
Safety Assessment of Glycol Stearate and Glycol Stearate SE as Used in Cosmetics

Status: Re-Review for Panel Consideration
Release Date: May 23, 2022
Panel Meeting Date: June 16-17, 2022

The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; David E. Cohen, M.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; Allan E. Rettie, Ph.D.; David Ross, Ph.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; Paul W. Snyder, D.V.M., Ph.D.; and Susan C. Tilton, Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D. This safety assessment was prepared by Regina Tucker, M.S. Scientific Analyst/Writer, CIR.



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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Regina Tucker, M.S. Scientific Analyst/Writer, CIR
Date: May 23, 2022
Subject: Re-Review of Glycol Stearate and Glycol Stearate SE

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published a review of the safety of Glycol Stearate and Glycol Stearate SE in 1982 (identified as *originalreport1_GlycolStearate_062022* in the pdf), with the conclusion that these ingredients are safe in the present practices of use and concentration, as described in that safety assessment. This conclusion was reaffirmed, as published in 2003 (*originalreport2_GlycolStearate_062022*). Glycol Distearate was included in the original report and 2003 re-review; however, because Glycol Distearate was included in the 2017 assessment of monoalkylglycol dialkyl acid esters, it is not being considered as part of this current re-review.

Because it has been at least 15 years since the previous re-review was published, in accord with Cosmetic Ingredient Review (CIR) Procedures, the Panel should consider whether the safety assessment of Glycol Stearate and Glycol Stearate SE should be re-opened. An exhaustive search of the world's literature was performed for studies dated 1997 forward. No relevant published data were found. An historical overview, comparison of original and new use data, and the search strategy used are enclosed herein (*newdata_GlycolStearate_062022*).

Also included for your review is a table of current and historical use data (*usetable_GlycolStearate_062022*). Since the initial re-review was considered, the frequency of use has increased for both ingredients. The maximum concentration of use for Glycol Stearate has decreased slightly, from 6% in 2001 to 5% in 2022. In 2001, Glycol Stearate SE was reported to be used at up to 12%; however, concentration of use data were not reported in 2022.

If, upon review of the new studies and updated use data, the Panel determines that a re-review is warranted, a draft amended report will be presented at an upcoming meeting.

Re-Review - Glycol Stearate - History and New Data

(Regina Tucker – June 2022 meeting)

Ingredients (2)	Citation	Conclusion	Use - New Data	Use -Historical Data	Notes
Glycol Stearate Glycol Stearate SE <i>Changes to Original List</i> <i>Glycol Distearate was in original report, but not included in this RR; it was part of a 2017 assessment</i>	JACT 1(2):1-11, 1982 IJT 22(S1):12-15, 2003	safe as used not re-opened	<u>Glycol Stearate</u> frequency of use (2022): 602 uses conc of use (2022): ≤ 5% <u>Glycol Stearate SE</u> frequency of use (2022): 24 uses conc of use (2022): NR	<u>Glycol Stearate</u> frequency of use (2001): 424 uses conc of use (2001): ≤ 6% <u>Glycol Stearate SE</u> frequency of use (2001): 14 uses conc of use (2001): ≤ 12%	frequency of use increased, but concentration of use decreased; no new use categories frequency of use increased, but concentration of use now not reported

NOTABLE NEW DATA

Publication	Study Type	Results – Brief Overview	Different from Existing Data?
<i>no new published data</i>			

Search (from 1997 on)

PubMed

(((“glycol stearate”) OR (111-60-4[EC/RN Number])) OR(864-55-5[EC/RN Number])) AND (“1997”[Date - Publication] : “3000”[Date - Publication])) – 10 hits; none useful

(((“glycol stearate”) OR (“glycol monostearate”) OR (hydroxyethyl octadecenoate) OR (stearic acid, 2-hydroxyethyl ester) OR (111-60-4[EC/RN Number])) OR(864-55-5[EC/RN Number])) AND (“1997”[Date - Publication] : “3000”[Date - Publication])) – 29 results; none useful

Current and historical frequency and concentration of use according to duration and exposure

