLYSILOXANE Data Profile for March, 2014. Writer - Lillian Becker

	ADME			Acute toxicity			Repeated dose toxicity			Irritation			Sensitization					
	Dermal Penetration	Log K_{ow}	Use	Oral	Dermal	Inhale	Oral	Dermal	Inhale	Ocular Irritation	Dermal Irr. Animal	Dermal Irr Human	Sensitization Animal	Sensitization Human	Repro/Devel toxicity	Genotoxicity	Carcinogenicity	Phototoxicity
Dimethicone																		
PEG/PPG-15/15 Dimethicone																		
PEG/PPG-15/5 Dimethicone																		
PEG/PPG-16/2 Dimethicone																		
PEG/PPG-16/8 Dimethicone																		
PEG/PPG-17/18 Dimethicone																		
PEG/PPG-18/12 Dimethicone																		
PEG/PPG-18/18 Dimethicone																		
PEG/PPG-18/6 Dimethicone																		
PEG/PPG-19/19 Dimethicone				X	X			X					X			X		
PEG/PPG-20/15 Dimethicone																		
PEG/PPG-20/20 Dimethicone																		
PEG/PPG-20/22 Butyl Ether Dimethicone																		
PEG/PPG-20/22 Methyl Ether Dimethicone																		
PEG/PPG-20/23 Dimethicone																		
PEG/PPG-20/29 Dimethicone																		
PEG/PPG-20/6 Dimethicone																		
PEG/PPG-22/22 Butyl Ether Dimethicone																		
PEG/PPG-22/23 Dimethicone																		
PEG/PPG-22/24 Dimethicone																		
PEG/PPG-23/23 Butyl Ether Dimethicone																		
PEG/PPG-23/6 Dimethicone																		
PEG/PPG-24/18 Butyl Ether Dimethicone																		
PEG/PPG-25/25 Dimethicone				X						X	X		X		X	X		
PEG/PPG-27/27 Dimethicone																		
PEG/PPG-27/9 Butyl Ether Dimethicone																		
PEG/PPG-3/10 Dimethicone																		
PEG/PPG-30/10 Dimethicone																		

ALKOXY POLYSILOXANE Data Profile for March, 2014. Writer - Lillian Becker

	ADME			Acute toxicity			Repeated dose toxicity			Irritation			Sensitization					
	Dermal Penetration	Log K_{ow}	Use	Oral	Dermal	Inhale	Oral	Dermal	Inhale	Ocular Irritation	Dermal Irr. Animal	Dermal Irr Human	Sensitization Animal	Sensitization Human	Repro/Devel toxicity	Genotoxicity	Carcinogenicity	Phototoxicity
PEG/PPG-4/12 Dimethicone																		
PEG/PPG-6/4 Dimethicone																		
PEG/PPG-6/11 Dimethicone																		
PEG/PPG-8/14 Dimethicone																		
PEG/PPG-8/26 Dimethicone																		
PEG-10 Dimethicone																		
PEG-10 Methyl Ether Dimethicone																		
PEG-10 Polydimethylsiloxyethyl Dimethicone/Bis-Vinyl Dimethicone Crosspolymer																		
PEG-11 Methyl Ether Dimethicone																		
PEG-12 Dimethicone					X	X	X	X		X	X				X			
PEG-14 Dimethicone																		
PEG-17 Dimethicone																		
PEG-3 Dimethicone																		
PEG-32 Methyl Ether Dimethicone																		
PEG-4 PEG-12 Dimethicone																		
PEG-6 Dimethicone																		
PEG-6 Methyl Ether Dimethicone																		
PEG-7 Dimethicone																		
PEG-7 Methyl Ether Dimethicone																		
PEG-8 Cetyl Dimethicone																		
PEG-8 Dimethicone																		
PEG-8 Dimethicone Dimer Dilinoleate																		
PEG-8 Dimethicone/Dimer Dilinoleic Acid Copolymer																		
PEG-8 Methicone																		
PEG-8 Methyl																		

ALKOXY POLYSILOXANE Data Profile for March, 2014. Writer - Lillian Becker

	ADME			Acute toxicity			Repeated dose toxicity			Irritation			Sensitization					
	Dermal Penetration	Log K_{ow}	Use	Oral	Dermal	Inhale	Oral	Dermal	Inhale	Ocular Irritation	Dermal Irr. Animal	Dermal Irr Human	Sensitization Animal	Sensitization Human	Repro/Devel toxicity	Genotoxicity	Carcinogenicity	Phototoxicity
Ether Dimethicone																		
PEG-8 PEG-4 Dimethicone																		
PEG-8 PPG-8 Dimethicone																		
PEG-9 Dimethicone																		
PEG-9 Methyl Ether Dimethicone																		
PEG-9 Polydimethylsiloxyethyl Dimethicone																		
Polysilicone-13																		
PPG-12 Butyl Ether Dimethicone																		
PPG-12 Dimethicone																		
PPG-2 Dimethicone										X						X		
PPG-25 Dimethicone																		
PPG-27 Dimethicone																		
PPG-4 Oleth-10 Dimethicone																		
Stearoxy Dimethicone																		
Stearoxymethicone/Dimethicone Copolymer																		
Polydimethylsiloxane polymer						X	X								X			
Bis-Stearoxydimethylsilane	X						X									X		

Minutes – Polyoxyalkylene Siloxane Copolymers, Alkyl-Polyoxyalkylene Siloxane Copolymers, and Related Ingredients

Dr. Marks's Team

DR. MARKS: …Okay. Let's move on to the polysiloxanes. Okay. Well, based on the rapidity in which we're moving through these ingredients, since this is the first review of these polysiloxanes, we'll see how we go with this. There are 111 ingredients. What are the needs? These are apparently inert and not absorbed. Refer back to a prior safe conclusion on dimethicone copolyol. So, Rons and Tom, do you like all 111 ingredients? Are there any that stand out that should be eliminated from this report? We can't use a no-brainer as a reason to eliminate.

DR. SHANK: (inaudible) has a question.

DR. HILL: I thought they all belonged. At least, I was just jogging my memory, but I don't remember proposing to eliminate anything.

DR. MARKS: Okay. Good. What are our needs then? So, all 111 are okay. Needs.

DR. HILL: I think we need skin penetration and sensitization data for the smallest compound that's used.

SPEAKER: (inaudible) was more general. We don't have molecular weight-range data for any of them. So, I had just made a note. If we found any with molecular weight less than 1,200, we might want at least a logP calculated, if that's the only thing available.

DR. MARKS: So, somewhere in here I had the note that they're inert and not absorbed. Is that not true? Is that what you're saying, Ron Shank, with a small size?

DR. SHANK: Where is that?

DR. MARKS: I should put a page number. Lillian, can you help me? Where did I get that idea?

MS. BECKER: Which one are we looking for?

DR. MARKS: That these compounds were inert and not absorbed.

MS. BECKER: That's what I thought.

DR. MARKS: But, I should have put a page number as a reference to it. I probably have it highlighted here. But, now, I've got to go through the whole report. Let me see.

DR. HILL: I found physically inert but not connected with absorbed.

MS. BECKER: There is absorption data on page 16. Is that what you got that from? Dr. Hill, what was that low range you had in line for --

DR. HILL: I said anything less than 1,200 molecular weight, because I've noted that we lacked molecular weight information for the vast majority of these.

MS. BECKER: Thank you.

DR. MARKS: I see where I got it, Ron Shank, and it was really under the -- let me see the page --

DR. SHANK: Under the Toxicokinetics?

DR. HILL: Yeah, it says due to the proclivity to wet surfaces, it's possible the low molecular weight alkoxy polysiloxanes penetrate and irritate the skin. That's what the statement is that's here. It gives reference 5 which is --

DR. MARKS: What page are you on, Ron?

DR. SHANK: Page 16.

DR. HILL: I'm on page 16 of the PDF. And, the reference is --

DR. MARKS: Oh, yeah.

DR. HILL: Way down 100 pages later.

DR. MARKS: So, do you like the idea -- Ron Hill, you said a molecular weight. Ron Shank, do you want to use just low molecular, or how did you state it? The smallest --

DR. SHANK: The smallest compound that's used.

DR. MARKS: So, can we identify which one that is?

DR. HILL: That's why I said we lacked molecular weight information whatsoever for the vast majority of these. Yeah, the reference 5 was a book chapter, and I didn't have access to that book or I would have looked, because that caught my attention, 2008.

DR. MARKS: So, we'll push that back to industry to identify which is the smallest needs, smallest --

DR. HILL: I wanted to see at least an estimate of logP -- grant you, these are probably all mixtures -- an estimate of logP if the molecular weight was 1,200. And, again, that would be an average of some sort.

MS. BECKER: You know, these ingredients are another one of those where it's a range of sizes --

DR. HILL: Right.

MS. BECKER: -- within the ingredients, and not every molecule's exactly the same as the next.

DR. HILL: I understood that.

DR. MARKS: Does the prior safety assessment with the dimethicone copolyol have any impact on these at all? Ron? Ron?

DR. HILL: Repeat that, please.

DR. MARKS: The prior safety reports on dimethicone and copolyol. Is that how you say it? Copolyol?

MR. ANSELL: Yeah. We've reviewed a large number of these already, you know, the dimethicone copolyol group in the early '80s and one of our recommendations is that we mine that data a little more extensively. We also have quite a large assessment that's ongoing now at the -- what is it -- NICNAS? The Australian NICNAS is reviewing, and there's a lot of data coming out of that as well. So, we'd like to have an opportunity to review that. We have a representative from Siloxanes Environmental Health and Safety Committee who are developing a lot of data that we think would help inform the Panel and request that there be an opportunity to submit all of that data as well as referencing the dimethicone copolyol reports from the '80s.

DR. MARKS: From the '80s. Right. That's what I was getting at, in that a number of these now split out individual ingredients were actually in that original. Yeah. So, again, Jay, let me -- if I understood, there's more data and so on coming in. There's a group reviewing these that, to me, the way to move is do we put an insufficient data, ask for the smallest molecule, or do we table and then ask to wait --

MR. ANSELL: Introduce yourself and --

DR. MARKS: Yes. I could see -- I was going to get to you, too. (Laughter) With Jay looking at you, that you had some comment. So, identify who you are and what group you represent, please.

MS. KOCH: Sure. I'm Wendy Koch and I'm here as the technical committee chair for SEHSC.

DR. MARKS: SCHC meaning --

MS. KOCH: Silicones Environmental Health and Safety Center.

DR. MARKS: Okay.

SPEAKER: So, it's a member of the ACC, American Chemistry Council. It's the Silicone and Specialty Group from the American Chemical Council.

MR. KENNEDY: Wayne Kennedy. I'm here for some nomenclature discussions on it, and I'm with the Evonik Corporation, one of the member companies.

MS. KOCH: So, introductions aside then, we are under way as far as conducting an data call-in of all of our members, and we anticipate having that information for you prior to the June meeting,

but we actually expect we would have it by the end of April. So, our data call-in is not complete. You don't have everything that we hold.

DR. SHANK: Maybe we should table it.

DR. MARKS: That's one of the things I said is do we table it. We'll let that include with Drs. Hill and Shank, with that on the smallest molecular weight absorption, and then actually I have skin irritation and sensitization that's okay at 100 percent, at least in some of these compounds. So, I wasn't as concerned about irritation and sensitization, Ron, but I didn't limit it to just to the smallest molecule. Will you be able to identify the smallest molecule or absorption data, address that issue?

MS. KOCH: Well, administratively, we're early enough in the process that we can request that information. And, Wayne, I think, as industry expert, is that something likely to be returned back?

MR. KENNEDY: Yeah. I think that's something we should be able to get a handle around as far as the amount of data available on those as well as some information on the molecular weight ranges for the smaller city's compounds. Most of them, as you indicated, are fairly large, into the multiple thousands of, you know, AMU or Dalton's, but there may be a few out there that are smaller.

DR. HILL: And a related concern I wrote in here in terms of information need -- I'm going to stir a beehive I've stirred before -- information as to rule out the presence of low molecular weight impurities without chelating capability, presumably would be residual from production processes.

MS. KOCH: So, you want impurity data?

DR. HILL: That's kind of -- I guess so. And, I mean, that's going to be hard to get, because the problem we had before with polymers was if you give away very much information, you're giving a lot of information as to how they're actually manufactured, and so then we ended up with a caveat. I don't remember how we settled it, but basically manufacturers are very well aware of what they use to produce it and the onus is on them to do quality control and measure release characteristics such that under conditions of use they weren't releasing these monomers, and I don't mean depolymerization. I mean residual monomers in the product so that they would cause sensitization problems or any other toxicology.

And, then, since it was specifically mentioned, when alkoxy polysiloxanes are manufactured, there is an excess of (inaudible) alcohol ethoxylate used. I don't know if that's true for all of them actually. So, the excess remains in the product and may be present up to 30 percent by weight. So, this is really for CIR staff. If that's true, have we captured the toxicology and the report of (inaudible) alcohol ethoxylate, and if not, we need to have a discussion on appearing in the report from where I sit. Thirty percent by weight is nothing to sneeze at for some of these.

DR. MARKS: So, it sounds like, as I mentioned earlier, one would be to move forward, with an insufficient data notice, the other would be to table. I get the sense that tabling is the way to proceed at this point. Is that what you would want to do, Tom, Ron, and Ron?

DR. SHANK: I think that would be better.

DR. MARKS: Table for more data from -- how do you want me to frame it? It sounds like it's from industry or --

DR. HILL: And, that will also provide the opportunity so that we don't have to have a protracted discussion today, that the nomenclature issues be communicated to CIR staff so that we can hammer them out before we -- I don't know exactly -- I mean, you may want to talk about them, but --

MS. BECKER: When you got back from lunch, there was a handout at your seat with the outline of their thoughts.

DR. HILL: I don't know if I have it.

SPEAKER: Looks like this.

DR. HILL: Oh, it's that three pages of slides. Yeah, I did look at that. I liked it.

DR. MARKS: Okay. So, I am going to be, hopefully, tomorrow seconding a motion that we table the discussion of these 111 ingredients, all of them are on the table, and that we are waiting for

more data from industry.

MS. BECKER: Can we make sure we understand what the data needs are? If we table, we won't go out and ask specifically, and we're subject to get whatever comes in. I would like to be specific on those things that we ask for, that they're not sure they're going to be able to provide. So, industry is on notice of the kinds of things we're looking for.

DR. MARKS: I think what Dr. Shank had indicated -- identify the smallest molecular weight ingredient and then what's the absorption data, that and what's the skin irritation and sensitization of that, and then obviously it's absorbed and we're going to need some systemic tox.

DR. HILL: And, I would be okay with that. I retract the less than 1,200 molecular weight. I retract that.

MS. KOCH: Yeah, and I would just add that this isn't our first time through the process, and so we are fairly well experienced with understanding what your needs are, so I have noted the specifics, and we'll make sure they're included in our data call-in.

DR. MARKS: Okay.

MR. KENNEDY: Did you want a brief explanation of the nomenclature question we had or concern that we had on --

DR. HILL: Is there anything more that needs to be said than what's on this handout?

MR. KENNEDY: Only if you were looking for sort of an explanation of industry's thought on --

DR. MARKS: Lillian?

MS. BECKER: I have Bart's thoughts on this, who came up with the name, and what he wants to point out is there are three primary configurations – the n-capped and the terminated at either end with and without an alkyl group, and that the name that he picked covers all those, and that their proposal does not -- I'm sorry -- I'm reading – the n-capped dimethicone (inaudible) dimethicone polymer is terminated at either end, with an alkyl group, an alkyl dimethicone copolymer, and some combination of 1 and 2. The ingredients configurations of at least some alkyl groups are not polymeric, and he feels that his name covers everything and, while it's good for a lot of them, it does not cover all of the ingredients in this group.

DR. HILL: And, really, what we're debating is what's going to appear in the report title, right?

MS. BECKER: Exactly.

DR. HILL: As the INCI ingredients are set. Yeah.

DR. MARKS: Is that okay? Why don't you comment on that --

DR. HILL: Sure. Industry --

DR. MARKS: We'll have time the next (inaudible) proposed. We'll have time to re-discuss it obviously.

DR. HILL: Do you want to just --

DR. MARKS: Yeah. And, then do you think June is going to be -- you mentioned you would have it. I don't know if that's enough time for Lillian to put the data in the next rendition of the report. It may not be till June the next time we get to it.

SPEAKER: (inaudible)

MS. KOCH: Tracy indicated end of April where she would submit something to you. That's what she anticipates. Hopefully, that'll allow you to come forward to June, I think, is her intent.

DR. BERGFELD: That's a little ambitious. We never hear from industry that quickly. (Laughter)

MS. KOCH: And, also the --

SPEAKER: There's no way. (Laughter)

SPEAKER: Forget it. (Laughter)

MS. KOCH: And, if the --

MR. ANSELL: It's also possible we'll be suggesting you add some ingredients to this list.

DR. MARKS: Oh. Okay.

MS. BECKER: So, if it comes in at the end of April, that'll give me 2 to 3 weeks to get that into the reports, and if it's a large amount, that may be difficult.

DR. MARKS: Yeah. Okay.

MR. KENNEDY: And, did you just want the comments on the nomenclature in writing for the same purpose, or is that what you're asking for?

DR. MARKS: I think that's a good idea. And, that way we can -- I think it would be very good. I don't want to truncate your comments about nomenclature now if you want to say anything.

MR. KENNEDY: Well, just briefly, industry -- the term alkoxy polysiloxanes as used is not commonly used in industry to refer to the types of chemistries that are covered in this -- we agree with all the INCI names and the description of the chemistries, but alkoxy siloxanes and alkoxy silanes have a very specific inference in industry, and that's typically short chain SIO 1 to 4 carbons, whereas many of these compounds have much different chemistries. They are poly alkoxies as opposed to single alkoxies, and the alkyls that are -- the modifications that are alkyl -- the large number of them are not alkoxy alkyls, they are cetyls and things that are bound directly by carbon to the silicon, so they're not even alkoxies. There's very few compounds in here, only five or six that are actually alkoxies which would be the behenals and the stearoxies that are described.

So, our concern is just that the inference of the nomenclature is a little misleading, while all the INCI names are correct. We agree with them. People who would read this from industries would make an inference from that nomenclature that's not exactly appropriate to what's in the heart of the report. So, I guess that's our concern.

DR. MARKS: Is Bart here? So, after --

MS. BECKER: He is on the other side.

DR. MARKS: Okay. Afterward you can arm wrestle with Bart --

MR. KENNEDY: Okay.

DR. MARKS: -- and decide.

DR. BERGFELD: Do you have a suggestion?

MR. KENNEDY: Yeah. We had issued two suggestions within there. One of them would be if you want something other than using a generic INCI description, like dimethicone copolyol, would be to use what, say, chemical abstract services generically calls these, and that's polyoxyalkylene silicone copolymers and alkyl polyoxyalkylene silicone copolymers. That's a little more specific and covers a fairly broad range of and most, probably 99 percent, of what's in the 100+ compounds.

DR. MARKS: So, you would suggest that this subject include both of those chemical names --

MR. KENNEDY: I think if you want to be fairly complete to cover the largest group of them; that would be the most accurate ways to describe the two of them.

DR. MARKS: Okay.

MR. KENNEDY: Yeah. It's really two different classes to some degree, and a few minor ones as well, but, for the, you know, for 99 percent of them, that would cover the bulk of what you're looking to describe in the report. There's some minor variations in the chemistries, but --

DR. MARKS: So, we'll let -- as far as Panel members, I would defer to Ron Hill and Dan Liebler to settle it, and they can arm wrestle with Bart along with you.

(Laughter) Do you have a short comment on this? This can be settled obviously as we move forward. That's not the greatest issue today, but -- Ron Hill, did you want to react to that just briefly --

DR. HILL: No, I was just going to say that when I say alkoxy it doesn't matter how long the carbon chain is, and so I was a little confused by what you mean when you say alkylene, polyoxyalkylene. I don't have a clue what that means.

MR. KENNEDY: What you're dealing with is really not an alkoxy. You're dealing with poly alkoxies, typically. These are polymer glycols from ethylene oxide and propylene oxide, so, technically, you know, dealing with a poly alkoxy which chemical abstract services technically calls polyoxyalkylene -- that's a chemical abstract name for polyalkylene.

DR. HILL: Okay.

DR. MARKS: So, I'm going to put a table for more data for the smallest compound and settle the chemical name, so to speak, of these ingredients. Okay. Any other comments? Questions?

DR. HILL: The other unresolved issue I saw in here was the business of the ECHA database states that dimethicones is harmful if inhaled. No further information was provided. You know where I'm talking about, right?

MS. BECKER: I'm sorry. I had a little thing going on. Would you say that again, please?

DR. MARKS: Which page?

DR. HILL: I have to go into the report to find where the statement is, but it says the -- or maybe it's from your memo. I don't remember which. ECHA database states that dimethicones is harmful if inhaled. No further information was provided. If you go back to the report and find that in a second, I'm sure.

MS. BECKER: That's on page 17 on the PDF?

DR. HILL: I don't know where it is in the report.

MS. BECKER: On page 17.

DR. HILL: Okay.

DR. SLAGA: There were also several times mentioned that there was data in the MSDAs, like on the carcinogenicity, and that's not sufficient to get that for (inaudible) data out there. There's data out there, but if it's in that (inaudible) so the data sheet, and --

MS. BECKER: I'm hoping that would be a call for industry to give us the rest of it. That says we know it's there. We just need the rest of it.

DR. MARKS: Okay. April may become more of a challenge, but thank you for your comments. Okay, the next that I have -- let's see, it's 3 o'clock, Panel members. I could suggest taking a break, but I have a feeling that --

SPEAKER: I'd like 3 minutes.

DR. MARKS: Five minutes. Oh, you can have more than 3 minutes. So, it is now 3 o'clock. We'll re-adjourn at 3:10. We will reconvene.

Dr. Belsito's Team

DR. BELSITO: So, the first question I had for you, Dan, is this is a rather large family, including a whole bunch of ether dimethicones.

DR. LIEBLER: Right.

DR. BELSITO: Are the ether dimethicones a) is it reasonable that they be in this? Will they behave differently?

DR. LIEBLER: No. I didn't think they would behave differently. I felt that despite small heterogeneities such as the ether alkoxy substitutions. These are really dominated by the very large PEG, or PPV-like moieties.

DR. BELSITO: Okay. So that takes care of a whole bunch of my questions there. So Lillian, when you see all these ether dimethicones highlighted in whatever table that is, or the ingredients we are looking, just ignore that. So the ethers remain, so the next question is, Table 1 is sufficient for all the related data that we are relying on. Do we like it just presented in table form, or that the data that we've reviewed before that goes into the safety assessment? Or would we like some verbiage? If you look at Table 1, it's a quick review of --

DR. LIEBLER: I see. Okay. It starts on PDF page 31, yes. Thank you. Perhaps other thought of some other way of looking at that.

DR. BELSITO: No. That's Figure-1, there's a --

DR. LIEBLER: There's a Table-1 that starts at the bottom of PDF, page 31.

SPEAKER: Related, yes?

DR. BELSITO: Yes. Okay. Well, I'm just generally raising issues here. Normally, when we've had reports, or often when we've had information from other reports that we thought gave credence to the safety, we added little blurbs under -- like the appropriate talks, endpoints in the document. Here we just have a table that says, "Safe to use in cosmetic ingredients when formative -- the skin irritation, for acrylates copolymer, for dimethicone is safe as a cosmetic ingredient."

Now, granted these parts of those molecules and probably they don't apply to anything, but just saying if you like this table concept? Or, do you want any of the other -- are there any issues in the relatively small amount of tox data that we actually have for this huge family, that you think need to be addressed specifically, because from where I come from, from skin sensitization and irritation these are not an issue. But I'm not a carcinogenicity expert. I'm not a repro expert.

DR. LIEBLER: I don't think that these are an issue for carcinogenicity or repro at all.

DR. SNYDER: Yeah. I think this was probably okay. This reaffirms these are really big molecules that aren't going to really do much, they are not going to go anywhere or do anything, I don't think. So, I mean -- if there was -- after a while that the ingredients that were previously assessed, there was some issue that might have pinged this, then I might have liked a little bit more discussion. But I didn't see any end notes to the documents they made.

DR. KLASSEN: But, do we -- in the text, even say Table-1, Figure-1?

DR. BELSITO: Yeah. We referred to Table 1, I believe.

MS. BECKER: Yes. On page 14.

DR. BELSITO: Yeah. I would say several structures relating to ingredients that were reviewed by the Panel, and all of these ingredients were safe as used, or safe with qualifications that are presented in Table 1.

DR. KLASSEN: Okay.

DR. LIEBLER: Under the introduction.

DR. BELSITO: And one line above that, is "cyclized" a word.

SPEAKER: Yeah.

DR. BELSITO: Cyclized dimethicones?

DR. LIEBLER: Cyclized, sure. I mean it's commonly used in, I think, chemistry. Or, cyclic and cyclized.

SPEAKER: --

DR. BELSITO: Well, I mean, that's why my -- it's not cyclic dimethicones, it's cyclized?

DR. LIEBLER: I guess I would see cyclic -- I mean, I don't know that dimethicone literature -- but for other chemicals I probably see cyclic more common than cyclized.

DR. BELSITO: So could we change it to cyclic.

DR. LIEBLER: So, we can go cyclic.

DR. BELSITO: Or we can go ballistic --

DR. SNYDER: Or you could just say the safety assessment only evaluates linear development.

DR. LIEBLER: Let's just say, not -- you know; those others.

DR. BELSITO: Okay. So we are just calling it, save as used, is that what we are doing?

DR. LIEBLER: Yes.

DR. BELSITO: Paul is worried about repro report. Increased number of absorption sites with siloxanes and silicones to hydroxypropyl, dimethyl under reprotox, ethoxylated in corn oil, increased absorptions. And there was the derma. You've got it?

MS. BECKER: It's a rabbit study too.

DR. BELSITO: So they get cleft lips with steroids, we shouldn't be concerned?

DR. LIEBLER: There were no deaths attributed to the test material, which is what I highlighted. One popular treatment group displayed clubbing of the extremities partial, acranius umbilical hernia, it's plain as far as the vital fetuses, number of (inaudible) fetuses were similar across control groups exposed. So is that what you were referring to?

DR. BELSITO: No. It says increased numbers of absorption sites on siloxanes and silicones. I just cut and pasted it to my general conclusion, so what page are you on, and then I'll tell you where it is?

MS. BECKER: Seventeen.

DR. BELSITO: Seventeen.

DR. LIEBLER: I'm on PDF 17.

MS. BECKER: Right. The very first sentence with the increased numbers of absorption.

DR. BELSITO: The New Zealand albino rabbit does, in equal study, right.

DR. SNYDER: Is there a reference along with that?

DR. BELSITO: Sure.

DR. SNYDER: Nineteen?

DR. BELSITO: The reference number is 19, yes.

DR. SNYDER: I get to see more data on that, to see whether they've adjusted to it, or they or licking it, or what --

DR. BELSITO: So that we need to table this, for you to review that paper.

DR. SNYDER: Can we get that other one, do you have that handy, or --

MS. BECKER: Hang on. I'll find out what it is. Hang on, let me see if I can get to it. I'm having trouble getting --

DR. BRESLAWEC: It's a DOW point incorporation and initial submission, rather to a call through study, 1966.

SPEAKER: Okay. There's also --

DR. SNYDER: Yeah. That's just one, it's just one pop, I mean, the rest of them were all similar cross control, but it's vehicle, there's not much there.

DR. BELSITO: Then it says, "Bis peg 15 methyl ether dimethicone was reported to be a reproductive toxin in material safety data sheet, no further information provided."

DR. SNYDER: Yeah. I don't if --

DR. BELSITO: Do we deal with it by saying, these aren't going to get it --

DR. SNYDER: Absorbed?

DR. BELSITO: -- absorbed? How do we deal with that?

DR. LIEBLER: I mean, because sometimes those will (inaudible) because they --

MS. BECKER: That's the Dow Corning.

DR. BELSITO: Because then under absorption distribution, the (inaudible) in administration, we have Reference 5 that says, "Due to their proclivity to wet surfaces, it is possible that low molecular weight alkoxy polysiloxanes, penetrate and irritate the skin." So it's sort of hard to make that statement, and say we are not worried about the repro because of lack of penetration. So, is that statement right, or --

DR. SNYDER: And what is Reference 5, I'm scrolling.

DR. BELSITO: Sorry about the shuffling.

(Recess)

DR. KLASSEN: Number five is actually dimethicone called polymer chemistry, it's the title of the --

DR. BELSITO: Chapter 6, in Silicones for Personal Care, Second Edition, 2008. That's pretty recent.

MS. BECKER: What's that O'Lenick?

DR. BELSITO: Oleric (sic) -- O'Lenick, yeah.

DR. KLASSEN: Did you actually have the chapter available?

MS. BECKER: Yeah. I have it.

DR. KLASSEN: Was it just an assertion that they made? Well, we can see.

DR. SNYDER: Well, you see, here in her discussion at a subsequent testing of that same product, demonstrated the material that we needed and (inaudible) applied when used with rabbits, at doses of 50, 100 or 200.

DR. LIEBLER: So this is the previous thing we are talking about, about the --

DR. SNYDER: Yeah. Yeah.

DR. LIEBLER: -- the absorptions?

DR. SNYDER: Yeah. So that statement yes --

SPEAKER: You're going to look?

DR. LIEBLER: Yeah. Let's take a quick look and see what the context was, that they said it. Because unless there are actual data to support that assertion I wouldn't be buying it.

SPEAKER: No.

DR. LIEBLER: I have a guess, it's doesn't necessarily --

MS. BECKER: Hang on. Let me find it.

DR. LIEBLER: Sure.

MS. BECKER: So that's chapters 7, 8 and 9. I'm a bit concerned about the names -- but they also [are working on a data call], and maybe I should let them just try to -- so if you want to table it and wait for more information that would be another option.

DR. BELSITO: I'm sorry. I missed it. I was on a bio break. What's happening?

MS. BECKER: I'll let them speak for themselves.

DR. BELSITO: Okay.

MS. KOCH: My name is Wendy Koch. I'm the Chair of Technical Committee at SEHSC. And, go ahead Wayne.

MR. KENNEDY: Wayne Kennedy. I'm with SEHSC, with member company, Avana Corporation.

MS. KOCH: And so, we came here with really two purposes. One, to let you know that we have initiated a data call in for this, and we anticipate having data for you by the end of April, so it is --

DR. BELSITO: What kind of data?

MS. KOCH: Well, I can't say. I don't have -- I haven't seen what's come back in, but we request the sort of data that this group normally wants to look at. It's not the first time we've done this for you. So it would be the same process, but what you get back, I can't say.

DR. BELSITO: So you're asking us to table that to the next meeting for -- to see that it's there.

MS. KOCH: Mm-hmm.

DR. BELSITO: I mean, I'm fine with that.

MS. KOCH: I'm not sure that's my place to ask you that, all I can do is tell your group, we are happy to provide you with what we have.

DR. BELSITO: So you're telling us there will be data forthcoming --

MS. KOCH: I would expect so.

DR. BELSITO: -- some time in April?

MS. KOCH: Mm-hmm.

DR. BELSITO: So then, why don't we table it to that date then. You can't make a decision, I mean, we know data is coming.

MS. KOCH: But it will help you -- it would help you make the decision to be able to look at all the --

DR. BELSITO: Yeah. Sure. I'm very comfortable saying, table it, and please send us your data. The more the merrier.

MS. KOCH: Exactly.

DR. BELSITO: Thank you.

MS. KOCH: And then I think it's if we have a moment, just to discuss the nomenclature, if that's -- if there's time.

DR. BELSITO: Sure.

SPEAKER: Yeah. Okay.

DR. BELSITO: I think this is across the board issues, we need to have discussions.

MR. KENNEDY: Okay. Very good. I'll give me. It's Wayne Kennedy. I'm one of the member companies, so we are one of the larger silicone producers. And in general, the nomenclature, the INCI nomenclature, the description of the chemistries contained within the CIR, no issues with. Technically, we don't see any problems with the way their groups are categorized or anything like that.

It's really sort of a minor issue in the way that we -- that they've been sort of generically categorized in the CIR Report. The use of the term alkoxy polysiloxanes, within the silicone industry as a whole, carries a somewhat specific meaning, it tends to refer to commonly, short carbon chain materials, one to four carbons that are bound with an oxygen to a silicone zone, SiOC bond.

The majority of the chemicals covered here, as you've indicated, are actually what we would call poly alkoxy-siloxanes, and more commonly within say, chemical abstract services, they call them polyoxyethylenes. They are not single alkoxy groups, they are poly alkoxy group, derived from polyethylene glycol, polypropylene glycol predominantly.

Of the 111 substances or so, roughly, there are only about five or so that I counted that would actually be considered alkoxy groups. They are the behno-base and the steroxy-based, and there's only about five of those of 111. The other aqua modifications that are described in there, where you have an additional -- a carbon, a long carbon chain, those are not alkoxies, they are bound directly to the silicone in most cases, so you have a silicone carbon bond. So it would be typically described as a silicone alkyl.

So we are just recommending that the general nomenclature for the group be modified or amended slightly, mainly so that it's not confused by those in industry with what they commonly call, alkoxy polysiloxanes, and really even more commonly, what you run into is alkoxy silanes. And people in the industry tend to get those confused sometimes, and they are very -- typically the alkoxy silanes are very, very distinctly different from the class of chemistry that you're reviewing.

So, again, no issue with the INCI nomenclature, the groupings of the chemicals are fine. Industry was just a little worried that the alkoxy polysiloxanes was a little bit confusing to those who use silicones in a number of different areas other than the cosmetic industry.

So, we had suggested that the nomenclature be amended slightly to call them poly alkoxy siloxane copolymers, and alkyl polyoxyalkylene siloxane copolymers. And a little bit wordy, I'm sorry, but we went with something that was known, as an industry we picked how Cassia, a chemical abstract services, generically refers to these chemicals, and they call them polyoxyalkylene.

So we thought at least that's a recognized chemical family. If you don't use INCI nomenclature to describe them that would be one that's commonly used in industry and that's a test.

DR. BELSITO: So you're suggesting the title, Polyoxyalkylenes?

MR. KENNEDY: Yes. Polyoxyalkylene --

DR. BELSITO: A-L-K-Y, or A?

MR. KENNEDY: It would be A-L-K-Y-L.

DR. BELSITO: E-N-E.

MR. KENNEDY: E-N-E, yeah. It should be at the bottom of the -- if you see it -- if you can read the small print, if not I have a larger one for you if you, if you like.

