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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%.

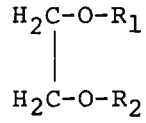
Animal data for acute oral toxicity, skin and eye irritation, and sensitization show that these ingredients have low acute toxicity. A repeated insult patch test with 50% Glycol Distearate on 125 subjects presented no evidence of skin irritation or hypersensitivity. Human studies using formulations containing 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 R_1 is the acyl portion of triple-pressed stearic acid and R_2 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

TABLE 1. Prc

Cosmetic pro	*Ingred.*
Glycol Stearate	
Bath oils, tablet	
Bubble baths	
Other bath prep	
Eyebrow pencil	
Eyeliner	
Eyeshadow	
Mascara	
Hair conditione	
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TABLE 1. Product Formulation Data.[a]

Cosmetic product type/ Ingredient	Concentration (%)	No. of product formulations
Glycol Stearate		
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
Glycol Stearate SE		
Other skin care preparations	>0.1–1	1
Glycol Distearate		
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

[a]Data 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]

Oral Toxicity:
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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]

Table 2. Acute Animal Toxicity.[a]

Ingredient	File No.	LD50–Acute oral			No. Rats/ Dose	Skin Irritation		Draize Woodard Calvary Irritation Index	Eye Irritation		Draize	
		Value	Conc.	Dosage		Conc.	Animals		Conc.	No. of Rabbits	Comment
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 Skin Irritation Test]				undiluted	6 rabbits	0.0			
	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			
	6.4b.v	>5000 mg/kg	undiluted	5000 mg/kg	10	undiluted	3 rabbits	0.8	undiluted	3	practically non-irritating
Glycol Stearate SE	6.4d.i					5% in water	3 rabbits	0.0	5% in water	3	not an irritant
Glycol Distearate	6.4c.i	>10 g/kg	50% in corn oil	0.464–10 g/kg	5	undiluted	6 rabbits	0.04	undiluted	6	practically non-irritating
	6.4c.ii	>16 g/kg	1:4 in corn oil	0.5–16 g/kg	5	undiluted	6 rabbits	0.0	undiluted	9	no irritation
	6.4c.ii	[Dept. of Transportation Skin Irritation Test]				undiluted	6 rabbits	0.0			
	6.4c.iv	>10 g/kg	undiluted	10 g/kg	10	undiluted	6 rabbits	0.085			
	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	undiluted	3	practically non-irritating

[a]Data from Ref. 14.

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6.4c.iv					undiluted	3 rabbits	1.0	undiluted	3	practically non-irritating	
4.4c.v	>5000 mg/kg	undiluted	5000 mg/kg	10							

[a]Data from Ref. 14.

Two formulations were tested for 28 days. The concentration of Glycol Distearate ranged from 0.05% to 0.5%. Following complete gross and microscopic examination, including hematologic, there was no evidence of systemic toxic effects. According to the report, the skin irritation that was caused by the surfactant ranged from slight to severe.[14]

A separate but similar 28-day study reported on two formulations containing Glycol Distearate at a concentration in the range of 0.05–0.4%. Investigators associated both formulations with the development of primary irritation. The report noted no "gross necropsy or microscopic alterations" in the tissue related to the test.[14]

A shampoo containing 1–3% Glycol Distearate was applied at concentrations of 0.05% and 0.3% to 10 animals (five male and five female) at each concentration. After four weeks, there were no systemic effects or deaths resulting from the application of the test compound. Slight transient skin irritation was observed in one rabbit at the 0.05% level and in most animals at the 0.3% level.[14]

Eye Irritation: The Draize procedure was used to evaluate the capacities of these three ingredients for irritating rabbits' eyes. The results showed the ingredients to be nonirritating or practically so. Table 2 gives details of these studies.

Potential Toxicity of Impurities: In any effort to assess the safety of Glycol Stearate, the toxicity of ethylene glycol must be considered, for this is present up to 4%, as an impurity. In addition, it is possible that Glycol Stearate will be hydrolyzed by skin bacteria or upon absorption, so that ethylene glycol will be released. A review of the extensive literature on the toxicity of ethylene glycol indicates that it has adverse effects only at dosage levels much higher than those which might be expected from cosmetics.