	Glycol Stearate				Glycol Stearate SE			
	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	2022 ¹	2001 ²	2022 ³	2001 ²	2022 ¹	2001 ²	2022 ³	2001 ²
Totals*	602	424	0.0002-5	0.0001-6	24	14	NR	0.2-12
Duration of Use								
Leave-On	311	111	0.04-5	0.02-6	23	13	NR	0.9-5
Rinse-Off	270	277	0.0002-4.3	0.0001-6	1	1	NR	0.2-12
Diluted for (Bath) Use	21	36	1.4	0.2-5	NR	NR	NR	0.2
Exposure Type								
Eye Area	1	NR	NR	3-6	NR	2	NR	NR
Incidental Ingestion	NR	1	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	2; 246 ^a ; 53 ^b	1; 40 ^a ; 36 ^b	0.04 -3.1 ^a	2-4; 1-5 ^a ; 0.7-5 ^b	11 ^a ; 8 ^b	7 ^a ; 3 ^b	NR	2-5 ^a
Incidental Inhalation-Powder	53 ^b ; 3 ^c	36 ^b	1.5-5 ^c	4; 0.7-5 ^b ; 5 ^c	8 ^b	3 ^b	NR	NR
Dermal Contact	473	217	0.017-5	0.2-6	24	14	NR	0.2-12
Deodorant (underarm)	NR	2 ^a	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	119	169	0.034-4	0.0001-4	NR	NR	NR	NR
Hair-Coloring	10	33	0.37	2-6	NR	NR	NR	NR
Nail	NR	3	0.0002	0.02	NR	NR	NR	NR
Mucous Membrane	121	86	0.017-1.4	0.2-6	NR	NR	NR	0.2
Baby Products	3	1	0.034-1.2	5	NR	NR	NR	NR

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

^a It is possible these products are sprays, but it is not specified whether the reported uses are sprays.

^b It is possible these products are powders, but it is not specified whether the reported uses are powders.

^c Not specified whether a spray or a powder, but it is possible the use can be as a spray or a powder, therefore the information is captured in both categories

NR – not reported

References

1. US Food and Drug Administration (FDA) Center for Food Safety & Applied Nutrition (CFSAN). 2022. Voluntary Cosmetic Registration Program - Frequency of Use of Cosmetic Ingredients. (Obtained under the Freedom of Information Act from CFSAN; requested as "Frequency of Use Data" January 4, 2022; received January 11, 2022) College Park, MD
2. Anderson FA (ed). Annual Review of Cosmetic Ingredient Safety Assessments--2001/2002. *Int J Toxicol.* 2003;22 Suppl 1:12-15.
3. Personal Care Products Council. 2022. Concentration of Use by FDA Product Category: Glycol Stearate and Glycol Stearate SE. (Unpublished data submitted to Personal Care Products Council on January 25, 2021.)

Final Report on the Safety Assessment of Glycol Stearate, Glycol Stearate SE, and Glycol Distearate

Glycol Stearate, Glycol Stearate SE, and Glycol Distearate consist primarily of the mono- and diesters of triple-pressed stearic acid. They are used in numerous categories of cosmetic products at concentrations ranging from less than 0.1 to 10%.

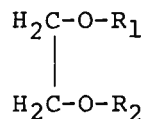
Animal data for acute oral toxicity, skin and eye irritation, and sensitization show that these ingredients have low acute toxicity. A repeated insult patch test with 50% Glycol Distearate on 125 subjects presented no evidence of skin irritation or hypersensitivity. Human studies using formulations containing Glycol Stearate at levels of 2-5% reported no skin irritation or sensitization.

Subchronic testing has not been adequately investigated in laboratory animals. Human test data for formulations containing > 4% Glycol Stearate or Glycol Distearate should be considered.

Based on the available information presented herein, it is concluded that Glycol Stearate, Glycol Stearate SE, and Glycol Distearate are safe as cosmetic ingredients in the present practices of use and concentration.

CHEMICAL AND PHYSICAL PROPERTIES

These ingredients are mixed esters of ethylene glycol and triple-pressed stearic acid. The latter consists of 42.5% stearic acid and about an equal amount of palmitic acid, along with lesser amounts of several other fatty acids. The general structural formula for these ingredients is:^(1,2)



Glycol Stearate: The ingredient is comprised of 40-70% of the monoester in which R₁ is the acyl portion of triple-pressed stearic acid and R₂ is H. Glycol

Stearate also contains a significant portion, 30–58%, of the diester in which both R_1 and R_2 are the acyl moiety of triple-pressed stearic acid.⁽²⁾

Glycol Stearate SE: This ingredient is a self-emulsifying grade of Glycol Stearate containing free stearic acid and some sodium and/or potassium stearate.⁽¹⁾

Glycol Distearate: This ingredient is the diester of ethylene glycol in which both R_1 and R_2 are the acyl moiety of triple-pressed stearic acid.⁽²⁾

Glycol Stearate, Glycol Stearate SE, and Glycol Distearate have similar physical properties. They are white to cream colored waxy solids. Their physical properties vary within specified limits according to their proportions of mono- and diesters and other components. Depending on the intended use, a purchasing specification is used to set specific limits on the physical characteristics of these ingredients.⁽²⁾

Analytical Methods

Glycol Stearate and Glycol Distearate can be analyzed by gas chromatography.⁽³⁾ Mass spectrometric analysis of long-chain esters of ethanediol (ethylene glycol) has been described⁽⁴⁾; this allows for the identification of individual esters of the diol as well as of classes of diol monoesters. A method of gel-permeation chromatography for Glycol Distearate on Sephadex LH-20 has also been reported.⁽⁵⁾ Standard methods have been suggested for determining the chemical properties of these ingredients.⁽²⁾

Impurities

Impurities such as free stearic acid (triple-pressed), the mono- or diesters, ethylene glycol, and corresponding derivatives of other fatty acids found in the stearic acid may be present in Glycol Stearate.⁽²⁾

Ethylene glycol and/or ethylene oxide are used as starting material for the synthesis of Glycol Stearate. Since the former is known to be contaminated with traces of 1,4-dioxane,⁽⁶⁾ it is possible that such traces also appear in the synthesized material. Analytical data on traces of 1,4-dioxane in Glycol Stearate were not available to the Expert Panel.