DR. BELSITO: Oh. I wasn't referring to -- I didn't realize it was --

MR. KENNEDY: If you'd larger one to read. You can see that?
DR. BELSITO: No. I can read it. I didn't realize that it --
MR. KENNEDY: I can't read that one so.
DR. BELSITO: You see I did a bio break, and I was totally lost.
MR. KENNEDY: We just started on this anyway.
DR. BELSITO: Okay. So, polyoxyalkylene siloxane copolymers?
MR. KENNEDY: And the second part.
DR. BELSITO: And alkyl polyoxyethylene siloxane copolymers. Okay.
MR. KENNEDY: Right.
DR. BELSITO: Because I'm a hunt and peck, and I wasn't following you that quickly. Okay. So now I see it. Fine. You know, I prefer to be chemically correct, and I'm not a chemist at all, so.
DR. SNYDER: Politically, no; chemically, yes.
DR. HELDRETH: I agree with both of these. The only thing is the 5 of 12 that you mentioned.
MR. KENNEDY: Yes. Yes.
DR. HELDRETH: The are actually end-capped dimethicone.
MR. KENNEDY: When you say end-capped dimethicone --
DR. HELDRETH: Like the henoxy dimethicone.
MR. KENNEDY: The henoxy dimethicone?
DR. HELDRETH: That's described in the dictionary as just dimethicone end-capped.
MR. KENNEDY: End-capped, yes, yes.
DR. HELDRETH: So that wouldn't fit under either of those, maybe, should we have a third name, for those?
MR. KENNEDY: You know, I would -- it's sort of how all-encompassing your nomenclature, you have about 111 compounds, and if you wanted to be perfectly correctly with all of your chemistry, you'd end up with about 8 to 10 different names. And I don't think that's the point in the title necessarily, I think it's an industry -- it's up to your group. You know, we would be comfortable with a fairly description like that. One might argue that an alkyl modified covers a steroxy, although it's not exactly right.

What we felt, was these two names covered the large majority by far of everything in there, and that when you go through you individually call out the chemistries as well, specifically, because there's probably a half-a-dozen others that are one-offs that this name doesn't describe perfectly, but your names are going to get awfully long, if you try to get everyone just right.
DR. HELDRETH: Right. And I understand what you're saying.
DR. BELSITO: But it's the better descriptor than what we currently have, which can be misinterpreted.
MR. KENNEDY: Well, we thought it was more encompassing and is less likely to be misinterpreted, that was our thought, yeah. We weren't trying to capture all of the names in here. We agreed it's not -- you're not going to -- with INCI or CAS, you're not going to incur it.

I mean, you could go to something as broad as -- organically modified siloxane, but that's so broad that nobody --
DR. BELSITO: We could say polyoxyalkylene siloxane copolymers and alkyl polyoxyalkylene siloxane copolymers, and related ingredients --
MR. KENNEDY: And related materials, or something.
DR. BELSITO: -- as used in -- related materials as used in cosmetics.
MR. KENNEDY: Or similar material, similar compound?
DR. BELSITO: Right.
MS. KOCH: Or actually the miscellaneous stuff.
MR. KENNEDY: Yeah.

DR. BELSITO: To catch the fact that the major groupings are those two families.

MS. KOCH: Are those two.

MR. KENNEDY: Right. I mean it's a --

DR. HELDRETH: They are not polyoxy and they are not copolymers, so.

MR. KENNEDY: Which ones?

DR. HELDRETH: Those five, like --

MR. KENNEDY: No. Well, they're actually -- I guess you would argue they are sort of copolymers and that they are copolymers with the siloxane, but they are actually individual reactants. They are attached via an SIOC linkage.

DR. HELDRETH: Right. But just how you either end, they're just end caps, it's not really copolymer.

MR. KENNEDY: Well, I mean, they are -- actually in industry those are reacted and there are cases where you put the alkyls on the ends as well. Maybe not in this industry as much, but there are cases where you can add an alkyl, but it's and SIC carbon bond directly to an end as well. So that's commonly done in industry also. I don't know if --

DR. HELDRETH: Right. But what I'm saying it's not a copolymer, because it is end-capped.

MR. KENNEDY: No -- I would agree, you know, I would agree. Right, I would agree. It's a reactive group on or otherwise on a polymer. Yeah.

DR. HELDRETH: On all of the polymers.

MR. KENNEDY: Yeah. Yeah. On all of the polymers, yes.

MS. KOCH: And related substances.

MR. KENNEDY: And related -- yeah, I agree. I mean, when we looked at this as an industry, we went back and forth quite a few times, and we just finally decided there was no single term that would catch everything. I mean, if you specifically wanted to call out those in the name, I don't think as industry we'd have an issue with it.

We were just concerned with the general name of alkoxy silanes, or alkoxy siloxanes, because it implies something that generally these are not, I mean for the most part in the industry. In the industry, I think, we'd be okay with related substances, or similar compounds, or something, if you guys are okay with that.

SPEAKER: And the same conditioning agent (inaudible).

DR. BELSITO: Or we could just list all the ingredients, and have our abstract end with the list of the ingredients.

MS. KOCH: Would be really long --

MR. KENNEDY: It would be about 19 pages long. Yeah, they are not all perfect, they're not, for sure, and the nomenclature is used -- indicated when you first started this whole thing, it's a crazy science as it is with the silicones.

DR. BELSITO: Okay. So we are going to rename for the industry slide, and also table for promise to industry data. That's what we are agreeing to do. So Dan, Curt, Paul?

DR. LIEBLER: Good.

DR. SNYDER: Yes.

DR. BELSITO: Yes. Yes. Yes. Okay.

Day Two

DR. BERGFELD: Moving on to the next ingredient, Dr. Belsito is up again with polysiloxanes.

DR. BELSITO: Yes. We were privileged to have some representatives from the Manufacturing Council, the American Chemical Council speak to us. They had two suggestions. One, to rename this group so that it is quite -- or more clear I should say, exactly what we're reviewing, and their suggestion was polyoxyalkylene siloxane in copolymers and alkylpolyoxyalkylene siloxane copolymers and related ingredients as used in cosmetics. And our team felt that we were comfortable with that change in the title. And their second request was that we table this for information that would be provided to us within the month, and we agreed to that table.

DR. BERGFELD: So your motion is to table?

DR. BELSITO: Yes.

DR. HILL: Second.

DR. BERGFELD: Second. No discussion on a motion to table? All those in favor of tabling?

DR. MARKS: There's discussion.

DR. BERGFELD: There's discussion afterwards but not --

DR. MARKS: Yeah.

DR. BERGFELD: -- in between. So it's approved.

(Motion passed)

DR. BERGFELD: We will table. And now discussion?

DR. MARKS: Yeah. What we wanted to do is get more data for the smallest compound because we were concerned that the smallest compound was absorbed and will be toxed out on that. So just to clarify what we're tabling it for.

DR. BERGFELD: Any other comments? Don's team?

DR. BELSITO: No. Fine.

DR. BERGFELD: Dan? Paul? Curt?

UNIDENTIFIED SPEAKER: Fine with me.

DR. BERGFELD: Okay. Ron Hill?

DR. HILL: These were raised yesterday on the record, but low molecular rate impurities, especially any with alkylating capability. And also because it was noted that there could be an excess of (inaudible) alcohol ethoxylate up to 30 percent by weight that we make sure we capture in our document anything known about the toxicology of that that might be relevant to these products.

And also, we still have that loose end statement about inhalation that needed to be addressed, but I think all that got captured in the record yesterday.

DR. BERGFELD: Thank you.

DR. HILL: And the Industry people, at least some of them are present, so.

DR. BERGFELD: Okay. Ron or Tom, any other comments? None? So we've moved to table. We've heard the discussion points. We're going to move on then.

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MEMORANDOM

To: CIR Expert Panel and Liaisons

From: Lillian C. Becker, M.S.
Scientific Analyst and Writer

Date: May 16, 2014

Subject: Unpublished data on Alkoxy Polysiloxanes as Used in Cosmetics

At the March, 2014 meeting, the Silicone Environmental, Health and Safety Center (SEHSC) informed the Panel that they were gathering data on these ingredients and were expecting to be able to deliver that data before the June meeting. Some of the data has been submitted and incorporated into the report. That information, along with updated concentration of use data, is provided here.

Summaries of toxicity studies submitted by SEHSC include:

- PPG-2 Dimethicone
  - Acute toxicity
  - Genetic toxicity
- Bis-Isobutyl PEG-24/PPG-7/Dimethicone Copolymer
  - Skin sensitization
- PEG/PPG-15/15 Acetate Dimethicone
  - Acute dermal toxicity
- Lauryl PEG/PPG-18/18 Methicone
  - Skin sensitization
  - Genetic toxicity in vitro
- PEG/PPG-19/19 DIMETHICONE
  - Acute toxicity
  - Skin sensitization
  - Genetic toxicity
  - Sub-acute dermal toxicity
- PEG-12 dimethicone
  - Acute inhalation and dermal toxicity
  - Eye and skin irritation/corrosion
  - Skin sensitization
  - Reproductive toxicity
  - Subacute oral and dermal toxicity

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Data sheets on generic polysiloxanes (CAS No. 68937-54-2) and cetyl PEG/PPG-10/1 dimethicone (CAS No. 191044-49-2) were also submitted.

Two more data sheets on similar polysiloxane-type compounds were submitted but they did not match any of the ingredients in this report. They are included for the Panel's information.

Safety Assessment of Polyoxyalkylene Siloxane Copolymers, Alkyl-Polyoxyalkylene Siloxane Copolymers, and Related Ingredients as Used in Cosmetics

Status: Draft Report for Panel Review
Release Date: May 16, 2014
Panel Meeting Date: June 9-10, 2014

The 2014 Cosmetic Ingredient Review Expert Panel members are: Chairman, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; Ronald A Hill, 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 report was prepared by Lillian C. Becker, Scientific Analyst/Writer.

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INTRODUCTION

This is a safety assessment of polyoxyalkylene siloxane copolymers, alkyl-polyoxyalkylene siloxane copolymers, and related ingredients as used in cosmetics. The functions of these ingredients include hair conditioning agents, viscosity increasing agents, emulsion stabilizers, and film formers (Table 1).

In 1982, the Cosmetic Ingredient Review (CIR) Expert Panel (Panel) published a safety assessment of dimethicone copolyol with a safe as used conclusion.[1] At the time, the term dimethicone copolyol referred to polymers of dimethylsiloxane with polyoxyethylene and/or polypropylene side chains. These polymers included straight-chain dimethicone polymers (up to 10000 repeating units of dimethyl polysiloxanes); cyclized dimethicones; silica-activated dimethicones; and cyclized dimethicone copolyol forms. The summary of the 1982 safety assessment is provided below.

Since the 1982 report, the International Nomenclature Cosmetic Ingredient (INCI) naming conventions have changed and each such compound has an individually assigned name and is no longer covered under the umbrella term of dimethicone copolyol.[2] In a re-review of dimethicone copolyol, published in 2005, the Panel identified several of these ingredients and included them under the safe as used conclusion reaffirmation.[1]

This safety assessment does not include any cyclic dimethicones, only linear copolymers.

Several structurally related ingredients have been reviewed by the Panel. All of these ingredients were safe as used or safe with qualifications (Table 2). Dilinoleic acid is a cosmetic ingredient that has not yet been reviewed by the Panel.

The Silicone Environmental, Health and Safety Center (SEHSC) collected unpublished toxicological data on several of these ingredients from their members. [3] Summaries of this data were submitted to CIR and the information has been incorporated into this report.

Dimethicone Copolyol Summary, 1982

Dimethicones are polymers of methylsiloxane. Dimethicone Copolyols are Dimethicones copolymerized with polyalkoxy chains.[1] The Copolyols are chemically and physically inert ingredients used in cosmetics in a concentration range of less than or equal to 0.l% -10% as surface tension depressants, wetting agents, emulsifiers, foam builders, plasticizers, and lubricants. Copolyol containing products may be applied to all surfaces of the body on an occasional or daily basis over a period of years.

Silicone compounds do not easily cross membrane barriers and are not absorbed through the skin. Silicones are not metabolized by the body or by microorganisms. Silicone fluids are relatively innocuous when administered orally and parenterally.

Dimethicone Copolyols were at most slightly toxic to the rat when administered orally in a single dose. Single dermal application of Copolyols to rats and rabbits were practically nontoxic. Copolyols were not primary skin or ocular irritants in the rabbit. Inhalation studies at ambient temperatures in the rat indicated that little hazard exists. An 89-day feeding study in the rat using two concentrations of a Copolyol B gave no evidence of subchronic oral toxicity. Subchronic dermal tests in the rabbit using two undiluted Copolyol A ingredients showed little effect other than slight to moderate skin irritation at the application sites.

Clinical studies on a total of 39 subjects indicated that both 40% Dimethicone Copolyol in aqueous solution and undiluted Dimethicone Copolyol are not primary skin irritants.

Fifty subjects showed no indication of skin irritation or sensitization when tested with undiluted Dimethicone Copolyol A ingredients. An unspecified concentration of Dimethicone Copolyol was found to be nonirritating and nonsensitizing when tested on 201 volunteers.

CHEMISTRY

Definition and Structure

All of the ingredients in this report are alkoxylated derivatives of polysiloxanes, specifically dimethicones. Within this grouping, there are three primary configurations: 1) end-capped dimethicone, wherein a dimethicone polymer is terminated on either end with an alkoxy group (e.g., cetyloxy); 2) alkoxy-dimethicone/dimethicone co-polymers; and 3) some combination of 1 and 2 (Figure 1).

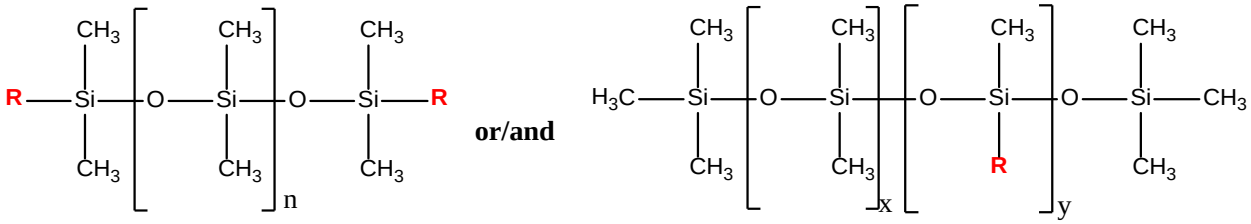
Physical and Chemical Properties

The physical and chemical properties of the ingredients in this safety assessment are presented in Table 3.

Under the generic listing of CAS No. 68937-54-2 (dimethylsiloxane, ethylene oxide block copolymer), it was reported that the melting point was -14°C, the boiling point was >250°C, and the density was 1.035 g/mL at 25°C.[4]

Alkoxy polysiloxanes with a PEG moiety tend to be hydrophilic and soluble in water and alcohols.[5] In general, the longer the PEG chain length, the greater the foaming and the higher the cloud point.

As the number of alkoxy groups in the polymer increases, the water solubility increases.[6] Compounds with >16 carbon atoms in the fatty acid group are the most hydrophobic.



-wherein **R** is an alkoxy or polyalkoxy group

Figure 1. Alkoxy Polysiloxanes

Molecular weight affects the orientation/configuration of the alkoxy polysiloxanes on the surface of the skin and, in general, low molecular weight polymers are very good wetting agents.[6]

Alkoxy polysiloxanes with < 12 carbon atoms in the fatty acid group are liquid at room temperature; those with >14 carbon atoms are solids.[7] Compounds with an unsaturated or branched fatty acid group are liquid at room temperature.[8]

Method of Manufacture

Alkoxy polysiloxanes are produced by hydrosilylation. In most cases hydrogen dimethicone polymer block is reacted with an allyl alkoxylate and alpha-olefin delta-alkene.[6,9] The product can be further polymerically modified with ethylene oxide or propylene oxide to produce PEG or PPG chains, respectively.

Newer catalyst systems allow for the manufacture of dimethicone copolyol compounds that contain simple hydroxypropyl groups.[6]

Impurities

Bis-PEG-15 methyl ethyl dimethicone is reported to contain 0.1% octamethylcycloterrasiloxane.[8] Analysis of three batches of bis-PEG-15 methyl ethyl dimethicone found that there was < 1% for each of Al, As, Ba, Be, Bi, Ca, Cd, Co, Cr, Cu, Fe, Hg, Mn, Mo, Ni, Pb, Sb, Sn, Sr, Tl, V, W, Zn, and Zr. A maximum of 0.1% of cyclotetrasiloxane and cyclopentasiloxane was reported.

PEG/PPG-25/25 dimethicone is reported to contain < 1% octamethylcyclotetrasiloxane.[10] Pt-catalyst residues were reported to be < 5 ppm. Cyclotetrasiloxane was reported to be present at a maximum of 1.0%, and cyclopentasiloxane at no greater than 0.5%. Volatile organic compounds (VOC) were reported at < 2%.

A product brochure reported that PEG-12 dimethicone (in three forms), PEG-17 dimethicone, PEG-10 dimethicone, and PEG-20/PPG-23 dimethicone are all 100% pure.[11]

When alkoxy polysiloxanes are manufactured, there is an excess of allyl alcohol ethoxylate used.[6] The excess remains in the product and may be present up to 30% by weight.

USE

Cosmetic

The Food and Drug Administration (FDA) collects information from manufacturers on the use of individual ingredients in cosmetics as a function of cosmetic product category in its Voluntary Cosmetic Registration Program (VCRP).[12] Use categories are summarized in Table 4. A survey was conducted by the Personal Care Products Council (Council) of the maximum use concentrations for ingredients in this group.[13] These ingredients were reported to be used in every FDA VCRP product category, the highest numbers in makeup and products used around the eyes. The highest concentrations of use were reported for PEG/PPG-19/19 dimethicone in eye products up to 10.7%, and bis-PEG/PPG-14/14 dimethicone in deodorants up to 3%, bis-hydroxythoxypropyl dimethicone in blushes up to 12%, and PEG/PPG-17/18 dimethicone in perfumes up to 14%

Data from both the VCRP and the Council were available for the following:

- Behenoxy dimethicone
- Bis-hydroxythoxypropyl dimethicone
- Bis-PEG-4 dimethicone
- Bis-PEG-12 dimethicone beeswax
- Bis-PEG-12 dimethicone candelillate
- Bis-PEG-15 methyl ether dimethicone
- Bis-PEG/PPG-14/14 dimethicone
- Bis-PEG/PPG-16/16 PEG/PPG-16/16 dimethicone
- Bis-PEG/PPG-20/20 dimethicone
- Cetyl PEG/PPG-10/1 dimethicon
- Lauryl PEG-9 polydimethyl siloxyethyl
- PEG/PPG-14/4 dimethicone
- PEG/PPG-17/18 dimethicone
- PEG/PPG-18/18 dimethicone
- PEG/PPG-19/19 dimethicone
- PEG/PPG-20/15 dimethicone
- PEG/PPG-20/20 dimethicone

- PEG/PPG-20/23 dimethicone
- PEG/PPG-20/6 dimethicone
- PEG/PPG-22/23 dimethicone
- PEG/PPG-22/24 dimethicone
- PEG/PPG-25/25 dimethicone
- PEG/PPG-30/10 dimethicone
- PEG/PPG-4/12 dimethicone
- PEG-10 dimethicone
- PEG-10 methyl ether dimethicone
- PEG-11 methyl ether dimethicone
- PEG-12 dimethicone
- PEG-14 dimethicone
- PEG-17 dimethicone
- PEG-7 dimethicone
- PEG-8 cetyl dimethicone
- PEG-8 dimethicone
- PEG-8 methicone
- PEG-9 dimethicone
- PEG-9 polydimethylsiloxyethyl dimethicone
- Polysilicone-13
- PPG-12 dimethicone
- PPG-2 dimethicone
- Stearoxy dimethicone

There were use data reported from the VCRP, but not the Council, for the following:

- Lauryl isopentyl-PEG/PPG-18/18 methicone
- Lauryl PEG-8 dimethicone
- PEG/PPG-15/15 dimethicone
- PEG-6 dimethicone
- PEG-6 methyl ether dimethicone
- PEG-8 dimethicone dimer dilinoleate
- PEG-8 dimethicone/dimer dilinoleic acid

There were only maximum concentrations of use data reported from the Council, but no data in the VCRP, for the following:

- Bis-PEG-12 dimethicone
- Lauryl PEG/PPG-18/18 methicone
- Methoxy PEG/PPG-25/4 dimethicone
- PEG/PPG-8/14 dimethicone
- PEG-3 dimethicone
- Stearoxy dimethicone

The VCRP has data under the previous umbrella names of these ingredients (Table 4).[12] There are 28 uses reported for cetyl dimethicone copolyol, 322 uses for dimethicone copolyol, 5 uses for dimethicone copolyol crosspolymer, and 1 use for dimethicone copolyol methyl ether.

Table 5 lists the ingredients for which there were no uses reported by either the VCRP or the Council.

Non-Cosmetic

Polydimethylsiloxanes are used for the siliconization of needles and syringes, lubrication of medical devices, and as topical formulation excipients in skin protecting compositions, and drug carriers.[14]

TOXICOKINETICS

Absorption, Distribution, Metabolism, and Excretion

Due to their proclivity to wet surfaces, it is possible that low molecular weight alkoxy polysiloxanes penetrate and irritate the skin.[6]

BIS-PEG-15 METHYL ETHYL DIMETHICONE

In a permeability test using pig skin and diffusion chambers (n = 6), bis-PEG-15 methyl ethyl dimethicone was not detected in the receptor chamber (detection limit 0.5%) at 0, 16, 24, 40, 64, and 72 h.[15] In a second run of the experiment (n = 3), the test substance was not detected (detection limit 1.25%) in pooled samples at 72 h. In both experiments, the test substance (16 mg/4 cm^2) was administered to the skin for 24 h and then washed with a neutral shampoo.

TOXICOLOGICAL STUDIES

Acute Toxicity

Oral – Non-human

BIS-PEG-15 METHYL ETHYL DIMETHICONE

The oral LD_{50} of bis-PEG-15 methyl ethyl dimethicone was > 4640 mg/kg for rats. No further information was provided.[8,16]

PEG/PPG-19/19 DIMETHICONE

The oral LD_{50} of PEG/PPG-19/19 dimethicone (100%) was > 16 mL/kg for CFE rats (n = 5/sex).[3] Controls were administered with tragacanth mucilage (0.5%). Clinical signs included piloerection and diuresis. All rats appeared healthy four days after dosing and gained weight normally. Necropsies were unremarkable.

PEG/PPG-25/25 DIMETHICONE

There were no mortalities or clinical signs in Sprague-Dawley rats (n = 5/sex) orally administered PEG/PPG-25/25 dimethicone (2007 mg/kg).[17] There were no behavioral abnormalities or physiological findings. Body weights were similar to controls. The test substance was administered neat. The rats were observed for 14 days and then necropsied. The authors concluded that the oral LD_{50} is $\geq$ 2007 mg/kg.

Dermal – Non-human

PEG-12 DIMETHICONE

The estimated acute dermal LD_{50} was > 5 g/kg PEG-12 dimethicone for male albino rabbits (n = 5).[3] One rabbit in the high-dose group was euthanized in a moribund condition. In the remaining animals, only slight exfoliation at the application site was observed. No test material-related lesions were observed microscopically in any of the rabbits. The test material (2 or 5 mg/kg) was administered to the clipped skin for 24 h on a cotton bandage under plastic wrap.

PEG/PPG-19/19 DIMETHICONE

When PEG/PPG-19/19 dimethicone (2000 mg/kg) was administered to the dorso-lumbar region of New Zealand White rabbits (n = 5/sex) for 24 h, none of the rabbits died during the course of the study.[3] There were no observed signs of systemic effects except that one male rabbit had few feces on Day 3 of the study. There was slight to well defined irritation in most of the rabbits, that resolved by the end of the study. There were no treatment related effects on body weight gain, nor were there macroscopic effects upon necropsy of the animals. The rabbits were observed for 15 days.

Inhalation – Non-Human

PEG-12 DIMETHICONE

In an acute inhalations study of PEG-12 dimethicone (0.68 mg/L) using Sprague-Dawley rats (n = 5/sex), there were no deaths in the control or test groups observed, and no abnormalities were observed during the 4-h exposure or the observation period.[3] Necropsies revealed no abnormalities in any major organs or tissues.

Inhalation – Human

The ECHA database states that dimethicones (under generic CAS No. 68937-54-2 and generic name polydimethylsiloxane polymer) are harmful if inhaled.[18] No further information was provided.

Repeated Dose Toxicity

Oral – Non-human

BIS-PEG-15 METHYL ETHYL DIMETHICONE

There were no clinical signs observed when CD Sprague Dawley rats (n = 5/sex) were orally administered bis-PEG-15 methyl ethyl dimethicone (0, 50, 200, 1000 mg/kg/d in corn oil) for 4 weeks.[19] There were no deaths during the study. Body weights and feed consumption were not affected by treatment. Clinical pathology, microscopic examination of the tissues, and necropsies were unremarkable. There was an increase in liver weight in the male in the high-dose group.

PEG-12 DIMETHICONE

The NOAEL of PEG- 12 dimethicone was 1000 mg/kg for Sprague-Dawley rats (n = 5/sex) when orally administered for 29 days.[3] There were no test substance-related microscopic pathological findings. There were no signs of toxicity and no deaths occurred. Functional observation battery (FOB) assessments, manipulation, and motor activity tests did not reveal any test substance-related effects. The only treatment-related clinical chemistry and organ weight findings were decreased albumin/ globulin ration and increased liver weight in the 1000 mg/kg/day females. However, there were no microscopic changes in the livers.

Dermal – Non-human

PEG-12 DIMETHICONE

PEG-12 dimethicone (100, 300, or 1000 mg/kg) did not produce any signs of systemic toxicity when dermally administered to New Zealand White rabbits (n = 10/sex) 6 h/day under semiocclusion for 29 days.[3] There were no deaths. Very slight erythema was observed in all treated groups and the incidence of erythema increased in a dose-dependent manner; it was higher in the female group. One female in the highest dose group showed severe erythema, which resolved by the end of the study. Administration of PEG-12 dimethicone produced no ophthalmologic findings attributable to treatment.

Hematological and blood chemistry testing did not reveal any toxicological findings. Organ weights were unaffected by treatment. There were no treatment-related macroscopic findings at necropsy, other than those associated with the local signs of irritation at the dermal application sites. Microscopic examination revealed a number of findings at the application site, consisting of diffuse subcutaneous inflammation, acanthosis and a single case of follicular abscess. Ulcers were present on the application sites examined for females in the low- and mid-dose groups.

PEG/PPG-19/19 DIMETHICONE

When PEG/PPG-19/19 dimethicone (0, 100, 300, 1000 mg/kg/d) was dermally administered to female New Zealand White rabbits (n = 10/sex) for 29 days, the no observed effect level (NOEL) with regard to systemic toxicity was found to be 1000 mg/kg/day.[3] Each treatment was in place for 6 h. There were no deaths or clinical signs. Local irritation was observed at the application site of the majority of rabbits from all treatment groups. These signs were generally limited to erythema, edema, exfoliation, and scabs. Body weight, body weight change and feed consumption were not affected by treatment. There were no ocular findings attributable to treatment; hematological and blood chemistry investigations were unremarkable. Absolute and relative organ weights were unaffected by treatment. There were no treatment-related macroscopic findings at necropsy, except those associated with the local signs of irritation at the application sites. Diffuse subcutaneous inflammation, acanthosis and follicular abscess were revealed upon microscopic examination of the application site.

REPRODUCTIVE AND DEVELOPMENTAL TOXICITY

GENERIC SILOXANES AND SILICONES, DI-METHYL, 3-HYDROXYPROPYL METHYL ETHOXYLATED

New Zealand albino rabbit does (n = 30) exhibited increased numbers of resorption sites when siloxanes and silicones, 3-hydroxypropyl methyl, di-methyl ethoxylated (generic compounds that fall within the description of the ingredients in this safety assessment with the CAS No. 68937-54-2; 200 mg/kg in corn oil) were dermally administered to shaved backs of the does (~10% body surface) on gestation days 6 to 18.[20] The two control groups were administered the vehicle or nothing. Does were killed and necropsied on gestation day 29. There were no deaths attributed to the test material. One pup in the treatment group displayed clubbing of the extremities, partial acranius, and an umbilical hernia. The 24-hour survival of fetuses, abnormalities in the fetuses, and number of abnormal fetuses were similar across the control groups exposed to the vehicle or unexposed to both the test material and the vehicle. No dermal effects were reported for the dams. Subsequent testing of the test substance demonstrated that it was neither embryotoxic nor teratogenic when dermally administered to New Zealand white rabbits at dose levels of 50, 100, or 200 mg/kg (data not provided).

BIS-PEG-15 METHYL ETHYL DIMETHICONE

Bis-PEG-15 methyl ethyl dimethicone was reported to not be a reproductive toxin in a material safety data sheet (MSDS). No further information was provided.[16]

PEG-12 DIMETHICONE

Dermally administered PEG-12 dimethicone (100%; 0, 50, 100 or 200 mg/kg) was not embryotoxic or teratogenic to New Zealand White rabbits on days 6 through 18 of gestation.[3] No adverse effects were observed in mean maternal body weight, feed consumption or liver weights of the treated rabbits. No differences were observed in the number of implantation sites, number of live fetuses per litter, mean litter size, fetal body weight or crown-rump length between the control and treated groups. The incidence of resorption among the total fetal population for rabbits treated with test material was similar to that of the control. No single alteration was observed in the treated litters at an incidence different from the control. No treatment related signs of toxicity or behavioral changes were observed in any of the pregnant rabbits. Three rabbits in the 50-mg/kg/day group, 1 in the 100-mg/kg/day group, and 3 in the 200-mg/kg/day group died during the study. Some pregnancies were terminated because of Pasteurella multocida infection, a known abortifacient in rabbits.
PEG-12 dimethicone or water (control) was administered to the skin of pregnant New Zealand white rabbits on days 6 through 18 of gestation. Litters were collected by cesarean section on day 29 and fetuses examined for external, visceral or skeletal defects.

GENOTOXICITY

BIS-PEG-15 METHYL ETHYL DIMETHICONE

In a reverse mutation assay using *Salmonella typhimurium* (strains TA98, TA100, TA1535, and TA1537) as a plate incorporation test and a pre-incubation test, bis-PEG-15 methyl ethyl dimethicone (0, 33.3, 100.0, 333.3, 1000.0, 2500.0, and 5000.0 μg/plate) was not genotoxic with or without metabolic activation.[21]

LAURYL PEG/PPG-18/18 METHICONE

In a reverse mutation assay using *S. typhimurium* (strains TA98, TA100, TA1535, and TA1537) and *E. coli* (WP2 *ur*A pKM101 and WP2 pKM101), lauryl PEG/PPG-18/18 methicone (0, 15, 50, 150, 500, and 1500 μg/plate in ethanol) was

not genotoxic with or without metabolic activation.[3] Precipitate was observed at 1500 µg/plate, but no appreciable toxicity was observed.

PPG-2 DIMETHICONE

In a reverse mutation assay using *S. typhimurium* (strains TA97 TA98, TA100, TA1535) and *Escherichia coli* (WP2), PEG-2 dimethicone (0, 312.5, 625, 1250, 2500.0, and 5000.0 µg/plate in dimethylsulfoxide (DMSO)) was not genotoxic with or without metabolic activation.[3] When repeated with another strain of *S. typhimurium* (strains TA1535), PEG-2 dimethicone (0, 15625, 31250, 62500, 125 000 and 250 000 µg/plate in ethanol) was not genotoxic with or without metabolic activation.

PEG/PPG-19/19 DIMETHICONE

In a reverse mutation assay using *S. typhimurium* (strains TA98, TA100, TA1535, TA1537, and TA1538), PEG/PPG-19/19 dimethicone (0, 0.5, 5, 100, and 500 µg/plate) was not genotoxic with or without metabolic activation.[3]

PEG/PPG-25/25 DIMETHICONE

In a reverse mutation assay using *S. typhimurium* (strains TA98, TA100, TA1535, TA1537) in a plate incorporation test and a pre-incubation test, PEG/PPG-25/25 dimethicone (33.3, 100.0, 333.3, 1000.0, 2500.0, 5000.0 µg/plate) was not genotoxic with or without metabolic activation.[22]

CARCINOGENICITY

BIS-PEG-15 METHYL ETHYL DIMETHICONE

Bis-PEG-15 methyl ethyl dimethicone was reported to not be a carcinogen in a material safety data sheet (MSDS). No further information was provided.[16]

IRRITATION AND SENSITIZATION

Irritation

Dermal – Non-human

BIS-CETYL/PEG-8 CETYL PEG-8 DIMETHICONE

Bis-cetyl/PEG-8 cetyl PEG-8 dimethicone (100%; 0.5 mL; MW > 10 000) was a dermal irritant when administered to the intact or abraded skin of New Zealand White rabbits (n = 6) under occlusion for 24 h.[3] The Draize scores were 2, 1.995, and 1.915 for all test sites, intact skin, and abraded skin, respectively. Well-defined erythema was observed for 5/6 abraded and 5/6 intact sites at 24 h. Barely perceptible erythema was observed at 1 intact and 1 abraded site. Barely perceptible edema was observed at all sites at 24 h. By 72 hours both incidence and severity of erythema and edema had subsided, but were not totally resolved.

BIS-PEG-15 METHYL ETHYL DIMETHICONE

Bis-PEG-15 methyl ethyl dimethicone was not an acute skin irritant to rabbits. No further information was provided.[8,16]

CETYL PEG/PPG-10/1 DIMETHICONE

When administered to the intact or abraded skin of New Zealand White rabbits (n = 6) for 24 h, cetyl PEG/PPG-10/1 dimethicone (MW < 1000; 0.5 mL) caused very slight redness (grade 1) in 5/6 abraded sites and 5/6 intact sites at 24 hours.[3] The Draizes score were 0.4 for both intact and abraded skin. There was no edema observed for any rabbit for any time point. All test sites were normal at 72 h.

When administered to the intact or abraded skin of New Zealand White rabbits (n = 6) for 24 h, cetyl PEG/PPG-10/1 dimethicone (MW > 10 000; 0.5 mL) caused slight irritation in all tested rabbits.[3] The Draize scores were 1.17, 0.75, and 1.58 for all test sites, intact skin, and abraded skin, respectively. At 24 h, all abraded sites and most intact sites exhibited erythema, most of these with edema. Irritation was more severe at the abraded sites. At 72 h, only 2 abraded sites had very slight erythema; all other irritations had cleared.

