

GLYCERYL ISOSTEARATES and GLYCERYL STEARATE/ACETATE

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published a safety assessment on Glyceryl Isostearates and Glyceryl Stearate/Acetate in 2004.¹ The Panel concluded that Glyceryl Isostearates and Glyceryl Stearate/Acetate are safe as cosmetic ingredients in the present practices of use and concentration as described in that report. It should be noted that the report published in 2004 assessed the safety of 43 ingredients; however, the majority of those ingredients have been included in other safety assessments and therefore were not considered in this re-review.

Because it has been at least 15 years since the final report was published, in accordance with Cosmetic Ingredient Review (CIR) Procedures, the Panel considered whether the safety of these two ingredients should be reassessed. At the March 2025 meeting, the Panel reviewed updated information regarding product types and ingredient use frequencies according to US Food and Drug Administration (FDA) Registration and Listing Data (RLD; 2024)² and the Voluntary Cosmetic Registration Program (VCRP; 2023) database,³ and maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council in 2022.⁴ According to RLD submitted to CIR in 2024, Glyceryl Isostearates has 2 uses in makeup preparations and Glyceryl Stearate/Acetate has 4 uses total, in eye makeup preparations, makeup preparations, and skin care preparations. No uses were reported for these ingredients in the VCRP in 2023. The cumulative frequency and concentration of use data are presented in Table 1.

In January 2025, an extensive search of the world's literature was performed for studies dated 1999 forward. No notable new data were found for these two ingredients.

Furthermore, the Panel discussed the possibility for these ingredients to be used in cosmetic products which may be incidentally inhaled. A detailed discussion and summary of the Panel's approach to evaluating incidental inhalation exposures to ingredients in cosmetic products is available at <https://www.cir-safety.org/cir-findings>. This resource document also notes that airbrush technology presents a potential safety concern. Although frequency and/or concentration of use data are now available (and in some cases mandated) for ingredients marketed for use with airbrush delivery systems in certain product categories, no data are available for consumer habits and practices thereof, product particle size, or other relevant particle data (e.g., diameter). As a result of deficiencies in these critical data needs, the data profile is incomplete, and the safety of cosmetic ingredients applied by airbrush delivery systems cannot be determined by the Panel. Accordingly, the Panel has concluded the data are insufficient to support the safe use of cosmetic ingredients applied via an airbrush delivery system.

In summary, the Panel reviewed updated frequency and concentration of use data. There were no reported use concentrations from the Personal Care Products Council survey conducted in 2022. After considering this information, as well as the information provided in the original safety assessment, the Panel reaffirmed the 2004 conclusion that Glyceryl Isostearates and Glyceryl Stearate/Acetate are safe in cosmetics in the present practices of concentration and use.

Table 1. Frequency (RLD/VCRP) and concentration of use according to likely duration and exposure and by product category

	Glyceryl Isostearates					Glyceryl Stearate/Acetate				
	# of Uses			Max Conc of Use		# of Uses			Max Conc of Use	
	RLD (2024) ²	VCRP (2023) ³	VCRP (1998) ¹	% (2022) ⁴	% (1999) ¹	RLD (2024) ²	VCRP (2023) ³	VCRP (1998) ¹	% (2022) ⁴	% (1999) ¹
Totals*	2	NR	NR	NR	NR	4	NR	NR	NR	1-7
summarized by likely duration and exposure**										
Duration of Use										
Leave-On	***	NR	NR	NR	NR	***	NR	NR	NR	2-7
Rinse-Off	***	NR	NR	NR	NR	***	NR	NR	NR	1
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	NR	NR	NR	***	NR	NR	NR	NR
Incidental Inhalation-Spray	***	NR	NR	NR	NR	***	NR	NR	NR	2-7 ^a , 2 ^b
Incidental Inhalation-Powder	***	NR	NR	NR	NR	***	NR	NR	NR	2 ^b
Dermal Contact	***	NR	NR	NR	NR	***	NR	NR	NR	1-3
Deodorant (underarm)	***	NR	NR	NR	NR	***	NR	NR	NR	NR
Hair - Non-Coloring	***	NR	NR	NR	NR	***	NR	NR	NR	7
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 Products	***	NR	NR	NR	NR	***	NR	NR	NR	NR
as reported by product category										
Eye Makeup Preparations (not children's)										
Mascara						2				
Eyelash and Eyebrow Preparations (primers, conditioners, serums, fortifiers)						1	NR	NR	NR	NR
						1	NA	NA	NA	NA
Hair Preparations (non-coloring)										
Tonics, Dressings, and Other Hair Grooming Aids						NR	NR	NR	NR	7
Makeup Preparations (not eye; not children's)										
Blushers and Rouges (all types)	2	NR	NR	NR	NR	1	NR	NR	NR	NR
Face Powders	2	NR	NR	NR	NR					
Skin Care Preparations										
Cleansing						1				
Face and Neck (excluding shaving preparations)						NR	NR	NR	NR	1
Body and Hand (excluding shaving preparations)						NR	NR	NR	NR	2
Moisturizing						1	NR	NR	NR	3
Suntan Preparations										
Suntan Gels, Creams, and Liquids						NR	NR	NR	NR	3
Indoor Tanning Preparations						NR	NR	NR	NR	2

