

POLYAMINO SUGAR CONDENSATE

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report of the Safety Assessment of Polyamino Sugar Condensate in 1982.¹ The Panel concluded that on the basis of the available animal data and limited human experience presented in the report, in the present practices of use and concentration, Polyamino Sugar Condensate is safe for topical application to humans. Upon re-review in 2002/2003, the Panel reaffirmed the original conclusion, as published in 2005.²

Because it has been at least 15 years since the prior review was published, in accordance with Cosmetic Ingredient Review (CIR) Procedures, the Panel again considered whether the safety assessment should be reopened. At its March 2023 meeting, the Panel reviewed updated (2022) information regarding product types and ingredient use frequencies as reported in the US Food and Drug Administration (FDA) Voluntary Cosmetic Registration Program (VCRP) database and maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council (Council). Polyamino Sugar Condensate had 1 reported use in a body and hand formulations in 2022.³ At the time this ingredient was last considered for review, 25 uses were reported.² Concentration of use data were neither reported at the time the initial re-review was considered in 2002/2003, nor in response to a survey conducted by the Council in 2022.^{2,4} The cumulative frequency and concentration of use data are presented in Table 1.

In January 2023, an extensive search of the world's literature was performed for studies dated 2000 forward. No relevant new data were found.

In summary, the Panel reviewed 2022 frequency and concentration of use data and noted the lack of any new, available, relevant safety data. Considering this information, as well as the information provided in the original safety assessment and the prior re-review document, the Panel reaffirmed the 1982 conclusion. The Panel discussed the possibility for this ingredient 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>.

Table 1. Frequency and concentration of use (2022/2001) according to likely duration and exposure by product category

	# of Uses		Max Conc of Use (%)	
	2022 ³	2001 ²	2022 ⁴	2001 ²
Totals*	1	25	NR	NR
summarized by likely duration and exposure**				
Duration of Use				
Leave-On	1	22	NR	NR
Rinse-Off	NR	3	NR	NR
Diluted for (Bath) Use	NR	NR	NR	NR
Exposure Type				
Eye Area	NR	4	NR	NR
Incidental Ingestion	NR	NR	NR	NR
Incidental Inhalation-Spray	1 ^a	5 ^a ; 11 ^b	NR	NR
Incidental Inhalation-Powder	1 ^a	5 ^a	NR	NR
Dermal Contact	1	25	NR	NR
Deodorant (underarm)	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR
Nail	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	NR
Baby Products	NR	NR	NR	NR
as reported by product category				
Eye Makeup Preparations				
Other Eye Makeup Preparations	NR	4	NR	NR
Skin Care Preparations				
Cleansing	NR	2	NR	NR
Face and Neck (exc shave)	NR	1	NR	NR
Body and Hand (exc shave)	1	4	NR	NR
Moisturizing	NR	9	NR	NR
Night	NR	1	NR	NR
Paste Masks (mud packs)	NR	1	NR	NR
Other Skin Care Preparations	NR	2	NR	NR
Suntan Preparations				
Suntan Gels, Creams, and Liquids	NR	1	NR	NR

NR – not reported

*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.

**likely duration and exposure is derived based on product category (see Use Categorization <https://www.cir-safety.org/cir-findings>)

^a 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

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

REFERENCES

1. Anderson FA (ed). Final Report of the Safety Assessment of Polyamino Sugar Condensate. *Journal of the American College of Toxicology*. 1982;1(4):25-32.
2. Cosmetic Ingredient Review Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments--2002/2003. *Int J Toxicol*. 2005;24 Suppl 1:1-102.
3. U.S. Food and Drug Administration Center for Food Safety & Applied Nutrition (CFSAN). 2022. Voluntary Cosmetic Registration Program - Frequency of Use of Cosmetic Ingredients (VCRP). (Obtained under the Freedom of Information Act from CFSAN; requested as "Frequency of Use Data" January 4, 2022; received January 11, 2022.)
4. Personal Care Products Council. 2022. Concentration of Use by FDA Product Category: Polyamino Sugar Condensate. (Unpublished data submitted by the Personal Care Products Council on October 24, 2022.)