Clinical Assessment of Safety

Unpublished clinical data for the Glycol Stearates and their products were reviewed and are summarized below.

Skin Irritation and Sensitization: A repeated insult patch test with 50% w/v Glycol Distearate in mineral oil was performed on 125 subjects ranging in age from 19 to 76 years. Patches containing 0.25 g of sample were applied for 24 hours to the dorsal aspect of the upper arm of each individual. Patches were applied to the same site each Monday, Wednesday, and Friday of the three-week induction period. Each site was scored for irritation a total of nine times. Challenge patches were applied to both arms of each subject 14 days after the final insult patch; the sites were graded for sensitization reactions after 48 and 96 hours. No visible skin changes characteristic of irritation or sensitization were observed in any subject; all scores were zero.[15]

Eyeshadow Containing 3.5% Glycol Stearate: Fifty female volunteers sequentially applied eyeliner, eyeshadow (known to contain 3.5 percent Glycol Stearate), blushing cream, and mascara once a day for 30 days. Approximately

one-half of the subjects were rated as hypersensitive prior to the start of the test. Dermatological examinations were made before the study began and at one-, two-, three-, and four-week intervals during the test period. The dermatologist reported that the products did not produce any reaction over the entire four-week period. It was concluded that "none of the products tested demonstrated any potential as allergic sensitizers or primary irritants."[16]

Eyeliner Containing 3.5% Glycol Stearate: In a 21-day cumulative irritancy assay (Maibach test) performed on seven individuals, eyeliner containing 3.5% Glycol Stearate was applied at full strength under an occlusive patch. A maximum individual subject value of 0.19 on a 4.0 maximum-effect basis was reported, and a cumulative value of 0.58 on a 28 maximum group value was noted. The average mean value for the entire group was 0.08.[16]

Eyecolor Cream Containing 4.0% Glycol Stearate: The formulation was subjected to a 21-day cumulative irritation assay on eight subjects. The average irritation score of 5.94 was obtained out of a maximum possible score of 84.0. Out of a 672 maximum total score for the eight subjects, a score of 47.5 was recorded. Twenty-two was the maximum score for a single individual.[16]

Cream Foundation Containing 3% Glycol Stearate: A repeated insult patch test was performed on 100 subjects, half of whom were considered sensitive. The undiluted formulation containing 3% of the ingredient did not evoke any reaction indicative of induced sensitization. No procedures were stated, and the duration of the study was not reported.

Sixty-two black males and females were tested with a cream containing 2.5% of the ingredient. An adaptation of the repeated insult patch test procedure was used. No skin irritation was reported, nor was there any indication of sensitization following a challenge test 14 days after the end of the repeated patch testing.[14]

Shampoo Containing 2–5% Ethylene Glycol Distearate: A repeated insult patch test was performed on 89 subjects. On Monday, Wednesday, and Friday of the first three weeks, an application of 0.5 ml of a 0.25% liquid solution of the formulation was made along the dorsal surface of the upper arm of each subject. (Since it was stated that the formulation contained 2–5%, the diluted test material would have contained 0.005–0.0125% ethylene glycol distearate.) Fourteen days after the final induction or insult application, the subject was challenged with a challenge patch at the insult site. The subjects were examined 48 and 96 hours after challenge. No evidence of sensitization was reported.[16]

Formulations Containing Ethylene Glycol Distearate: A repeated insult patch test was performed on 103 subjects using 0.5 ml of a 0.2% solution of a shampoo. It was stated that the formulation contained 2–5% ethylene glycol distearate, so that the diluted test material would have contained 0.004–0.01% ethylene glycol distearate. The test procedures were identical to those in the preceding study. No evidence of sensitization was reported.[16]

Four dishwashing liquids containing 1–5% ethylene glycol distearate were tested by means of the repeated insult patch test. Over a three-week period, patches were applied to the upper arm on three alternate days. Fourteen days after the final induction application, the subjects were given challenge patches.

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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

[a]Data 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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