When rats were given high doses of 1,4-dioxane in drinking water (~1.0%) for 13 months, liver lesions including hepatomas occurred.⁽⁷⁾

USE

Purpose and Frequency of Use in Cosmetics

These ingredients are used as emulsifiers, dispersants, opacifiers, and viscosity modifiers. As wax ingredients in stick preparations, they have served to control hardness, add slip, and increase opacity. They give lotion, cream, and detergent formulations an opaque or milky appearance.^(8,9)

As shown in Table 1, these ingredients are used in a variety of categories of cosmetic products; their concentrations range from less than 0.1% to as high as 10%. The cosmetic product formulation computer printout which is made

ASSESSMENT: GLYCC

TABLE 1. Proc

Cosmetic pro
Ingred.

Glycol Stearate
Bath oils, tablets
Bubble baths

Other bath prep
Eyebrow pencil
Eyeliner
Eyeshadow

Mascara
Hair conditione
Hair straightene
Rinses (noncolo
Shampoos (non

Tonics, dressing
hair grooming
Hair shampoos
Blushers (all typ
Foundations
Lipsticks
Makeup bases
Rouges
Other makeup p
Bath soaps and

Aftershave lotio
Cleansing (cold
cleansing lotic
and pads)
Face, body and
(excluding sha
preparations)
Moisturizing

Other skin care

Suntan gels, cre
liquids

Glycol Stearate
Other skin care

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ASSESSMENT: GLYCOL STEARATE, GLYCOL STEARATE SE, AND GLYCOL DISTEARATE

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INGREDIENT REVIEW

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TABLE 1. Product Formulation Data.^a

Cosmetic product type/ Ingredient	Concentration (%)	No. of product formulations
<i>Glycol Stearate</i>		
Bath oils, tablets and salts	>0.1-1	6
Bubble baths	>1-5	3
	>0.1-1	44
Other bath preparations	>0.1-1	6
Eyebrow pencil	>1-5	3
Eyeliner	>1-5	9
Eyeshadow	>5-10	1
	>1-5	75
Mascara	>1-5	2
Hair conditioners	>5-10	2
Hair straighteners	>5-10	4
Rinses (noncoloring)	>0.1-1	3
Shampoos (noncoloring)	>5-10	1
	>1-5	46
	>0.1-1	28
	≤0.1	2
Tonics, dressings, and other hair grooming aids	>1-5	1
Hair shampoos (coloring)	>1-5	2
Blushers (all types)	>1-5	5
Foundations	>1-5	88
Lipsticks	>1-5	1
Makeup bases	>1-5	2
Rouges	>1-5	8
Other makeup preparations	>1-5	2
Bath soaps and detergents	>1-5	1
	>0.1-1	1
Aftershave lotions	>0.1-1	1
Cleansing (cold creams, cleansing lotions, liquids, and pads)	>1-5	3
	>0.1-1	5
Face, body and hand (excluding shaving preparations)	>1-5	9
	>0.1-1	2
Moisturizing	>5-10	1
	>1-5	8
	>0.1-1	3
Other skin care preparations	>5-10	2
	>1-5	2
	>0.1-1	1
Suntan gels, creams, and liquids	>1-5	1
<i>Glycol Stearate SE</i>		
Other skin care preparations	>0.1-1	1
<i>Glycol Distearate</i>		
Hair conditioners	>0.1-1	1
Permanent waves	>1-5	5
Shampoos (noncoloring)	>1-5	9
	>0.1-1	6
Hair dyes and colors (all types requiring caution statement and patch test)	>0.1-1	1

TABLE 1. (Continued.)

Cosmetic product type/ Ingredient	Concentration (%)	No. of product formulations
Deodorants (underarm)	> 1-5	1
Other personal cleanliness products	> 5-10	1
Other shaving preparation products	> 1-5	1
Cleansing (cold creams, cleansing lotions, liquids, and pads)	> 1-5	1

^aData from Ref. 10.

