

Erythorbic Acid and Sodium Erythorbate

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Abstract

The Expert Panel for Cosmetic Ingredient Safety reviewed newly available studies since their original assessment in 1999, along with updated information regarding product types and concentrations of use, and confirmed that Erythorbic Acid and Sodium Erythorbate are safe as cosmetic ingredients in the practices of use and concentration as described in this report.

Keywords

Erythorbic Acid, Sodium Erythorbate, Safety, Cosmetics

The Expert Panel for Cosmetic Ingredient Safety first published a Final Report on the Safety Assessment of Erythorbic Acid and Sodium Erythorbate, as part of a larger group of ingredients, in 1999.¹ The Expert Panel concluded that these ingredients are safe for use as cosmetic ingredients in the present practices of use. It should be noted that Ascorbyl Palmitate, Ascorbyl Dipalmitate, and Ascorbyl Stearate, which were a part of the original review, were added to a grouping of ethers and esters of ascorbic acid for which a safety assessment was published in 2017, and therefore, are not included as part of this rereview.

Because it has been at least 15 years since the final report was published, in accordance with Cosmetic Ingredient Review Procedures, the Expert Panel determined whether the safety assessment should be reopened. At the September 2022 meeting, the Expert 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) database² and the maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council.³ In the original 1999 report, there were 727 reported uses for Erythorbic Acid, which has since decreased to 300 reported uses in 2022. Similarly, the overall reported concentrations of use have decreased for both ingredients. In both the historical and 2022 data, the bulk of reported uses are for non-coloring hair preparations. Sodium Erythorbate, which was reported to be used in hair coloring preparations at > 50% in 1984, is reported to be used at up to 0.3% in hair dyes and colors in 2022. 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 1994 forward, and minimal new published

data were found.^{4–15} One noteworthy finding included a local lymph node assay performed in female mice in which Sodium Erythorbate was tested at 5, 10, or 25% in propylene glycol.¹⁵ The stimulation index for the maximum concentration tested (25%) was 1.29; all stimulation index values were < 3, indicating that Sodium Erythorbate is not a sensitizer.

The Expert Panel reviewed 2022 frequency and concentration of use data, in addition to any new, available, relevant safety data, and reaffirmed the 1999 conclusion that these ingredients are safe for use as cosmetic ingredients in the present practices of use.

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

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Table I. 2022 and Historical Frequency and Concentration of Use of Erythorbic Acid and Sodium Erythorbate According to Duration and Exposure.

	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	Erythorbic Acid				Sodium Erythorbate			
	2022 ²	1996 ¹	2022 ³	1984 ¹	2022 ²	1996 ¹	2022 ³	1984 ¹
Totals*	300	727	0.1-0.7	1**	6	19	0.3	> 50**
Duration of Use								
Leave-On	2	1	0.1	**	NR	NR	NR	**
Rinse-Off	298	726	0.2-0.7	**	6	19	0.3	**
Diluted for (Bath) Use	NR	NR	NR	**	NR	NR	NR	**
Exposure Type								
Eye Area	1	NR	0.1	**	NR	NR	NR	**
Incidental Ingestion	NR	1	NR	**	NR	NR	NR	**
Incidental Inhalation-Spray	1 ^a	1 ^a	0.1 ^a ; 0.1 ^b	**	NR	NR	NR	**
Incidental Inhalation-Powder	NR	NR	0.1 ^b	**	NR	NR	NR	**
Dermal Contact	2	NR	0.1	**	NR	NR	NR	**
Deodorant (underarm)	NR	NR	NR	**	NR	NR	NR	**
Hair – Non-Coloring	NR	4	NR	**	NR	NR	NR	**
Hair-Coloring	298	721	0.2-0.7	**	6	19	0.3	>50**
Nail	NR	1	NR	**	NR	NR	NR	**
Mucous Membrane	NR	1	NR	**	NR	NR	NR	**
Baby Products	NR	NR	NR	**	NR	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.

**At the time of the 1999 safety assessment, concentration of use data were not reported. However, data provided to the FDA in 1984 data were presented; use categories were not indicated.

^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.

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