PEG-12 DIMETHICONE

In a patch test of PEG-12 dimethicone (100%; 0.5 mL) using female New Zealand White rabbits (n = 3), a single semi-occlusive application of the test material to intact clipped skin for 4 h elicited very slight erythema, which resolved within 72 h and no edema.[3] The Primary Irritation Index (PII) was calculated to be 0.44. The sites were scored for irritation at 60 min and 24, 48 and 72 h.

PEG/PPG-25/25 DIMETHICONE

PEG/PPG-25/25 dimethicone (100%; 0.5 mL) was not a dermal irritant when administered to the skin of male New Zealand hybrid albino rabbits (n = 6) for 4 h under semi-occlusion. The test sites were examined at 1, 24, 48, and 72 h after

removal. All scores for erythema and edema were 0 at all observation times.

GENERIC SILOXANES AND SILICONES, DI-METHYL, 3-HYDROXYPROPYL METHYL ETHOXYLATED

Siloxanes and silicones, di-methyl, 3-hydroxypropyl methyl ethoxylated (10% in distilled water; 0.5 mL; MW 1000 - 5000) was not an irritant when administered to the clipped intact or abraded skin of New Zealand White rabbits (n = 6) for 24 h under occlusion.[3] The remaining test material was wiped from the skin. The skin was evaluated for irritation 24 and 72 h.

Dermal – Human

PEG-12 DIMETHICONE

When PEG-12 dimethicone (0.5%, 2%, and 5%) was administered simultaneously with SLS (1% aqueous) to the backs of subjects (n = 48 female, 5 male) under occlusion for 24 h, the test material provided protection against the primary dermal irritation produced by the SLS when compared to the SLS control.[3] The high dose provided the greatest protection. The sites were evaluated for erythema and edema at 24 and 48 h.

Ocular

As the molecular weight of an alkyl polysiloxane (exact compounds, species, and number not provided) increased, irritation scores decrease, as measured using the Draize Irritation Rating Scale (Table 6).[6]

In two tests using the Skin[2] Epi-Ocular Tissue Model OCL-100 kit, silicone polyether (polydimethylsiloxane/ polyethoxy copolymer; generic term that could represent any of the alkoxy polysiloxanes with the name PEG-x Dimethicone), was classified as yielding none-to-mild irritation and minimal irritation.[23] There was minimal-to-no effect on corneal opacity and permeability, compared to the controls. There were no histologic changes observed.

The ECHA Summary and Classification and Labeling database states that PEG-dimethicones (under the CAS No. 68937-54-2 and generic name polydiemethylsiloxane polymer) causes serious eye irritation.[18]

BIS-PEG-15 METHYL ETHYL DIMETHICONE

Bis-PEG-15 methyl ethyl dimethicone was not an acute eye irritant to rabbits. No further information was provided.[8,16]

PEG-12 DIMETHICONE

In a repeated eye irritation test of PEG-12 dimethicone (0.1 mL) using male rabbits (n = 6), there were no signs of irritation of the cornea or iris observed in any of the rabbits, but slight, transient conjunctival redness was noted at 24 hours following each instillation.[3] The test substance was administered daily for 5 days and observations continued for 7 more days.

In a second study, the average mean eye irritation scores of PEG-12 dimethicone and sodium lauryl sulfate (SLS) versus those treated with SLS alone decreased from 10.4/38 to 1/38 and from 19.0/38 to 5.8/38, respectively.[3] The treated eyes of the rabbits in both groups showed signs of irritation consisting of moderate conjunctival redness, swelling and discharge. Rabbits treated with SLS alone also showed transient corneal opacity and iridal congestion. The test material in SLS solution showed evidence of rapid reduction in ocular irritation over a period of 48 h when compared to the control solution of SLS alone. These results indicated that the test fluid in SLS was effective in reducing eye irritation in rabbits. A 1:1 ratio of PEG-12 dimethicone (100%) and sodium lauryl sulfate (SLS; 3%) or a solution of SLS alone were administered into the right eye of male rabbits (n = 6) per group. Observations were made by slit lamp at 1, 6, 24, 48, and 72 h, and at 7 days.

PEG/PPG-25/25 DIMETHICONE

In a Draize test, PEG/PPG-25/25 dimethicone (100%; 0.1 mL) was a slight ocular irritant when administered to the eyes of male New Zealand hybrid albino rabbits (n = 6) for 4 h under semi-occlusion.[24] All irritation signs, except for mild congestion, were resolved by 72 h.

PPG-2 DIMETHICONE

Male rabbit (n = 3) eyes treated with PPG-2 Dimethicone (100%)/SLS (3%) in a 1:1 mixture (0.1 mL) showed reduced irritation during the first 48 hours compared with SLS alone.[3] The mean irritation scores decreased from a peak of 4.7/13.0 to 0.3/13.0 at 48 h. The rabbits were observed for indications of pain and discomfort and ocular observations using a hand-held slit-lamp were made at 1, 24, 48, 72 h and 7 days, including the use of sodium fluorescein (except at the 1-hour reading). All treated eyes exhibited signs of irritation consisting of moderate to marked redness, slight swelling and discharge. One rabbit had moderate corneal irritation at 24h only. All eyes appeared normal with no signs of irritation observed in any of the rabbits when examined at 72 h and at 7 days post-instillation.

Sensitization

Non-Human

BIS-CETYL/PEG-8 CETYL PEG-8 DIMETHICONE

In a local lymph node assay, bis-cetyl/PEG-8 cetyl PEG-8 dimethicone (100%; 0.5 mL; MW > 10 000) was not sensitizing to guinea pigs (n = 20).[3] Very faint to faint erythema (0.5-1) was noted at several test sites at 24 and 48 h. Very faint erythema (0.5) was observed at 2 test sites 24 h after challenge; very faint erythema persisted at one site at 48 h. No erythema was noted at any test site following rechallenge. For the induction phase, the test or control substance was administered via intradermal induction followed by topical application 6 days later. The intradermal injections were made in combination with Freunds Complete Adjuvant. A challenge dose of the test or positive control substance (at the highest non-irritating concentration) was administered to a naive site of each animal 12 days later. The sites were scored 24 to 48 h later. The positive control was 2-mercaptobenzothiazole

BIS-ISOBUTYL PEG-24/PPG-7/DIMETHICONE COPOLYMER

Bis-isobutyl PEG-24/PPG7/dimethicone copolymer (100%) was not sensitizing to Harley albino gunea pigs (n = 10/sex) when dermally challenged at 25% (in petrolatum).[3] The guinea pigs were administered 3 pairs of intradermal injections, with and without the test material. During the second week of the induction phase, topical applications of the test material were made to the induction site. Two weeks after the topical induction, the challenge applications were made to virgin sites for 24 h. The challenge concentration was the determined highest non-irritating concentration of the test article (25% in petrolatum). The guinea pigs were observed at 48 and 72 h for erythema, edema and other effects.

BIS-PEG-15 METHYL ETHYL DIMETHICONE

Bis-PEG-15 methyl ethyl dimethicone was not a sensitizer in a Magnusson & Kligman assay using guinea pigs (n = 20; control = 10).[25] Induction was performed by injection at 20% (in Alembicol D or Freund's complete adjuvant) followed a week later by dermal application on the injection site at 75%. The challenge was 2 weeks later by topical application at 50%. One death unrelated to the test substance occurred. There were responses in 15 guinea pigs in the test group and seven in the control group. There were no reactions when the guinea pigs were rechallenged at 5% in petrolatum.

PEG-12 DIMETHICONE

In a Magnusson and Kligman sensitization assay, PEG-12 dimethicone was not sensitizing when dermally administered to Dunkin-Hartley guinea pigs (n = 20; negative control = 10; positive control = 5).[3] There were no signs of toxicity and there were no body weight changes. Most of the positive control group reacted to the known sensitizer, hexyl cinnamic aldehyde (10% v/v). The incidence and severity of reactions seen in the test group and negative control group were considered to represent skin irritation rather than sensitization.

The intradermal induction consisted of 2 injections of 1:1 Freund's Complete Adjuvant: water (0.1 mL), 2 injections of the test substance (50% in water; 0.1 mL), 2 injections of the test material (50% in Freund's Complete Adjuvant; 0.1 mL). The control animals were treated similarly to test animals with the exception that the test material was omitted. Six days after injection, the application sites for the test group and negative control group were pre-treated with SLS (10% w/w in petrolatum; 0.5 mL) on the day prior to topical induction. Topical induction consisted of the test material (100%), hexyl cinnamic aldehyde (100%), or vehicle were administered under occlusion for 48 h. Challenge doses, administered 2 weeks after the topical induction, were administered to the anterior shaved sites on the flanks under occlusion. The treatment group and negative control group were treated on 3 sites with the test material at 100% and 50% water, and the vehicle under occlusion for 24 h. Dermal reactions to the challenge were evaluated using the Draize scale at 24 and 48 h after patch removal. Determination of sensitization potential was made by comparison of the challenge reactions in induced animals versus the respective control group.

PEG/PPG-19/19 DIMETHICONE

In a sensitization test using albino Dunkin-Hartley guinea pigs (n = 20; controls = 5), PEG/PPG-19/19 dimethicone (5% in water; 0.1 mL) was not a sensitizer when administered to clipped and shaved skin.[3] Positive controls exposed to hexyl cinnamic aldehyde (HCA).

On Day 1 of the study, 3 pairs of intradermal injections (0.1 ml/site) were made in the shaved region: a 50:50 dilution of Freund's Complete Adjuvant in Water; the test (5% solution of the test substance in water) or control materials (water or 10% HCA in Alembicol D); or 50:50 dilution of Freund's Complete Adjuvant with either the injected test or control solutions. Dermal responses were evaluated 24 h later. Six days after the injection, the same site on each animal was again cleared of hair and sodium lauryl sulfate (10%; 0.5 mL in petrolatum) was gently rubbed on the site. The next day, a filter paper patch was soaked with neat test or control materials and administered to the hair-free area for 48 hours. Skin reactions were evaluated upon removal of the dressing. No effects were noted by treatment with the test substance in clinical observations or body weight gain. Severe irritation was noted at all injection sites of Freund's Complete Adjuvant, slight to moderate irritation at injection sites of the test substance, slight irritation was seen at the HCA injection sites, but no irritation was seen at the control injection sites. Upon topical application, slight to well-defined redness was noted with the test

substance and HCA, but slight redness was seen in some control guinea pigs. After the second topical application, effects were the same for the test and control animals, though the HCA exposed animals had more marked and longer lasting effects indicative of skin sensitization. After 2 weeks, the left flank of each guinea pig was clipped and shaved and a filter paper patch, soaked with the test material or the control materials, was administered to the hair-free sites for 24 h. The sites were evaluated upon removal of the patch, and at 24 and 48 h. All animals were observed daily for signs of ill health or toxicity, and body weights were taken prior to the first injection and at study termination.

PEG/PPG-25/25 DIMETHICONE

In a sensitization test using albino Dunkin-Hartley guinea pigs (n = 40/sex), PEG/PPG-25/25 dimethicone (100%; 0.1 mL) was not a sensitizer when administered to the skin.[24] The induction included injections of Freund's complete adjuvant (50%), PEG/PPG-25/25 dimethicone (2.0% in 50/50 Freund's complete adjuvant/water) and PEG/PPG-25/25 dimethicone (2.0% w/v in water). This concentration (2%) was chosen because it provoked a weak to moderate irritation response during preliminary testing. Challenge was dermally administered (2.0%; 0.5 mL) on an occlusive patch left in place for 24 h.

Human

LAURYL PEG/PPG-18/18 METHICONE

In a HRIPT (n = 103), lauryl PEG/PPG-18/18 methicone (100%; 0.2 mL) was not sensitizing.[3] None of the subjects exhibited signs of irritation or sensitization during any part of the study. Nine patches were administered every 48 or 72 h under semiocclusion. Substances were not reapplied until Monday if the applications had been made on the previous Friday. Patches were administered to the infrascapular area of the back to one side of the midline. After a 12-14 day rest period, the same dose method was used on a previously unexposed site. The subjects removed the patches after 24 h. The sites were observed 24 and 48 h after the challenge patch was removed.

Other Dermal Effects

Comedogenicity

Dimethicone, dimethicone copolyol, and silicone wax (10% in dimethicone) were reported to be non-comedogenic using the rabbit ear assay.[26]

SUMMARY

This is a safety assessment of alkoxy polysiloxanes as used in cosmetics. The functions of these ingredients include hair conditioning agents, viscosity increasing agents, emulsion stabilizers, and film formers.

Alkoxy polysiloxanes are alkoxylated derivatives of polysiloxanes, specifically dimethicones.

These ingredients were reported to be used in every FDA product category, the highest numbers in makeup and products used around the eyes. PEG-12 dimethicone had the most reported uses of 521 cosmetic products up to 6.5%. PEG/PPG-17/18 Dimethicone was reported to be used up to 14% in perfumes and Cetyl PEG/PPG-10/1was reported to be used up to 15% in non-spray deodorants.

Bis-PEG-15 methyl ethyl dimethicone did not penetrate pig ear skin in in vitro experiments.

The oral LD_{50} of bis-PEG-15 methyl ethyl dimethicone was >4640 for rats. There were no mortalities or clinical signs in rats orally administered 2007 mg/kg PEG/PPG-25/25 dimethicone. The oral LD_{50} of PEG/PPG-19/19 dimethicone was > 16 mL/kg rats.

There were no observed signs of systemic effects when 2000 mg/kg PEG/PPG-19/19 dimethicone was dermally administered rabbits.

In an acute inhalations study of PEG-12 dimethicone at 0.68 mg/L rats, there were no deaths and no abnormalities were observed during the 4-h exposure or the 4-h observation period.

The oral NOAEL of PEG- 12 dimethicone was 1000 mg/kg for rats when administered for 29 days. Orally administered bis-PEG-15 methyl ethyl dimethicone was not toxic to rats at 1000 mg/kg/d for 4 weeks.

PEG-12 dimethicone up to 1000 mg/kg did not produce any signs of systemic toxicity when dermally administered to rabbits 6 h/day for 29 days. The NOEL for dermally administered PEG/PPG-19/19 dimethicone was 1000 mg/kg/d for 29 days for rabbits.

Rabbit does exhibited increased numbers of resorption sites when 200 mg/kg siloxanes and silicones, 3-hydroxypropyl Me, di-Me, ethoxylated were dermally administered to shaved backs of the does on gestation days 6 to 18. Dermally administered PEG-12 dimethicone up to 200 mg/kg was not embryotoxic or teratogenic to rabbits on days 6 through 18 of gestation. A dermally administered alkoxy polysiloxanes on gestation days 6 to 18 was not teratogenic to New Zealand albino rabbits. There were increased resorptions in the treated group.

Bis-PEG-15 methyl ethyl dimethicone and PEG/PPG-25/25 dimethicone were not genotoxic to *S. typhimurium* up to 5000 µg/plate. lauryl PEG/PPG-18/18 methicone was not genotoxic to *S. typhimurium* and *E. coli* up to 1500 µg/plate. PEG-2 dimethicone was not genotoxic to *S. typhimurium* and *E. coli* up to 5000.0 µg/plate and up to 250 000 µg/plate for the TA1535 strain. PEG/PPG-19/19 dimethicone was not genotoxic to *S. typhimurium* up to500 µg/plate.

Bis-cetyl/PEG-8 cetyl PEG-8 dimethicone at100% with a MW > 10 000 was a dermal irritant when administered to the intact or abraded skin of rabbits for 24 h. The Draize scores were 2, 1.995, and 1.915 for all test sites, intact skin, and abraded skin, respectively.

Cetyl PEG/PPG-10/1 dimethicone with a MW < 1000 caused very slight redness (grade 1) in 5/6 abraded sites and 5/6 intact sites at 24 hours in rabbits. The Draizes score were 0.4 for both intact and abraded skin.

PEG-12 dimethicone at 100% elicited very slight erythema, which resolved within 72 h, in rabbits. The Primary Irritation Index (PII) was calculated to be 0.44.

PEG/PPG-25/25 dimethicone at 100% was not a dermal irritant to rabbits. There were mixed reports of the ocular irritation potential of alkyl polysiloxanes. Increased molecular weight was reported to decrease the potential of ocular irritation.

PEG-12 dimethicone at 0.5%, 2%, and 5% provided protection against the dermal irritation effect of 1% SLS.

Bis-PEG-15 methyl ethyl dimethicone, PEG/PPG-25/25 dimethicone, and PPG-2 Dimethicone demonstrated little or no ocular irritation.

Bis-cetyl/PEG-8 cetyl PEG-8 dimethicone at 100% and MW > 10 000; bis-isobutyl PEG-24/PPG7/dimethicone copolymer at 100%; bis-PEG-15 methyl ethyl dimethicone at 20%; PEG-12 dimethicone at 100%; PEG/PPG-19/19 dimethicone at 5%; and PEG/PPG-25/25 dimethicone at 100% were not sensitizers to guinea pigs.

Lauryl PEG/PPG-18/18 methicone at 100% was not sensitizing in an HRIPT. None of the subjects exhibited signs of irritation or sensitization during any part of the study.

Dimethicone-based compounds were not comedogenic.

DISCUSSION

The Discussion will be developed by the Panel at the June, 2014 meeting.

CONCLUSION

The Conclusion will be developed by the Panel at the June, 2014 meeting.

TABLES

Table 1. Definitions and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

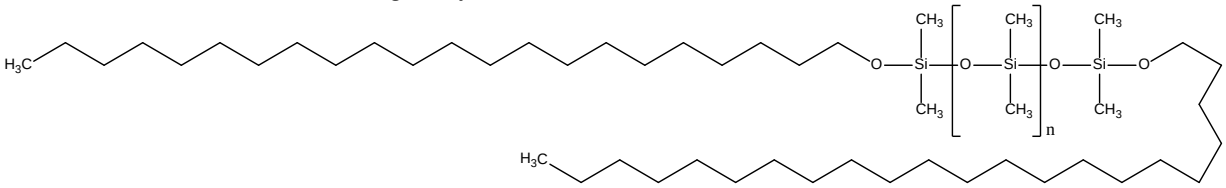
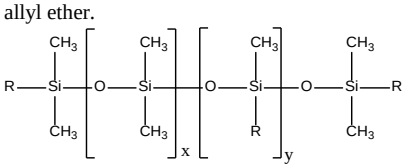
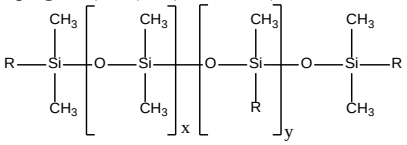
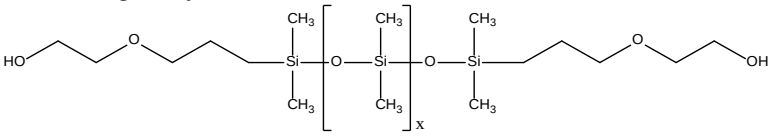
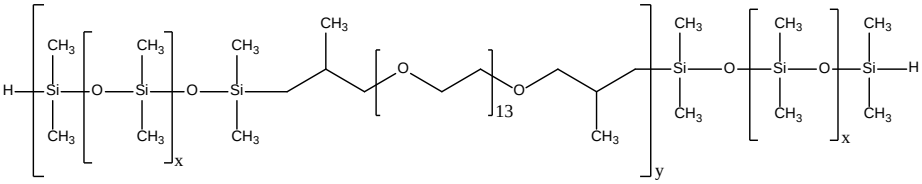
Ingredient CAS No.	Definition / Structure	Function
Behenoxy Dimethicone	Behenoxy Dimethicone is a dimethyl siloxane polymer that conforms generally to the formula. 	Skin-conditioning agent – emollient
Behenoxy PEG-10 Dimethicone 1136947-78-8	Behenoxy PEG-10 Dimethicone is the product obtained by the reaction of Hydrogen Dimethicone with Behenyl Alcohol and PEG-10 allyl ether.  where R may be a behenyl grouping or $-(CH_2)_3O(CH_2CH_2O)_8H$	Humectant; viscosity increasing agent – aqueous
Bis-Cetyl/PEG-8 Cetyl PEG-8 Dimethicone	Bis-Cetyl/PEG-8 Cetyl PEG-8 Dimethicone is the silicone compound that conforms generally to the formula, where R may be a cetyl grouping or $-(CH_2)_3O(CH_2CH_2O)_8H$.  where R may be a cetyl grouping or $-(CH_2)_3O(CH_2CH_2O)_8H$	Emulsion stabilizer
Bis-Hydroxyethoxypropyl Dimethicone 222416-17-3	Bis-Hydroxyethoxypropyl Dimethicone is the siloxane polymer that conforms generally to the formula. 	Skin-conditioning agent – emollient
Bis-Isobutyl PEG/PPG-10/7/ Dimethicone Copolymer 158451-77-5 (generic)	Bis-Isobutyl PEG/PPG-10/7/Dimethicone Copolymer is a random copolymer of polyethylene glycol, polypropylene glycol and Dimethicone containing an average of 10 moles of ethylene oxide and 7 moles of propylene oxide.	Surfactant – emulsifying agent
Bis-Isobutyl PEG-13/Dimethicone Copolymer 197980-52-2	Bis-Isobutyl PEG-13/Dimethicone Copolymer is a block copolymer made by reacting Bis-Hydrogen Dimethicone with the bis-methallyl ether of PEG-13. 	Film former
Bis-Isobutyl PEG-24/PPG-7/ Dimethicone Copolymer 158451-77-5 (generic)	Bis-Isobutyl PEG-24/PPG-7/Dimethicone Copolymer is a block copolymer of polyethylene glycol, polypropylene glycol and Dimethicone containing an average of 24 moles of ethylene oxide and 7 moles of propylene oxide.	Film former; humectant
Bis-PEG-1 Dimethicone	Bis-PEG-1 Dimethicone is Dimethicone end-blocked with an average of 1 mole of ethylene oxide.	Hair conditioning agent; plasticizer; skin-conditioning agent – miscellaneous; surfactants – dispersing agent

Table 1. Definitions and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

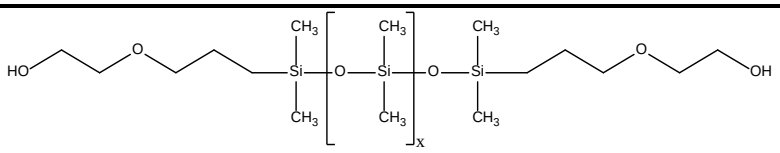
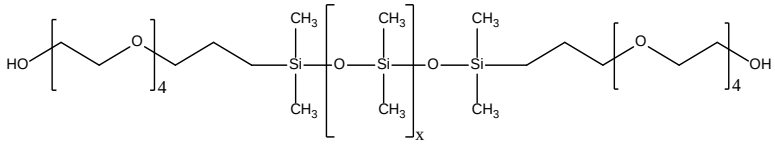
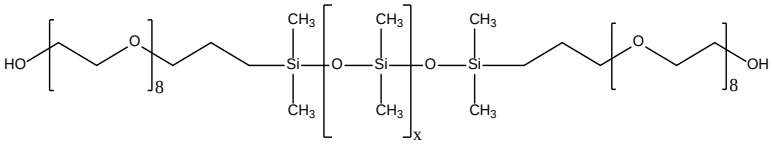
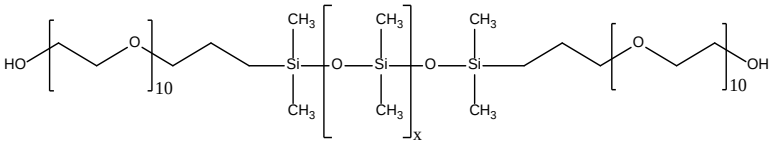
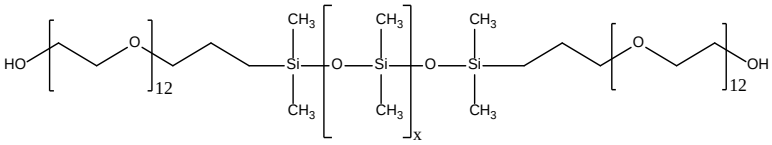
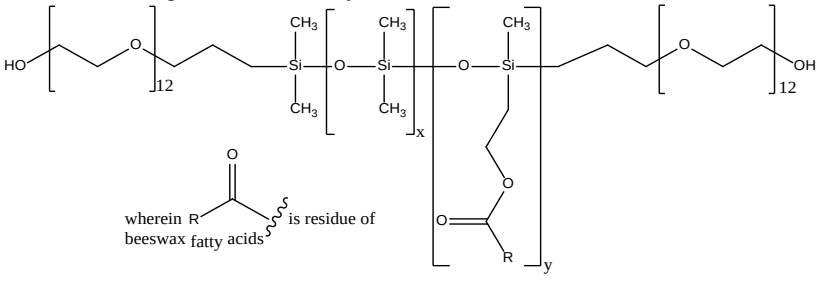
Ingredient CAS No.	Definition / Structure	Function
		
Bis-PEG-4 Dimethicone	Bis-PEG-4 Dimethicone is the siloxane polymer that conforms generally to the formula: 	Hair conditioning agent; plasticizer; skin-conditioning agent – emollient
Bis-PEG-8 Dimethicone	Bis-PEG-8 Dimethicone is Dimethicone end-blocked with an average of 8 moles of ethylene oxide. 	Hair conditioning agent; plasticizer; skin-conditioning agent – miscellaneous; surfactants – dispersing agent
Bis-PEG-10 Dimethicone	Bis-PEG-10 Dimethicone is Dimethicone end-blocked with an average of 10 moles of ethylene oxide 	Dispersing agent – nonsurfactant; hair conditioning agent; plasticizer; skin-conditioning agent – miscellaneous
Bis-PEG-12 Dimethicone	Bis-PEG-12 Dimethicone is Dimethicone end-blocked with an average of 12 moles of ethylene oxide. 	Hair conditioning agent; skin-conditioning agent – emollient
Bis-PEG-12 Dimethicone Beeswax [151661-97-1]	Bis-PEG-12 Dimethicone Beeswax is the partial ester of the fatty acids derived from beeswax and a derivative of Dimethicone, end-blocked with an average of 12 moles of ethylene oxide. 	Hair conditioning agent; skin-conditioning agent – occlusive
Bis-PEG-12 Dimethicone Candelillate	Bis-PEG-12 Dimethicone Candelillate is the partial ester of the fatty acids derived from candelilla wax and a derivative of Dimethicone, end-blocked with an average of 12 moles of ethylene oxide.	Hair conditioning agent; skin-conditioning agent – occlusive

Table 1. Definitions and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

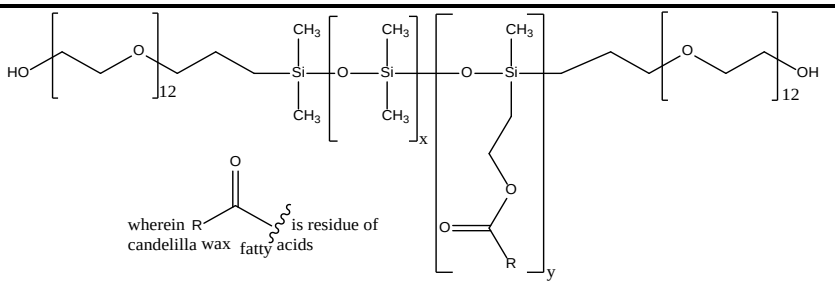
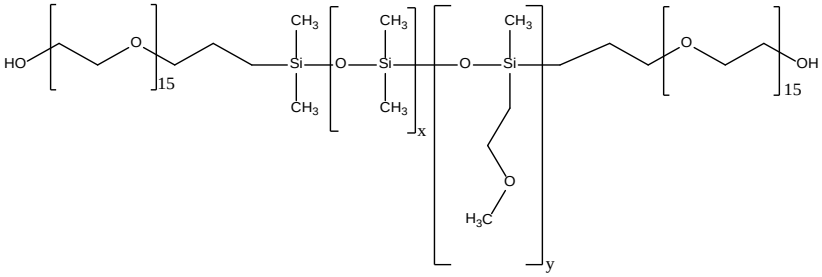
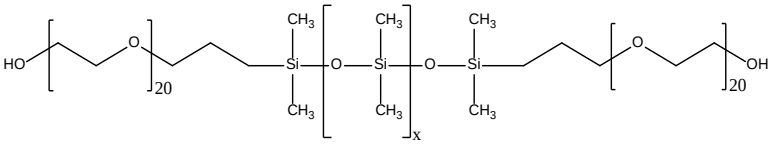
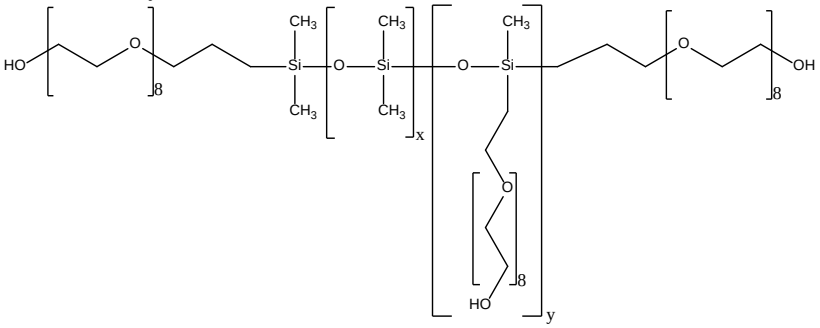
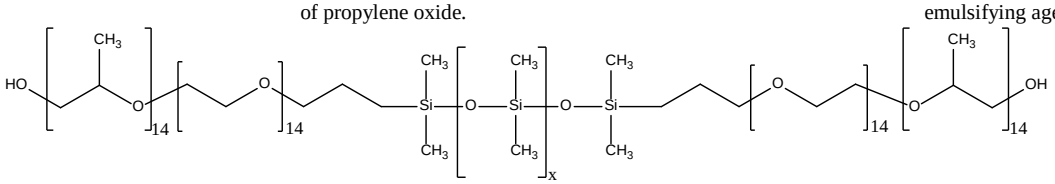
Ingredient CAS No.	Definition / Structure	Function
		
Bis-PEG-15 Methyl Ether Dimethicone	Bis-PEG-15 Methyl Ether Dimethicone is the methyl ether of a derivative of Dimethicone end-blocked with an average of 15 moles of ethylene oxide. 	Hair conditioning agent; skin-conditioning agent – miscellaneous; surfactants – emulsifying agent
Bis-PEG-20 Dimethicone	Bis-PEG-20 Dimethicone is the siloxane polymer that conforms generally to the formula, where n has an average value of 20. 	Hair conditioning agent; skin-conditioning agent – miscellaneous
Bis-PEG-8 PEG-8 Dimethicone	Bis-PEG-8 PEG-8 Dimethicone is a derivative of Dimethicone containing alkoxylated side chain with an average of 8 moles of ethylene oxide, and end-blocked with an average of 8 moles of ethylene oxide. 	Hair conditioning agent
Bis-PEG/PPG-14/14 Dimethicone 151662-01-0	Bis-PEG/PPG-14/14 Dimethicone is Dimethicone end-blocked with an average of 14 moles of ethylene oxide and an average of 14 moles of propylene oxide. 	Skin-conditioning agents – emollients; surfactant – emulsifying agent
Bis-PEG/PPG-15/5 Dimethicone	Bis-PEG/PPG-15/5 Dimethicone is Dimethicone end-blocked with the random addition of an average of 15 moles of ethylene oxide and 5 moles of propylene oxide.	Emulsion stabilizer; humectant

Table 1. Definitions and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

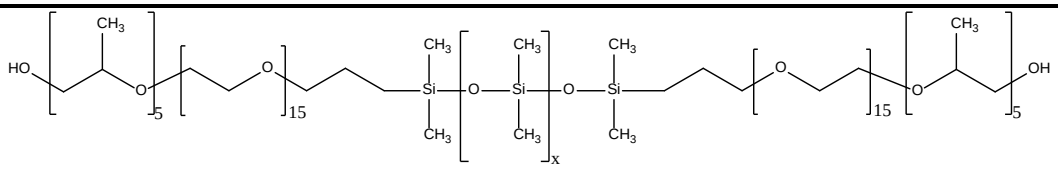
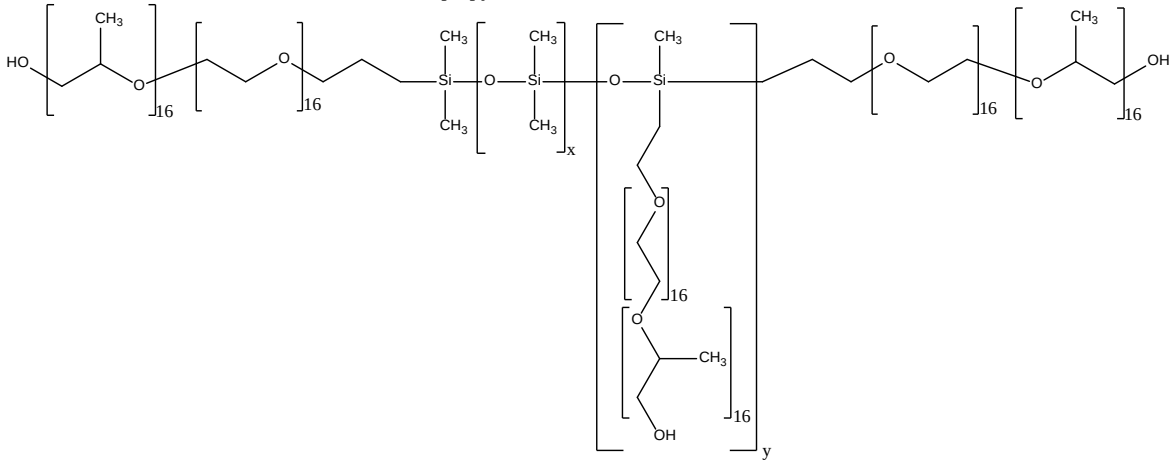
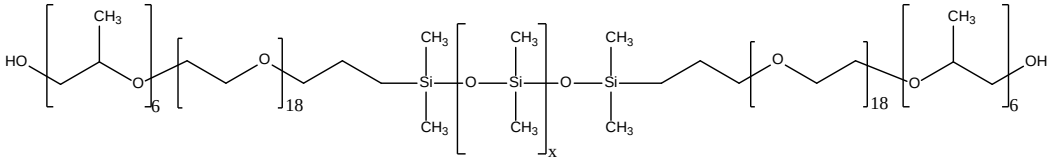
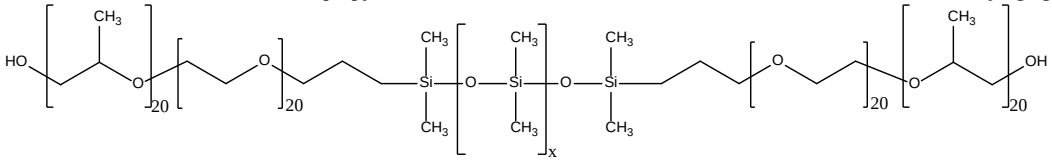
Ingredient CAS No.	Definition / Structure	Function
		