available by the Food and Drug Administration (FDA) is compiled through voluntary filing of such data in accordance with Title 21 part 720.4 of the Code of Federal Regulations (1979). Ingredients are listed in prescribed concentration ranges under specific product type categories. Since certain cosmetic ingredients are supplied by the manufacturer at less than 100% concentration, the value reported by the cosmetic formulator may not necessarily reflect the true, effective concentration found in the finished product; the effective concentration in such a case would be a fraction of that reported to the FDA. The fact that data are only submitted within the framework of preset concentration ranges also provides the opportunity for overestimation of the actual concentration of an ingredient in a particular product. An entry at the lowest end of a concentration range is considered the same as one entered at the highest end of that range, thus introducing the possibility of a two- to ten-fold error in the assumed ingredient concentration. According to FDA, Glycol Stearate SE is used in one unspecified skin-care product. Glycol Distearate is principally employed in hair-care preparations⁽¹⁰⁾; however, its use as a lyophilic component of self-emulsifying ointment bases has been described.⁽¹¹⁾

Products containing these ingredients are used on all body orifices. Thus they may enter the body by several routes (though the inhalation of sprays appears to be minor as a mode of exposure and absorption).

These ingredients may be applied as often as several times a day (lipsticks and lotions) or as infrequently as once every one or two months (hair dyes and colors). The period of time for which they remain in contact may be conditioned by the frequency with which the affected part of the body is washed.

BIOLOGICAL PROPERTIES

General Effects

The addition of 12.5 percent Glycol Stearate as a surfactant to a vaseline-based ointment increased the cutaneous absorption of the following compounds through the shaved skin of rats by the factors shown: 10% potassium iodide (4X); 5% sodium salicylate (4.6X); and 5% ammonium thiocyanate (3.1X). A two-gram sample of each emulsion was rubbed into the skin for five minutes and then covered with a protective bandage. Absorption was determined by the analysis of urine specimens collected at 12 and 24 hours.⁽¹²⁾

ASSESSMENT: GLYCC

Oral Toxicity:

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For 91 days, f five females, were dients was ethyle and 5%. The equ 0.0025-0.0125%, histopathologic e and test groups.⁽⁶⁾

Primary Skin

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Sensitization

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IC INGREDIENT REVIEW

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Animal Toxicology

Oral Toxicity: Glycol Stearate and Glycol Distearate have each been tested in five studies for acute oral toxicity in rats; the data from these studies are summarized in Table 2. During the various studies, doses of 13 or more g/kg body weight in corn oil produced effects which included diarrhea, wet oily coats, and nasal hemorrhage; the symptoms appeared within four days following administration, but disappeared within the next six days. No animals were dosed with high levels of corn oil alone. One study on Glycol Distearate reported that at the 14-day gross autopsy, the stomach contained residues which appeared to be the test material.⁽¹³⁾

For 91 days, four groups of weanling rats, each comprised of five males and five females, were fed a diet containing a dishwashing liquid one of whose ingredients was ethylene glycol distearate at a concentration range of between 1% and 5%. The equivalent dosing levels of the ethylene glycol distearate were 0, 0.0025–0.0125%, 0.005–0.025%, and 0.01–0.05%. Following both gross and histopathologic examination, no differences were observed between the controls and test groups.⁽¹⁴⁾

Primary Skin Irritation Studies: Draize type procedures were used to test Glycol Stearate, Glycol Stearate SE, and Glycol Distearate for primary irritation of albino rabbit skin; the ingredients were found to be nonirritating to slightly irritating (See Table 2). In addition, when Glycol Stearate and Glycol Distearate were tested for corrosivity according to the procedures of the U.S. Department of Transportation, they were found to be noncorrosive to rabbit skin.⁽¹³⁾

Sensitization: Sensitization studies were conducted in guinea pigs on Glycol Stearate and Glycol Distearate. Each ingredient was injected intradermally into the shaven back of each of two male, white guinea pigs. Following an initial 0.05 ml injection, 0.1 ml injections were given three times a week for a total of ten injections. Two weeks later a challenge injection was given, and readings were taken 24 hours later. Both ingredients were found to be nonsensitizing.⁽¹³⁾

Subchronic: For 90 days, Glycol Stearate at 3% in a liquid foundation formulation was applied five times a week for 13 weeks to the clipped backs of 15 female rats. Observations were made for survival, body weight, appearance and behavior, hematology, clinical chemistry, organ weights, and gross and histopathologic changes. No effects were attributed to the repeated application of the test formulation.⁽¹³⁾

A shampoo formulation containing Glycol Distearate was tested in three separate experiments on groups containing six rabbits each (three males and three females). A fourth experiment involved similar procedures, but had five male and five female rabbits per group. The material was applied daily, five days per week to intact or abraded skin equivalent to 10% of the skin area of the back; this remained on the animal for seven hours each day before washing.⁽¹⁴⁾

Two formulations were tested for 91 days. The concentration of Glycol Distearate applied to the animals ranged from 0.05% to 0.5%. No evidence of treatment-induced systemic effects was observed. The skin irritation that resulted was reported to be similar to that produced by other forms of shampoo.⁽¹⁴⁾

