

CHOLETH-24

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report on the Safety Assessment of Choleth-24 as Used in Cosmetics in 1982.¹ The Panel concluded that Choleth-24 is safe for topical applications to humans in the present practices of use and concentration, as stated in that report. Upon re-review, 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 considered whether the safety assessment should be reopened. At its December 2022 meeting, the Panel considered 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,³ and maximum use concentrations provided in response to a survey conducted by the Personal Care Products Council.⁴ The frequency of use for Choleth-24 decreased from 191 uses reported in 2002 to 33 uses reported in 2022. In 2002, Choleth-24 was reported to be used at up to 1.3%. In 2022, no concentrations of use were reported for Choleth-24 in response to the industry survey. The frequency and concentration of use data are presented in Table 1.

In December 2022, an extensive search of the world's literature was performed for studies dated 1998 forward, and no new toxicological data were found. However, it should be noted that Choleth-24 is an inactive ingredient in two FDA-approved drug formulations.⁵

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 for Choleth-24.

Table 1. Frequency and concentration of use (2022; 2002) according to likely duration and exposure and by product category

	<i># of Uses</i>		<i>Max Conc of Use (%)</i>	
	2022³	2002²	2022⁴	2002²
Totals*	33	191	NR	0.002 – 1.3
summarized by likely duration and exposure**				
<i>Duration of Use</i>				
<i>Leave-On</i>	24	140	NR	0.008 – 1.3
<i>Rinse-Off</i>	9	49	NR	0.002 – 1
<i>Diluted for (Bath) Use</i>	NR	1	NR	NR
<i>Exposure Type</i>				
Eye Area	NR	4	NR	0.2 – 0.3
Incidental Ingestion	NR	NR	NR	NR
Incidental Inhalation-Spray	12 ^a ; 7 ^b	17; 44 ^a ; 33 ^b	NR	0.3; 0.008 – 1.3 ^a ; 0.1 – 0.7 ^b
Incidental Inhalation-Powder	7 ^b	33 ^b	NR	0.2; 0.1 – 0.7 ^b
Dermal Contact	20	138	NR	0.002 – 1.3
Deodorant (underarm)	NR	NR	NR	NR
Hair - Non-Coloring	5	15	NR	0.2 – 1
Hair-Coloring	7	38	NR	0.5
Nail	1	NR	NR	0.3
Mucous Membrane	NR	2	NR	0.002 – 0.7
Baby Products	NR	NR	NR	NR
as reported by product category				
<i>Bath Preparations (diluted for use)</i>				
Bubble Baths	NR	2	NR	NR
<i>Eye Makeup Preparations</i>				
Eyeliner	NR	NR	NR	0.3
Eye Shadow	NR	1	NR	NR
Eye Lotion	NR	1	NR	0.3
Mascara	NR	NR	NR	0.2
Other Eye Makeup Preparations	NR	2	NR	0.3
<i>Fragrance Preparations</i>				
Perfumes	NR	9	NR	0.3
Sachets	‡	NR	‡	0.3
Other Fragrance Preparation	NR	8	NR	NR
<i>Hair Preparations (non-coloring)</i>				
Hair Conditioner	2	9	NR	0.3 – 1
Rinses (non-coloring)	NR	NR	NR	0.2
Shampoos (non-coloring)	NR	1	NR	NR
Tonics, Dressings, and Other Hair Grooming Aids	2	2	NR	NR
Other Hair Preparations	1	3	NR	NR
<i>Hair Coloring Preparations</i>				
Hair Dyes and Colors (all types requiring caution statements and patch tests)	7	38	NR	0.5

Table 1. Frequency and concentration of use (2022; 2002) according to likely duration and exposure and by product category

	# of Uses		Max Conc of Use (%)	
	2022 ³	2002 ²	2022 ⁴	2002 ²
Makeup Preparations				
Face Powders	NR	NR	NR	0.2
Foundations	NR	19	NR	0.2 – 0.3
Makeup Bases	NR	NR	NR	0.5
Other Makeup Preparations	NR	2	NR	0.2 – 0.5
Manicuring Preparations (Nail)				
Cuticle Softeners	1	NR	NR	0.3
Personal Cleanliness Products				
Bath Soaps and Detergents	NR	NR	NR	0.002 – 0.7
Shaving Preparations				
Aftershave Lotion	NR	7	NR	0.3
Skin Care Preparations				
Cleansing	NR	NR	NR	0.3
Face and Neck (exc shave)	4	4	NR	0.4
Body and Hand (exc shave)	3	28	NR	0.1 – 0.7
Foot Powders and Sprays	NR	1	NR	0.3
Moisturizing	4	28	NR	0.008 – 1.3
Night	3	6	NR	0.2 – 0.3
Paste Masks (mud packs)	NR	1	NR	0.3
Skin Fresheners	NR	2	NR	NR
Other Skin Care Preparations	3	11	NR	0.1 – 0.3
Suntan Preparations				
Suntan Gels, Creams, and Liquids	2	3	NR	0.3
Indoor Tanning Preparations	1	2	NR	NR
Other Suntan Preparations	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 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

[†] This product category is no longer included in the VCRP.

REFERENCES

1. Andersen FA (ed). Final Report on the Safety Assessment of Choleth-24. *J Am Coll Toxicol*. 1982;1(4):119-126.
2. Andersen FA (ed). Annual review of cosmetic ingredient safety assessments - 2002/2003. *IJT*. 2005;24:1-102.
3. US Food and Drug Administration (FDA) Center for Food Safety & Applied Nutrition (CFSAN). 2022. 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, 2022; received January 11, 2022).
4. Personal Care Products Council. 2022. Concentration of use by FDA product category: Propylene Carbonate. Unpublished data submitted by Personal Care Products Council on November 22, 2022.
5. U.S. Food and Drug Administration. Inactive ingredient search for approved drug products. <https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm>. Last Updated 2022. Accessed November 1, 2022.