Bis-PEG/PPG-16/16 PEG/PPG-16/16 Dimethicone	Bis-PEG/PPG-16/16 PEG/PPG-16/16 Dimethicone is a derivative of Dimethicone containing an alkoxylated side chain with an average of 16 moles of ethylene oxide and 16 moles of propylene oxide, and end-blocked with an average of 16 moles of ethylene oxide and 16 moles of propylene oxide.	Skin-conditioning agent – occlusive; surfactant – emulsifying agent
		
Bis-PEG/PPG-18/6 Dimethicone	Bis-PEG/PPG-18/6 Dimethicone is Dimethicone end-blocked with the random addition of an average of 18 moles of ethylene oxide and 6 moles of propylene oxide.	Skin-conditioning agent – emollient; surfactant – emulsifying agent
		
Bis-PEG/PPG-20/20 Dimethicone	Bis-PEG/PPG-20/20 Dimethicone is Dimethicone end-blocked with an average of 20 moles of ethylene oxide and an average of 20 moles of propylene oxide.	Skin-conditioning agent – emollient; surfactant – emulsifying agent
		
Bis-PEG/PPG-20/5 PEG/PPG-20/5 Dimethicone	Bis-PEG/PPG-20/5 PEG/PPG-20/5 Dimethicone is a derivative of Dimethicone containing an alkoxylated side chain with an average of 20 moles of ethylene oxide and 5 moles of propylene oxide, and end-blocked with an average of 20 moles of ethylene oxide and 5 moles of propylene oxide.	Emulsion stabilizer; surfactant – emulsifying agent

Table 1. Definitions and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

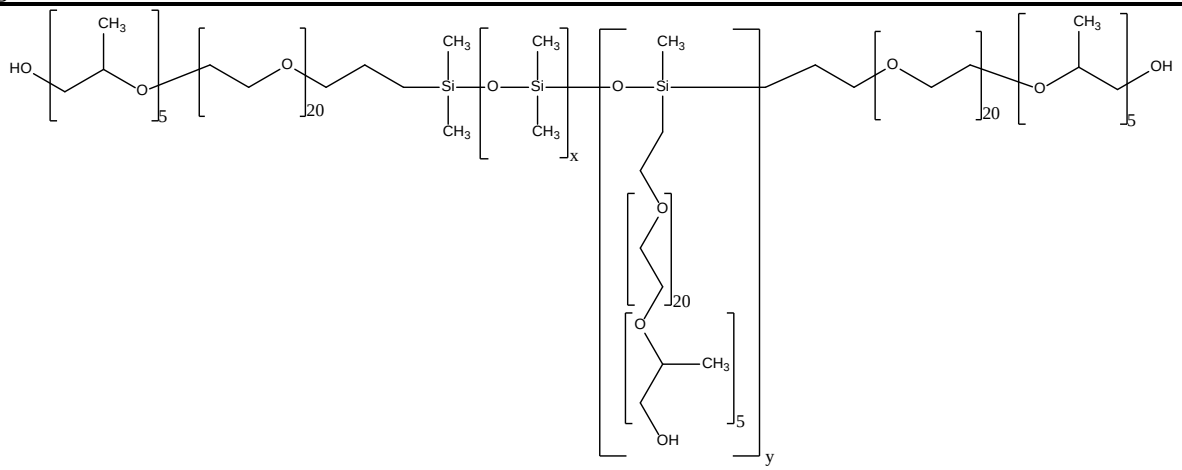
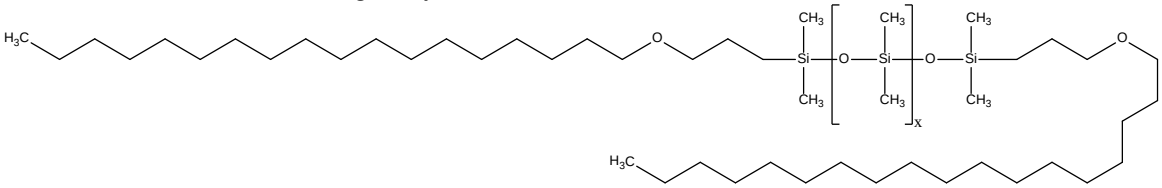
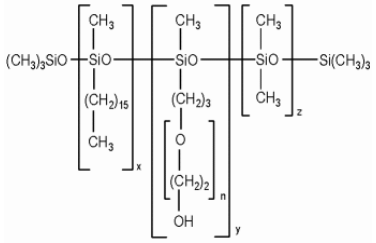
Ingredient CAS No.	Definition / Structure	Function
		
Bis-Stearoxy Dimethicone	Bis-Stearoxy Dimethicone is the polymer formed by the reaction between Bis-Hydrogen Dimethicone and allyl stearyl ether.	Film former; skin-conditioning agent - emollient
Bis-Stearoxyethyl Dimethicone 128446-57-1	Bis-Stearoxyethyl Dimethicone is the silicone polymer that conforms generally to the formula: 	Skin-conditioning agent – emollient
Cetyl PEG/PPG-10/1 Dimethicone 191044-49-2	Cetyl PEG/PPG-10/1 Dimethicone is a copolymer of Cetyl Dimethicone and an alkoxylated derivative of Dimethicone containing an average of 10 moles of ethylene oxide and 1 mole of propylene oxide.	Skin-conditioning agent – miscellaneous; surfactant – emulsifying agent
Cetyl PEG/PPG-15/15 Butyl Ether Dimethicone	Cetyl PEG/PPG-15/15 Butyl Ether Dimethicone is the copolymer of Cetyl Dimethicone and a butyl ether of a derivative of Dimethicone containing an average of 15 moles of ethylene oxide and 15 moles of propylene oxide.	Skin-conditioning agent – miscellaneous; surfactant – emulsifying agent
Cetyl PEG/PPG-7/3 Dimethicone	Cetyl PEG/PPG-7/3 Dimethicone is a copolymer of Cetyl Dimethicone and an alkoxylated derivative of Dimethicone containing an average of 7 moles of ethylene oxide and 3 moles of propylene oxide.	Emulsion stabilizer; surfactant – emulsifying agent
Cetyl PEG-8 Dimethicone	Cetyl PEG-8 Dimethicone is the polydimethylsiloxane that conforms to the formula where n has an average value of 8. 	Surfactant – emulsifying agent
Lauryl Isopentyl-PEG/PPG-18/18 Methicone 1112315-26-0	Lauryl Isopentyl-PEG/PPG-18/18 Methicone is the copolymer formed by the reaction of Methicone with dodecene and a dimethyallyl-terminated polyethylene oxide/polypropylene oxide copolymer.	Surfactant – emulsifying agent
Lauryl PEG/PPG-18/18 Methicone	Lauryl PEG/PPG-18/18 Methicone is an alkoxylated derivative of Lauryl Methicone containing an average of 18 moles of ethylene oxide and 18 moles of propylene oxide.	Skin-conditioning agent – miscellaneous; surfactant – emulsifying agent
Lauryl PEG-10 Methyl Ether Dimethicone	Lauryl PEG-10 Methyl Ether Dimethicone is the silicone polymer that conforms generally to the formula.	Surfactant – emulsifying agent

Table 1. Definitions and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

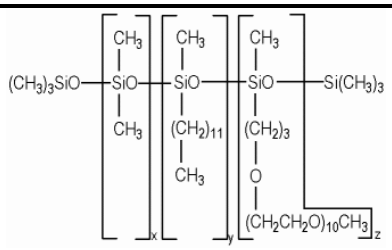
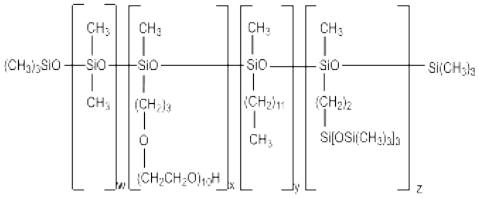
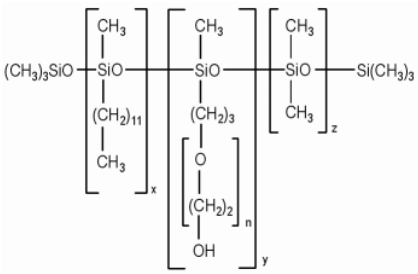
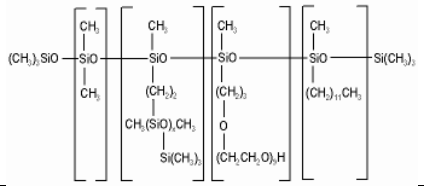
Ingredient CAS No.	Definition / Structure	Function
		
Lauryl PEG-10 Tris(Trimethylsiloxy)silylethyl Dimethicone	Lauryl PEG-10 Tris(Trimethylsiloxy)silylethyl Dimethicone is the silicone compound that conforms generally to the formula. 	Surfactant – emulsifying agent
Lauryl PEG-8 Dimethicone	Lauryl PEG-8 Dimethicone is the polydimethylsiloxane that conforms to the formula, where n has an average value of 8. 	External analgesics; surfactant – emulsifying agent
Lauryl PEG-8 PPG-8 Dimethicone	Lauryl PEG-8 PPG-8 Dimethicone is a terpolymer obtained by reacting Hydrogen Dimethicone with dodecene, the allyl ether of PEG-8, and the allyl ether of PPG-8.	Surfactant – emulsifying agent
Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone	Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone is the silicone polymer that conforms generally to the formula 	Hair conditioning agent; hair fixative; skin-conditioning agent – miscellaneous; surface modifier; surfactant – emulsifying agent; surfactant – solubilizing agent; viscosity increasing agent – aqueous
Lauryl Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone	Lauryl Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone is a derivative of Dimethicone in which some of the methyl groups on the siloxane backbone have been replaced by lauryl, polyglyceryl-3, and polydimethylsiloxyethyl groups. It conforms generally to the formula.	Hair conditioning agent; skin-conditioning agent – miscellaneous; surfactant – cleansing agent; surfactant – emulsifying agent; surfactant – solubilizing agent; viscosity increasing agent – aqueous

Table 1. Definitions and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

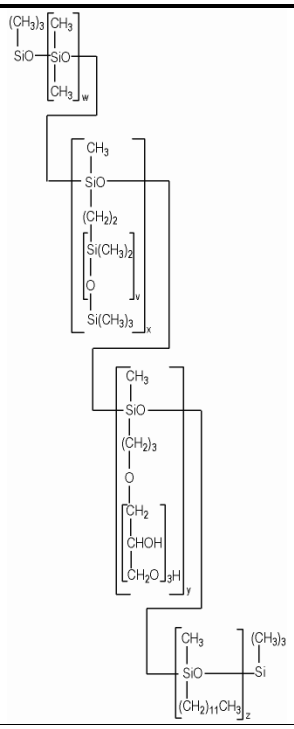
Ingredient CAS No.	Definition / Structure	Function
		
Methoxy PEG-11 Methoxy PPG-24 Dimethicone 472975-82-9	Methoxy PEG-11 Methoxy PPG-24 Dimethicone is the methyl ether of an alkoxylated derivative of dimethicone containing an average of 11 moles of ethylene oxide and 24 moles propylene oxide.	Antifoaming agent
Methoxy PEG/PPG-25/4 Dimethicone	Methoxy PEG/PPG-25/4 Dimethicone is the methyl ether of an alkyoxylated derivative of Dimethicone containing an average of 25 moles of ethylene oxide and 4 moles of propylene oxide.	Emulsion stabilizer; surfactant – emulsifying agent
Methoxy PEG-13 Ethyl Polysilsesquioxane	Methoxy PEG-13 Ethyl Polysilsesquioxane is the polymerized resin of polysilsesquioxane containing ethyl methoxy PEG-13 groupings.	Humectant
PEG/PPG-10/2 Dimethicone	PEG/PPG-10/2 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 10 moles of ethylene oxide and 2 moles of propylene oxide.	Hair conditioning agent; skin-conditioning agent – emollient
PEG/PPG-10/3 Oleyl Ether Dimethicone	PEG/PPG-10/3 Oleyl Ether Dimethicone is the oleyl ether of a derivative of Dimethicone containing an average of 10 moles of ethylene oxide and 3 moles of propylene oxide.	Emulsion stabilizer; hair conditioning agent; skin-conditioning agent – miscellaneous; surfactant – emulsifying agent; surfactant – solubilizing agent
PEG/PPG-12/16 Dimethicone	PEG/PPG-12/16 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 12 moles of ethylene oxide and 16 moles of propylene oxide.	Antifoaming agent; skin-conditioning agent – miscellaneous; slip modifier; surfactant – emulsifying agent
PEG/PPG-12/18 Dimethicone	PEG/PPG-12/18 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 12 moles of ethylene oxide and 18 moles of propylene oxide.	Antifoaming agent; skin-conditioning agent – miscellaneous; slip modifier; surfactant – emulsifying agent
PEG/PPG-14/4 Dimethicone	PEG/PPG-14/4 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 14 moles of ethylene oxide and 4 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-15/15 Dimethicone	PEG/PPG-15/15 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 15 moles of ethylene oxide and 15 moles of propylene oxide.	Anticaking agent; surfactant – emulsifying agent
PEG/PPG-15/5 Dimethicone	PEG/PPG-15/5 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 15 moles of ethylene oxide and 5 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-16/2 Dimethicone	PEG/PPG-16/2 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 16 moles of ethylene oxide and 2 moles of propylene oxide.	Surfactant – emulsifying agent

Table 1. Definitions and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

Ingredient CAS No.	Definition / Structure	Function
PEG/PPG-16/8 Dimethicone	PEG/PPG-16/8 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 16 moles of ethylene oxide and 8 moles of propylene oxide.	Antifoaming agent; skin-conditioning agent – miscellaneous; slip modifier; surfactant – emulsifying agent
PEG/PPG-17/18 Dimethicone	PEG/PPG-17/18 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 17 moles of ethylene oxide and 18 moles of propylene oxide	Surfactant – emulsifying agent
PEG/PPG-18/12 Dimethicone	PEG/PPG-18/12 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 18 moles of ethylene oxide and 12 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-18/18 Dimethicone	PEG/PPG-18/18 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 18 moles of ethylene oxide and 18 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-18/6 Dimethicone	PEG/PPG-18/6 Dimethicone is alkoxylated derivative of Dimethicone containing a random addition of an average of 18 moles of ethylene oxide and 6 moles of propylene oxide.	Skin-conditioning agent – emoliant
PEG/PPG-19/19 Dimethicone	PEG/PPG-19/19 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 19 moles of ethylene oxide and 19 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-20/15 Dimethicone	PEG/PPG-20/15 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 20 moles of ethylene oxide and 15 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-20/20 Dimethicone	PEG/PPG-20/20 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 20 moles of ethylene oxide and 20 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-20/22 Butyl Ether Dimethicone 67762-87-2	PEG/PPG-20/22 Butyl Ether Dimethicone is the butyl ether of a derivative of Dimethicone containing an average of 20 moles of ethylene oxide and 22 moles of propylene oxide.	Hair conditioning agent; skin-conditioning agent – miscellaneous
PEG/PPG-20/22 Methyl Ether Dimethicone 125857-75-2	PEG/PPG-20/22 Methyl Ether Dimethicone is the methyl ether of a derivative of Dimethicone containing an average of 20 moles of ethylene oxide and 22 moles of propylene oxide.	Hair conditioning agent; surfactant – cleansing agent; surfactant – dispersing agent; surfactant – emulsifying agent
PEG/PPG-20/23 Dimethicone	PEG/PPG-20/23 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 20 moles of ethylene oxide and 23 moles of propylene oxide.	Emulsion stabilizer; hair conditioning agent; skin-conditioning agent – miscellaneous; slip modifier; surface modifier; surfactant – solubilizing agent
PEG/PPG-20/29 Dimethicone	PEG/PPG-20/29 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 20 moles of ethylene oxide and 29 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-20/6 Dimethicone	PEG/PPG-20/6 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 20 moles of ethylene oxide and 6 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-22/22 Butyl Ether Dimethicone	PEG/PPG-22/22 Butyl Ether Dimethicone is the butyl ether of a derivative of Dimethicone containing an average of 22 moles of ethylene oxide and 22 moles of propylene oxide.	Hair conditioning agent; skin-conditioning agent – miscellaneous; surfactant – emulsifying agent
PEG/PPG-22/23 Dimethicone	PEG/PPG-22/23 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 22 moles of ethylene oxide and 23 moles of propylene oxide.	Emulsion stabilizer; hair conditioning agent; skin-conditioning agent – miscellaneous; slip modifier; surface modifier; surfactant – solubilizing agent
PEG/PPG-22/24 Dimethicone	PEG/PPG-22/24 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 22 moles of ethylene oxide and 24 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-23/23 Butyl Ether Dimethicone	PEG/PPG-23/23 Butyl Ether Dimethicone is the butyl ether of a derivative of Dimethicone containing an average of 23 moles of ethylene oxide and 23 moles of propylene oxide.	Hair conditioning agent; humectant; skin-conditioning agent – miscellaneous; surfactant – dispersing agent; surfactant – emulsifying agent

Table 1. Definitions and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

Ingredient CAS No.	Definition / Structure	Function
PEG/PPG-23/6 Dimethicone	PEG/PPG-23/6 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 23 moles of ethylene oxide and 6 moles of propylene oxide.	Emulsion stabilizer; slip modifier; surface modifier; surfactant – solubilizing agent
PEG/PPG-24/18 Butyl Ether Dimethicone 67762-87-2	PEG/PPG-23/23 Butyl Ether Dimethicone is the butyl ether of a derivative of Dimethicone containing an average of 23 moles of ethylene oxide and 23 moles of propylene oxide.	Hair conditioning agent; humectant; surfactant – cleansing agent; surfactant – dispersing agent; surfactant – emulsifying agent
PEG/PPG-25/25 Dimethicone	PEG/PPG-25/25 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 25 moles of ethylene oxide and 25 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-27/27 Dimethicone	PEG/PPG-27/27 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 27 moles of ethylene oxide and 27 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-27/9 Butyl Ether Dimethicone	PEG/PPG-27/9 Butyl Ether Dimethicone is the butyl ether of a derivative of Dimethicone containing an average of 27 moles of ethylene oxide and 9 moles of propylene oxide.	Hair conditioning agent; skin-conditioning agent - miscellaneous; surfactant – emulsifying agent
PEG/PPG-3/10 Dimethicone	PEG/PPG-3/10 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 3 moles of ethylene oxide and 12 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-30/10 Dimethicone	PEG/PPG-30/10 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 30 moles of ethylene oxide and 10 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-4/12 Dimethicone	PEG/PPG-4/12 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 4 moles of ethylene oxide and 12 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-6/4 Dimethicone	PEG/PPG-6/4 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 6 moles of ethylene oxide and 4 moles of propylene oxide.	Emulsion stabilizer; humectant
PEG/PPG-6/11 Dimethicone	PEG/PPG-6/11 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 6 moles of ethylene oxide and 11 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-8/14 Dimethicone	PEG/PPG-8/14 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 8 moles of ethylene oxide and 14 moles of propylene oxide.	Surfactant – emulsifying agent
PEG/PPG-8/26 Dimethicone	PEG/PPG-8/26 Dimethicone is the alkoxylated derivative of Dimethicone containing an average of 8 moles of ethylene oxide and 26 moles of propylene oxide.	Antifoaming agent; plasticizer; skin-conditioning agent – miscellaneous; surfactant – dispersing agent
PEG-10 Dimethicone 68937-54-2 (generic)	PEG-10 Dimethicone is the polyethylene glycol derivative of Dimethicone containing an average of 10 moles of ethylene oxide.	Hair condition agent; skin-conditioning agent – miscellaneous
PEG-10 Methyl Ether Dimethicone 68938-54-5 (generic)	PEG-10 Methyl Ether Dimethicone is the methyl ether of a derivative of Dimethicone containing an average of 10 moles of ethylene oxide.	Hair condition agent; skin-conditioning agent – miscellaneous; surfactant – emulsifying agent
PEG-10 Polydimethylsiloxyethyl Dimethicone/Bis-Vinyl Dimethicone Crosspolymer	PEG-10 Polydimethylsiloxyethyl Dimethicone/Bis-Vinyl Dimethicone Crosspolymer is a copolymer of PEG-10 polydimethylsiloxyethyl dimethicone crosslinked with Bis-Vinyldimethicone.	Film former; skin-conditioning agent – emollient; slip modifier; surfactant – emulsifying agent
PEG-11 Methyl Ether Dimethicone 68938-54-5 (generic)	PEG-11 Methyl Ether Dimethicone is the methyl ether of a derivative of Dimethicone containing an average of 11 moles of ethylene oxide.	Hair condition agent; skin-conditioning agent – miscellaneous; surfactant – emulsifying agent
PEG-12 Dimethicone 68937-54-2 (generic)	PEG-12 Dimethicone is the polyethylene glycol derivative of Dimethicone containing an average of 12 moles of ethylene oxide.	Hair condition agent; skin-conditioning agent – miscellaneous
PEG-14 Dimethicone 68937-54-2 (generic)	PEG-14 Dimethicone is the polyethylene glycol derivative of Dimethicone containing an average of 14 moles of ethylene oxide.	Hair condition agent; skin-conditioning agent – miscellaneous
PEG-17 Dimethicone	PEG-17 Dimethicone is the polyethylene glycol derivative of Dimethicone containing an average of 17 moles of ethylene oxide.	Hair condition agent; skin-conditioning agent – miscellaneous

Table 1. Definitions and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

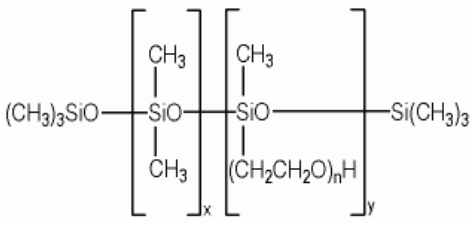
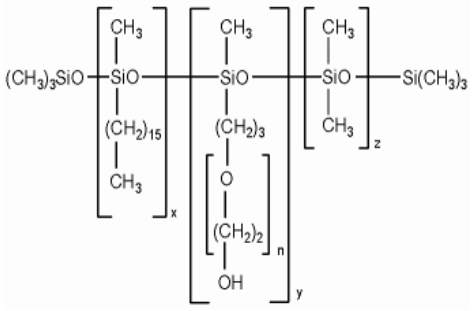
Ingredient CAS No.	Definition / Structure	Function
PEG-3 Dimethicone 68937-54-2 (generic)	PEG-3 Dimethicone is the siloxane polymer that conforms generally to the formula  where n has an average value of 3.	Hair condition agent; skin-conditioning agent – miscellaneous
PEG-32 Methyl Ether Dimethicone 68938-54-5 (generic)	PEG-32 Methyl Ether Dimethicone is the methyl ether of a derivative of Dimethicone containing an average of 32 moles of ethylene oxide.	Hair condition agent; skin-conditioning agent – miscellaneous; surfactant – emulsifying agent
PEG-4 PEG-12 Dimethicone	PEG-4 PEG-12 Dimethicone is the reaction product of Hydrogen Dimethicone and allyl PEG-4 and allyl PEG-12.	Emulsion stabilizers
PEG-6 Dimethicone 68937-54-2 (generic)	PEG-6 Dimethicone is the polyethylene glycol derivative of Dimethicone containing an average of 6 moles of ethylene oxide.	Humectant; plasticizer; slip modifier
PEG-6 Methyl Ether Dimethicone 68938-54-5 (generic)	PEG-6 Methyl Ether Dimethicone is the methyl ether of a polyethylene glycol derivative of Dimethicone containing an average of 6 moles of ethylene oxide	Hair condition agent; skin-conditioning agent – miscellaneous; surfactant – emulsifying agent
PEG-7 Dimethicone 68937-54-2 (generic)	PEG-7 Dimethicone is the polyethylene glycol derivative of Dimethicone containing an average of 7 moles of ethylene oxide.	Film former
PEG-7 Methyl Ether Dimethicone 68938-54-5 (generic)	PEG-7 Methyl Ether Dimethicone is the methyl ether of a derivative of Dimethicone containing an average of 7 moles of ethylene oxide.	Hair condition agent; skin-conditioning agent – humectant; surfactant – emulsifying agent
PEG-8 Cetyl Dimethicone	PEG-8 Cetyl Dimethicone is the polydimethylsiloxane that conforms to the formula  where n has an average value of 8.	Skin-conditioning agent – miscellaneous
PEG-8 Dimethicone 68937-54-2 (generic)	PEG-8 Dimethicone is the polyethylene glycol derivative of Dimethicone containing an average of 8 moles of ethylene oxide.	Hair condition agent; skin-conditioning agent – miscellaneous
PEG-8 Dimethicone Dimer Dilinoleate	PEG-8 Dimethicone Dimer Dilinoleate is the ester formed by the reaction of PEG-8 Dimethicone and Dilinoleic Acid.	Film former
PEG-8 Dimethicone/Dimer Dilinoleic Acid Copolymer	PEG-8 Dimethicone Dimer Dilinoleate is the ester formed by the reaction of PEG-8 Dimethicone and Dilinoleic Acid.	Skin-conditioning agent – emollient
PEG-8 Methicone	PEG-8 Methicone is the polyethylene glycol derivative of Methicone containing an average of 8 moles of ethylene oxide.	Hair condition agent; skin-conditioning agent – emollient
PEG-8 Methyl Ether Dimethicone 68938-54-5 (generic)	PEG-8 Methyl Ether Dimethicone is the methyl ether of a derivative of Dimethicone containing an average of 8 moles of ethylene oxide.	Hair conditioning agent; humectant; surfactant – cleansing agent; surfactant – dispersing agent
PEG-8 PEG-4 Dimethicone	PEG-8 PEG-4 Dimethicone is the reaction product of Hydrogen Dimethicone and allyl PEG-8 and allyl PEG-4.	Hair conditioning agent; surfactant – emulsifying agent
PEG-8 PPG-8 Dimethicone	PEG-8 PPG-8 Dimethicone is the polyoxypropylene, polyoxyethylene ether of Dimethicone with an average propoxylation value of 8 and an average ethoxylation value of 8.	Surfactant – emulsifying agent

Table 1. Definitions and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

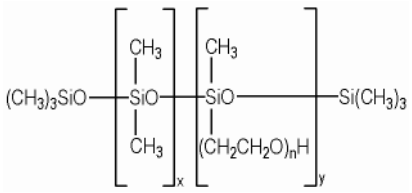
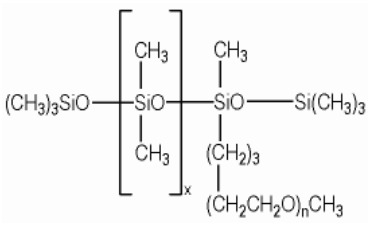
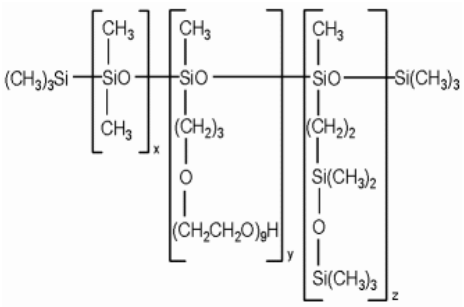
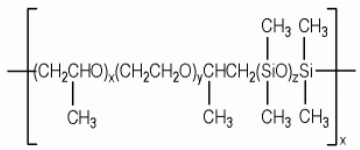
Ingredient CAS No.	Definition / Structure	Function
PEG-9 Dimethicone 68937-54-2 (generic)	PEG-9 Dimethicone is the siloxane polymer that conforms generally to the formula  where n has an average value of 9.	Hair conditioning agent; skin-conditioning agent – miscellaneous
PEG-9 Methyl Ether Dimethicone	PEG-9 Methyl Ether Dimethicone is a siloxane polymer that conforms generally to the formula  where n has an average value of 9.	Hair conditioning agent; skin-conditioning agent – miscellaneous; surfactant – emulsifying agent
PEG-9 Polydimethylsiloxyethyl Dimethicone	PEG-9 Polydimethylsiloxyethyl Dimethicone is the siloxane polymer that conforms generally to the formula. 	Skin-conditioning agent – miscellaneous; surfactant – emulsifying agent
Polysilicone-13 158451-77-5 197980-52-2	Polysilicone-13 is the siloxane polymer that conforms generally to the formula. 	Hair conditioning agent
PPG-12 Butyl Ether Dimethicone	PPG-12 Butyl Ether Dimethicone is a butyl ether of a derivative of Dimethicone containing an average of 12 moles of propylene oxide.	Hair conditioning agent; humectant; surfactant – dispersing agent; surfactant – emulsifying agent
PPG-12 Dimethicone	PPG-12 Dimethicone is the polypropylene glycol derivative of Dimethicone containing an average of 12 moles of propylene oxide.	Hair conditioning agent; skin-conditioning agent – emollient
PPG-2 Dimethicone 68440-66-4 68554-64-3	PPG-2 Dimethicone is the polypropylene glycol derivative of Dimethicone containing an average of 2 moles of propylene oxide.	Skin-conditioning agent – miscellaneous; surfactant – dispersing agent
PPG-25 Dimethicone 68957-00-6 (generic)	PPG-25 Dimethicone is the polypropylene glycol derivative of Dimethicone containing an average of 25 moles of propylene oxide.	Hair conditioning agent; skin-conditioning agent - miscellaneous; surfactant – emulsifying agent

Table 1. Definitions and idealized structures of the ingredients in this safety assessment based on the *International Cosmetic Dictionary and Handbook*.[2]

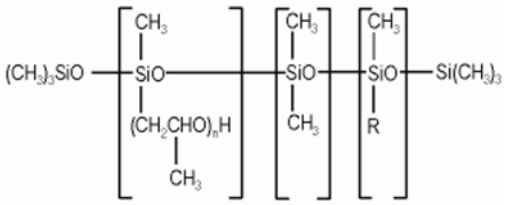
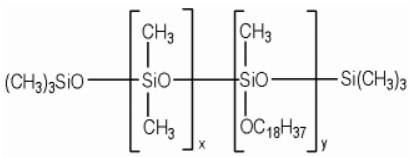
Ingredient CAS No.	Definition / Structure	Function
PPG-27 Dimethicone	PPG-27 Dimethicone is the polypropylene glycol derivative of Dimethicone containing an average of 27 moles of propylene oxide.	Hair conditioning agent; skin-conditioning agent – miscellaneous
PPG-4 Oleth-10 Dimethicone	PPG-4 Oleth-10 Dimethicone is the silicone polymer that conforms generally to the formula  where R represents Oleth-10 and n has an average value of 4.	Film former
Stearoxy Dimethicone 68554-53-0	Stearoxy Dimethicone is a polymer of dimethylpolysiloxane with some methyl groups replaced by stearoxy groups.	Skin-conditioning agent – emollient
Stearoxymethicone/Dimethicone Copolymer	Stearoxymethicone/Dimethicone Copolymer is the siloxane polymer that conforms generally to the formula. 	Skin-conditioning agent – occlusive; viscosity increasing agent – nonaqueous

Table 2. Safety assessments of cosmetic ingredients related to the alkoxy polysiloxanes in this report.

Ingredients	Conclusion	Maximum use concentration (%)	Reference
Dimethicone copolyol Re-review also included: Dimethicone PEG-7 Phosphate, Dimethicone PEG-10 Phosphate, Dimethicone PEG/PPG-7 /4 Phosphate, Dimethicone PEG/PPG-12/4 Phosphate, Dimethicone PEG/PPG-20/23 Benzoate, Dimethicone PEG-8 Benzoate, Dimethicone PEG-6 Acetate, Dimethicone PEG-8 Adipate, PEG-3 Dimethicone, PEG-9 Dimethicone, PEG/PPG-20/29 Dimethicone, PEG/PPG-6111 Dimethicone, PEG-7 Dimethicone, PEG-8 Dimethicone, PEG-14 Dimethicone, PEG/PPG-14/4 Dimethicone, PEG/PPG-4/12 Dimethicone, PEG/PPG-20/20 Dimethicone, PEG/PPG-8114 Dimethicone, PEG/PPG-20/6 Dimethicone, PEG/PPG-20/15 Dimethicone, PEG-12 Dimethicone, PEG/PPG-18/ 18 Dimethicone, PEG/PPG-17 *I* 18 Dimethicone, PEG-10 Dimethicone, PEG/PPG-25/25 Dimethicone, PEG/PPG-19/19 Dimethicone, PEG/PPG-27 /27 Dimethicone, PEG/ PPG-22/23 Dimethicone, PEG/PPG-3110 Dimethicone, PEG/PPG-16/2 Dimethicone, PEG/PPG-22/24 Dimethicone, PEG/PPG-15115 Dimethicone, PEG-17 Dimethicone, PEG/PPG-20/23 Dimethicone, and PEG/PPG-23/6 Dimethicone.	Safe as cosmetic ingredients in the present practices of use and concentration. Conclusion confirmed at re-review.	10	[1,27]
Dimethicone crosspolymers: acrylates/bis-hydroxypropyl dimethicone crosspolymer, behenyl dimethicone/bis-vinyldimethicone crosspolymer, bis-phenylisopropyl phenylisopropyl dimethicone/vinyl dimethicone crosspolymer, bis-vinyldimethicone/bis-isobutyl PPG-20 crosspolymer, bis-vinyldimethicone crosspolymer, bis-vinyldimethicone/PEG-10 dimethicone crosspolymer, bis-vinyldimethicone/PPG-20 crosspolymer, butyldimethicone methacrylate/methyl methacrylate crosspolymer, C30-45 alkyl cetearyl dimethicone crosspolymer, C4-24 alkyl dimethicone/divinyldimethicone crosspolymer, C30-45 alkyl dimethicone/polycyclohexene oxide crosspolymer, cetearyl dimethicone crosspolymer, cetearyl dimethicone/vinyl dimethicone crosspolymer, cetyl dimethicone/bis-vinyldimethicone crosspolymer, cetyl hexacosyl dimethicone /bis-vinyldimethicone crosspolymer, crotonic acid/vinyl C8-12 isoalkyl esters /VA/bis-vinyldimethicone crosspolymer, dimethicone/bis-isobutyl PPG-20 crosspolymer, dimethicone/bis-vinyldimethicone/silsesquioxane crosspolymer, dimethicone crosspolymer, dimethicone crosspolymer-3, dimethicone/ divinyldimethicone/silsesquioxane crosspolymer, dimethicone/lauryl dimethicone/bis-vinyldimethicone crosspolymer, dimethicone/PEG-10 crosspolymer, dimethicone/PEG-10/15 crosspolymer, dimethicone/PEG-15 crosspolymer, dimethicone/phenyl vinyl dimethicone crosspolymer, dimethicone/polyglycerin-3 crosspolymer, dimethicone/PPG-20 crosspolymer, dimethicone/titanate crosspolymer, dimethicone/vinyl dimethicone crosspolymer,	Safe in the present practices of use and concentration described in this safety assessment.	46	[28]

Table 2. Safety assessments of cosmetic ingredients related to the alkoxy polysiloxanes in this report.

