

Polyacrylamide

Preethi S. Raj*, **Wilma F. Bergfeld****, **Donald V. Belsito****,
David E. Cohen**, **Curtis D. Klaassen****, **Daniel C. Liebler*****,
Allan E. Rettie**, **David Ross****, **Thomas J. Slaga****, **Paul W. Snyder****,
Susan Tilton**, **Monice Fiume[†]**, and **Bart Heldreth[‡]**

International Journal of Toxicology
2023, Vol. 42(Supplement 3) 89S–90S
© The Author(s) 2023
Article reuse guidelines:
sagepub.com/journals-permissions
DOI: 10.1177/10915818231204573
journals.sagepub.com/home/ijt



Abstract

The Expert Panel for Cosmetic Ingredient Safety reviewed updated information that has become available since their original assessment from 1991, along with updated information regarding product types, and frequency and concentrations of use, and reaffirmed their original conclusion that Polyacrylamide is safe as a cosmetic ingredient in the practices of use and concentration as described in this report.

Keywords

Cosmetics, Polyacrylamide, Safety

The Expert Panel for Cosmetic Ingredient Safety first published a Final Report of the Safety Assessment of Polyacrylamide in 1991, with the conclusion that Polyacrylamide, with less than .01% acrylamide monomer content, is safe as a cosmetic ingredient as currently used.¹ Subsequently, because a large number of relevant safety studies on acrylamide became available, in 2005 the Expert Panel published an Amended Final Report on the Safety Assessment of Polyacrylamide and Acrylamide Residues in Cosmetics.² The Expert Panel concluded that Polyacrylamide is safe as a cosmetic ingredient in the present practices of use and concentration described in the safety assessment, if the level of acrylamide monomer in formulation is not greater than 5 ppm; it was acknowledged that acrylamide is a demonstrated neurotoxicant in humans (at high exposure levels that could not be attained with cosmetic use), a known carcinogen in animal tests, and is probably carcinogenic to humans.³

Because it has been at least 15 years since the final amended report was published, in accordance with Cosmetic Ingredient Review Procedures, the Expert Panel determined whether the safety assessment should be reopened. At the June 2022 meeting, the Expert Panel considered updated information regarding product types and ingredient use frequencies as reported by the US Food and Drug Administration (FDA) Voluntary Cosmetic Registration Program database in 2022,⁴ and the maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council in 2020.⁵ Generally, there has been an increase in frequency of use since the last review in 2005. In 2022, data indicated that

Polyacrylamide has 552 reported uses, compared to 110 uses reported in 2002. However, the maximum reported concentration of use for this ingredient has remained constant; in 2001, the maximum reported concentration of use was 2.8%, and in 2020, it was 3%. Additionally, there was 1 reported use in baby lotions, powder, oil, and creams, and 2% concentration of use in other baby products, when no baby product use was reported in the 2005 report. 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 2000 forward. No new published data were found. The Expert Panel considered the reported use in a baby lotion (concentration of use not reported) and discussed the typical average daily consumption of Polyacrylamide in foods, which mitigated systemic toxicity concerns. The Expert Panel noted that the mean dietary intake of Polyacrylamide has been reported to average .5 µg/kg/bw/d in adults, whereas intake is higher among children.⁶

After reviewing updated frequency and concentration of use data, and considering the lack of new toxicological data,

*Cosmetic Ingredient Review Senior Scientific Analyst/Writer

**Expert Panel for Cosmetic Ingredient Safety Member

***Expert Panel for Cosmetic Ingredient Safety Former Member

[†]Cosmetic Ingredient Review Senior Director

[‡]Cosmetic Ingredient Review Executive Director

Corresponding Author:

Bart Heldreth, Executive Director, Cosmetic Ingredient Review, 1620 L Street, NW, Suite 1200, Washington, DC 20036, USA.

Email: cirinfo@cir-safety.org

Table 1. Current and Historical Frequency and Concentration of Use According to Duration and Exposure.

	# of Uses		Max Conc of Use (%)	
	Polyacrylamide			
	2022 ^d	2002 ²	2020 ⁵	2001 ²
Totals^d	552	110	.03-3	.05-2.8
Duration of use				
Leave-on	511	97	.05-3	.05-2.8
Rinse-off	41	13	.03-2.8	.3-1.4
Diluted for (bath) use	NR	NR	NR	NR
Exposure type				
Eye area	58	2	.05-1	.05-2.5
Incidental ingestion	2	NR	NR	NR
Incidental inhalation-spray	1; 195 ^a ; 167 ^b	2; 43 ^a ; 33 ^b	.32-2.1 ^a	.5-1; 0.3-2 ^a ; 0.2-2.8 ^b
Incidental inhalation-powder	2; 167 ^b ; 1 ^c	33 ^b	.49; .44-3 ^c	.2-2.8 ^b
Dermal contact	503	105	.03-3	.05-2.8
Deodorant (underarm)	2 ^a	1 ^a	NR	NR
Hair – non-coloring	45	5	.2-2.1	.7-2
Hair-coloring	NR	NR	.12	.9-1.4
Nail	2	NR	.4-1.5	0.6
Mucous membrane	5	2	1.6	NR
Baby products	1	NR	2	NR

NR, not reported.

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

^bNot 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.

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

^dBecause 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.

the Expert Panel determined to not reopen this safety assessment on Polyacrylamide and reaffirmed the conclusion published in 2005.

Review. The Cosmetic Ingredient Review is financially supported by the Personal Care Products Council.

Author Contributions

The articles in this supplement were sponsored by the Cosmetic Ingredient Review.

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 Interest

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: The articles in this supplement were sponsored by the Cosmetic Ingredient Review.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: The articles in this supplement were sponsored by the Cosmetic Ingredient

References

- Andersen FA, ed. Final report on the safety assessment of polyacrylamide. *J Am Coll Toxicol*, 1991;10(Suppl 1):193-203.
- Andersen FA, ed. Amended final report on the safety assessment of polyacrylamide and acrylamide residues in cosmetics. *Int J Toxicol*, 2005;24(Suppl 2):21-50.
- International Agency for Research on Cancer. IARC monographs on the evaluation carcinogenic risks to humans. 1994;60: 389-433.
- U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition (CFSAN). 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.)
- Personal Care Products Council. Concentration of use by FDA product category: polyacrylamide. (Unpublished data submitted by Personal Care Products Council on October 13, 2020.); 2020
- Mucci LA, Wilson KM. Acrylamide intake through diet and human cancer risk. *J Agric Food Chem*, 2008;56(15):6013-6019.