

## **ZINC PHENOLSULFONATE**

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report on the Safety of Zinc Phenolsulfonate in 1986.<sup>1</sup> The Panel concluded that Zinc Phenolsulfonate is safe as a cosmetic ingredient in the present practices of use and concentration as described in that safety assessment. Upon re-review in 2004, the Panel reaffirmed the original conclusion, as published in 2006.<sup>2</sup>

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 reviewed updated (2023) information regarding product types and ingredient use frequency as reported in the US Food and Drug Administration (FDA) Voluntary Cosmetic Registration Program (VCRP) database<sup>3</sup> and maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council.<sup>4</sup> According to these data, the frequency and concentrations of use of Zinc Phenolsulfonate have decreased. In 2023, Zinc Phenolsulfonate is reported to be used in 1 formulation; however, concentration of use data were reported for several product categories, with a maximum leave-on concentration of 1% in deodorant pump spray products. In 2002, Zinc Phenolsulfonate was reported to be used in 23 formulations, and according to 2004 concentration of use data, it was used at up to 4% in deodorant formulations. The cumulative frequency and concentration of use data are presented in Table 1.

In July 2023, an extensive search of the world's literature was performed for studies dated 2001 forward, and new data were found.<sup>5,6</sup> Zinc Phenolsulfonate is categorized in Annex III of the European Union, i.e., the list of substances which cosmetic products must not contain except subject to the restrictions laid down. Zinc Phenolsulfonate is confined to use in deodorants, antiperspirants, and astringent lotions at a maximum concentration of 6% (as % anhydrous substance), and eye contact is to be avoided.<sup>5</sup> Additionally, according to 21CFR 310.545, there are inadequate data to establish general recognition of the safety and effectiveness of Zinc Phenolsulfonate in over-the-counter (OTC) drug products.<sup>6</sup>

In summary, the Panel reviewed 2023 frequency and concentration of use data, in addition to 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 1986 conclusion. The Panel discussed the possibility for Zinc Phenolsulfonate 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 (2023/2002) and concentration (2023/2004) of use according to likely duration and exposure and by product category**

	# of Uses		Max Conc of Use (%)	
	2023 <sup>3</sup>	2002 <sup>2</sup>	2023 <sup>4</sup>	2004 <sup>2</sup>
<b>Totals</b>	<b>1</b>	<b>23</b>	<b>0.041-1</b>	<b>3-4</b>
<b>summarized by likely duration and exposure</b>				
<b>Duration of Use</b>				
Leave-On	1	23	0.041-1	3-4
Rinse-Off	NR	NR	NR	NR
Diluted for (Bath) Use	NR	NR	1	NR
<b>Exposure Type</b>				
Eye Area	NR	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR
Incidental Inhalation-Spray	NR	1 <sup>a</sup> ; 3 <sup>b</sup>	0.42	3 <sup>b</sup>
Incidental Inhalation-Powder	NR	1; 3 <sup>b</sup>	0.1-0.2 <sup>c</sup>	3 <sup>b</sup>
Dermal Contact	1	23	0.041-1	3-4
Deodorant (underarm)	NR	15 <sup>a</sup>	0.041-1 (spray)	4 <sup>a</sup>
Hair - Non-Coloring	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR
Nail	NR	NR	NR	NR
Mucous Membrane	NR	NR	1	NR
Baby Products	NR	NR	NR	NR
<b>as reported by product category</b>				
<b>Bath Preparations</b>				
Bath Oils, Tablets, and Salts	NR	NR	1	NR
<b>Fragrance Preparations</b>				
Powders (dusting and talcum, exc aftershave talc)	NR	1	NR	NR
<b>Personal Cleanliness</b>				
Deodorants (underarm)	NR	15	0.041 (spray) 1 (pump spray)	4
<b>Shaving Preparations</b>				
Aftershave Lotion	NR	2	NR	NR
<b>Skin Care Preparations</b>				
Face and Neck (exc shave)	NR	NR	0.2 (not spray)	NR
Body and Hand (exc shave)	NR	2	0.1 (not spray) 0.42 (spray)	NR
Foot Powders and Sprays	NR	1	NR	3
Moisturizing	NR	1	NR	NR
Other Skin Care Preparations	1	1	0.25	NR

NR – not reported

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

<sup>a</sup> It is possible these products are sprays, but it is not specified whether the reported uses are sprays.

<sup>b</sup> 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

<sup>c</sup> It is possible these products are powders, but it is not specified whether the reported uses are powders.

## REFERENCES

1. Elder RL (ed.). Final Report on the Safety Assessment of Zinc Phenolsulfonate. *J Am Coll Toxicol*. 1986;5(5):373-390.
2. Andersen, FA (ed.). Annual Review of Cosmetic Ingredient Safety Assessments—2004/2005. *Int J Toxicol* 2006;25(S2):89.
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. 2023. Concentration of Use by FDA Product Category: Zinc Phenolsulfonate. (Unpublished data submitted by Personal Care Products Council on April 28, 2023).
5. European Union. EUR-Lex: Access to European law <https://eur-lex.europa.eu/homepage.html>. Last Updated 2023. Accessed July 14, 2023.
6. Code of Federal Regulations. <https://www.ecfr.gov>. Last Updated July 21, 2023 Accessed July 26, 2023.