POLYQUATERNIUM-11

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report of the safety of Polyquaternium-11 in 1983.[1] The Panel concluded that Polyquaternium-11 is safe as a cosmetic ingredient in the present practices of use as described in that safety assessment. Upon re-review in 2001, the Panel reaffirmed the original conclusion, as published in 2005.[2]

Because it has been at least 15 years since the prior re-review was published, in accordance with Cosmetic Ingredient Review (CIR) Procedures, the Panel again determined whether the safety assessment should be reopened. At its September 2023 meeting, the Panel considered updated (2023) 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 maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council.[4] According to these data, the frequency and concentrations of use of Polyquaternium-11 have decreased. In 2023, Polyquaternium-11 is used in 192 formulations at up to 2.9% in leave-on products; in 2001, Polyquaternium-11 was reported to be used in 254 formulations at up to 12% in rinse-off products and up to 10% in leave-on products. The cumulative frequency and concentration of use data are presented in Table 1.

In September 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 2023 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 1983 conclusion. The Panel discussed the possibility for Polyquaternium-11 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 (2003/2001) according to likely duration and exposure and by product category

	# of Uses		*Max Conc of Use (%)*	
	2023[3]	**2001[2]**	**2023[4]**	**2001[2]**
Totals*	**192**	**254**	**0.05 – 2.9**	**0.05 - 12**
summarized by likely duration and exposure**				
Duration of Use				
Leave-On	108	127	0.05-2.9	0.05-10
Rinse-Off	84	126	0.08-0.6	0.05-12
Diluted for (Bath) Use	NR	1	NR	NR
Exposure Type				
Eye Area	1	1	0.1-1.2	NR
Incidental Ingestion	NR	NR	NR	NR
Incidental Inhalation-Spray	7;74[a]	89[a]	0.2-2.9;0.05-2.3[a]	2;0.05-10[a],0.05[c]
Incidental Inhalation-Powder	NR	NR	NR	0.05c
Dermal Contact	1	5	NR	0.05-12
Deodorant (underarm)	NR	NR	NR	NR
Hair - Non-Coloring	172	241	0.05-2.9	0.05-10
Hair-Coloring	18	7	NR	0.3
Nail	NR	NR	NR	NR
Mucous Membrane	1	2	NR	12
Baby Products	NR	NR	NR	NR
as reported by product category				
Bath Preparations (diluted for use)				
Other Bath Preparations	NR	1	NR	NR
Eye Makeup Preparations				
Mascara	1	1	0.1-1.2	NR
Hair Preparations (non-coloring)				
Hair Conditioner	22	69	0.08-0.6	0.8-3
Hair Spray (aerosol fixatives)	7	NR	0.2-2.9	2
Permanent Waves	4	14	NR	NR
Rinses (non-coloring)	NR	1	NR	0.8
Shampoos (non-coloring)	39	24	0.15	0.05-4
Tonics, Dressings, and Other Hair Grooming Aids	74	88	0.05-2.3	0.05-10
Wave Sets	NR	8	NR	2-3
Other Hair Preparations	26	37	0.08	0.1-4
Hair Coloring Preparations				
Hair Dyes and Colors (all types requiring caution statements and patch tests)	11	NR	NR	NR
Hair Tints	NR	4	NR	NR
Hair Shampoos (coloring)	1	NR	NR	NR

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	# of Uses		*Max Conc of Use (%)*	
	2023[3]	**2001[2]**	**2023[4]**	**2001[2]**
Hair Bleaches	NR	3	NR	NR
Other Hair Coloring Preparation	6	NR	NR	0.3
Personal Cleanliness Products				
Bath Soaps and Detergents	1	NR	NR	NR
Other Personal Cleanliness Products	NR	1	NR	12
Shaving Preparations				
Shaving Cream	NR	2	NR	NR
Skin Care Preparations				
Cleansing	NR	NR	NR	0.4
Face and Neck (exc shave)	NR	NR	NR	0.05
Night	NR	NR	NR	0.05
Paste Masks (mud packs)	NR	NR	NR	4
Skin Fresheners	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 are derived based on product category (see Use Categorization https://www.cir-safety.org/cir-findings)
[a] It is possible these products are sprays, but it is not specified whether the reported uses are sprays.
[b] It is possible these products are powders, but it is not specified whether the reported uses are powders.
[c] 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 on the Safety Assessment of Polyquaternium-11. *Journal of the American College of Toxicology* 1983;2(5):161-178.

2. Andersen FA (ed.). Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. *Int J Toxicol* 2005;20 (Suppl 1):1-102.

3. U.S. Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition (CFSAN). 2023. Voluntary Cosmetic Registration Program- Frequency of use of Cosmetic Ingredients Obtained under the Freedom of Information Act from CFSAN; requested as "Frequency of Use Data" January 4, 2023; received February 2, 2023. .

4. Personal Care Products Council. 2022. . Concentration of Use by FDA Product Category: Polyquaternium-11. (Unpublished data submitted by Personal Care Products Council on November 4, 2022).