Ingredients	Conclusion	Maximum use concentration (%)	Reference
dimethicone/vinyltrimethylsiloxysilicate crosspolymer, diphenyl dimethicone crosspolymer, diphenyl dimethicone/vinyl diphenyl dimethicone/ silsesquioxane crosspolymer, divinyldimethicone/dimethicone crosspolymer, hydroxypropyl dimethicone/polysorbate 20 crosspolymer, isopropyl titanium triisostearate/triethoxysilylethyl polydimethylsiloxyethyl dimethicone crosspolymer, lauryl dimethicone PEG-15 crosspolymer, lauryl dimethicone/ polyglycerin-3 crosspolymer, lauryl polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer, PEG-10 dimethicone crosspolymer, PEG-12 dimethicone crosspolymer, PEG-8 dimethicone/polysorbate 20 crosspolymer, PEG-12 dimethicone/bis-isobutyl PPG-20 crosspolymer, PEG-12 dimethicone/ PPG-20 crosspolymer, PEG-10 dimethicone/vinyl dimethicone crosspolymer, PEG-10/lauryl dimethicone crosspolymer, PEG-15/lauryl dimethicone crosspolymer, PEG-15/lauryl polydimethylsiloxyethyl dimethicone crosspolymer, perfluorononyl dimethicone/methicone/amodimethicone crosspolymer, polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer, polyglyceryl-3/lauryl polydimethylsiloxyethyl dimethicone crosspolymer, silicone quaternium-16/glycidoxy dimethicone crosspolymer, styrene/acrylates/dimethicone acrylate crosspolymer, trifluoropropyl dimethicone/PEG-10 crosspolymer, trifluoropropyl dimethicone/trifluoropropyl divinyldimethicone crosspolymer, trifluoropropyl dimethicone/vinyl trifluoropropyl dimethicone/silsesquioxane crosspolymer, trimethylsiloxysilicate/dimethicone crosspolymer, vinyl dimethicone/lauryl/ behenyl dimethicone crosspolymer, vinyl dimethicone/lauryl dimethicone crosspolymer, vinyl dimethicone/methicone silsesquioxane crosspolymer, vinyldimethyl/trimethylsiloxysilicate/dimethicone crosspolymer, vinyldimethyl/ trimethylsiloxysilicate stearyl dimethicone crosspolymer			
Silicates: Silica, alumina magnesium metasilicate, aluminum calcium sodium silicate, aluminum iron silicates, hydrated silica, and sodium potassium aluminum silicate	Safe as cosmetic ingredients in the practices of use and concentrations as described in this safety assessment when formulated to be non -respirable.	44	[29]
Acrylates copolymers: acrylates copolymer, ammonium acrylates copolymer, ammonium VA/acrylates copolymer, sodium acrylates copolymer, ethylene/acrylic acid copolymer, ethylene/calcium acrylate copolymer, ethylene/magnesium acrylate copolymer, ethylene/sodium acrylate copolymer, ethylene/zinc acrylate copolymer, ethylene/acrylic acid/VA copolymer, acrylates/PVP copolymer, acrylates/va copolymer, steareth-10 allyl ether/ acrylates copolymer, acrylates/steareth-50 acrylate copolymer, acrylates/steareth-20 methacrylate copolymer, acrylates/ammonium methacrylate copolymer, styrene/acrylates copolymer, styrene/acrylates/ammonium methacrylate copolymer, ammonium styrene/acrylates copolymer, sodium styrene/acrylates copolymer, acrylates/hydroxyesters acrylates copolymer, methacryloyl ethyl betaine/acrylates copolymer, lauryl acrylate/VA copolymer, VA/butyl maleate/isobornyl acrylate copolymer, ethylene/methacrylate copolymer, vinyl caprolactam/PVP/dimethylaminoethyl methacrylate copolymer, sodium acrylates/acrolein copolymer, PVP/dimethylaminoethylmethacrylate copolymer, AMP-acrylates copolymer, polyacrylic acid, ammonium polyacrylate, potassium aluminum polyacrylate, potassium polyacrylate, and sodium polyacrylate	Safe for use in cosmetic ingredients when formulated to avoid skin irritation	<50%	[30]
Dimethicone: stearoxy dimethicone, dimethicone, methicone, amino bispropyl dimethicone, aminopropyl dimethicone, amodimethicone, amodimethicone hydroxystearate, behenoxy dimethicone, C24-28 alkyl methicone, C30-45 alkyl methicone, C30-45 alkyl dimethicone, cetearyl methicone, cetyl dimethicone, dimethoxysilyl ethylenediaminopropyl dimethicone, hexyl methicone, hydroxypropyldimethicone, stearamidopropyl dimethicone, stearyl dimethicone, stearyl methicone, and vinyldimethicone	Safe as a cosmetic ingredient	80	[31]
Polyethylene glycols: PEG-6, -8, -32, -75, -150, -14M, and -20M Amended report: Triethylene Glycol and Polyethylene Glycols (PEGs)-4, -6, -7, -8, -9, -10, -12, -14, -16, -18, -20, -32, -33, -40, -45, -55, -60, -75, -80, -90, -100, -135, -150, -180, -200, -220, -240, -350, -400, -450, -500, -800, -2M, -5M, -7M, -9M, -14M, -20M, -23M, -25M, -45M, -65M, -90M, -115M, -160M and -180M and any PEGs ≥ 4	Safe in the present practices of use and concentration. PEGs are not to be used on damaged skin. Safe for use in cosmetics in the present practices of use and concentration.	50; 85	[32,33]
PEGs: PG, tripropylene glycol, PPG-3, -7, -9, -12, -13, -15, -16, -17, 20, -26, -30, -33, -34, -51, -52, -69, and any PPG ≥3	Safe as cosmetic ingredients in when formulated to be nonirritating.	99	[34,35]
Siloxysilicates and silylates: trimethylsiloxysilicate, trifluoropropyldimethyl/trimethylsiloxy silicate, silica dimethyl silylate, silica silylate	Safe as used when formulated and delivered in the final product to be not irritating or sensitizing to the respiratory tract	30	[36]
Beeswax and euphorbia cerifera (candelilla) wax	Safe as used in cosmetics under present practices of	>25 – 50; 56	[27,37]

Table 2. Safety assessments of cosmetic ingredients related to the alkoxy polysiloxanes in this report.

Ingredients	Conclusion	Maximum use concentration (%)	Reference
	concentration and use. Confirmed at re-review.		

Table 3. Chemical and physical properties of alkoxyl polysiloxanes.

Property	Value	Reference
Bis-PEG-12 dimethicone beeswax		
Color	White to light yellow	38
Melting Point °C	62-72	38
Bis-PEG-15 methyl ether dimethicone		
Physical Form	Solid	39
Color	White, opaque	39
Odor	Slight	16
Molecular Weight g/mol	~1600	8
Density/Specific Gravity @ °C	1.05	16
Viscosity kg/(s m)@ 25°C	52.5	16
Melting Point °C	~30	39
Water Solubility	Dispersable	8,16
Other Solubility g/L @ °C & pH		
Castor oil	>10% soluble	39
Oleyl alcohol	>10% soluble	39
Propylene glycol	>10% soluble	39
Isopropanol	>10% soluble	39
Ethanol	>10% soluble	39
Glycerol	>10% soluble	39
Mineral oils	Insoluble	39
Ester oils/waxes	Insoluble	39
Olive oil	Insoluble	39
PEG 20/PPG-23 dimethicone		
Physical Form	Liquid	11
Color	Clear, pale yellow	11
Density/Specific Gravity @ °C	1.023	11
PEG/PPG-20/15 dimethicone		
Physical Form	Liquid	11
Color	Clear, straw-colored	11
Density/Specific Gravity	1.04	11
PEG/PPG-25/25 dimethicone		
Physical Form	Liquid	40,41
Color	Yellowish	40,41
Odor	Slight	40
Molecular Weight g/mol	~17 000	10
Density/Specific Gravity @ 25°C	1.03	40,41
Water Solubility	> 10% soluble	41
	Completely miscible	40
Other Solubility		
Octyl dodecanol	> 10% soluble	41
Oleyl alcohol	> 10% soluble	41
Isopropanol	> 10% soluble	41
Ethanol	> 10% soluble	41
Ethyl acetate	1%-10% soluble	41
Mineral oils	Insoluble	41
Olive oil	Insoluble	41
Propylene glycol	Insoluble	41
Glycerol	Insoluble	41
PEG-8 dimethicone		
Physical Form		
Pendent	Liquid	5
End-blocked	Liquid	5
Color		
Pendent	Clear, pale yellow	5
End-blocked	Clear, straw	5
Water Solubility		
Pendent	Insoluble	5

Table 3. Chemical and physical properties of alkoxyl polysiloxanes.

Property	Value	Reference
Other Solubility		
End-blocked		
Ethanol	Soluble	5
Mineral oil	Insoluble	5
Pendant		
Ethanol	Soluble	5
Mineral oil	Soluble	5
PEG-10 dimethicone		
Physical Form		
End-blocked	Liquid	5
Color		
End-blocked	Clear, straw	5
Density/Specific Gravity	1.002	11
Water Solubility		
Linear	Soluble	5
Other Solubility		
End-blocked		
Ethanol	Soluble	5
PEG-12 dimethicone		
Physical Form		
Pendant	Liquid	5
End-blocked	Liquid	5
Pendant	Liquid	5
Pendant	Liquid	5
Color		
Pendant	Colorless	5
End-blocked	Clear, straw	5
Pendant	Amber	5
Pendant	Pale yellow	5
Density/Specific Gravity	1.09	11
	1.07	11
	0.989	11
Water Solubility		
Pendant	Soluble	5
End-blocked	Soluble	5
Pendant	Soluble	5
Other Solubility		
Pendant		
Ethanol	Soluble	5
Mineral oil	Insoluble	5
End-blocked		
Ethanol	Soluble	5
Pendant		
Ethanol	Soluble	5
Mineral oil	Insoluble	5
Pendant		
Ethanol	Soluble	5
PEG-17 dimethicone		
Physical Form		
Pendant	Liquid	
Color		
Pendant	Straw	
Density/Specific Gravity	1.078	11
Water Solubility		
Pendant	Soluble	5
Other Solubility		
Pendant		
Ethanol	Soluble	5
Mineral oil	Insoluble	5
PPG-2 dimethicone		
Color	Clear	42
Density/Specific Gravity	0.99	42
Water Solubility		
Pendant	Insoluble	42
Other Solubility g/L @ °C & pH		
Pendant		
Acetone	Soluble	42

Table 3. Frequency and concentration of use according to duration and exposure of alkyloxy polysiloxanes with 2014 VCRP data.[13,43]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	Behenoxy dimethicone		**Bis-hydroxythoxypropyl dimethicone**		**Bis-PEG-4 dimethicone**		**Bis-PEG-12 dimethicone**	
Total/range	**20**	**0.5-3**	**19**	**0.7-12**	**9**	**0.4**	**NR**	**0.28**
Duration of use								
Leave-on	17	0.5-3	19	0.7-12	3	NR	NR	0.28
Rinse-off	3	0.5	NR	NR	6	0.4	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type[1]								
Eye area	6	NR	14	1.3-3.4	NR	NR	NR	0.28
Incidental ingestion	2	NR	2	0.7-1	NR	NR	NR	NR
Incidental Inhalation-sprays	9	NR	NR	NR	NR3	NR	NR	NR
Incidental inhalation-powders	8	NR	NR	NR	NR	NR	NR	NR
Dermal contact	18	0.5-3	17	1.3-12	NR	NR	NR	0.28
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair-noncoloring	NR	NR	NR	NR	9	NR	NR	NR
Hair-coloring	NR	NR	NR	NR	NR	0.4	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	2	NR	2	0.7-1	NR	NR	NR	NR
Baby	NR	NR	NR	NR	NR	NR	NR	NR

	Bis-PEG-12 dimehticone beeswax		**Bis-PEG-12 dimethicone candelillate**		**Bis-PEG-15 methyl ether dimethicone**		**Bis-PEG/PPG-14/14 dimethicone**	
Total/range	**23**	**0.01-5.7**	**19**	**0.5-5.1**	**2**	**1-1.5**	**77**	**0.2-5**
Duration of use								
Leave-on	23	0.01-5.7	19	0.5-5.1	2	1-1.5	77	0.2-5
Rinse-off	NR	NR	NR	NR	NR	NR	NR	0.9
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	10	1-4.5	2	1	1	1	5	0.42-1.1
Incidental ingestion	NR	NR	14	5.1	NR	NR	2	NR
Incidental Inhalation-sprays	6	0.01[2]	1	NR	NR	1.5	24	NR
Incidental inhalation-powders	6	NR	NR	NR	NR	NR	19	NR
Dermal contact	16	0.2-5.7	1	NR	1	NR	65	0.2-5
Deodorant (underarm)	NR	NR	NR	NR	1	NR	NR	3[3]
Hair-noncoloring	2	0.01	3	NR	NR	NR	10	NR
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	14	5.1	NR	NR	2	NR
Baby	NR	NR	NR	NR	NR	NR	NR	NR

Table 3. Frequency and concentration of use according to duration and exposure of alkyloxy polysiloxanes with 2014 VCRP data.[13,43]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	Bis-PEG/PPG-16/16 PEG/PPG-16/16 dimethicone		**Bis-PEG/PPG-20/20 dimethicone**		**Cetyl PEG/PPG-10/1 dimethicone**		**Lauryl PEG/PPG-18/18 methicone**	
Total/range	**30**	**0.4-1.7**	**4**	**0.2-5**	**404**	**0.02-15**	**78**	**0.5-5**
Duration of use								
Leave-on	26	0.4-1.7	2	0.2-5	399	0.02-15	46	0.5-5
Rinse-off	4	0.65	2	0.5	5	0.5-2.5	32	2
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	15	0.99	NR	NR	59	0.53-15	11	0.5-2.2
Incidental ingestion	NR	NR	NR	NR	46	0.098-3.8	2	3.8
Incidental Inhalation-sprays	8	NR	1	0.35[3]; 0.35-5[2]	78	1-3[2]	11	1.4[2]
Incidental inhalation-powders	8	NR	1	0.35[4]; 0.35-5[3]	58	0.4[4]	8	NR
Dermal contact	28	0.4-1.7	4	0.2-5	334	0.034-15	37	0.5-5
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair-noncoloring	NR	NR	NR	NR	11	0.5-3.5	39	1.4
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	N8	0.02	NR	NR
Mucous Membrane	3	NR	2	NR	46	0.098-3.8	2	3.8
Baby	3	NR	NR	NR	1	NR	NR	NR

	Lauryl PEG-8 dimethicone		**Lauryl PEG-9 polydimethyl siloxyethyl dimethicone**		**Methoxy PEG/PPG-25/4 dimethicone**		**PEG/PPG-14/4 dimethicone**	
Total/range	2	**1-8**	27	**0.2-6**	**NR**	**0.8-1.1**	**49**	**0.092-2**
Duration of use								
Leave-on	2	1-5	27	0.2-6	NR	0.8-1.1	43	0.092-2
Rinse-off	NR	NR	NR	NR	NR	NR	2	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	4	NR
Exposure type								
Eye area	NR	NR	2	1-2	NR	NR	17	0.95-2
Incidental ingestion	1	NR	NR	NR	NR	NR	4	0.95-1
Incidental Inhalation-sprays	NR	1[5]	15	0.2[5]	NR	NR	18	0.092-0.14[5]
Incidental inhalation-powders	NR	NR	14	NR	NR	NR	10	NR
Dermal contact	1	1-5	27	0.2-6	NR	0.8-1.1	36	0.092-0.25
Deodorant (underarm)	NR	NR	NR	0.29[5]; 0.8[3]	NR	NR	1	NR
Hair-noncoloring	NR	NR	NR	NR	NR	NR	9	NR
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	1	NR	NR	NR	NR	NR	8	0.95-1
Baby	NR	5	NR	NR	NR	NR	NR	NR

Table 3. Frequency and concentration of use according to duration and exposure of alkyloxy polysiloxanes with 2014 VCRP data.[13,43]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	PEG/PPG-15/15 dimethicone		PEG/PPG-17/18 dimethicone		PEG/PPG-18/18 dimethicone		PEG/PPG-19/19 dimethicone	
Total/range	**12**	**NR**	**112**	**0.019-14**	**461**	**0.0001-10**	**40**	**0.32-10.7**
Duration of use								
Leave-on	8	NR	108	0.019-14	373	0.0001-10	40	0.32-10.7
Rinse-off	4	NR	4	0.5	87	0.0001-3	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	1	NR	NR	NR
Exposure type								
Eye area	NR	NR	44	0.6	29	0.015-9.8	9	1-10.7
Incidental ingestion	NR	NR	NR	NR	1	1.6	NR	2
Incidental Inhalation-sprays	6	NR	41	0.019-14[2]; 0.027-1[5]	202	0.006-3[2]; 0.0001-1[5]	5	7[2]; 2[5]
Incidental inhalation-powders	NR	NR	2	NR	122	0.006-1.2[4]	NR	NR
Dermal contact	1	NR	6	14	335	0.0001-10	40	0.32-10.7
Deodorant (underarm)	NR	NR	NR	NR	21	0.24-5	17	NR
Hair-noncoloring	8	NR	62	0.019-13	106	0.0001-3	NR	2-7
Hair-coloring	3	NR	NR	NR	19	NR	NR	NR
Nail	NR	NR	NR	NR	NR	0.1	NR	NR
Mucous Membrane	NR	NR	NR	NR	24	0.0001-1.6	NR	2
Baby	NR	NR	NR	NR	1	NR	NR	NR

	PEG/PPG-20/15 dimethicone		PEG/PPG-20/20 dimethicone		PEG/PPG-20/23 dimethicone		PEG/PPG-20/6 dimethicone	
Total/range	**68**	**0.00045-2.3**	**21**	**0.11-0.33**	**29**	**0.0006-1.3**	**46**	**0.2-0.51**
Duration of use								
Leave-on	64	0.00045-2	20	0.11-0.33	21	0.0006-1.3	13	0.2-0.51
Rinse-off	4	NR	1	NR	8	0.1-0.25	33	0.28
Diluted for (bath) use	NR	2.3	NR	NR	NR	0.0006	NR	NR
Exposure type								
Eye area	6	1.1	4	0.27	NR	NR	2	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-sprays	38	0.046-1.4[2]; 0.35-0.9[5]	14	0.26-0.33[2]; 0.21[5]	11	NR	8	0.2[2]; 0.43[5]
Incidental inhalation-powders	15	0.54[4]	6	0.26[4]	7	0.0038[6]	7	NR
Dermal contact	39	0.00045-2.3	13	0.11-0.3	19	0.0006-1.3	38	0.28-0.51
Deodorant (underarm)	NR	0.75[3]	NR	NR	1	0.0006[3]	NR	0.51[3]
Hair-noncoloring	25	0.046-1.4	8	0.21-0.33	10	0.1-1.3	8	0.2-0.43
Hair-coloring	NR	NR	NR	NR	NR	0.25	NR	NR
Nail	2	0.18-0.75	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	2.3	NR	NR	4	0.0006	26	0.28
Baby	NR	NR	NR	NR	NR	NR	NR	NR

Table 3. Frequency and concentration of use according to duration and exposure of alkyloxy polysiloxanes with 2014 VCRP data.[13,43]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	PEG/PPG-22/23 dimethicone		PEG/PPG-22/24 dimethicone		PEG/PPG-25/25 dimethicone		PEG/PPG-30/10 dimethicone	
Total/range	**4**	**0.0025**	**22**	**0.1-1**	**2**	**0.7**	**1**	**0.00005-0.3**
Duration of use								
Leave-on	4	0.00025	21	0.1-1	2	0.7	1	0.00005-0.3
Rinse-off	NR	NR	1	NR	NR	0.7	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	NR	NR	NR	1	NR	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-sprays	3	0.0025[2]	9	0.25[2];0.11-1[5]	1	0.7[2]	1	NR
Incidental inhalation-powders	3	0.0025[4]	3	NR	NR	NR	1	NR
Dermal contact	4	0.0025	3	NR	1	NR	1	0.00005-0.3
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair-noncoloring	NR	NR	19	0.1-1	1	0.7	NR	NR
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	NR	NR	NR	NR	NR
Baby	NR	NR	NR	NR	NR	NR	NR	NR

	PEG/PPG-4/12 dimethicone		PEG/PPG-8/14 dimethicone		PEG-10 dimethicone		PEG-10 methyl ether dimethicone	
Total/range	**34**	**0.6-2.9**	**NR**	**0.05-0.88**	**240**	**0.013-6**	**4**	**0.01-5**
Duration of use								
Leave-on	20	0.6-2.9	NR	0.05-0.75	238	0.013-6	3	0.1-3
Rinse-off	14	1.4	NR	0.12-0.88	2	0.1-6	1	0.01-5
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	NR	NR	NR	46	0.38-4.2	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	4	NR	NR
Incidental Inhalation-sprays	4	1-2.9[2]; 0.6-1[5]	NR	0.4[2]; 0.05-0.12[5]	83	0.013-6[2]; 1[5]	3	3[2]; 0.16[5]
Incidental inhalation-powders	2	NR	NR	NR	77	0.5[6]	3	NR
Dermal contact	3	0.95-1	NR	0.1-0.88	229	0.013-5.3	4	0.3-5
Deodorant (underarm)	NR	NR	NR	NR	NR	0.3[3]	NR	NR
Hair-noncoloring	28	0.6-2.9	NR	0.05-0.55	2	0.3-6	NR	0.1-3
Hair-coloring	3	1.4	NR	NR	NR	0.35-0.4	NR	0.01
Nail	NR	0.95	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	NR	NR	4	NR	NR
Baby	NR	NR	NR	NR	NR	NR	NR	NR

Table 3. Frequency and concentration of use according to duration and exposure of alkyloxy polysiloxanes with 2014 VCRP data.[13,43]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	PEG-11 methyl ether dimethicone		PEG-12 dimethicone		PEG-14 dimethicone		PEG-17 dimethicone	
Total/range	**26**	**0.1-7**	**538**	**0.0016-6.5**	**41**	**0.006-2.8**	NR	**0.48-0.79**
Duration of use								
Leave-on	22	0.1-7	311	0.0016-6.5	35	0.006-2.8	NR	0.48
Rinse-off	4	0.45-6	220	0.1-5	6	0.6-1.8	NR	0.79
Diluted for (bath) use	NR	NR	7	0.5-1	NR	NR	NR	NR
Exposure type								
Eye area	8	0.75-7	10	0.0016-2	4	0.95-1	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-sprays	13	2[2]; 0.16[5]	219	0.03-5[2]; 0.1-0.4[5]	6	1.6[2]; 0.006-2.8[5]	NR	NR
Incidental inhalation-powders	13	NR	53	0.2-2[4]	NR	NR	NR	NR
Dermal contact	25	0.1-7	230	0.0016-6.5	4	0.95-1	NR	0.48-0.79
Deodorant (underarm)	NR	0.5[3]	10	0.1[5]; 0.5-2.8[3]	NR	NR	NR	NR
Hair-noncoloring	1	0.16-2	288	0.03-5	37	0.006-2.8	NR	NR
Hair-coloring	NR	NR	9	0.1-1	NR	NR	NR	NR
Nail	NR	NR	5	0.24	NR	NR	NR	NR
Mucous Membrane	NR	NR	83	0.5-3	NR	NR	NR	NR
Baby	NR	NR	2	4	NR	NR	NR	NR

	PEG-3 Dimethicone		PEG-32 methyl ether dimethicone		PEG-6 dimethicone		PEG-6 methyl ether dimethicone	
Total/range	**NR**	**0.5-5**	**1**	**NR**	**8**	**NR**	**8**	**NR**
Duration of use								
Leave-on	NR	0.5-5	1	NR	5	NR	5	NR
Rinse-off	NR	NR	NR	NR	3	NR	3	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	NR	NR	NR	NR	NR	NR	NR
Incidental ingestion	NR	0.5	NR	NR	NR	NR	NR	NR
Incidental Inhalation-sprays	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation-powders	NR	3[6]	NR	NR	NR	NR	NR	NR
Dermal contact	NR	1-5	1	NR	NR	NR	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair-noncoloring	NR	NR	NR	NR	8	NR	8	NR
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	0.5	NR	NR	NR	NR	NR	NR
Baby	NR	NR	NR	NR	NR	NR	NR	NR

Table 3. Frequency and concentration of use according to duration and exposure of alkyloxy polysiloxanes with 2014 VCRP data.[13,43]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	PEG-7 dimethicone		PEG-8 cetyl dimethicone		PEG-8 dimethicone		PEG-8 dimethicone/dimer dilinoleic acid copolymer	
Total/range	**2**	**4.3-5**	**5**	**0.0005**	**175**	**0.059-5.6**	**1**	**NR**
Duration of use								
Leave-on	2	4.3-5	5	0.0005	108	0.059-5.6	1	NR
Rinse-off	NR	NR	NR	NR	67	0.5-2	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	NR	1	NR	9	0.24-1.2	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-sprays	1	NR	2	NR	92	0.059-1.7[2]; 0.1-0.24[5]	1	NR
Incidental inhalation-powders	NR	NR	2	NR	55	1[4]	NR	NR
Dermal contact	1	4.3-5	5	0.0005	142	0.38-5.6	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair-noncoloring	1	NR	NR	NR	30	0.059-0.8	1	NR
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	NR	55	NR	NR	NR
Baby	NR	NR	NR	NR	NR	NR	NR	NR

	PEG-8 methicone		PEG-9 dimethicone		PEG-9 polydimethylsiloxyethyl dimethicone		Polysilicone-13	
Total/range	**10**	**0.5**	**25**	**0.0016-5.6**	**30**	**0.3-4**	**11**	**0.003-4**
Duration of use								
Leave-on	10	0.5	23	0.0016-5.6	30	0.3-4	4	0.003-1
Rinse-off	NR	NR	2	0.5-1.5	NR	NR	7	0.072-4
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	NR	16	0.0056-0.4	2	0.3	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	2	NR	NR
Incidental Inhalation-sprays	10	0.5[2]	5	0.05-0.26[2]	7	NR	2	0.003[5]
Incidental inhalation-powders	NR	NR	5	NR	4	NR	2	NR
Dermal contact	NR	NR	9	0.0016-5.6	30	0.3-4	11	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair-noncoloring	10	0.5	NR	0.059-0.5	NR	NR	NR	0.003-0.1
Hair-coloring	NR	NR	NR	0.05-1.5	NR	NR	NR	4
Nail	NR	NR	NR	NR	NR	NR	NR	1
Mucous Membrane	NR	NR	1	NR	NR	2	NR	NR
Baby	NR	NR	NR	NR	NR	NR	NR	NR

Table 3. Frequency and concentration of use according to duration and exposure of alkyloxy polysiloxanes with 2014 VCRP data.[13,43]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	PPG-12 dimethicone		PPG-2 dimethicone		Stearoxy dimethicone		Stearoxymethicone/ dimethicone copolymer	
Total/range	17	**0.0001-0.05**	14	**0.001-1**	**50**	**0.45-22**	**9**	**0.2-2**
Duration of use								
Leave-on	17	0.0001-0.05	14	0.001-1	49	0.45-6	9	0.2-2
Rinse-off	NR	NR	NR	NR	1	22	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	0.0006	NR	NR	13	0.9-6	NR	NR
Incidental ingestion	NR	NR	NR	NR	11	0.99-5.5	2	2
Incidental Inhalation-sprays	16	0.0001[2]; 0.0008-0.05[5]	NR	NR	17	NR	2	NR
Incidental inhalation-powders	NR	NR	NR	NR	17	NR	2	NR
Dermal contact	2	0.0001-0.0006	NR	NR	38	0.45-6	7	0.2-2
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair-noncoloring	15	0.0008-0.05	NR	NR	1	22	NR	NR
Hair-coloring	NR	NR	NR	NR		NR	NR	NR
Nail	NR	0.001	14	0.001-1	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	NR	11	0.99-5.5	2	2
Baby	NR	NR	NR	NR	NR	NR	NR	NR

	Cetyl dimethicone copolyol[6]		Dimethicone copolyol[6]		Dimethicone copolyol crosspolymer[6]		Dimethicone copolyol methyl ether[6]	
Total/range	**28**	**NS**	**322**	**NS**	**5**	**NS**	**1**	**NS**
Duration of use								
Leave-on	22	NS	249	NS	5	NS	1	NS
Rinse-off	6	NS	73	NS	NR	NS	NR	NS
Diluted for (bath) use	NR	NS	NR	NS	NR	NS	NR	NS
Exposure type								
Eye area	4	NS	11	NS	NR	NS	NR	NS
Incidental ingestion	1	NS	8	NS	NR	NS	NR	NS
Incidental Inhalation-sprays	4[2]	NS	143[2]	NS	5[2]	NS	NR	NS
Incidental inhalation-powders	4[4]	NS	69[4]	NS	NR	NS	NR	NS
Dermal contact	19	NS	190	NS	NR	NS	1	NS
Deodorant (underarm)	NR	NS	3	NS	NR	NS	NR	NS
Hair-noncoloring	6	NS	121	NS	NR	NS	NR	NS
Hair-coloring	NR	NS	NR	NS	NR	NS	NR	NS
Nail	1	NS	1	NS	NR	NS	NR	NS
Mucous Membrane	1	NS	22	NS	NR	NS	NR	NS
Baby	NR	NS	NR	NS	NR	NS	NR	NS

NR = Not Reported; NS = Not Surveyed; Totals = Rinse-off + Leave-on Product Uses.

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

[1] 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.

[2] It is possible these products may be sprays, but it is not specified whether the reported uses are sprays.

[3] Not spray product(s).

[4] It is possible these products may be powders, but it is not specified whether the reported uses are powders.

[5] Spray product(s)

[6] Powder product that may be inhaled

[7] Old umbrella term for this class of ingredients still used in the VCRP.

Table 5. Ingredients that do not have any reported uses in the VCRP or concentrations of use reported to the Council.[12,13]

Behenoxy PEG-10 dimethicone	PEG/PPG-18/12 dimethicone
Bis-cetyl/PEG-8 cetyl PEG-8 dimethicone	PEG/PPG-18/6 dimethicone
Bis-isobutyl PEG/PPG-10/7/dimethicone copolymer	PEG/PPG-20/22 methyl ether dimethicone
Bis-isoburyl PEG-13/dimethicone copolymer	PEG/PPG-20/29 dimethicone
Bis-isobutyl PEG-24/PPG-7/dimthicone copolymer	PEG/PPG-22/22 butyl ether dimethicone
Bis-PEG-1 dimethicone	PEG/PPG-23/23 butyl ether dimethicone
Bis-PEG-8 dimethicone	PEG/PPG-23/6 dimethicone
Bis-PEG-10 dimethicone	PEG/PPG-24/18 butyl ether dimethicone
Bis-PEG-20 dimethicone	PEG/PPG-27/27 dimethicone
Bis-PEG-8 PEG-8 dimethicone	PEG/PPG-27/9 butyl ether dimethicone
Bis-PEG/PPG-15/5 dimethicone	PEG/PPG-3/10 dimethicone
Bis-PEG/PPG-18/6 dimethicone	PEG/PPG-6/4 dimethicone
Bis-PEG/PPG-20/5 PEG/PPG-20/5 dimethicone	PEG/PPG-6/11 dimethicone
Bis-stearoxyethyl dimethicone	PEG/PPG-8/26 dimethicone
Cetyl PEG/PPG-15/15 butyl ether dimethicone	PEG-10 polydimethylsiloxyethyl dimethicone/bis-vinyl dimethicone crosspolymer
Cetyl PEG/PPG-7/3 dimethicone	PEG-3 methyl ether dimethicone
Cetyl PEG-8 dimethicone	PEG-4 PEG-12 dimethicone
Lauryl PEG-10 methyl ether dimethicone	PEG-10/lauryl dimethicone crosspolymer
Lauryl PEG-10 tris(trimethylsiloxy)silylethyl dimethicone	PEG-12 dimethicone/bis-isobutyl PPG-20 crosspolymer
Lauryl PEG-8 PPG-8 dimethicone	PEG-15/lauryl polydimethylsiloxyethyl dimethicone crosspolymer
Lauryl polyglyceryl-3 polydimethylsiloxyethyl dimethicone	PEG-4 PEG-12 dimethicone
Methoxy PEG-11 methoxy PPG-24 dimethicone	PEG-7 methyl ether dimethicone
Methoxy PEG-13 ethyl polysilsesquioxane	PEG-8 methyl ether dimethicone
PEG/PPG-10/2 dimethicone	PEG-8 PEG-4 dimethicone
PEG/PPG-10/3 oleyl ether dimethicone	PEG-8 PPG-8 dimethicone
PEG/PPG-12/16 dimethicone	PEG-9 methyl ether dimethicone
PEG/PPG-12/18 dimethicone	PPG-12 butyl ether dimethicone
PEG/PPG-15/5 dimethicone	PPG-25 dimethicone
PEG/PPG-16/2 dimethicone	PPG-27 dimethicone
PEG/PPG-16/8 dimethicone	PPG-4 oleth-10 dimethicone

Table 6. Eye irritation rating of alkyl polysiloxanes according to molecular weight.[6]

Molecular weight	Draize score[1]		
	Day 1	Day 3	Day 7
632	28.3	17.0	4.3
701	13.0	9.0	2.0
1240	4.7	9.3	2.0
1917	4.0	2.0	0.0
2525	2.0	0.7	0.0
2594	0.0	0.0	0.0

[1] Moderately irritating – 25.1-50; mildly irritating – 15.1-25.0; minimally irritating – 2.6 – 15.0; practically non-irritating – 0.6-2.5; non-irritating – 0-0.5.