COSMETIC INGREDIENT REVIEW

ASSESSMENT: GLYCOL

Table 2. Acute Animal Toxicity.^a

Ingredient	File No.	LD50—Acute oral			No. Rats/ Dose	Skin Irritation		Animals	Draize Woodward Calvary Irritation Index	Eye Irritation	Draize No. of Rabbits	Comment
		Value	Conc.	Dosage		Conc.	Conc.					
Glycol Stearate	6.4b.i	>10 g/kg	50% in corn oil	0.464–10 g/kg	5	undiluted	6 rabbits	0.13	undiluted	6	mild transient irritant in 1/6	
	6.4b.ii	>21.3 g/kg	1:2 in corn oil	0.7–21.3 g/kg	5	undiluted	6 rabbits	0.0	undiluted	9	no irritation	
	6.4b.ii	[Dept. of Transportation >10 g/kg	(Dept. of Transportation Skin Irritation Test)	undiluted	10	undiluted	6 rabbits	0.0	undiluted			
	6.4b.iv	>10 g/kg	undiluted	10 g/kg	10	undiluted	6 rabbits	0.375				
6.4b.iv	[Skin Sensitization Test]					i.c. inject. of 0.1% in saline	2 guinea pigs	not a sensitizer				
Glycol Stearate SE	6.4d.i	>5000 mg/kg	undiluted	5000 mg/kg	10	undiluted	3 rabbits	0.8	undiluted	3	practically non- irritating	
Glycol Distearate	6.4c.i	>10 g/kg	50% in corn oil	0.464–10 g/kg	5	undiluted	3 rabbits	0.0	undiluted	3	not an irritant	
	6.4c.ii	>16 g/kg	1:4 in corn oil	0.5–16 g/kg	5	5% in water	3 rabbits	0.0	5% in water	3	practically non- irritating	
6.4c.ii	[Dept. of Transportation >10 g/kg	(Dept. of Transportation Skin Irritation Test)	undiluted	10	undiluted	6 rabbits	0.0	0.04	undiluted	6	practically non- irritating	
	6.4c.iv	>10 g/kg	undiluted	10 g/kg	10	undiluted	6 rabbits	0.0	undiluted	9	no irritation	
6.4c.iv	[Skin Sensitization Test]					i.c. inject. of 0.1% in saline	2 guinea pigs	not a sensitizer				
4.4c.v	>5000 mg/kg	undiluted	5000 mg/kg	10	undiluted	3 rabbits	1.0	1.0	undiluted	3	practically non- irritating	

^aData from Ref. 14.

Two formulations of Glycol Distearate ranged from 19 to 76 years of age. Microscopic examination of the skin showed no systemic toxic effects by the surfactant.

A separate butyl Glycol Distearate associated with both formulations reported noted no effect to the test.⁽¹⁴⁾

A shampoo containing concentrations of 0.05% and 0.1% concentration. After 1 hour from the application, no irritation was observed in one level.⁽¹⁴⁾

Eye Irritation
These three ingredients were found to be nonirritating.

Potential Toxicity
Glycol Distearate, the toxic ingredient, was hydrolyzed by skin to 4%, as an impurity. A review of the literature indicates that it has been used in products which might be expected to be used.

Unpublished data reviewed and are available.

Skin Irritation
Glycol Distearate was applied from 19 to 76 years of age to the dorsum of the back for a 24-hour induction period. Challenge patches were applied for a final insult patch; no irritation was observed in any of the subjects.

Eyeshadow
Glycol Distearate (sequentially applied as a Stearate), blushing agent.

ETIC INGREDIENT REVIEW

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rate: A repeated insult dnesday, and Friday of uid solution of the for-r arm of each subject. he diluted test material tearate.) Fourteen days was challenged with a nined 48 and 96 hours d. (16)

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glycol distearate were a three-week period, te days. Fourteen days ven challenge patches.

ASSESSMENT: GLYCOL STEARATE, GLYCOL STEARATE SE, AND GLYCOL DISTEARATE

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TABLE 3. Sensitization Tests on Dishwashing Liquids Containing Ethylene Glycol Distearate.^a

Dishwashing liquid	No. of subjects	Detergent conc. (%)	Range of conc. of ethylene glycol distearate (%)
1	67	1	0.01-0.05
2	69	1	0.01-0.05
3	87	1.5	0.015-0.075
4	78	0.5	0.005-0.025

^aData from Ref. 14.

Table 3 shows the range of concentration of ethylene glycol distearate for each group of subjects.

