International Journal of Toxicology
2024, Vol. 43(Supplement 3) 138S–140S

DOI: 10.1177/10915818241249416
journals.sagepub.com/home/ijt
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Zinc Phenolsulfonate

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Abstract

The Expert Panel for Cosmetic Ingredient Safety reviewed newly available studies since their original assessment in 1986 and a previous re-review in 2004, along with updated information regarding product types and concentrations of use. Considering this information, the Panel confirmed that Zinc Phenolsulfonate is safe as a cosmetic ingredient in the present practices of use and concentration as described in this report.

Keywords

Cosmetic Ingredient Review, Expert Panel for Cosmetic Ingredient Safety, Safety, Cosmetics, Zinc Phenolsulfonate

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report on the Safety of Zinc Phenolsulfonate in 1986.[1] 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.[2]

Because it had 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[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 Zinc Phenolsulfonate have both decreased. This ingredient is reported to function as an antiperspirant agent, astringent, biocide, or deodorant agent. In 2023, Zinc Phenolsulfonate was 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.[5,6] Zinc Phenolsulfonate is categorized in Annex III of the European Union, that is, 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.[5] 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.[6]

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

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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[3]	2002[2]	2023[4]	2004[2]
Totals	1	23	0.041-1	3-4
Summarized by likely duration and exposure				
Duration of Use				
Leave-On	*1*	*23*	*0.041-1*	*3-4*
Rinse-Off	*NR*	*NR*	*NR*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*1*	*NR*
Exposure Type				
Eye Area	NR	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR
Incidental Inhalation-Spray	NR	1[a]; 3[b]	0.42	3[b]
Incidental Inhalation-Powder	NR	1; 3[b]	0.1-0.2[c]	3[b]
Dermal Contact	1	23	0.041-1	3-4
Deodorant (underarm)	NR	15[a]	0.041-1 (spray)	4[a]
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
As reported by product category				
Bath Preparations				
Bath Oils, Tablets, and Salts	NR	NR	1	NR
Fragrance Preparations				
Powders (dusting and talcum, excluding aftershave)	NR	1	NR	NR
Personal Cleanliness				
Deodorants (underarm)	NR	15	0.041 (spray) 1 (pump spray)	4
Shaving Preparations				
Aftershave Lotion	NR	2	NR	NR
Skin Care Preparations				
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).
[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.
[c]It is possible these products are powders, but it is not specified whether the reported uses are powders.

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.

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.

Author Contributions

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

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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

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