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Personal Care Products Council
Committed to Safety, Quality & Innovation

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

FROM: Halyna Breslawec, Ph.D.
Industry Liaison to the CIR Expert Panel

DATE: April 18, 2014

SUBJECT: Updated Concentration of Use Information for Polyoxyalkylene Siloxane Copolymers, Alkyl-Polyoxyalkylene Copolymers and Related Ingredients

Concentration of Use by FDA Product Category*

Behenoxy Dimethicone
Behenoxy PEG-10 Dimethicone
Bis-Cetyl/PEG-8 Cetyl PEG-8 Dimethicone
Bis-Hydroxyethoxypropyl Dimethicone
Bis-Isobutyl PEG/PPG-10/7/Dimethicone Copolymer
Bis-Isobutyl PEG-13/Dimethicone Copolymer
Bis-Isobutyl PEG-24/PPG-7/Dimethicone Copolymer
Bis-PEG-1 Dimethicone
Bis-PEG-4 Dimethicone
Bis-PEG-8 Dimethicone
Bis-PEG-10 Dimethicone
Bis-PEG-12 Dimethicone
Bis-PEG-12 Dimethicone Beeswax
Bis-PEG-12 Dimethicone Candelillate
Bis-PEG-15 Methyl Ether Dimethicone
Bis-PEG-20 Dimethicone
Bis-PEG-8 PEG-8 Dimethicone
Bis-PEG/PPG-14/14 Dimethicone
Bis-PEG/PPG-15/5 Dimethicone
Bis-PEG/PPG-16/16 PEG/PPG-16/16 Dimethicone
Bis-PEG/PPG-18/6 Dimethicone
Bis-PEG/PPG-20/20 Dimethicone
Bis-PEG/PPG-20/5 PEG/PPG-20/5 Dimethicone
Bis-Stearoxy Dimethicone
Bis-Stearoxyethyl Dimethicone
Cetyl PEG/PPG-10/1 Dimethicone
Cetyl PEG/PPG-15/15 Butyl Ether Dimethicone
Cetyl PEG/PPG-7/3 Dimethicone
Cetyl PEG-8 Dimethicone
Lauryl Isopentyl-PEG/PPG-18/18 Methicone
Lauryl PEG/PPG-18/18 Methicone
Lauryl PEG-10 Methyl Ether Dimethicone
Lauryl PEG-10 Tris(Trimethylsiloxy)silylethyl Dimethicone
Lauryl PEG-8 Dimethicone
Lauryl PEG-8 PPG-8 Dimethicone
Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone
Lauryl Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone
Methoxy PEG-11 Methoxy PPG-24 Dimethicone
Methoxy PEG/PPG-25/4 Dimethicone
Methoxy PEG-13 Ethyl Polysilsesquioxane
PEG/PPG-10/2 Dimethicone
PEG/PPG-10/3 Oleyl Ether Dimethicone
PEG/PPG-12/16 Dimethicone
PEG/PPG-12/18 Dimethicone
PEG/PPG-14/4 Dimethicone
PEG/PPG-15/15 Dimethicone
PEG/PPG-15/5 Dimethicone
PEG/PPG-16/2 Dimethicone
PEG/PPG-16/8 Dimethicone
PEG/PPG-17/18 Dimethicone
PEG/PPG-18/12 Dimethicone
PEG/PPG-18/18 Dimethicone
PEG/PPG-18/6 Dimethicone
PEG/PPG-19/19 Dimethicone
PEG/PPG-20/15 Dimethicone
PEG/PPG-20/20 Dimethicone
PEG/PPG-20/22 Butyl Ether Dimethicone
PEG/PPG-20/22 Methyl Ether Dimethicone
PEG/PPG-20/23 Dimethicone
PEG/PPG-20/29 Dimethicone
PEG/PPG-20/6 Dimethicone
PEG/PPG-22/22 Butyl Ether Dimethicone
PEG/PPG-22/23 Dimethicone
PEG/PPG-22/24 Dimethicone
PEG/PPG-23/23 Butyl Ether Dimethicone
PEG/PPG-23/6 Dimethicone
PEG/PPG-24/18 Butyl Ether Dimethicone
PEG/PPG-25/25 Dimethicone
PEG/PPG-27/27 Dimethicone
PEG/PPG-27/9 Butyl Ether Dimethicone
PEG/PPG-3/10 Dimethicone
PEG/PPG-30/10 Dimethicone
PEG/PPG-4/12 Dimethicone
PEG/PPG-6/4 Dimethicone
PEG/PPG-6/11 Dimethicone
PEG/PPG-8/14 Dimethicone
PEG/PPG-8/26 Dimethicone
PEG-10 Dimethicone
PEG-10 Methyl Ether Dimethicone
PEG-10 Polydimethylsiloxyethyl Dimethicone/Bis-Vinyl Dimethicone Crosspolymer
PEG-11 Methyl Ether Dimethicone
PEG-12 Dimethicone
PEG-14 Dimethicone
PEG-17 Dimethicone
PEG-3 Dimethicone
PEG-32 Methyl Ether Dimethicone
PEG-4 PEG-12 Dimethicone
PEG-6 Dimethicone
PEG-6 Methyl Ether Dimethicone
PEG-7 Dimethicone
PEG-7 Methyl Ether Dimethicone
PEG-8 Cetyl Dimethicone
PEG-8 Dimethicone
PEG-8 Dimethicone Dimer Dilinoleate
PEG-8 Dimethicone/Dimer Dilinoleic Acid Copolymer
PEG-8 Methicone
PEG-8 Methyl Ether Dimethicone
PEG-8 PEG-4 Dimethicone
PEG-8 PPG-8 Dimethicone
PEG-9 Dimethicone
PEG-9 Methyl Ether Dimethicone
PEG-9 Polydimethylsiloxyethyl Dimethicone
Polysilicone-13
PPG-12 Butyl Ether Dimethicone

PPG-12 Dimethicone
PPG-2 Dimethicone
PPG-25 Dimethicone
PPG-27 Dimethicone
PPG-4 Oleth-10 Dimethicone
Stearoxy Dimethicone
Stearoxymethicone/Dimethicone Copolymer

Ingredient	**Product Category**	**Maximum Concentration of Use**
Behenoxy Dimethicone	Skin cleansing	0.5%
Behenoxy Dimethicone	Face and neck products not spray	2-3%
Behenoxy Dimethicone	Body and hand products not spray	0.5%
Behenoxy Dimethicone	Moisturizing products not spray	2%
Behenoxy Dimethicone	Night products not spray	2%
Behenoxy Dimethicone	Other skin care preparations	0.5%
Bis-Hydroxyethoxypropyl Dimethicone	Eye liner	1.3-2%
Bis-Hydroxyethoxypropyl Dimethicone	Eye shadow	3.4%
Bis-Hydroxyethoxypropyl Dimethicone	Blushers	12%
Bis-Hydroxyethoxypropyl Dimethicone	Lipstick	0.7-1%
Bis-Hydroxyethoxypropyl Dimethicone	Other makeup preparations	9.4%
Bis-PEG/PPG-14/14 Dimethicone	Eye lotion	0.42-1.1%
Bis-PEG/PPG-14/14 Dimethicone	Foundations	0.94-5%
Bis-PEG/PPG-14/14 Dimethicone	Leg and body paints	0.85%
Bis-PEG/PPG-14/14 Dimethicone	Makeup fixatives	0.94%
Bis-PEG/PPG-14/14 Dimethicone	Deodorant not spray	3%
Bis-PEG/PPG-14/14 Dimethicone	Face and neck products not spray	0.2-1.2%
Bis-PEG/PPG-14/14 Dimethicone	Moisturizing products not spray	0.41-0.85%
Bis-PEG/PPG-14/14 Dimethicone	Night products not spray	0.39%
Bis-PEG/PPG-14/14 Dimethicone	Paste masks and mud packs	0.9%
Bis-PEG/PPG-16/16 PEG/PPG-16/16 Dimethicone	Eyeliner	0.99%

Bis-PEG/PPG-16/16 PEG/PPG-16/16 Dimethicone	Mascara	0.99%
Bis-PEG/PPG-16/16 PEG/PPG-16/16 Dimethicone	Depilatories	0.65%
Bis-PEG/PPG-16/16 PEG/PPG-16/16 Dimethicone	Face and neck products not spray	1.7%
Bis-PEG/PPG-16/16 PEG/PPG-16/16 Dimethicone	Moisturizing products not spray	0.4%
Bis-PEG/PPG-20/20 Dimethicone	Foundations	0.2%
Bis-PEG/PPG-20/20 Dimethicone	Aftershave lotions	0.2%
Bis-PEG/PPG-20/20 Dimethicone	Skin cleansing	0.5%
Bis-PEG/PPG-20/20 Dimethicone	Face and neck products not spray	0.35-0.5%
Bis-PEG/PPG-20/20 Dimethicone	Skin fresheners	0.35%
Bis-PEG-12 Dimethicone	Eye lotion	0.28%
Bis-PEG-12 Dimethicone Beeswax	Eye liner	1.4-1.8%
Bis-PEG-12 Dimethicone Beeswax	Eye shadow	1%
Bis-PEG-12 Dimethicone Beeswax	Mascara	2.6-4.5%
Bis-PEG-12 Dimethicone Beeswax	Tonics, dressings and other hair grooming aids	0.01%
Bis-PEG-12 Dimethicone Beeswax	Blushers	0.72%
Bis-PEG-12 Dimethicone Beeswax	Foundations	5.7%
Bis-PEG-12 Dimethicone Beeswax	Suntan products not spray	0.2%
Bis-PEG-12 Dimethicone Candelillate	Mascara	1%
Bis-PEG-12 Dimethicone Candelillate	Lipstick	5.1%
Bis-PEG-12 Dimethicone Candelillate	Moisturizing products not sprays	0.5%
Bis-PEG-15 Methyl Ether Dimethicone	Mascara	1%
Bis-PEG-15 Methyl Ether Dimethicone	Moisturizing products spray	1.5%
Bis-PEG-4 Dimethicone	Hair conditioners	0.4%
Cetyl PEG/PPG-10/1 Dimethicone	Eyebrow pencil	15%
Cetyl PEG/PPG-10/1 Dimethicone	Eye liner	0.53%

Cetyl PEG/PPG-10/1 Dimethicone	Eye shadow	3.1-13.6%
Cetyl PEG/PPG-10/1 Dimethicone	Eye lotion	1.5-3%
Cetyl PEG/PPG-10/1 Dimethicone	Mascara	3%
Cetyl PEG/PPG-10/1 Dimethicone	Hair conditioners	0.5%
Cetyl PEG/PPG-10/1 Dimethicone	Shampoos (noncoloring)	0.7%
Cetyl PEG/PPG-10/1 Dimethicone	Tonics, dressings and other hair grooming aids	2-3%
Cetyl PEG/PPG-10/1 Dimethicone	Other hair preparations (non coloring)	3.5%
Cetyl PEG/PPG-10/1 Dimethicone	Blushers	0.7%
Cetyl PEG/PPG-10/1 Dimethicone	Face powders	0.4%
Cetyl PEG/PPG-10/1 Dimethicone	Foundations	0.067-5.5%
Cetyl PEG/PPG-10/1 Dimethicone	Leg and body paints	3%
Cetyl PEG/PPG-10/1 Dimethicone	Lipstick	0.098-3.8%
Cetyl PEG/PPG-10/1 Dimethicone	Makeup bases	3%
Cetyl PEG/PPG-10/1 Dimethicone	Makeup fixatives	5%
Cetyl PEG/PPG-10/1 Dimethicone	Other makeup preparations	2.4%
Cetyl PEG/PPG-10/1 Dimethicone	Nail polish and enamel	0.02%
Cetyl PEG/PPG-10/1 Dimethicone	Deodorants not spray	0.7-2%
Cetyl PEG/PPG-10/1 Dimethicone	Aftershave lotions	2%
Cetyl PEG/PPG-10/1 Dimethicone	Skin cleansing	2.5%
Cetyl PEG/PPG-10/1 Dimethicone	Face and neck products not spray	1-3.8%
Cetyl PEG/PPG-10/1 Dimethicone	Body and hand products not spray	1-3%
Cetyl PEG/PPG-10/1 Dimethicone	Moisturizing products not spray	0.034-3%
Cetyl PEG/PPG-10/1 Dimethicone	Night products not spray	1%
Cetyl PEG/PPG-10/1 Dimethicone	Other skin care preparations	0.75-2.5%
Cetyl PEG/PPG-10/1 Dimethicone	Suntan products not spray	1-3.3%
Cetyl PEG/PPG-10/1 Dimethicone	Indoor tanning products	1%
Cetyl PEG/PPG-10/1 Dimethicone	Other suntan preparations	1.8%

Lauryl PEG/PPG18/18 Dimethicone	Eyeliner	2.2%
Lauryl PEG/PPG18/18 Dimethicone	Eye shadow	0.8-2%
Lauryl PEG/PPG18/18 Dimethicone	Eye lotion	0.5%
Lauryl PEG/PPG18/18 Dimethicone	Tonics, dressings and other hair grooming aids	1.4%
Lauryl PEG/PPG18/18 Dimethicone	Foundations	2.5-5%
Lauryl PEG/PPG18/18 Dimethicone	Lipstick	3.8%
Lauryl PEG/PPG18/18 Dimethicone	Makeup bases	5%
Lauryl PEG/PPG18/18 Dimethicone	Other makeup preparations	0.5-2%
Lauryl PEG/PPG18/18 Dimethicone	Face and neck products not spray	 0.54%
Lauryl PEG/PPG18/18 Dimethicone	Body and hand products not spray	 0.86-2%
Lauryl PEG/PPG18/18 Dimethicone	Paste masks and mud packs	2%
Lauryl PEG-8 Dimethicone	Baby lotions, oils and creams not powder	5%
Lauryl PEG-8 Dimethicone	Moisturizing products not spray	 5%
Lauryl PEG-8 Dimethicone	Suntan products not spray aerosol	 2.5% 1%
Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone	Eye lotion	1-2%
Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone	Blushers	3%
Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone	Foundations	1.5-6%
Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone	Makeup bases	2.8%
Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone	Makeup fixatives	0.6%
Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone	Deodorants not spray aerosol	 0.8% 0.29%
Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone	Face and neck products not spray	 2.5-2.8%

Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone	Body and hand products not spray spray	 0.2% 0.2%
Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone	Moisturizing products not spray	 0.69%
Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone	Suntan products not spray	 1-2.5%
Methoxy PEG/PPG-25/4 Dimethicone	Face and neck products not spray	 0.8%
Methoxy PEG/PPG-25/4 Dimethicone	Body and hand products not spray	 1.1%
PEG/PPG-14/4 Dimethicone	Eyebrow pencil	0.95-1%
PEG/PPG-14/4 Dimethicone	Eyeliner	0.95-2%
PEG/PPG-14/4 Dimethicone	Eye shadow	0.95-2%
PEG/PPG-14/4 Dimethicone	Eye lotion	1%
PEG/PPG-14/4 Dimethicone	Hair sprays aerosol pump spray	 0.092% 0.14%
PEG/PPG-14/4 Dimethicone	Tonics, dressings and other hair grooming aids	0.16-0.25%
PEG/PPG-14/4 Dimethicone	Lipstick	0.95-1%
PEG/PPG-14/4 Dimethicone	Body and hand products not spray	 2%
PEG/PPG-14/4 Dimethicone	Other skin care preparations	1%
PEG/PPG-17/18 Dimethicone	Mascara	0.6%
PEG/PPG-17/18 Dimethicone	Perfumes	14%
PEG/PPG-17/18 Dimethicone	Hair conditioners	0.5%
PEG/PPG-17/18 Dimethicone	Hair sprays aerosol pump spray	 0.027-0.5% 1%
PEG/PPG-17/18 Dimethicone	Tonics, dressing and other hair grooming aids	0.019-13%
PEG/PPG-18/18-Dimethicone	Eye liner	0.5-9.8%
PEG/PPG-18/18-Dimethicone	Eye shadow	0.44-5%
PEG/PPG-18/18-Dimethicone	Eye lotion	0.015-2.1%
PEG/PPG-18/18-Dimethicone	Hair conditioners	0.21-3%

PEG/PPG-18/18-Dimethicone	Hair sprays aerosol pump spray	 0.0001-0.35% 0.1-1%
PEG/PPG-18/18-Dimethicone	Hair straighteners	0.0001%
PEG/PPG-18/18-Dimethicone	Shampoos (noncoloring)	0.05%
PEG/PPG-18/18-Dimethicone	Tonics, dressings and other hair grooming aids	0.2-3%
PEG/PPG-18/18-Dimethicone	Foundations	1-7.4%
PEG/PPG-18/18-Dimethicone	Leg and body paints	2.9-3%
PEG/PPG-18/18-Dimethicone	Lipstick	1.6%
PEG/PPG-18/18-Dimethicone	Makeup bases	0.9-1.2%
PEG/PPG-18/18-Dimethicone	Makeup fixatives	2%
PEG/PPG-18/18-Dimethicone	Other makeup preparations	0.075-10%
PEG/PPG-18/18-Dimethicone	Nail polish and enamel removers	0.1%
PEG/PPG-18/18-Dimethicone	Deodorants not spray	 0.24-5%
PEG/PPG-18/18-Dimethicone	Other personal cleanliness products	0.0001%
PEG/PPG-18/18-Dimethicone	Aftershave lotions	0.053-1.6%
PEG/PPG-18/18-Dimethicone	Skin cleansing	0.061-0.6%
PEG/PPG-18/18-Dimethicone	Face and neck products not spray	 0.54-2.4%
PEG/PPG-18/18-Dimethicone	Body and hand products not spray	 0.068-1%
PEG/PPG-18/18-Dimethicone	Moisturizing products not spray	 0.006-1.2%
PEG/PPG-18/18-Dimethicone	Night products not spray	 0.2%
PEG/PPG-18/18-Dimethicone	Other skin care preparations	0.15%
PEG/PPG-18/18-Dimethicone	Suntan products not spray	 0.4-2.5%
PEG/PPG-18/18-Dimethicone	Indoor tanning preparations	0.5-2.8%
PEG/PPG-19/19-Dimethicone	Eyebrow pencil	4.7%
PEG/PPG-19/19-Dimethicone	Eye liner	9.8-10%
PEG/PPG-19/19-Dimethicone	Eye shadow	5.5-10.7%
PEG/PPG-19/19-Dimethicone	Eye lotion	1-5%

PEG/PPG-19/19-Dimethicone	Mascara	1.5%
PEG/PPG-19/19-Dimethicone	Hair sprays pump sprays	2%
PEG/PPG-19/19-Dimethicone	Tonics, dressings and other hair grooming aids	7%
PEG/PPG-19/19-Dimethicone	Foundations	0.32-7%
PEG/PPG-19/19-Dimethicone	Lipstick	2%
PEG/PPG-19/19-Dimethicone	Makeup bases	7%
PEG/PPG-19/19-Dimethicone	Face and neck products not spray	2-5%
PEG/PPG-19/19-Dimethicone	Body and hand products not spray	2%
PEG/PPG-19/19-Dimethicone	Moisturizing products not spray	0.65%
PEG/PPG-19/19-Dimethicone	Suntan products not spray	0.53-6%
PEG/PPG-20/15 Dimethicone	Other bath preparations	2.3%
PEG/PPG-20/15 Dimethicone	Eye liner	1.1%
PEG/PPG-20/15 Dimethicone	Hair sprays aerosol	0.35-0.9%
PEG/PPG-20/15 Dimethicone	Tonics, dressings and other hair grooming aids	0.046-1.4%
PEG/PPG-20/15 Dimethicone	Face powders	0.54%
PEG/PPG-20/15 Dimethicone	Foundations	0.5-2%
PEG/PPG-20/15 Dimethicone	Leg and body paints	0.049%
PEG/PPG-20/15 Dimethicone	Other makeup preparations	0.04%
PEG/PPG-20/15 Dimethicone	Cuticle softeners	0.75%
PEG/PPG-20/15 Dimethicone	Nail creams and lotions	0.75%
PEG/PPG-20/15 Dimethicone	Other manicuring preparations	0.18%
PEG/PPG-20/15 Dimethicone	Deodorants not spray	0.75%
PEG/PPG-20/15 Dimethicone	Face and neck products not spray	0.00045-1.6%
PEG/PPG-20/15 Dimethicone	Moisturizing products not spray	0.1-0.75%

PEG/PPG-20/15 Dimethicone	Night products not spray	0.4-0.85%
PEG/PPG-20/15 Dimethicone	Indoor tanning preparations	0.8%
PEG/PPG-20/20 Dimethicone	Eye lotion	0.27%
PEG/PPG-20/20 Dimethicone	Hair sprays aerosol	0.21%
PEG/PPG-20/20 Dimethicone	Tonics, dressings and other hair grooming aids	0.33%
PEG/PPG-20/20 Dimethicone	Foundations	0.11-0.3%
PEG/PPG-20/20 Dimethicone	Face and neck products not spray	0.16-0.21%
PEG/PPG-20/20 Dimethicone	Moisturizing products not spray	0.26%
PEG/PPG-20/23 Dimethicone	Other bath preparations	0.0006%
PEG/PPG-20/23 Dimethicone	Hair conditioners	0.1%
PEG/PPG-20/23 Dimethicone	Other hair preparations (noncoloring)	1-1.3%
PEG/PPG-20/23 Dimethicone	Hair dyes and colors	0.25%
PEG/PPG-20/23 Dimethicone	Face powders	0.0038%
PEG/PPG-20/23 Dimethicone	Foundations	0.2%
PEG/PPG-20/23 Dimethicone	Makeup bases	1.3%
PEG/PPG-20/23 Dimethicone	Other makeup preparations	0.0006%
PEG/PPG-20/23 Dimethicone	Deodorants not spray	0.0006%
PEG/PPG-20/23 Dimethicone	Face and neck products not spray	0.83%
PEG/PPG-20/23 Dimethicone	Body and hand products not spray	0.0028%
PEG/PPG-20/23 Dimethicone	Moisturizing products not spray	0.0011%
PEG/PPG-20/23 Dimethicone	Other skin care preparations	1.3%
PEG/PPG-20/6 Dimethicone	Hair sprays aerosol	0.43%
PEG/PPG-20/6 Dimethicone	Tonics, dressings and other hair grooming aids	0.2%
PEG/PPG-20/6 Dimethicone	Deodorants not spray	0.51%

PEG/PPG-20/6 Dimethicone	Other personal cleanliness products	0.28%
PEG/PPG-20/6 Dimethicone	Body and hand products not spray	 0.5%
PEG/PPG-22/23 Dimethicone	Other fragrance preparations	0.00025%
PEG/PPG-22/23 Dimethicone	Face and neck products not spray	 0.0025%
PEG/PPG-22/23 Dimethicone	Skin fresheners	0.0025%
PEG/PPG-22/24 Dimethicone	Hair sprays aerosol pump spray	 0.11% 1%
PEG/PPG-22/24 Dimethicone	Tonics, dressings and other hair grooming aids	0.25%
PEG/PPG-22/24 Dimethicone	Other hair preparations (noncoloring)	0.1%
PEG/PPG-25/25 Dimethicone	Hair conditioners	0.7%
PEG/PPG-25/25 Dimethicone	Tonics, dressings and other hair grooming aids	0.7%
PEG/PPG-30/10 Dimethicone	Makeup bases	0.00005%
PEG/PPG-30/10 Dimethicone	Face and neck products not spray	 0.3%
PEG/PPG-4/12 Dimethicone	Colognes and toilet waters	1%
PEG/PPG-4/12 Dimethicone	Hair sprays aerosol pump	 1.7% 0.6%
PEG/PPG-4/12 Dimethicone	Tonics, dressings and other hair grooming aids	2.9%
PEG/PPG-4/12 Dimethicone	Hair dyes and colors	1.4%
PEG/PPG-4/12 Dimethicone	Other manicuring preparations	0.95%
PEG/PPG-8/14 Dimethicone	Hair conditioners	0.55%
PEG/PPG-8/14 Dimethicone	Hair sprays aerosol pump	 0.12% 0.05%
PEG/PPG-8/14 Dimethicone	Tonics, dressings and other hair grooming aids	0.4%
PEG/PPG-8/14 Dimethicone	Aftershave lotions	0.75%
PEG/PPG-8/14 Dimethicone	Shaving cream	0.88%
PEG/PPG-8/14 Dimethicone	Skin cleansing	0.12%

PEG/PPG-8/14 Dimethicone	Moisturizing products not spray	0.1%
PEG-10 Dimethicone	Eyebrow pencil	4%
PEG-10 Dimethicone	Eye liner	4%
PEG-10 Dimethicone	Eye shadow	0.45-4%
PEG-10 Dimethicone	Eye lotion	0.38-3.3%
PEG-10 Dimethicone	Eye makeup remover	3%
PEG-10 Dimethicone	Mascara	4-4.2%
PEG-10 Dimethicone	Hair conditioners	6%
PEG-10 Dimethicone	Hair sprays pump	1%
PEG-10 Dimethicone	Shampoos (noncoloring)	1-2%
PEG-10 Dimethicone	Tonics, dressings and other hair grooming aids	0.3-6%
PEG-10 Dimethicone	Other hair preparations (noncoloring)	0.65-2%
PEG-10 Dimethicone	Hair tints	0.35-0.4%
PEG-10 Dimethicone	Blushers	1-4%
PEG-10 Dimethicone	Face powders	0.5%
PEG-10 Dimethicone	Foundations	0.5-5.3%
PEG-10 Dimethicone	Lipstick	4%
PEG-10 Dimethicone	Makeup bases	0.03-4%
PEG-10 Dimethicone	Makeup fixatives	2%
PEG-10 Dimethicone	Other makeup preparations	0.3-5%
PEG-10 Dimethicone	Deodorants not spray	0.3%
PEG-10 Dimethicone	Skin cleansing	0.1-2%
PEG-10 Dimethicone	Depilatories	0.74%
PEG-10 Dimethicone	Face and neck products not spray	1.2-4%
PEG-10 Dimethicone	Body and hand products not spray	0.013-3%
PEG-10 Dimethicone	Moisturizing products not spray	0.38-3%

PEG-10 Dimethicone	Night products not spray	0.38%
PEG-10 Dimethicone	Other skin care preparations	1.5%
PEG-10 Dimethicone	Suntan products not spray	3-4%
PEG-10 Dimethicone	Indoor tanning preparations	0.75%
PEG-10 Dimethicone	Other suntan preparations	0.013%
PEG-10 Methyl Ether Dimethicone	Hair conditioners	0.2%
PEG-10 Methyl Ether Dimethicone	Hair sprays pump	0.16%
PEG-10 Methyl Ether Dimethicone	Tonics, dressings and other hair grooming aids	3%
PEG-10 Methyl Ether Dimethicone	Wave sets	2%
PEG-10 Methyl Ether Dimethicone	Other hair preparations (noncoloring)	0.1%
PEG-10 Methyl Ether Dimethicone	Hair tints	0.01%
PEG-10 Methyl Ether Dimethicone	Foundations	1.8%
PEG-10 Methyl Ether Dimethicone	Skin cleansing	5%
PEG-10 Methyl Ether Dimethicone	Face and neck products not spray	0.3-1%
PEG-10 Methyl Ether Dimethicone	Other skin care preparations	0.44%
PEG-11 Methyl Ether Dimethicone	Eye shadow	2%
PEG-11 Methyl Ether Dimethicone	Eye lotion	0.75-7%
PEG-11 Methyl Ether Dimethicone	Hair sprays pump spray	0.16%
PEG-11 Methyl Ether Dimethicone	Permanent waves	0.45%
PEG-11 Methyl Ether Dimethicone	Tonics, dressings and other hair grooming aids	2%
PEG-11 Methyl Ether Dimethicone	Foundations	1-2%
PEG-11 Methyl Ether Dimethicone	Makeup bases	0.2%
PEG-11 Methyl Ether Dimethicone	Deodorants not spray	0.5%
PEG-11 Methyl Ether Dimethicone	Skin cleansing	6%
PEG-11 Methyl Ether Dimethicone	Face and neck products not spray	0.1-1%

PEG-11 Methyl Ether Dimethicone	Moisturizing products not spray	 2%
PEG-12 Dimethicone	Other baby productcs	4%
PEG-12 Dimethicone	Bubble baths	1%
PEG-12 Dimethicone	Other bath preparations	0.5-1%
PEG-12 Dimethicone	Eyebrow pencil	0.0078%
PEG-12 Dimethicone	Eye shadow	0.0016-2%
PEG-12 Dimethicone	Eye lotion	0.79%
PEG-12 Dimethicone	Mascara	0.002-0.083%
PEG-12 Dimethicone	Other eye makeup preparations	1%
PEG-12 Dimethicone	Colognes and toilet waters	1.1%
PEG-12 Dimethicone	Other fragrance preparations	0.5%
PEG-12 Dimethicone	Hair conditioners	0.75-2.5%
PEG-12 Dimethicone	Hair sprays aerosol pump	 0.1-2% 0.15-0.5%
PEG-12 Dimethicone	Shampoos (noncoloring)	0.15-3%
PEG-12 Dimethicone	Tonics, dressings and other hair grooming aids	0.03-5%
PEG-12 Dimethicone	Other hair preparations (noncoloring)	1%
PEG-12 Dimethicone	Hair dyes and colors	1%
PEG-12 Dimethicone	Hair rinses (coloring)	1%
PEG-12 Dimethicone	Hair bleaches	0.1-0.5%
PEG-12 Dimethicone	Other hair coloring preparations	1%
PEG-12 Dimethicone	Blushers (all types)	1%
PEG-12 Dimethicone	Face powders	0.6%
PEG-12 Dimethicone	Foundations	0.082-1%
PEG-12 Dimethicone	Makeup bases	0.5-3%
PEG-12 Dimethicone	Other makeup preparations	1.9%
PEG-12 Dimethicone	Nail polish and enamel	0.24%
PEG-12 Dimethicone	Bath soaps and detergents	0.5-1%

PEG-12 Dimethicone	Deodorants not spray aerosol	 0.5-2.5% 0.1%
PEG-12 Dimethicone	Other personal cleanliness products	1-3%
PEG-12 Dimethicone	Aftershave lotions	0.5-2%
PEG-12 Dimethicone	Shaving cream	1-3%
PEG-12 Dimethicone	Other shaving preparations	3% (rinse-off)
PEG-12 Dimethicone	Skin cleansing	1-5%
PEG-12 Dimethicone	Face and neck products not spray	 0.4-2%
PEG-12 Dimethicone	Body and hand products not spray spray	 0.3-6.5% 0.4%
PEG-12 Dimethicone	Foot products	2%
PEG-12 Dimethicone	Moisturizing products not spray	 0.5-2%
PEG-12 Dimethicone	Night products not spray	 0.6%
PEG-12 Dimethicone	Paste masks and mud packs	0.4-2%
PEG-12 Dimethicone	Skin fresheners	0.2-0.4%
PEG-12 Dimethicone	Other skin care preparations	1%
PEG-12 Dimethicone	Suntan products not spray	 0.0059%
PEG-12 Dimethicone	Indoor tanning preparations	0.1%
PEG-14 Dimethicone	Eye liner	0.95-1%
PEG-14 Dimethicone	Eye lotion	1%
PEG-14 Dimethicone	Hair conditioners	0.99%
PEG-14 Dimethicone	Hair sprays aerosol pump	 0.006% 2.8%
PEG-14 Dimethicone	Hair straighteners	1.8%
PEG-14 Dimethicone	Shampoos (noncoloring)	0.6%
PEG-14 Dimethicone	Tonics, dressings and other hair grooming aids	1.6%
PEG-17 Dimethicone	Skin cleansing	0.79%

PEG-17 Dimethicone	Moisturizing products not spray	 0.48%
PEG-3 Dimethicone	Face powders	3%
PEG-3 Dimethicone	Foundations	3%
PEG-3 Dimethicone	Lipstick	0.5%
PEG-3 Dimethicone	Makeup bases	3-5%
PEG-3 Dimethicone	Face and neck products not spray	 1-3%
PEG-7 Dimethicone	Foundations	5%
PEG-7 Dimethicone	Suntan products not spray	 4.3%
PEG-8 Cetyl Dimethicone	Foundations	0.0005%
PEG-8 Cetyl Dimethicone	Face and neck products not spray	 0.0005%
PEG-8 Cetyl Dimethicone	Suntan products not spray	 0.0005%
PEG-8 Dimethicone	Eye liner	0.96-1.2%
PEG-8 Dimethicone	Mascara	0.024%
PEG-8 Dimethicone	Perfumes	1.7%
PEG-8 Dimethicone	Hair sprays aerosol pump	 0.24% 0.1%
PEG-8 Dimethicone	Shampoos (noncoloring)	0.5%
PEG-8 Dimethicone	Tonics, dressings and other hair grooming aids	0.059-0.8%
PEG-8 Dimethicone	Foundations	1.1-3%
PEG-8 Dimethicone	Other makeup preparations	2%
PEG-8 Dimethicone	Other personal cleanliness products	1%
PEG-8 Dimethicone	Skin cleansing	0.5-1.2%
PEG-8 Dimethicone	Face and neck products not spray	 0.38-5.6%
PEG-8 Dimethicone	Body and hand creams not spray	 1.7%
PEG-8 Dimethicone	Moisturizing products not spray	 1%

PEG-8 Dimethicone	Night products not spray	0.65-4%
PEG-8 Dimethicone	Paste masks and mud packs	2%
PEG-8 Dimethicone	Skin fresheners	1%
PEG-8 Dimethicone	Other skin care preparations	2%
PEG-8 Methicone	Tonics, dressings and other hair grooming aids	0.5%
PEG-9 Dimethicone	Eyebrow pencil	0.0056%
PEG-9 Dimethicone	Mascara	0.4%
PEG-9 Dimethicone	Permanent waves	0.5%
PEG-9 Dimethicone	Tonics, dressings and other hair grooming aids	0.059-0.26%
PEG-9 Dimethicone	Hair dyes and colors	1.5%
PEG-9 Dimethicone	Hair color sprays	0.05%
PEG-9 Dimethicone	Foundations	0.2-3%
PEG-9 Dimethicone	Makeup bases	2.3%
PEG-9 Dimethicone	Face and neck products not spray	0.0016-5.6%
PEG-9 Dimethicone	Night products not spray	0.65%
PEG-9 Dimethicone	Suntan products not spray	2.5%
PEG-9 Polidymethylsiloxyethyl Dimethicone	Eye lotion	0.3%
PEG-9 Polidymethylsiloxyethyl Dimethicone	Foundations	2-4%
PEG-9 Polidymethylsiloxyethyl Dimethicone	Lipstick	2%
PEG-9 Polidymethylsiloxyethyl Dimethicone	Makeup bases	2.5-4%
PEG-9 Polidymethylsiloxyethyl Dimethicone	Other makeup preparations	2.5%
PEG-9 Polidymethylsiloxyethyl Dimethicone	Face and neck products not spray	1.8-4%
PEG-9 Polidymethylsiloxyethyl Dimethicone	Body and hand products not spray	3%

PEG-9 Polidymethylsiloxyethyl Dimethicone	Moisturizing products not spray	4%
PEG-9 Polidymethylsiloxyethyl Dimethicone	Suntan products not spray	1-2.5%
Polysilicone-13	Hair conditioners	0.1%
Polysilicone-13	Hair sprays pump	0.003%
Polysilicone-13	Rinses (noncoloring)	0.072%
Polysilicone-13	Other hair coloring preparations	4%
Polysilicone-13	Nail polish and enamel	1%
PPG-12 Dimethicone	Eye liner	0.0006%
PPG-12 Dimethicone	Colognes and toilet waters	0.0001%
PPG-12 Dimethicone	Hair sprays aerosol pump	0.0008-0.05% 0.037%
PPG-2 Dimethicone	Nail polish and enamel	0.001-1%
Stearoxy Dimethicone	Eye liner	0.9%
Stearoxy Dimethicone	Eye shadow	6%
Stearoxy Dimethicone	Eye lotion	1.1%
Stearoxy Dimethicone	Hair conditioners	22%
Stearoxy Dimethicone	Blushers	1.5%
Stearoxy Dimethicone	Lipstick	0.99-5.5%
Stearoxy Dimethicone	Makeup fixatives	0.45%
Stearoxy Dimethicone	Other makeup preparations	1.9%
Stearoxy Dimethicone	Body and hand products not spray	2%
Stearoxymethicone/Dimethicone Copolymer	Foundations	2%
Stearoxymethicone/Dimethicone Copolymer	Lipstick	2%
Stearoxymethicone/Dimethicone Copolymer	Face and neck products not spray	0.2%
Stearoxymethicone/Dimethicone Copolymer	Night products not spray	0.45%

*Ingredients included in the title of the table, but not found in the table were included in the concentration of use

survey, but no uses were reported.