No results were presented on irritation caused by the test compounds. In all cases, there was no reported evidence of sensitization after challenge.⁽¹⁴⁾

Consumer Information: Two companies reported on the incidence of consumer complaints related to their products containing Glycol Stearate. One indicated that it was unaware of any complaints having arisen over a 20-year period from the use of over two million units of products (various creams and lotions) containing 0.5-5% Glycol Stearate. According to the second company, the unscreened adverse reaction rate for shampoos containing 4.0% Glycol Stearate averaged 1.2 complaints per million.⁽¹⁴⁾

Occupational Exposure: Two manufacturers reported that they have been manufacturing Glycol Stearates and Glycol Distearates for between 20 and 30 years. According to both, no employee reported that his or her health might have been adversely affected by exposure to these compounds. This conclusion was based upon: (a) 30 employees who for 10 years had potentially been exposed to Glycol Stearate for 1% of their work time; (b) 70 employees who for 20 years had potentially been exposed to Glycol Distearate for 20% of their work time; and (c) 50 employees who for 30 years had potentially been exposed to Glycol Stearate for 5% of their work time. One manufacturer noted that its labor turnover was very low, so that some individuals had been exposed to the ingredients for many of the years during which they had been produced there.⁽¹⁴⁾

SUMMARY

Glycol Stearate, Glycol Stearate SE, and Glycol Distearate are comprised primarily of the mono- and diesters of triple-pressed stearic acid. They are used at concentrations ranging from less than 0.1% to 10% in numerous categories of cosmetic products. They function as emulsifiers, dispersants, opacifiers, and viscosity modifiers, and have been used as wax ingredients in stick preparations. Because they are used on all body surfaces, these ingredients may be absorbed through several routes; and their contact with the body may be frequent and prolonged. Animal studies indicate that Glycol Stearate serves as a surfactant and enhances percutaneous absorption.

The animal data indicate that these ingredients have low acute oral toxicity, skin and eye irritation, and sensitization. One subchronic skin painting study with a product formulation containing 3% Glycol Stearate showed no toxic effects throughout the 90-day test period and after necropsy.

A repeated insult patch test with 50% Glycol Distearate on 125 subjects presented no evidence of skin irritation or hypersensitivity. Human studies using formulations containing Glycol Stearate at levels of 2–5% reported no skin irritation or sensitization. Additional human studies using Glycol Distearate, at levels of the test compound 500 times lower than that which a consumer would actually use, showed no irritation or sensitization upon challenge. Prolonged repeated insult patch testing on the forearm was used to approximate the high-level exposure consumers would experience when they applied a shampoo containing Glycol Distearate to their scalps, under hot and wet conditions, for a very short period of time.

Subchronic testing has not been adequately investigated in laboratory animals. Human test data for formulations containing > 4% Glycol Stearate or Glycol Distearate should be considered.

CONCLUSION

On the basis of the available information presented herein, the Panel concludes that Glycol Stearate, Glycol Stearate SE, and Glycol Distearate are safe as cosmetic ingredients in the present practices of use and concentration.

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TABLE 8
Isodecyl Oleate use

Product category	1976 use (CIR 1982)	2001 use (FDA 2001)	1976 concentrations (CIR 1982)	2001 concentrations (CTFA 2001)
Bath oils, tablets and salts	1	—	>5%–10%	—
Other bath preparations	1	—	>0.1%–1%	—
Eyeshadow	8	—	>1%–5%	2%
Eye makeup remover	—	1	—	2%
Hair conditioners	—	3	—	—
Hair tonics, dressings, etc.	—	—	—	2%
Hair sprays	—	1	—	—
Blushers	1	—	>1%–5%	8%
Foundations	2	1	>1%–5%	5%
Lipstick	—	22	—	4%–8%
Other makeup preparations	2	2	>1%–5%	5%
Other manicuring preparations	—	1	—	—
Deodorants	1	—	>1%–5%	2%
Other personal cleanliness products	1	—	>1%–5%	—
Aftershave lotion	—	3	—	—
Other shaving preparation products	—	1	—	—
Skin cleansing preparations	1	2	>10%–25%	3%
Face and neck skin care preparations ^a	2	—	>5%–25%	2%–5%
Body and hand skin care preparations ^a	2	1	>5%–25%	4%
Moisturizing preparations	4	5	>1%–10%	2%–3%
Night creams, lotions, etc.	—	1	—	5%
Other skin preparations	—	—	—	3%–4%
Suntan gels, creams, and liquids	—	—	—	3%
Totals/ranges	24	44	>0.1%–25%	2%–8%

^aOriginally, Face and Neck and Body and Hand were combined as one category, but now they are separated.

Isodecyl Oleate

Isodecyl Oleate was used in 24 cosmetic products in 1976, with the largest uses in eyeshadows in the >1% to 5% concentration range. In 2001, Isodecyl Oleate was used in 44 preparations, with the largest single use in lipsticks (FDA 2001). Concentration of use data from 2001 was provided (CTFA 2001). Complete Isodecyl Oleate information is shown in Table 8.

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GLYCOL STEARATE, GLYCOL STEARATE SE, AND GLYCOL DISTEARATE

A safety assessment of Glycol Stearate, Glycol Stearate SE, and Glycol Distearate was published in 1982 with the conclusion that these ingredients “are safe as cosmetic ingredients in the present practices of use and concentrations” (Elder 1982). New studies, along with the updated information below regarding types and concentrations of use were considered by the CIR Expert Panel. The Panel determined to not reopen this safety assessment.