NA – not applicable (this category was not part of the VCRP); NR – not reported

*The total FOU provided for RLD refers to the ingredient count supplied by FDA, and is not a summation of the number of uses per category because each product may be categorized under multiple product categories. For data supplied via the VCRP or by the Council survey, the sum of all exposure types may not equal the sum of total uses because each ingredient may be used in cosmetics with multiple exposure types.

**Likely duration and exposure are derived from VCRP and survey data based on product category (see Use Categorization <https://www.cir-safety.org/cir-findings>)

***In the RLD each ingredient may be reported under several product categories, making a summation of RLD misleading in comparison to VCRP data. Accordingly, RLD are presented below by product category (as supplied by FDA), but are not summarized by likely duration and exposure.

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

^b 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.

REFERENCES

1. Andersen FA (ed). Final Report of the Amended Safety Assessment of Glyceryl Laurate, Glyceryl Laurate SE, Glyceryl Laurate/Oleate, Glyceryl Adipate, Glyceryl Alginate, Glyceryl Arachidate, Glyceryl Arachidonate, Glyceryl Behenate, Glyceryl Caprate, Glyceryl Caprylate, Glyceryl Caprylate/Caprates, Glyceryl Citrate/Lactate/Linoleate/Oleate, Glyceryl Cocoate, Glyceryl Collagenate, Glyceryl Erucate, Glyceryl Hydrogenated Rosinate, Glyceryl Hydrogenated Soyate, Glyceryl Hydroxystearate, Glyceryl Isopalmitate, Glyceryl Isostearate, Glyceryl Isostearate/Myristate, Glyceryl Isostearates, Glyceryl Lanolate, Glyceryl Linoleate, Glyceryl Linolenate, Glyceryl Montanate, Glyceryl Myristate, Glyceryl Isotridecanoate/Stearate/Adipate, Glyceryl Oleate SE, Glyceryl Oleate/Elaidate, Glyceryl Palmitate, Glyceryl Palmitate/Stearate, Glyceryl Palmitoleate, Glyceryl Pentadecanoate, Glyceryl Polyacrylate, Glyceryl Rosinate, Glyceryl Sesquioleate, Glyceryl/Sorbitol Oleate/Hydroxystearate, Glyceryl Stearate/Acetate, Glyceryl Stearate/Maleate, Glyceryl Tallowate, Glyceryl Thiopropionate, and Glyceryl Undecylenate. *Int J Toxicol.* 2004;23(Suppl 2):55–94.
2. US Food and Drug Administration Office of the Chief Scientist. 2024. Registration and Listing Data - Frequency of Use of Cosmetic Products. College Park, MD [Obtained under the Freedom of Information Act from the Division of Freedom of Information; requested as "Frequency of Use Data" July 17, 2024; received July 30, 2024].
3. US Food and Drug Administration Center for Food Safety & Applied Nutrition. 2023. Voluntary Cosmetic Registration Program - Frequency of Use of Cosmetic Ingredients. College Park, MD [Obtained under the Freedom of Information Act from CFSAN; requested as "Frequency of Use Data" 2023; received February 2, 2023].
4. Personal Care Products Council. 2022. Concentration of Use by FDA Product Category: Glyceryl Collagenate, Glyceryl Isostearates, Glyceryl Sesquioleate, Glyceryl/Sorbitol Oleate/Hydroxystearate, Glyceryl Stearate/Acetate, Glyceryl Stearate/Malate and Glyceryl Thiopropionate. [Unpublished data submitted to Personal Care Products Council on January 12, 2022.].