Information collected 2013-2014
Table prepared January 31, 2014
Updated April 17, 2014: Bis-PEG/PPG-14/14 Foundations: high concentration from 3.3% to 5%; Bis-PEG/PPG-20/20 Dimetnicone Face and neck products high concentration from 5% to 0.5% Cetyl PEG/PPG-10/1 Dimethicone Foundations high concentration from 5% to 5.5%; added Other makeup preparations; Lauryl PEG/PPG-18/18 Methicone Eye shadow added 0.8% as low concentration; Other makeup preparations added 0.5% as low concentration; added Lauryl PEG-8 Dimethicone; PEG/PPG-18/18 Dimethicone Eyeliner add 9.8% as high concentration; Eye shadow high concentration from 1.5% to 5%; Other Makeup preparations high concentration from 2% to 10%; Deodorants (not spray) high concentration from 2.7% to 5%;PEG/PPG-20/15 Dimethicone Foundations low concentration from 1.1% to 0.5%; PEG-10 Dimethicone Eye shadow low concentration from 1% to 0.45%; Mascara added high concentration 4.2% Foundations low concentration from 1.2% to 0.5%; PEG-12 Dimethicone Deodorants (not spray) high concentration from 1% to 2.5%; PPG-2 Dimethicone Nail polish and enamel added high concentration 1%; Stearoxy Dimethicone added Eye shadow, Hair conditioners

DOW CORNING

PPG-2 Dimethicone

Acute Toxicity

Eye Irritation. An acute study was designed to evaluate the ocular anti-irritancy of PPG-2 Dimethicone in comparison with a control solution of 3% sodium lauryl sulfate alone. The test substance was administered as a 1:1 mixture with a 3% solution of sodium lauryl sulfate. A single instillation of 0.1 ml of the prepared test substance was made into the right eye of three male rabbits. All animals were observed for indications of pain and discomfort. Ocular observations using a hand-held slit-lamp were made at 1, 24, 48, 72 hours and 7 days following treatment, including the use of sodium fluorescein (except at the 1-hour reading). The eyes of all rabbits treated with the test substance preparation exhibited signs of irritation consisting of moderate to marked redness, slight swelling and discharge. One rabbit had moderate corneal irritation at the 24-hour reading only. All eyes appeared normal and no signs of eye irritation were observed in any of the animals that received the test substance formulation when examined at 72 hours and at 7 days post-instillation. No evidence of pain or discomfort or iridial irritation was observed. Eyes treated with PPG-2 Dimethicone plus sodium lauryl sulfate resulted in notable reduction of irritation during the first 48 hours (as compared with sodium lauryl sulfate alone) with the mean irritation scores decreasing from 4.7/13.0 to 0.3/13.0 (1).

Genetic Toxicity

In Vitro. A bacterial reverse mutation assay was conducted in *Salmonella typhimurium* (four strains, TA-1535, TA-97, TA-98 and TA-100) and *Escherichia coli* (one strain, WP2) to assess the mutagenic potential of the test substance. All strains were tested both without and in the presence of Aroclor 1254-induced rat liver S9 activation. The test substance was diluted in dimethylsulfoxide for testing at dosages of 312.5, 625, 1250, 2500 and 5000 μg/plate. In addition, the *S. Typhimurium* TA-1535 strain was tested at dosages of 15,625, 31,250, 62,500, 125,000 and 250,000 μg/plate (both with and without S9 activation) using ethanol as the diluent. All dosages/strains were tested in triplicate. Expected results, i.e., large increases in revertant counts, were seen for all positive controls, thereby demonstrating the reliability of the test system. The numbers of revertants on test substance-treated plates did not exceed those seen on corresponding solvent controls. No evidence of mutagenic potential was observed (2).

References

1. Dow Corning Internal Report –1982-I0005-0976
2. Dow Corning Internal Report –1985-I0005-1288

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Bis-Isobutyl PEG-24/PPG-7/Dimethicone Copolymer

Skin Sensitization

Bis-Isobutyl PEG-24/PPG-7/Dimethicone Copolymer was tested for skin sensitization in 20 (10M: 10F) Hartley-strain albino guinea pigs. An additional ten (5M:5F) Hartley-strain guinea pigs were utilized as the control group. For induction, each animal in the test group received three (3) pairs of intradermal injections, with and without the test article. During the second week of the induction phase, topical applications of the test article were made to the induction site of each animal in the test group. Two (2) weeks after the topical induction applications, the challenge applications were made. These 24 hour challenge applications were made to virgin sites on the flank of each animal in the test and control groups, at the screen determined, highest non-irritating concentration of the test article (25% in petrolatum). Observations of erythema, edema and other effects were recorded 48 and 72 hours after the challenge applications. Conclusion: The test substance is not a sensitizer in guinea pigs under the conditions of this test.

References

1. 2012-I0000-66134

PEG/PPG-15/15 Acetate Dimethicone

Acute Dermal Toxicity

An acute study was conducted to determine the dermal toxicity potential of PEG/PPG-15/15 Acetate Dimethicone (78% purity) in albino rabbits. A single, occluded dose of either 2 or 5 g/kg was applied for 24 hours to the intact skin of five male rabbits.

The animals treated with the test substance showed no signs of toxicity. All rabbits survived to terminal sacrifice and no test substance related changes were observed grossly or microscopically in animals which received a dermal application of 2 or 5 g/kg. (1)

References

1. 1990-I0000-35545

Lauryl PEG/PPG-18/18 Methicone

Skin Sensitization.

In a human repeat insult patch test (HRIPT), 103 volunteers were exposed to the test substance in 3 phases. The first phase consisted of 9 consecutive patch applications of 0.2 ml of the substance to the same site every 48 hours under semiocclusive wraps; the subjects removed the patches after 24 hours of exposure. Substances were not reapplied until Monday if the applications had been made on the previous Friday. Patches were applied to the infrascapular area of the back to one side of the midline. Following the ninth evaluation, the subjects were dismissed for a 12-14 day rest period. After the rest period, the same dose method was used on a previously unexposed site and the volunteers removed the patches after 24 hours; the sites were graded 24 and 48 hours after patch removal (48 and 72 hours after patch application). None of the volunteers exhibited signs of irritation or sensitization during any part of the study. Therefore, the test substance was not considered sensitizing under the conditions of this study (1).

Genetic Toxicity In Vitro

The genetic activity of the test substance was evaluated in an Ames assay using *Salmonella typhimurium* strains TA-98, TA-100, TA-1535, and TA-1537, plus *Escherichia coli* strains WP2 *uvr*A (pKM101) and WP2 (pKM101) in the presence and absence of Aroclor-induced rat liver S9. The assay was performed using the preincubation method. Each strain was plated with 0, 15, 50, 150, 500, or 1500 μg of test substance per plate; the material was diluted with ethanol. Precipitate was observed at 1500 μg/plate, but no appreciable toxicity was observed. No positive responses were observed at any of the dose levels. Therefore, the test substance was not considered to be mutagenic in the bacterial reverse mutation assay (2).

References

1. Dow Corning Internal Report – 1998-I0000-45918
2. Dow Corning Internal Report – 1999-I0000-46001

PEG/PPG-19/19 DIMETHICONE

Acute Toxicity

Oral. The test substance was assessed for its acute oral toxicity in rats. Ten rats of the CFE strain (five males and five females) received 16 ml/kg of undiluted test substance by gastric intubation. Control animals were dosed with 0.5% tragacanth mucilage. Nonspecific reactions observed during the first 24 to 72 hours after treatment included piloerection and diuresis. All rats appeared healthy four days after dosing and gained weight normally. Autopsy findings at the conclusion of the study were unremarkable. These data indicate that the estimated oral LD50 for the fluid was greater than 16 ml/kg body weight for CFE rats (1).

Dermal. The toxicity of the test substance was determined following a single dermal dose applied to rabbits. The material was applied to the dorso-lumbar region of five male and five female New Zealand White rabbits at a dose of 2000 mg/kg body weight. The animals were observed immediately after dosing and every hour for the remainder of the day. The treated area was washed with mild detergent 24 hours after application of the test substance and the dermal irritation was assessed 48 hours after application. All animals were observed twice daily for mortality and morbidity and the application sites were observed daily for irritation for 15 days (the length of the study). Body weight was measured for each of the animals immediately prior to dosing, and on days 8 and 15 of the study. None of the animals died during the course of the study. There were no observed signs of systemic effects except that one male rabbit had few feces on Day 3 of the study. There was slight to well defined irritation in most of the rabbits, though this had cleared by the end of the study. There were no treatment related effects on body weight gain, nor were there macroscopic effects upon necropsy of the animals. The material was not considered to elicit toxic effects at the dose tested. (2).

Skin Sensitization

The skin sensitization potential of the test substance was assessed in the guinea pig. A total of 30 male Dunkin/Hartley albino guinea pigs were allocated into three groups: 20 animals were exposed to test substance; five were controls; and five were positive controls exposed to hexyl cinnamic aldehyde (HCA). On the day prior to the first exposure, the skin of the scapular region of the back of each guinea pig was clipped and shaved free of hair. On Day 1 of the study, three pairs of intradermal injections (0.1 ml/site) were made in the shaved region: a 50:50 dilution of Freund's Complete Adjuvant in Water; the test (5% solution of the test substance in water) or control materials (water or 10% HCA in Alembicol D); or 50:50 dilution of Freund's Complete Adjuvant with either the injected test or control solutions. Skin responses were evaluated 24 hours later. Six days after the injection, the same site on each animal was again made free of hair and 0.5 ml of 10% sodium lauryl sulfate in petrolatum was gently rubbed on the site. The next day, a filter paper patch was soaked with neat test or control materials and applied to the hair-free area. The patch was left in place for 48 hours. Skin reactions were

evaluated upon removal of the dressing. Two weeks after the topical application, the left flank of each animal was clipped and shaved free of hair. A filter paper patch was soaked with test or control materials and applied, as appropriate, to the hair-free sites. The patches remained in place for 24 hours, and the sites were evaluated upon removal of the patch, and 24 and 48 hours later. During the course of the study, all animals were provided food and water ad libitum, were observed daily for signs of ill health or toxicity, and body weights were taken prior to the first injection and at study termination. No effects were noted by treatment with the test substance in clinical observations or body weight gain. Severe irritation was noted at all injection sites of Freund's Complete Adjuvant, slight to moderate irritation at injection sites of the test substance, slight irritation was seen at the HCA injection sites, but no irritation was seen at the control injection sites. Upon topical application, slight to well-defined redness was noted with the test substance and HCA, but slight redness was seen in some control guinea pigs. After the second topical application, effects were the same for the test and control animals, though the HCA exposed animals had more marked and longer lasting effects indicative of skin sensitization. The material was not judged to have sensitizing potential (3).

Genetic Toxicity

Ames. Mutagenicity of the test substance was determined by measuring the ability of the fluid to produce reverse mutations in Salmonella typhimurium tester strains TA-1535, TA-1537, TA-1538, TA-100 and TA-98, both in the presence and absence of Aroclor-induced rat liver microsomal enzymes. In the first phase of the study, a spot plate test used 10 µl of the fluid spotted on plates containing the microorganism in the absence or presence of the microsomal enzymes. The plates were incubated for 48 hours at 37C. In the second phase of the study, concentrations of 0 (the solvent control), 0.5 µl, 5 µl, 100 µl or 500 µl of each fluid per plate, along with positive controls, were plated with each tested strain in the presence or absence of microsomal enzymes. Sodium azide, 9-amino acridine, 2-nitrofluorene and 2-anthramine served as positive controls. No mutagenic responses were produced by the fluid in either study phase in any of the tester strains, with and without metabolic activation. Based on these results and under the conditions of testing, the test substance was considered non-mutagenic (4).

Sub-acute Toxicity

Dermal. The systemic toxicity of the test substance was assessed following 29 days of dermal exposure. The fluid was administered by dermal application to three groups of 10 male and 10 female New Zealand White rabbits at doses of 100, 300, or 1000 mg/kg/day. The test substance was removed after six hours of exposure on each day of treatment. A similarly constituted additional group, serving as controls, was subjected to the same procedures as the treated animals, but no test substance was applied. Throughout the study the animals were observed daily for signs associated with treatment. Before each administration the dermal test site was examined for signs of irritation. Body weights were determined twice each week and food consumption once each week. Blood samples

were taken for hematology and blood chemistry investigations on Days 29 and 30 for males and days 30 and 31 for females. After a minimum of 29 days of treatment the animals were sacrificed and subjected to a full macroscopic examination. Selected organs were weighed and tissues were processed and examined microscopically. There were no deaths or signs of systemic reaction. Local signs of irritation were observed at the application site of the majority of animals from all groups treated with fluid. These signs were generally limited to erythema, edema, exfoliation and scabs. Body weight, body weight change and food consumption were not affected by treatment. There were no ocular findings attributable to treatment; hematological and blood chemistry investigations did not reveal any findings of significance. Absolute and body weight-relative organ weights were unaffected by treatment. There were no treatment-related macroscopic findings at necropsy, except those associated with the local signs of irritation at the application sites. Diffuse subcutaneous inflammation, acanthosis and follicular abscess were revealed upon microscopic examination of the application site. Since the study was to assess the systemic toxic potential of the test substance, the No-Observed-Effect-Level (NOEL) with regard to systemic toxicity was considered to be 1000 mg/kg/day (5).

References

1. Dow Corning Internal Report – 1968-I0065-1007-03
2. Dow Corning Internal Report – 1999-I0000-47461
3. Dow Corning Internal Report – 1999-I0000-47446
4. Dow Corning Internal Report – 1979-I0005-702
5. Dow Corning Internal Report – 2000-I0000-48262

PEG-12 DIMETHICONE

Acute Toxicity

Inhalation. Acute aerosol inhalation toxicity studies were conducted with test substance. The control and test groups each consisted of 5 male and 5 female Sprague-Dawley rats. The test group was exposed to an average aerosol concentration of 0.68 mg/l of the material for 4 hours; the control group was exposed to filtered room air for the same period. No deaths in the control or test animal groups were observed, and no apparent abnormalities were seen during the exposure or observation period. Necropsy of the test animals revealed no apparent abnormalities in any major organs or tissues in the control or test group (1).

Dermal Toxicity. The acute dermal toxicity of the test substance was evaluated in albino rabbits. The dorsal hair was closely clipped in the test area, and a single dose of either 2-g/kg or 5-g/kg was applied for 24 hours to the intact skin of 5 male rabbits per dose group. The test substance was held in close contact with the skin under plastic wrap and a cotton bandage secured with adhesive tape. One rabbit dosed with 5-g/kg of the material was euthanized in a moribund condition. In the remaining animals, only slight exfoliation at the application site was seen. No test-related lesions were observed microscopically in any of the rabbits. Based on the results of this study, the test substance has an estimated acute dermal LD_{50} greater than 5-g/kg in male rabbits (2).

Irritation/Corrosion

Eye. A 5-day repeated instillation eye irritation study was designed to evaluate the ocular irritation potential of the material under conditions of repeated exposure. A 0.1 ml sample of test substance was instilled into the right eye of 6 male rabbits for 5 consecutive days. Observations were made 24 hours after each instillation and for 7 days following the fifth treatment. No evidence of irritation of the cornea or iris was observed in any of the test animals, but slight, transient conjunctival redness was noted at 24 hours following each instillation. Under the conditions of this test, the test substance was considered to be a nonirritant to the eyes of rabbits; however, repeated direct contact with the test substance may produce very slight conjunctival redness (3).

This effect was studied further by combining, at a 1:1 ratio, test Fluid with 3% sodium lauryl sulfate (SLS) and comparing it to a control solution of 3% SLS alone. A single dose of 0.1 ml of each test substance was instilled into the right eye of 6 male rabbits per group. Observations were made by slit lamp at 1, 6, 24, 48, and 72 hours, and at 7 days following treatment. The treated eyes of rabbits in both groups showed signs of irritation consisting of moderate conjunctival redness, swelling and discharge. Animals treated with SLS alone also showed transient corneal opacity and iridal congestion. The test substance in SLS solution showed evidence of rapid reduction in ocular irritation over a period of 48 hours when compared to the control solution of SLS alone. The average mean eye irritation scores of animals treated with the test substance and SLS versus those

treated with SLS alone decreased from 10.4/38 to 1/38 and from 19.0/38 to 5.8/38, respectively. These results indicated that the test fluid in SLS was effective in reducing eye irritation in rabbits (4).

Skin. A dermal irritation test was conducted with the test substance in New Zealand White rabbits. The test substance was administered under semi-occlusive dressings at a dose of 0.5 ml/site to one intact skin site on the clipped dorsolumbar region of 3 female rabbits. The duration of exposure was 4 hours, after which each treatment site was washed with warm water. The sites were scored for irritation at 60 minutes and 24, 48 and 72 hours following removal of the dressings. There was no evidence of systemic response to treatment. A single semi-occlusive application of test substance to intact rabbit skin for 4 hours elicited very slight erythema that resolved within 72 hours and no edema in all 3 animals. The Primary Irritation Index (PII) was calculated to be 0.44 (7).

A study with human subjects evaluated the ability of the material to prevent or reduce the dermal irritation produced by SLS. The test substance was incorporated in a 1% aqueous SLS solution at concentrations of 0.5%, 2%, and 5%. A 1% solution of SLS also was tested as the control. Each concentration of the test substance was applied to the backs of 48 female and 5 male human volunteers and covered with an occlusive patch for 24 hours. After 24 hours, the test sites were rinsed with water and patted dry. The sites were evaluated for erythema and edema at 24 and 48 hours after patch removal. Results indicated that when applied simultaneously with SLS, the test substance (at all concentrations tested) provided protection against the primary dermal irritation produced by the SLS, when compared to the SLS control. The sample containing 5% test substance provided the greatest protection (5).

Skin Sensitization

The dermal sensitization potential of the test substance was evaluated in Dunkin-Hartley guinea pigs (Magnusson and Kligman method). In a Preliminary dose range-finding experimentation, 12 animals were used to determine the appropriate test substance dose concentrations for the induction phase (intradermal and topical application) and for the challenge. There were 3 groups of male guinea pigs on the main study. The test group, the negative control group and the positive control group consisted of 20, 10 and 5 animals, respectively.

Intradermal induction treatment consisted of two 0.1 mL injections of 1:1 Freund's Complete Adjuvant: water, two 0.1 mL injections of the test substance (50% in water), two 0.1 ml injections of the test substance (50% in Freund's Complete Adjuvant). The control animals were treated similarly to test animals with the exception that the test substance was omitted. The positive control animals were treated similarly but the test substance was replaced with 10% v/v Hexyl cinnamic aldehyde in Alembicol D (the vehicle). Injections were made in the scapular area. Six days after injection, the application sites for the test group and negative control group were pre-treated with Sodium Lauryl Sulphate (0.5 mL, 10% w/w in petrolatum) on the day prior to topical

induction. During the topical induction, doses (0.4 mL) of the test substance (100%), Hexyl cinnamic aldehyde (100%) or vehicle were applied under occluded 2 x 4 cm filter paper patches for 48 hours. Two weeks after the topical induction, challenge doses were applied to anterior shaved sites on the flanks. The test group and negative control group were treated on 3 sites and received 100% test substance, 50% test substance in water and vehicle. The positive control animals were treated similarly with Hexyl cinnamic aldehyde. All challenge doses were 0.2 mL and were applied under occluded 2 cm x 2 cm filter paper patches for 24 hours.

Animals were observed daily for signs of toxicity and ill health. Body weights were recorded at the beginning and end of the test. Dermal reactions to the challenge exposures were evaluated using the Draize scale at 24 and 48 hours after patch removal. Determination of sensitization potential was made by comparison of the challenge reactions in induced animals versus the respective control group. There were no signs of toxicity or ill health, and there were no remarkable body weight changes. Most of the positive control group animals reacted positively to the known sensitizer, Hexyl cinnamic aldehyde. The incidence and severity of reactions seen in the test group and negative control group were considered to represent skin irritation rather than sensitization. It was concluded that the test substance did not produce skin sensitization in guinea pigs under the conditions of this study (8).

Reproductive Toxicity

Teratogenicity. The test substance was evaluated for its embryotoxic and teratogenic potential in rabbits. Undiluted test fluid or water (control) was applied to the skin of pregnant New Zealand white rabbits on days 6 through 18 of gestation. Applications were made daily at dose levels of 0, 50, 100 or 200 mg/kg of body weight. Litters were collected by cesarean section on day 29 and fetuses were examined for external, visceral or skeletal defects. No treatment related signs of toxicity or behavioral changes were observed in any of the pregnant rabbits. Three rabbits in the 50-mg/kg/day group, 1 in the 100-mg/kg/day group, and 3 in the 200-mg/kg/day group died during the study. Some pregnancies were terminated because of *Pasteurella multocida* infection, a known abortifacient in rabbits.

No adverse effects were observed in mean maternal body weight, food consumption or liver weights of the treated rabbits. No statistically significant differences were observed in the number of implantation sites, number of live fetuses per litter, mean litter size, fetal body weight or crown-rump length between the control and treated groups. The incidence of resorption among the total fetal population for animals treated with test substance was similar to that of the control, indicating the test substance is not embryolethal in rabbits at the dose levels tested. A few scattered incidences of fetal alterations were observed in the external, soft tissue or skeletal examinations among treated and, in some cases, control litters. However, no single alteration was observed in treated litters at an incidence significantly different from the control. When considered collectively, the incidence of total major malformations observed in the external, soft tissue, or the

skeletal examination was not significantly different among the treated groups and controls. In summary, the test substance was not embryotoxic or teratogenic in rabbits at dermal dose levels of 50, 100 or 200 mg/kg/day (6).

Subacute Toxicity

Oral. The subacute toxicity of the test substance was evaluated in an oral gavage study in Sprague-Dawley rats. The test substance mixed with water was administered for 29 consecutive days to 3 groups of rats (5/sex) at dosages of 100, 300 and 1000 mg/kg/day. A control group of 5 rats per sex received the vehicle (water) only at 10 ml/kg/day. The rats were 34-38 days old and weighed 127 $\pm$ 15 grams at commencement of dosing. Throughout the treatment period, the rats were observed frequently for signs of toxicity and ill health. Detailed physical examinations and functional observation battery (FOB) assessments were performed weekly. Manipulation and motor activity tests were performed pretreatment and during the fourth week of dosing. Body weights and food consumption were recorded weekly, with an additional final body weight being taken just prior to necropsy. On the day after the final dosing, blood was collected (retro-orbital sinus) for hematology and clinical chemistry evaluations and detailed necropsies were performed. Selected organs were weighed and tissue samples were processed and examined microscopically. No deaths occurred during the study. Transient salivation was frequently observed shortly after dosing in the 1000 mg/kg/day group. There were no other signs that were attributable to treatment. FOB and manipulation and motor activity tests did not reveal any test substance-related effects. Body weight, body weight change, food consumption and hematology were unaffected by treatment with the test substance. The only test substance-related clinical chemistry and organ weight findings were decreased albumin/ globulin ration and increased liver weight in the 1000 mg/kg/day females. These findings were considered to represent a metabolic/adaptive response in the liver and, in the absence of any microscopic changes in the liver, of no toxicological significance. There were no test substance-related microscopic pathological findings. The test substance did not produce any overt signs of toxicity when administered via oral gavage for 29 consecutive days to male and female Sprague-Dawley rats at dosages up to 1000-mg/kg/day, which corresponds to the No-Observed-Adverse-Effect Level (NOAEL) (9).

Dermal. The test substance was administered by dermal application to 3 groups of 10 male and 10 female New Zealand White (NZW) rabbits for 4 weeks at dosages of 100, 300, or 1000 mg/kg/day under semi-occlusive dressing. The test substance was removed after 6 hours of exposure on each day of treatment. A sham control group consisting of 10 rabbits/sex was subjected to the same procedures as the treated animals, but no test substance was applied. Throughout the study, the animals were observed daily for signs associated with treatment. Before each administration, the dermal application site was examined for signs of irritation. Body weights were determined twice each week and food consumption once each week. Blood samples were taken for hematology and clinical chemistry investigations near the end of the treatment period. After a minimum of 29 days of treatment, the animals were euthanized and subjected to a full macroscopic

examination. Selected organs were weighed and tissues were processed and examined microscopically. There were no deaths and no signs of systemic reaction to treatment. Very slight erythema was observed in all treated groups - and the number of animals showing erythema is higher in the female group. The numbers of animal- impacted increased as the doses increased.- Only one female in the highest dose showed severe erythema, which was reversible. In this study very slight edema was also observed in smaller number of animals compared to animals with erythema in each of the treated group. Body weight, body weight change and food consumption were not considered to be affected by treatment. There were no ophthalmologic findings attributable to treatment. Hematological and blood chemistry investigations did not reveal any findings of toxicological significance. Organ weights were considered to be unaffected by treatment. There were no treatment-related macroscopic findings at necropsy, other than those associated with the local signs of irritation at the dermal application sites. Microscopic examination revealed a number of findings at the application site, consisting of diffuse subcutaneous inflammation, acanthosis and a single case of follicular abscess. Ulcers were present on the application sites examined for females treated at 100 or 300 mg/kg/day. Although local reversible slight irritation reactions were present in all treated groups, the test substance did not produce any overt signs of systemic toxicity when applied daily for 6 hours to the skin of male and female NZW rabbits at dosages up to 1000 mg/kg/day for 29 days (10).

References

1. Dow Corning Internal Report – 1987-I0005-1618 – Acute aerosol inhalation
2. Dow Corning Internal Report – 1990-I0000-35553 – Acute Dermal Toxicity
3. Dow Corning Internal Report – 1982-I0005-0971 – Eye irritation
4. Dow Corning Internal Report – 1982-I0005-0975 – Eye irritation
5. Dow Corning Internal Report – 1984-I0065-1025-30 – Dermal irritation
6. Dow Corning Internal Report – 1983-I0005-1044 – Teratogenicity
7. Dow Corning Internal Report –1999-I0000-47457 – Skin irritation
8. Dow Corning Internal Report –1999-I0000-47440 – Skin Sensitization
9. Dow Corning Internal Report –2000-I0000-48265 – subchronic oral toxicity
10. Dow Corning Internal Report –2000-I0000-48263 – subchronic dermal toxicity

Printing Date 2014-04-18 12:39:53 EDT

Restriction of specific regulatory purposes

Confidentiality

Name Siloxanes & silicones, di-Me, 3-hydroxypropyl Me. ethoxylated

Legal entity owner Epona Associates, LLC / Willington / United States

Substance: Siloxanes & silicones, di-Me, 3-hydroxypropyl Me. ethoxylated

UUID IUC5-98e50ad9-4489-436e-ba35-1cef2b9b8bed

Dossier UUID 0

Author Collette / Epona Associates, LLC / Willington / United States

Date 2014-04-16 15:18:08 EDT

Remarks Created endpoint study record 7.3.1 Skin irritation / corrosion

0 Related Information
0.1 Templates
0.2 Categories
0.3 Mixtures
1 General Information
1.1 Identification
Substance identification

Chemical name Siloxanes & silicones, di-Me, 3-hydroxypropyl Me. ethoxylated

Legal entity Epona Associates, LLC / Willington / United States

Reference substance

Siloxanes & silicones, di-Me, 3-hydroxypropyl Me, ethoxylated / 68937-54-2

EC number **EC name**

CAS number **CAS name**

68937-54-2

IUPAC name

1.2 Composition
1.3 Identifiers
1.4 Analytical information
1.5 Joint submission
1.6 Sponsors
1.7 Suppliers
1.8 Recipients
1.9 Product and process oriented research and development
2 Classification & Labelling and PBT assessment
2.1 GHS
2.2 DSD - DPD
3 Manufacture, use and exposure
3.1 Technological process

Technological process

3.2 Estimated quantities
3.3 Sites
3.4 Information on mixtures
3.5 Life Cycle description
3.6 Uses advised against
3.7 Exposure Scenarios, exposure and risk assessment
3.7.2 Environmental assessment for aggregated sources
3.7.3 Generic exposure potential
3.8 Biocidal information
3.10 Application for authorisation of uses
7 Toxicological information
7.3 Irritation / corrosion
7.3.1 Skin irritation / corrosion

Endpoint study record: Skin irritation / corrosion.

UUID	IUC5-95d81c54-c51c-4055-9097-4d77f0bd13fe
Dossier UUID	0
Author	Collette / Epona Associates, LLC / Willington / United States
Date	2014-04-18 09:38:56 EDT
Remarks	

Administrative Data

Purpose flag	supporting study
Study result type	experimental result
Reliability	1 (reliable without restriction)
Rationale for reliability incl. deficiencies	Guideline study, GLP

Data source

Reference

Reference type	Author	Year	Title	Bibliographic source	Testing laboratory	Report no.	Owner company	Company study no.	Report date
study report	Hazelton Laboratories	1984	[Trade name protected] Primary Skin Irritation Study in the Rabbit		Hazelton Laboratories	408-348/37			1984-07-20

Materials and methods

Type of method

in vivo

Test guideline

Qualifier	Guideline	Deviations
according to	other guideline: US FDA	

GLP compliance

yes

Test materials

Identity of test material same as for substance defined in section 1 (if not read-across)

yes

Test material identity

Identifier	Identity
CAS number	68937-54-2

Details on test material

MS: 1000-5000 amu. Product is a polymer and not a pure substance . It is tested as produced for commercial use. It typically contains approximately 25% free polyether polymer and small amounts of stabilizers and trace impurities.

pH was a 10% dilution of the test substance in distilled water was 5

Test animals

Species

rabbit

Strain

New Zealand White

Details on test animals and environmental conditions

weight range of 2.96 to 3.84 kg; age 11-17 weeks

Test system

Type of coverage

occlusive

Preparation of test site

other: intact and abraded

Vehicle

water (10% dilution in distilled water)

Amount/concentration applied

0.5 ml

Duration of treatment / exposure

Observation period

72 hours

Number of animals

6

Control animals

no

Details on study design

0.5 ml was applied to the clipped, intact or abraded skin of 6 rabbits under an occlusive cover for 24 hours. After the contact period, the skin was wiped of remaining material and evaluated for skin irritation 24 and 72 hours later.

Results and discussions

Irritation / corrosion results

Irritation parameter	Basis	Time point	Score	Max. score	Reversibility	Remarks
primary dermal irritation index (PDII)	mean	24 and 72 hours	0			

Irritant/corrosive response data

There were no reactions.

Applicant's summary and conclusion

Interpretation of results

not irritating

14 Information requirements

14.2 Alternative name request

Legal entity: Epona Associates, LLC

UUID IUC5-c761b429-cb5e-4220-afe7-f1502995c432

Dossier UUID 0

Author XML Transformation V2.0 Plug-In

Date 2009-05-14 10:54:32 EDT

Remarks Successfully migrated to IUCLID 5.3 format.