Glycol Stearate

Glycol Stearate was used in 284 formulations in 1976, at concentrations from ≤0.1% to 10%. In 2001, there were 424 formulations reported to the FDA that contained Glycol Stearate (FDA 2001). Glycol Stearate was reported to be used in 16 new product categories and no longer used in 11 categories as compared to the 1976 FDA database. Concentration of use data from 2001 was provided (CTFA 2001). Table 9 presents the available use information for Glycol Stearate.

TABLE 9
Glycol Stearate use

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentrations (Elder 1982)	2001 concentrations (CTFA 2001)
Baby lotions, oils, powders, etc.	—	—	—	5%
Other baby products	—	1	—	—
Bath oils, tablets, and salts	6	4	>0.1%–1%	—
Bubble baths	47	20	>0.1%–5%	2%
Other bath preparations	6	12	>0.1%–1%	0.2%–5%
Eyebrow pencil	3	—	>1%–5%	5%
Eyeliner	9	—	>1%–5%	4%
Eye shadow	76	—	>1%–10%	6%
Mascara	2	—	>1%–5%	3%
Perfumes	—	—	—	4%
Powders (dusting and talcum)	—	—	—	4%
Sachets	—	—	—	4%
Other fragrance preparations	—	1	—	2%
Hair conditioners	2	17	>5%–10%	0.0001%–3%
Hair straighteners	4	—	>5%–10%	—
Permanent Waves	—	1	—	—
Rinses (noncoloring)	3	—	>0.1%–1%	—
Shampoos (noncoloring)	77	149	≤0.1%–10%	0.05%–4%
Hair tonics, dressings, etc.	1	2	>1%–5%	1%
Hair dyes and colors	—	32	—	2%–6%
Hair shampoos (coloring)	2	1	>1%–5%	—
Blushers (all types)	5	—	>1%–5%	2%
Foundations	88	2	>1%–5%	4%
Leg and body paints	—	—	—	2%
Lipstick	1	1	>1%–5%	—
Makeup bases	2	—	>1%–5%	—
Rouges	8	—	>1%–5%	2%
Makeup fixatives	—	—	—	2%
Other makeup preparations	2	—	>1%–5%	2%–3%
Cuticle softeners	—	1	—	—
Nail creams and lotions	—	1	—	—
Nail polish and enamel removers	—	1	—	—
Other manicuring preparations	—	—	—	0.02%
Bath soaps and detergents	2	40	>0.1%–5%	0.3%–5%
Deodorants (underarm)	—	2	—	—
Douches	—	1	—	—
Other personal cleanliness products	—	8	—	0.2%–6%
Aftershave lotions	1	—	>0.1%–1%	—
Shaving cream	—	3	—	1%
Skin cleansing preparations	8	21	>0.1%–5%	0.2%–5%
Face and neck skin preparations ^a	—	8	>0.1%–5%	5%
Body and hand skin preparations ^a	11	24	>0.1%–5%	0.7%–5%
Foot powders and sprays	—	4	—	5%
Moisturizing preparations	12	27	>0.1%–10%	5%
Night preparations	—	4	—	3%
Paste masks (mud packs)	—	3	—	—
Other skin care preparations	5	26	>0.1%–10%	3%–4%
Suntan gels, creams, and liquids	1	5	>1%–5%	—
Indoor tanning preparations	—	1	—	—
Other suntan preparations	—	1	—	2%
Totals/ranges	284	424	≤0.1%–10%	0.0001%–6%

^aOriginally, Face and Neck and Body and Hand were combined as one category, but now they are separated.

TABLE 10
Glycol Stearate SE

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentrations (Elder 1982)	2001 concentrations (CTFA 2001)
Other bath preparations	—	—	—	0.2%
Other eye makeup preparations	—	2	—	—
Makeup bases	—	—	—	0.9%
Makeup fixatives	—	1	—	—
Other personal cleanliness products	—	—	—	0.2%
Skin cleansing preparations	—	1	—	0.2%
Body and hand skin preparations	—	3	—	—
Moisturizing preparations	—	6	—	—
Paste masks (mud packs)	—	—	—	12%
Other skin care preparations	1	—	>0.1%–1%	—
Suntan gels, creams, and liquids	—	1	—	2%
Other suntan preparations	—	—	—	5%
Totals/ranges	1	14	>0.1%–1%	0.2%–12%

Glycol Stearate SE

There was one formulation reported to the FDA in 1976 that contained Glycol Stearate SE, in the >0.1% to 1% concentration range. In 2001, there were 14 formulations reported to the FDA that contained Glycol Stearate SE, in five new product categories (FDA 2001). Concentration of use data from 2001 was provided (CTFA 2001). Table 10 presents the available use information for Glycol Stearate SE.

