# CIR Supplement Manuscript

# Chloroxylenol

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## Abstract

The Expert Panel for Cosmetic Ingredient Safety reviewed updated information that has become available since their original assessment from 1985, along with updated information regarding product types, and frequency and concentrations of use, and reaffirmed their original conclusion that Chloroxylenol is safe as a cosmetic ingredient in the practices of use and concentration as described in this report.

## **Keywords**

Chloroxylenol, Safety, Cosmetics

The Expert Panel for Cosmetic Ingredient Safety first published the Final Report on the Safety Assessment of Chloroxylenol in 1985.<sup>1</sup> The Expert Panel concluded that Chloroxylenol is safe as used in cosmetics, as described in the safety assessment. Upon re-review, the Expert Panel reaffirmed the original conclusion, as published in 2006.<sup>2</sup>

Because it has been at least 15 years since the prior rereview was published, in accordance with Cosmetic Ingredient Review Procedures, the Expert Panel again 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) database<sup>3</sup> and maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council.<sup>4</sup> The frequency of use of Chloroxylenol increased slightly. In 2002, Chloroxylenol was reported to be used in 43 formulations.<sup>2</sup> According to 2022 VCRP data, Chloroxylenol is now reported to be used in 51 formulations. The maximum reported concentration of use, .05%, has not changed since the last review. 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 2000 forward, and new data were found.<sup>5-18</sup> The Expert Panel agreed, however, that the published literature did not reveal toxicity or other data that warrant re-evaluation of the safety of this ingredient in cosmetic products. The Expert Panel noted depigmentation following dermal exposure to undiluted Chloroxylenol and an antiseptic formulation containing predominantly

Chloroxylenol. Depigmentation/skin lightening is considered a drug effect, and therefore, evaluation of this effect is not within the purview of the Expert Panel; however, manufacturers should take caution when formulating cosmetic products containing Chloroxylenol to ensure that skin lightening is not a side effect. Furthermore, concern for this endpoint with the use of this ingredient in cosmetics was mitigated in that the concentrations the subjects were exposed to when depigmentation was observed were much higher than what is used in cosmetics.

The Expert Panel reviewed 2022 frequency and concentration of use data, in addition to any new, available, relevant safety data, and once again reaffirmed the 1985 conclusion regarding the safety of Chloroxylenol in cosmetics.

## **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.

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	# of Uses		Max Conc of Use (%)	
	2022 <sup>3</sup>	2002 <sup>2</sup>	2022 <sup>4</sup>	2003 <sup>2</sup>
Totals <sup>a</sup>	51	43	.1–0.5	.1–0.5
Duration of use				
Leave-on	40	20	.1 0.3	.1–0.2
Rinse-off	10	23	.2–0.5	.4–0.5
Diluted for (bath) use	I	NR	NR	NR
Exposure type				
Eye area	8	I	NR	NR
Incidental ingestion	NR	NR	NR	0.4
Incidental inhalation-spray	20 <sup>b</sup> ; 5 <sup>c</sup>	7 <sup>b</sup> ; 2 <sup>c</sup>	NR	0.1 <sup>s</sup> ; 0.2 <sup>c</sup>
Incidental inhalation-powder	5 <sup>°</sup>	2 <sup>c</sup>	.1–0.3 <sup>d</sup>	0.2 <sup>c</sup> ; 0.1 <sup>d</sup>
Dermal contact	40	31	.1–0.5	.1–0.5
Deodorant (underarm)	NR	۱ <sup>ь</sup>	NR	NR
Hair – non-coloring	4	12	0.3	NR
Hair-coloring	NR	NR	NR	NR
Nail	NR	NR	NR	NR
Mucous membrane	4	12	.2–0.5	0.4
Baby products	NR	NR	.1–0.3	0.1

 Table I. Frequency (2022; 2002) and Concentration (2022; 2003)

 of Use According to Duration and Exposure.

NR, not reported.

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

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

# **Author Contributions**

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