General information

Legal entity name Epona Associates, LLC

Legal entity type consultant

Identifiers

Other IT system identifiers

Flags	IT system	ID	Remarks
	LEO	10472	

Contact information

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E-mail	wendykoch@eponallc.com
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Contact persons

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Town	Willington
Region / State	CT
Country	United States

Reference substance: Siloxanes & silicones, di-Me, 3-hydroxypropyl Me, ethoxylated

UUID	IUC5-40429c8e-2926-4b86-b0cb-df4e49c28e3b
Dossier UUID	0
Author	Collette / Epona Associates, LLC / Willington / United States
Date	2014-04-16 10:34:10 EDT
Remarks	

General information

Reference substance name Siloxanes & silicones, di-Me, 3-hydroxypropyl Me, ethoxylated

Reference substance information

CAS information

CAS number 68937-54-2

Printing Date 2014-04-18 12:38:32 EDT

Restriction of specific regulatory purposes

Confidentiality

Name Siloxanes & silicones cetyl Me, diMe

Legal entity owner Epona Associates, LLC / Willington / United States

Substance: Siloxanes & silicones cetyl Me, diMe

UUID IUC5-a5e6a207-045a-44c3-965c-27717ea77fe9

Dossier UUID 0

Author Collette / Epona Associates, LLC / Willington / United States

Date 2014-04-16 10:59:23 EDT

Remarks Created endpoint study record 7.3.1 Skin irritation / corrosion

0 Related Information

0.1 Templates

0.2 Categories

0.3 Mixtures

1 General Information

1.1 Identification

Substance identification

Chemical name Siloxanes & silicones cetyl Me, diMe

Legal entity Epona Associates, LLC / Willington / United States

Reference substance

Siloxanes & silicones, cetyl Me, di-Me / 191044-49-2

EC number **EC name**

CAS number **CAS name**

191044-49-2

IUPAC name

1.2 Composition

1.3 Identifiers
1.4 Analytical information
1.5 Joint submission
1.6 Sponsors
1.7 Suppliers
1.8 Recipients
1.9 Product and process oriented research and development
2 Classification & Labelling and PBT assessment
2.1 GHS
2.2 DSD - DPD
3 Manufacture, use and exposure
3.1 Technological process

Technological process

3.2 Estimated quantities
3.3 Sites
3.4 Information on mixtures
3.5 Life Cycle description
3.6 Uses advised against
3.7 Exposure Scenarios, exposure and risk assessment
3.7.2 Environmental assessment for aggregated sources
3.7.3 Generic exposure potential
3.8 Biocidal information
3.10 Application for authorisation of uses
7 Toxicological information
7.3 Irritation / corrosion
7.3.1 Skin irritation / corrosion

Endpoint study record: Skin irritation / corrosion.<1000 amu

UUID	IUC5-80fefb54-30e1-4a2a-ad60-6155e22b5af3
Dossier UUID	0
Author	Collette / Epona Associates, LLC / Willington / United States
Date	2014-04-18 11:35:58 EDT
Remarks	

Administrative Data

Purpose flag	supporting study
Study result type	experimental result
Reliability	1 (reliable without restriction)
Rationale for reliability incl. deficiencies	Guideline study, GLP

Data source

Reference Distributed for Comment Only -- Do Not Cite or Quote

Reference type	Author	Year	Title	Bibliographic source	Testing laboratory	Report no.	Owner company	Company study no.	Report date
study report	Hazelton Laboratories		[Trade name protected] A Primary Skin Irritation study in the Rabbit		Hazelton Laboratories	4310-348/74			1985-01-01

Materials and methods

Type of method

in vivo

Test guideline

Qualifier	Guideline	Deviations
according to	other guideline: USFDA	

GLP compliance

yes

Test materials

Identity of test material same as for substance defined in section 1 (if not read-across)

yes

Test material identity

Identifier	Identity
CAS number	191044-49-2

Details on test material

MW < 1000 amu.
Product is a polymer and not a pure substance. It is tested as produced for commercial use. It is typically 90% CAS 191044-49-2 with the remainder being residual hexadecene and trace impurities.

Test animals

Species

rabbit

Strain

New Zealand White

Details on test animals and environmental conditions

Rabbits aged 11-17 weeks, 3.11 - 3.27 kg. Acclimated three days and examined before use.

Test system

Type of coverage

occlusive

Preparation of test site

other: intact and abraded sites

Vehicle

unchanged (no vehicle)

Amount/concentration applied

0.5 ml

Duration of treatment / exposure

24 hours

Observation period

72 hours

Number of animals

6

Control animals

no

Details on study design

0.5 ml was applied to the clipped, intact or abraded skin of 6 rabbits under an occlusive cover for 24 hours. After the contact period, the skin was wiped of remaining material and evaluated for skin irritation 24 and 72 hours later using the Draize scale.

Results and discussions

Irritation / corrosion results

Irritation parameter	Basis	Time point	Score	Max. score	Reversibility	Remarks
primary dermal irritation index (PDII)	mean	24 and 72 hours	0.4		fully reversible within: 72 hours	Results for both intact and abraded sites. All skin sites normal at 72 hour reading
primary dermal irritation index (PDII)	mean	24 and 72 hours	0.4		fully reversible within: 72 hours	Results for intact sites only. All intact skin sites normal at 72 hour reading.
primary dermal irritation index (PDII)	mean	24 and 72 hours	0.4		fully reversible within: 72 hours	Results for abraded sites only. All abraded skin sites normal at 72 hour reading.

Irritant/corrosive response data

Very slight redness (grade 1) was observed in at 5/6 abraded sites and at 5/6 intact sites at 24 hours. No edema observed for any animal/time point. All skin sites were normal at the 72 hour reading.

Applicant's summary and conclusion

Interpretation of results

slightly irritating

Endpoint study record: Skin irritation / corrosion.>10,000 amu

UUID IUC5-fa3e7b62-5383-4084-8230-682383edc4cb

Dossier UUID 0

Author Collette / Epona Associates, LLC / Willington / United States

Date 2014-04-18 11:25:22 EDT

Remarks

Administrative Data

Purpose flag	supporting study
Study result type	experimental result
Reliability	2 (reliable with restrictions)
Rationale for reliability incl. deficiencies	Guideline study, not GLP

Data source

Reference

Reference type	Author	Year	Title	Bibliographic source	Testing laboratory	Report no.	Owner company	Company study no.	Report date
study report	Product Safety Labs	1991	FHSA Dermal Irritation Test		Product Safety Labs	T-924			1991-07-17

Materials and methods

Type of method

in vivo

Test guideline

Qualifier	Guideline	Deviations
according to	other guideline: FHSA 16 CFR 1500.41	

GLP compliance

no

Test materials

Identity of test material same as for substance defined in section 1 (if not read-across)

yes

Test material identity

Identifier	Identity
CAS number	191044-49-2

Details on test material

MW >10,000 amu. Test substance is a polymer and not a pure substance. It is tested as produced for commercial use. It is typically about 90% CAS 191044-49-2 with the remainder identified as residual hexadecane and polyether polymer as well as small amounts of stabilizers and trace impurities.

Test animals

Species

rabbit

Strain

New Zealand White

Test system

Type of coverage

occlusive

Preparation of test site

other: intact and abraded

Vehicle

unchanged (no vehicle)

Amount/concentration applied

0.5 ml

Duration of treatment / exposure

24 hours

Observation period

72 hours

Number of animals

6

Control animals

no

Details on study design

0.5 ml was applied to the clipped, intact or abraded skin of 6 rabbits under an occlusive cover for 24 hours. After the contact period, the skin was wiped of remaining material and evaluated for skin irritation 24 and 72 hours later using the Draize scale.

Results and discussions

Irritation / corrosion results

Irritation parameter	Basis	Time point	Score	Max. score	Reversibility	Remarks
primary dermal irritation index (PDII)	mean	24 and 72 hours	1.17		fully reversible within: 72 hours for intact skin	PDII includes results for both intact and abraded skin. For the abraded skin, erythema and eschar not fully reversed at 72 hours in two of six animals.
primary dermal irritation index (PDII)	mean	24 and 72 hours	0.75		fully reversible (72 hours)	PDII includes results for intact skin only.
primary dermal irritation index (PDII)	mean	24 and 72 hours	1.58		not fully reversible within: 72 hours	PDII includes results for abraded skin only. For the abraded skin, erythema and eschar not fully reversed at 72 hours in two of six animals.

Other effects

No effects other than skin irritation. At 24 hours post-dosing, all abraded sites and most intact sites had erythema, most with edema. Irritation was more severe at the abraded sites. For 72 hours only 2 abraded sites had very slight erythema. All other irritations had cleared.

Applicant's summary and conclusion

Interpretation of results

slightly irritating

Criteria used for interpretation of results

other: FHSA 16 CFR 1500.41

Conclusions

Classified as "mild" skin iritant

14 Information requirements

14.2 Alternative name request

Reference substance: Siloxanes & silicones, cetyl Me, di-Me

UUID IUC5-4822cd36-a1d9-4da8-b2b3-f9426ab86834

Dossier UUID 0

Author Collette / Epona Associates, LLC / Willington / United States

Date 2014-04-16 10:26:38 EDT

Remarks

General information

Reference substance name Siloxanes & silicones, cetyl Me, di-Me

Reference substance information

CAS information

CAS number 191044-49-2

Legal entity: Epona Associates, LLC

UUID IUC5-c761b429-cb5e-4220-afe7-f1502995c432

Dossier UUID 0

Author XML Transformation V2.0 Plug-In

Date 2009-05-14 10:54:32 EDT

Remarks Successfully migrated to IUCLID 5.3 format.

General information

Legal entity name Epona Associates, LLC

Legal entity type consultant

Identifiers

Other IT system identifiers

Flags	IT system	ID	Remarks
	LEO	10472	

Contact information

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Town	Willington
Region / State	CT
Country	United States
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E-mail	wendykoch@eponallc.com
Web site	eponallc.com

Contact persons

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Title	President
First name	Wendy
Last name	Koch
Phone	860-429-0038
E-mail	wendykoch@eponallc.com
Address	156 River Rd
Address	Studio 3
Postal code	06279
Town	Willington
Region / State	CT
Country	United States

Printing Date 2014-04-18 12:36:49 EDT

Restriction of specific regulatory purposes

Confidentiality

Name Siloxanes & silicones, cetyl Me, di-Me, Me hydrogen, rx products with polyethylene glycol monoally ether

Legal entity owner Epona Associates, LLC / Willington / United States

Substance: Siloxanes & silicones, cetyl Me, di-Me, Me hydrogen, rx products with polyethylene glycol monoally ether

UUID IUC5-c56327ca-6849-4d1f-b276-dc6944bf6081

Dossier UUID 0

Author Collette / Epona Associates, LLC / Willington / United States

Date 2014-04-16 13:15:22 EDT

Remarks Created endpoint study record 7.4.1 Skin sensitisation

0 Related Information
0.1 Templates
0.2 Categories
0.3 Mixtures
1 General Information
1.1 Identification
Substance identification

Chemical name Siloxanes & silicones, cetyl Me, di-Me, Me hydrogen, rx products with polyethylene glycol monoally ether

Legal entity Epona Associates, LLC / Willington / United States

Reference substance

Siloxanes & silicones, cetyl Me, di-Me, Me hydrogen, rx products with polyethylene glycol monoallyl ether / 144243-53-8

EC number **EC name**

CAS number **CAS name**

144243-53-8

IUPAC name

1.2 Composition
1.3 Identifiers
1.4 Analytical information
1.5 Joint submission
1.6 Sponsors
1.7 Suppliers
1.8 Recipients
1.9 Product and process oriented research and development
2 Classification & Labelling and PBT assessment
2.1 GHS
2.2 DSD - DPD
3 Manufacture, use and exposure
3.1 Technological process

Technological process

3.2 Estimated quantities
3.3 Sites
3.4 Information on mixtures
3.5 Life Cycle description
3.6 Uses advised against
3.7 Exposure Scenarios, exposure and risk assessment
3.7.2 Environmental assessment for aggregated sources
3.7.3 Generic exposure potential
3.8 Biocidal information
3.10 Application for authorisation of uses
7 Toxicological information
7.3 Irritation / corrosion
7.3.1 Skin irritation / corrosion

Endpoint study record: Skin irritation / corrosion.

UUID	IUC5-66071f03-e2cb-41a5-8a98-e014d4ca4f17
Dossier UUID	0
Author	Collette / Epona Associates, LLC / Willington / United States
Date	2014-04-18 11:47:09 EDT
Remarks	

Administrative Data

Purpose flag	supporting study
Study result type	experimental result
Reliability	1 (reliable without restriction)
Rationale for reliability incl. deficiencies	Guideline study. GLP

Data source

Reference

Reference type	Author	Year	Title	Bibliographic source	Testing laboratory	Report no.	Owner company	Company study no.	Report date
study report	Product Safety Labs	1990	[Trade name protected] FHSA Primary dermal irritation test in the rabbit		Product Safety Labs	T-104			1990-08-14

Materials and methods

Type of method

in vivo

Test guideline

Qualifier	Guideline	Deviations
according to	other guideline: FHSA 16 CFR 1500.41	

GLP compliance

no

Test materials

Identity of test material same as for substance defined in section 1 (if not read-across)

yes

Test material identity

Identifier	Identity
CAS number	144243-53-8

Details on test material

MS >10,000 amu. Product is a polymer and not a pure substance . It is tested as produced for commercial use. It is typically 90% of the CAS number shown with the remainder being residual hexadecane and polyether polymer as well as small amounts of stabilizers and trace impurities.

Test animals

Species

rabbit

Strain

New Zealand White

Test system

Type of coverage

occlusive

Preparation of test site

other: intact and abraded

Vehicle

unchanged (no vehicle)

Amount/concentration applied

0.5 ml

Duration of treatment / exposure

24 hours

Observation period

72 hours Distributed for Comment Only -- Do Not Cite or Quote

Number of animals

6

Control animals

no

Details on study design

0.5 ml was applied to the clipped, intact or abraded skin of 6 rabbits under an occlusive cover for 24 hours. After the contact period, the skin was wiped of remaining material and evaluated for skin irritation 24 and 72 hours later using the Draize scale.

Results and discussions

Irritation / corrosion results

Irritation parameter	Basis	Time point	Score	Max. score	Reversibility	Remarks
primary dermal irritation index (PDII)	mean	24 and 72 hours	2		not fully reversible within: 72 hours	Result for both intact and abraded sites.
primary dermal irritation index (PDII)	mean	24 and 72 hours	1.995		not fully reversible within: 72 hours	Result for intact sites only
primary dermal irritation index (PDII)	mean	24 and 72 hours	1.915		not fully reversible within: 72 hours	Results for abraded sites only

Irritant/corrosive response data

Well-defined erythema at 5 abraded and 5 intact sites 24 hours after dosing. One intact and 1 abraded site exhibited barely perceptible erythema. Barley perceptible edema was noted at all sites at 24 hours. By 72 hours both incidence and severity of erythema and edema had subsided.

Other effects

There were no other effects.

Applicant's summary and conclusion

Interpretation of results

slightly irritating

Criteria used for interpretation of results

other: FHSA 16 CFR 1500.41

Conclusions

mild irritant

7.4 Sensitisation

7.4.1 Skin sensitisation

Endpoint study record: Skin sensitisation.

UUID IUC5-65d34d83-11c4-4186-8f77-1e7306fc2121

Dossier UUID 0

Author Collette / Epona Associates, LLC / Willington / United States

Date 2014-04-18 12:35:30 EDT

Remarks

Administrative Data

Purpose flag supporting study

Study result type experimental result

Reliability 1 (reliable without restriction) - Do Not Cite or Quote

Rationale for reliability incl. deficiencies Guideline study, GLP

Data source

Reference

Reference type	Author	Year	Title	Bibliographic source	Testing laboratory	Report no.	Owner company	Company study no.	Report date
study report	Product Safety Labs	1995	Dermal Sensitization Test - Magnussen Kligman Method		Product Safety Labs	3867			1995-10-18

Materials and methods

Type of method

in vivo

Type of study

Guinea pig maximisation test

Test guideline

Qualifier	Guideline	Deviations
equivalent or similar to	OECD Guideline 406 (Skin Sensitisation)	

GLP compliance

yes

Test materials

Identity of test material same as for substance defined in section 1 (if not read-across)

yes

Details on test material

>10,000 amu. Product is a polymer and not a pure substance . It is tested as produced for commercial use. It is typically 90% of the CAS number shown with the remainder being residual hexadecane and polyether polymer as well as small amounts of stabilizers and trace impurities.

Test animals

Species

guinea pig

Strain

no data

Sex

no data

Details on test animals and environmental conditions

Received from Davidson' Mill Farm, NJ

Test system

Traditional sensitisation test

Route of induction exposure

intradermal and epicutaneous

Route of challenge exposure

epicutaneous, occlusive

Vehicle

unchanged (no vehicle)

Concentration

100% for induction and challenge

No. of animals per dose

Test group 20
Naive control group 10
Positive control group 10
Positive naive control group 5

Details on study design (Traditional tests)

During the induction phase, the test or control substance was adminstered via intradermal induction followed by topical application six days later.Th e intradermal injections were made in combination with Freunds Complete Adjuvant. Twelve days after the topical application, a challenge dose of the test or positive control substance (at the highest non-irrtating concentration) was applied to a naive site of each animal. 24 - 48 hours later the sites were scored.

Positive control substance(s)

yes (2-mercaptobenzothiazole)

Results and discussion

Positive control results

See detailed results below.
As a result of the failure of the positive control animals to respond at challenge and rechallenge, historical control data was provided in the report to validate the test system. A July 7, 1995 Magnusson-Kligman sensitization test (PSL study #3797) was conducted on a group of ten test and five naïve control animals following procedures similar to those described in this test. Topical induction and challenge scores were consistent with what would be expected for a positive control. The results of this study clearly demonstrate a positive response to DNCB and validate the procedures used in this study.

LLNA

Any other information on results incl. tables

Very faint to faint erythema (0.5-1) was noted at several test sites 24 -48 hours after topical induction.

No erythema was noted at any of the test naive/vehicle control sites after topical induction.

Very faint to faint erythema (0.5-1) was noted at 8/10 positive control sites 24-48 hours after topical induction.

No erythema was noted at any of the positive naive/vehicle (95% ethanol) control sites after topical induction.

Very faint erythema (0.5) was noted at two test sites 24 hours after challenge dosing; very faint erythema persisted at one site at 48 hours.

Very faint erythema (0.5) was noted at one test naive/vehicle control site 24 hours after challenge dosing; irritation cleared by 48 hours.

No erythema was noted at any of the positive control or positive naive/vehicle (95% ethanol) control sites following challenge. Due to the absence of a positive response in the positive control group at challenge, a re-challenge was conducted nine days later on the test and positive (two different sites tested, 10% in acetone and 50% in 95% ethanol) control groups.

No erythema was noted at any test site following rechallenge.

No erythema was noted at any test naïve/vehicle control site 24 hours after rechallenge. Very faint (0.5) erythema was noted at one test naive/vehicle control site 48 hours after rechallenge.

Very faint erythema (0.5) was noted at only one positive control site (10% with acetone), 24 hours after rechallenge and at two sites at 48 hours.

Very faint erythema (0.5) was noted at only one positive control site (50% with 95% ethanol), 24 hours after rechallenge. Irritation cleared by 48 hours.

No erythema was noted at any of the positive naïve/vehicle control sites following rechallenge, with either of the rechallenge solutions.

A summary of the responses during challenge and rechallenge are provided in the table below.

	Sensitization Response Indices			
	Incidence(1)		Severity(2)	
	24	48	24	48
Test Animals - Challenge	0/20	0/20	0.05	0.03
Test Naïve Control Animals - Challenge	0/10	0/10	0.05	0.00
Test Animals - Rechallenge	0/20	0/20	0.00	0.00
Test Naïve Control Animals - Rechallenge	0/10	0/10	0.00	0.05
Positive Control Animals - Challenge	0/10	0/10	0.00	0.00
Positive Naïve/Vehicle Control Animals - Challenge	0/5	0/5	0.00	0.00
Positive Control Animals – Rechallenge(3)	0/10	0/10	0.05	0.10
Positive Control Animals – Rechallenge(4)	0/10	0/10	0.05	0.00
Positive Naïve/Vehicle Control Animals – Rechallenge(3)	0/5	0/5	0.00	0.00
Positive Naïve/Vehicle Control Animals – Rechallenge(4)	0/5	0/5	0.00	0.00

(1) Animals with scores greater than 0.5.

(2) Sum of the erythema scores divided by the number of animals evaluated.

(3) Site No. 1: Positive control applied as a 10% w/w solution in acetone.

(4) Site No. 2: Positive control applied as a 50% w/w suspension in 95% aqueous ethanol.

Applicant's summary and conclusion

Interpretation of results

not sensitising

14 Information requirements

14.2 Alternative name request

Legal entity: Epona Associates, LLC

UUID	IUC5-c761b429-cb5e-4220-afe7-f1502995c432
Dossier UUID	0
Author	XML Transformation V2.0 Plug-In
Date	2009-05-14 10:54:32 EDT
Remarks	Successfully migrated to IUCLID 5.3 format.

General information

Legal entity name Epona Associates, LLC

Legal entity type consultant

Identifiers

Other IT system identifiers

Flags	IT system	ID	Remarks
	LEO	10472	

Contact information

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Region / State CT

Country United States

Phone 860-429-0038

E-mail wendykoch@eponallc.com

Web site eponallc.com

Contact persons

Organisation Epona Associates, LLC

Title President

First name Wendy

Last name Koch

Phone 860-429-0038

E-mail wendykoch@eponallc.com

Address 156 River Rd

Address Studio 3

Postal code 06279

Town Willington

Region / State CT

Country United States

Reference substance: Siloxanes & silicones, cetyl Me, di-Me, Me hydrogen, rx products with polyethylene glycol monoallyl ether

UUID IUC5-fa92f254-908e-4be9-a366-2bb55962312c

Dossier UUID 0

Author Collette / Epona Associates, LLC / Willington / United States

Date 2014-04-16 10:32:18 EDT

Remarks

General information

Reference substance name Siloxanes & silicones, cetyl Me, di-Me, Me hydrogen, rx products with polyethylene glycol monoallyl ether

Reference substance information

CAS information

CAS number 144243-53-8

Printing Date 2014-04-18 12:40:51 EDT

Restriction of specific regulatory purposes

Confidentiality

Name Siloxanes & silicones, di-Me, 3-hydroxypropyl Me, ethoxylated, propoxylated

Legal entity owner Epona Associates, LLC / Willington / United States

Substance: Siloxanes & silicones, di-Me, 3-hydroxypropyl Me, ethoxylated, propoxylated

UUID IUC5-8b674557-479a-419f-ad72-1d75d9055c69

Dossier UUID 0

Author Collette / Epona Associates, LLC / Willington / United States

Date 2014-04-17 10:29:43 EDT

Remarks

0 Related Information
0.1 Templates
0.2 Categories
0.3 Mixtures
1 General Information
1.1 Identification
Substance identification

Chemical name Siloxanes & silicones, di-Me, 3-hydroxypropyl Me, ethoxylated, propoxylated

Legal entity Epona Associates, LLC / Willington / United States

Reference substance

Siloxanes & silicones, di-Me, 3-hydroxypropyl Me, ethoxylated, propoxylated / 68937-55-3

EC number **EC name**

CAS number **CAS name**

68937-55-3

IUPAC name

1.2 Composition
1.3 Identifiers
1.4 Analytical information
1.5 Joint submission
1.6 Sponsors
1.7 Suppliers
1.8 Recipients
1.9 Product and process oriented research and development
2 Classification & Labelling and PBT assessment
2.1 GHS
2.2 DSD - DPD
3 Manufacture, use and exposure
3.1 Technological process

Technological process

3.2 Estimated quantities
3.3 Sites
3.4 Information on mixtures
3.5 Life Cycle description
3.6 Uses advised against
3.7 Exposure Scenarios, exposure and risk assessment
3.7.2 Environmental assessment for aggregated sources
3.7.3 Generic exposure potential
3.8 Biocidal information
3.10 Application for authorisation of uses
7 Toxicological information
7.3 Irritation / corrosion
7.3.1 Skin irritation / corrosion

Endpoint study record: Skin irritation / corrosion.

UUID	IUC5-0820a22c-5d1b-4c86-a784-9a56d9b96773
Dossier UUID	0
Author	Collette / Epona Associates, LLC / Willington / United States
Date	2014-04-18 10:48:25 EDT
Remarks	

Administrative Data

Purpose flag	supporting study
Study result type	experimental result
Reliability	1 (reliable without restriction)
Rationale for reliability incl. deficiencies	Guideline study, GLP

Data source

Reference

Reference type	Author	Year	Title	Bibliographic source	Testing laboratory	Report no.	Owner company	Company study no.	Report date
study report	Hazelton Laboratories	1984	[Trade name protected] Primary Skin Irritation Study in the Rabbit		Hazelton Laboratories	499-348/68			1984-11-20

Materials and methods

Type of method

in vivo

Test guideline

Qualifier	Guideline	Deviations
according to	other guideline: US FDA	

GLP compliance

yes

Test materials

Identity of test material same as for substance defined in section 1 (if not read-across)

yes

Test material identity

Identifier	Identity
CAS number	68937-55-3

Details on test material

MW 5000-10,000 amu. Product is a polymer and not a pure substance. It is tested as produced for commercial use. It typically contains approximately 25% free polyether polymer and small amounts of stabilizers and trace impurities.

pH of the 10% dilution of the test substance in water was 6.

Test animals

Species

rabbit

Strain

New Zealand White

Details on test animals and environmental conditions

Weight of the rabbits at study initiation was 2.6 - 3.2 kg.

Test system

Type of coverage

occlusive

Preparation of test site

other: intact and abraded

Vehicle

water (10% dilution in water)

Amount/concentration applied

0.5 ml

Duration of treatment / exposure

24 hours

Observation period

72 hours

Number of animals

6

Control animals

no

Details on study design

0.5 ml of a 10% dilution of the test substance in water was applied to the clipped, intact or abraded skin of 6 rabbits under an occlusive cover for 24 hours. After the contact period, the skin was wiped of remaining material and evaluated for skin irritation 24 and 72 hours later using the Draize scale.

Results and discussions

Irritation / corrosion results

Irritation parameter	Basis	Time point	Score	Max. score	Reversibility	Remarks
primary dermal irritation index (PDII)	mean	24 and 72 hours	0			

Irritant/corrosive response data

There were no reactions.

Applicant's summary and conclusion

Interpretation of results

not irritating (10% dilution of the test substance in water)

Endpoint study record: Skin irritation / corrosion.

UUID IUC5-a7bb9bb2-946b-457d-82dd-a173bfe76d3d

Dossier UUID 0

Author Collette / Epona Associates, LLC / Willington / United States

Date 2014-04-18 10:40:58 EDT

Remarks

Administrative Data

Purpose flag	supporting study
Study result type	experimental result
Reliability	1 (reliable without restriction)
Rationale for reliability incl. deficiencies	Guideline study, GLP

Data source

Reference

Reference type	Author	Year	Title	Bibliographic source	Testing laboratory	Report no.	Owner company	Company study no.	Report date
study report	Product Safety Labs	1993	FHSA Dermal Irritation Test		Product Safety Labs	T-2088			1993-03-04

Materials and methods

Type of method

in vivo

Test guideline

Qualifier	Guideline	Deviations
according to	other guideline: FHSA 16 CFR 1500.41	

GLP compliance

yes

Test materials

Identity of test material same as for substance defined in section 1 (if not read-across)

yes

Test material identity

Identifier	Identity
CAS number	68937-55-3

Details on test material

MW > 10,000 amu. Product is a polymer and not a pure substance . It is tested as produced for commercial use. It typically contains approximately 25% free polyether polymer and small amounts of stabilizers and trace impurities.

Test animals

Species

rabbit

Strain

New Zealand White

Test system

Type of coverage

occlusive

Preparation of test site

other: intact and abraded

Vehicle

water

Amount/concentration applied

0.5 ml

Duration of treatment / exposure

24 hours

Observation period

72 hours

Number of animals

6

Control animals

no

Details on study design

0.5 ml was applied to the clipped, intact or abraded skin of 6 rabbits under an occlusive cover for 24 hours. After the contact period, the skin was wiped of remaining material and evaluated for skin irritation 24 and 72 hours later using the Draize scale.

Results and discussions

Irritation / corrosion results

Irritation parameter	Basis	Time point	Score	Max.	Reversibility	Remarks

primary dermal irritation index (PDII)	mean	24 and 72 hours	2.7		not fully reversible within: 72 hours	PDII includes results observed on both the intact and abraded skin.
primary dermal irritation index (PDII)	mean	24 and 72 hours	26.5		not fully reversible within: 72 hours	PDII includes results observed on intact skin only.
primary dermal irritation index (PDII)	mean	24 and 72 hours	27.5		not fully reversible within: 72 hours	PDII includes results observed on abraded skin only

Irritant/corrosive response data

24 hours after test substance application all treated sites exhibited slight to well defined erythema and very slight to slight edema. The incidence and severity of irritation decreased with time. At 72 hours, very slight erythema and edema remained at most treated sites.

Applicant's summary and conclusion

Interpretation of results

moderately irritating

7.4 Sensitisation

7.4.1 Skin sensitisation

Endpoint study record: Skin sensitisation.

UUID IUC5-2e0270da-e7ef-4166-99bb-2b9e0b0db464

Dossier UUID 0

Author Collette / Epona Associates, LLC / Willington / United States

Date 2014-04-18 10:20:17 EDT

Remarks

Administrative Data

Purpose flag	supporting study
Study result type	experimental result
Reliability	1 (reliable without restriction)
Rationale for reliability incl. deficiencies	Guideline study, GLP

Data source

Reference

Reference type	Author	Year	Title	Bibliographic source	Testing laboratory	Report no.	Owner company	Company study no.	Report date
study report	Hazelton Laboratories	1985	Skin Sensitization Study in the Guinea Pig - Magnussen Kligman Maximisation Test		Hazelton Laboratories	4904-561/2			1985-12-01

Materials and methods

Type of method

in vivo

Type of study

Guinea pig maximisation test

Test guideline

Qualifier	Guideline	Deviations
according to	OECD Guideline 406 (Skin Sensitisation)	

GLP compliance

yes

Test materials

Identity of test material same as for substance defined in section 1 (if not read-across)

yes

Test material identity

Identifier	Identity
CAS number	68937-55-3

Details on test material

MS 5,000 - 10,000. Product is a polymer and not a pure substance . It is tested as produced for commercial use. It typically contains approximately 25% free polyether polymer and small amounts of stabilizers and trace impurities.

Test animals

Species

guinea pig

Strain

Dunkin-Hartley

Sex

female

Details on test animals and environmental conditions

Weight at test initiation: 269-386 kg

Test system

Traditional sensitisation test

Route of induction exposure

intradermal and epicutaneous

Route of challenge exposure

epicutaneous, occlusive

Vehicle

other: PEG 200 and adjuvant

Concentration

5% dilution in PEG 200 and adjuvant for intradermal induction
100% for topical induction and challenge

No. of animals per dose

Test group 20
Naive control group 20
Positive control group 10
Positive naive control group 5

Details on study design (Traditional tests)

A screening study was conducted to determine the highest non-irritant concentration and the threshold irritant concentration to be used for the topical induction and challenge application. As a result of this study, the test substance undiluted was used for both the topical induction and challenge applications.

During the induction phase, the test or control substance was adminstered via intradermal induction followed by topical application seven days later.The intradermal injections were made in combination with Freunds Complete Adjuvant. Fourteen days after the topical application, a challenge dose of the test or positive control substance (at the highest non-irrtating concentration) was applied to a naive site of each animal. 24 - 48 hours later the sites were scored.

Positive control substance(s)

no data

Results and discussion

LLNA

Any other information on results incl. tables

None of the 20 animals showed a response 24 or 48 hours after challenge.

Applicant's summary and conclusion

Interpretation of results

not sensitising

Endpoint study record: Skin sensitisation.

UUID IUC5-cc688228-7826-4307-9ac2-c436e467cd06

Dossier UUID 0

Author Collette / Epona Associates, LLC / Willington / United States

Date 2014-04-18 10:27:23 EDT

Remarks

Administrative Data

Purpose flag	supporting study
Study result type	experimental result
Reliability	1 (reliable without restriction)
Rationale for reliability incl. deficiencies	Guideline study, GLP

Data source

Reference

Reference type	Author	Year	Title	Bibliographic source	Testing laboratory	Report no.	Owner company	Company study no.	Report date
study report	Reprotox HRC	1982	Screening tests for the delayed contact hypersensitivity with [trade name protected] in the albino Guinea Pig - Magnussen Kligman Method		Reprotox HRC	1111/3/82			1982-06-02

Materials and methods

Type of method

in vivo

Type of study

Guinea pig maximisation test

Test guideline

Qualifier	Guideline	Deviations
equivalent or similar to	OECD Guideline 406 (Skin Sensitisation)	

GLP compliance

no data

Test materials

Identity of test material same as for substance defined in section 1 (if not read-across)

yes

Test material identity

Identifier	Identity
CAS number	68937-55-3

Details on test material

MS 5000 - 10,000 amu. Product is a polymer and not a pure substance . It is tested as produced for commercial use. It typically contains approximately 25% free polyether polymer and small amounts of stabilizers and trace impurities.

Test animals

Species

guinea pig

Strain

Pirbright-Hartley

Sex

female

Details on test animals and environmental conditions

weight at test initiation 380-490 kg

Test system

Traditional sensitisation test

Route of induction exposure

intradermal and epicutaneous

Route of challenge exposure

epicutaneous, occlusive

Vehicle

water (10% dilution in water used for intradermal injection only)

Concentration

10% for intradermal injection induction
100% for topical induction and challenge

No. of animals per dose

Test group 10
Naive control group 5

Details on study design (Traditional tests)

A screening study was conducted to determine the highest non-irritant concentration and the threshold irritant concentration to be used for the topical induction and challenge application, and to determine the concentration that would produce only slight irritation when injection intradermally. As a result of this study, the test substance undiluted was used for both the topical induction and challenge applications and a 10% concentration was used for the intradermal injection.

During the induction phase, the test or control substance was adminstered via intradermal induction followed by topical application one week later.The intradermal injections were made in combination with Freunds Complete Adjuvant. Two weeks after the topical application, a challenge dose of the test or positive control substance (at the highest non-irrtating concentration) was applied to a naive site of each animal. 24 - 48 hours later the sites were scored.

Positive control substance(s)

no data

Results and discussion

LLNA

Any other information on results incl. tables

No dermal reactions were seen in any test or control animals following the challenge

application.

Applicant's summary and conclusion

Interpretation of results

not sensitising

14 Information requirements

14.2 Alternative name request

Legal entity: Epona Associates, LLC

UUID	IUC5-c761b429-cb5e-4220-afe7-f1502995c432
Dossier UUID	0
Author	XML Transformation V2.0 Plug-In
Date	2009-05-14 10:54:32 EDT
Remarks	Successfully migrated to IUCLID 5.3 format.

General information

Legal entity name	Epona Associates, LLC
Legal entity type	consultant

Identifiers

Other IT system identifiers

Flags	IT system	ID	Remarks
	LEO	10472	

Contact information

Contact address

Address	156 River Rd
Address	Studio 3
Postal code	06279
Town	Willington
Region / State	CT
Country	United States
Phone	860-429-0038
E-mail	wendykoch@eponallc.com
Web site	eponallc.com

Contact persons

Organisation	Epona Associates, LLC
Title	President
First name	Wendy
Last name	Koch
Phone	860-429-0038
E-mail	wendykoch@eponallc.com
Address	156 River Rd
Address	Studio 3
Postal code	06279

Town	Willington	Distributed for Comment Only -- Do Not Cite or Quote
Region / State	CT	
Country	United States	

Reference substance: Siloxanes & silicones, di-Me, 3-hydroxypropyl Me, ethoxylated, propoxylated

UUID	IUC5-ea4906f6-2bfd-4ab4-94ab-e1eb6ef81eb1
Dossier UUID	0
Author	Collette / Epona Associates, LLC / Willington / United States
Date	2014-04-16 10:36:14 EDT
Remarks	

General information

Reference substance name Siloxanes & silicones, di-Me, 3-hydroxypropyl Me, ethoxylated, propoxylated

Reference substance information

CAS information

CAS number 68937-55-3