Glycol Distearate

There were 26 formulations that contained Glycol Distearate at concentrations from >0.1% to 10% in 1976. In 2001, there were 28 formulations reported to the FDA that contained Glycol Distearate (FDA 2001). Glycol Distearate was reported to be used in three new product categories and no longer used in four categories as compared to the 1976 data. Concentration of use data from 2001 was provided (CTFA 2001).

TABLE 11
Glycol Distearate use

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentrations (Elder 1982)	2001 concentrations (CTFA 2001)
Other baby products	—	—	—	1%
Bath oils, tablets, and salts	—	—	—	0.4%
Bubble baths	—	—	—	2%
Other bath preparations	—	1	—	0.7%–3%
Mascara	—	—	—	3%
Hair conditioners	1	1	>0.1%–1%	2%–9%
Permanent waves	5	—	>1%–5%	—
Shampoos (noncoloring)	15	7	>0.1%–5%	—
Other hair preparations	—	1	—	2%
Hair dyes and colors	1	—	>0.1%–1%	0.2%
Other hair coloring preparations	—	—	—	0.5%
Bath soaps and detergents	—	15	—	2%–3%
Deodorants (underarm)	1	—	>1%–5%	—
Other personal cleanliness products	1	—	>5%–10%	0.5%–3%
Other shaving preparation products	1	1	>1%–5%	—
Skin cleansing preparations	1	2	>1%–5%	0.2%–3%
Body and hand skin preparations	—	—	—	6%
Foot powders and sprays	—	—	—	2%
Other skin care preparations	—	—	—	4%
Totals/ranges	26	28	>0.1%–10%	0.2%–9%

Table 11 presents the available use information for Glycol Distearate.

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IMIDAZOLIDINYL UREA

A safety assessment of Imidazolidinyl Urea was published in 1980 with the conclusion that this ingredient is “safe when incorporated in cosmetic products in amounts similar to those presently marketed” (Elder 1980). New studies, along with the updated information below regarding uses and use concentrations, were considered by the CIR Expert Panel. The Panel determined to not reopen this safety assessment.

In 1976, Imidazolidinyl Urea was used in 1061 cosmetic products, with the largest single use in face powder products in the concentration range of $\leq 0.1\%$ to 5%. In 2001, there were uses reported in 2025 products, with the largest single use in eye shadow (FDA 2001). In 2001, the maximum use concentration

TABLE 12
Imidazolidinyl Urea use

Product category	1976 use (Elder 1980)	2001 use (FDA 2001)	1976 concentrations (Elder 1980)	2001 concentrations (CTFA 2001)
Baby shampoos	2	1	$\leq 0.1\%$ –1%	0.5%
Baby lotions, oils, powders, etc.	1	2	$> 0.1\%$ –1%	0.3%–0.6%
Other baby products	—	1	—	0.3%
Bath oils, tablets, and salts	12	—	$> 0.1\%$ –1%	0.2%–0.5%
Bubble baths	15	26	$\leq 0.1\%$ –1%	0.3%–0.4%
Other bath preparations	12	60	$\leq 0.1\%$ –1%	0.5%
Eyebrow pencil	13	4	$\leq 0.1\%$ –1%	0.3%
Eyeliners	99	18	$\leq 0.1\%$ –5%	0.01%–0.6%
Eye shadow	—	301	—	0.2%–0.5%
Eye lotion	—	7	—	0.5%
Eye makeup remover	3	16	$\leq 0.1\%$ –1%	0.1%–0.5%
Mascara	46	59	$\leq 0.1\%$ –1%	0.3%–0.5%
Other eye makeup preparations	18	28	$\leq 0.1\%$ –1%	0.3%–0.5%
Colognes and toilet waters	1	3	$\leq 0.1\%$	0.4%
Perfumes	—	11	—	0.4%–0.5%
Powders	52	19	$\leq 0.1\%$ –1%	0.2%–0.4%
Sachets	13	—	$\leq 0.1\%$ –1%	0.1%
Other fragrance preparations	2	17	$\leq 0.1\%$	0.4%–0.5%
Hair conditioners	35	35	$\leq 0.1\%$ –5%	—
Hair sprays (aerosol fixatives)	—	1	—	0.4%
Permanent waves	1	6	$\leq 0.1\%$ –1%	—
Rinses (noncoloring)	6	2	$\leq 0.1\%$ –5%	0.2%
Shampoos (noncoloring)	43	46	$\leq 0.1\%$ –5%	0.2%–0.5%
Hair tonics, dressings, etc.	8	24	$\leq 0.1\%$ –1%	0.4%
Wave sets	4	3	$\leq 0.1\%$ –1%	0.3%
Other hair preparations	4	7	$\leq 0.1\%$ –1%	0.2%
Hair dyes and colors	—	3	—	—

(Continued on next page)

²Available from Director, Cosmetic Ingredient Review, 1101 17th Street NW, Suite 310, Washington, DC 20036, USA.