

Glycol Stearate and Glycol Stearate SE

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Abstract

The Expert Panel for Cosmetic Ingredient Safety reviewed newly available studies since their original assessment in 1982, along with updated information regarding product types and concentrations of use, and confirmed that Glycol Stearate and Glycol Stearate SE are safe as cosmetic ingredients in the practices of use and concentration as described in this report.

Keywords

Cosmetics, Safety, Glycol Stearate, Glycol Stearate SE

The Expert Panel for Cosmetic Ingredient Safety first published the Final Report on the Safety Assessment of Glycol Stearate and Glycol Stearate SE in 1982; the Expert Panel concluded that these ingredients are safe in the present practices of use and concentration, as described in that assessment. Upon review, the Expert Panel reaffirmed the original conclusion, as published in 2003. A third ingredient originally included in these two previous reviews, Glycol Distearate, has subsequently been included in the Safety Assessment of Monoalkylglycol Dialkyl Acid Esters and is thereby excluded herein.

Because it has been at least 15 years since the final report was published, in accordance with Cosmetic Ingredient Review Procedures, the Expert Panel again considered whether the safety assessment should be reopened. At the June 2022 meeting, the Expert Panel reviewed updated information regarding product types and ingredient use frequencies as reported in the US Food and Drug Administration (FDA) Voluntary Cosmetic Registration Program (VCRP) database,³ and the maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council (Council).⁴ 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 2022.4 The cumulative frequency and concentration of use data are presented in Table 1.

An extensive search of the world's literature was performed for studies dated 1997 forward. No new toxicity or safety data were found.

After reviewing data on ingredient use frequencies and concentrations, and considering the lack of new toxicological and safety data, the Expert Panel determined to not reopen this safety assessment on Glycol Stearate and Glycol Stearate SE and again reaffirmed the original conclusion.

Author Contributions

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Author's Note

Unpublished sources cited in this report are available from the Director, Cosmetic Ingredient Review, 1620 L Street, NW, Suite 1200, Washington, DC 20036, USA.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Table 1. 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 ³	200 I ²	2022 ⁴	2001 ²	2022 ³	2001 ²	2022 ⁴	200 I ²
Totals ^a	602	424	.0002-5	.0001-6	24	14	NR	.2-12
Duration of use								
Leave-on	311	111	.04-5	.02-6	23	13	NR	.9-5
Rinse-off	270	277	.0002-4.3	.0001-6	1	1	NR	.2-12
Diluted for (bath) use	21	36	1.4	.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 ^b ; 53 ^c	I; 40 ^b ; 36 ^c	.04-3.1 ^b	2-4; I-5 ^b ; .7-5 ^c	11 <mark>b</mark> ; 8 ^c	7 ^b ; 3 ^c	NR	2-5 ^b
Incidental inhalation-powder	53 ^c ; 3 ^d	36°	1.5-5 ^d	4; .7-5 ^c ; 5 ^d	8 ^c	3 ^c	NR	NR
Dermal contact	473	217	.017-5	.2-6	24	14	NR	.2-12
Deodorant (underarm)	NR	2 ^b	NR	NR	NR	NR	NR	NR
Hair – non-coloring	119	169	.034-4	.0001-4	NR	NR	NR	NR
Hair-coloring	10	33	.37	2-6	NR	NR	NR	NR
Nail	NR	3	.0002	.02	NR	NR	NR	NR
Mucous membrane	121	86	.017-1.4	.2-6	NR	NR	NR	0.2
Baby products	3	I	.034-1.2	5	NR	NR	NR	NR

NR, not reported.

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^aBecause 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.

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

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

dNot 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.