

# Hexamidine and Hexamidine Diisethionate

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## Abstract

The Expert Panel for Cosmetic Ingredient Safety reviewed newly available studies since their original assessment in 2007, along with updated information regarding product types and concentrations of use, and confirmed that Hexamidine and Hexamidine Diisethionate are safe as cosmetic ingredients in the practices of use and concentration as described in this report if used at concentrations less than or equal to .10%.

## Keywords

Cosmetics, Safety, Hexamidine, Hexamidine Diisethionate

The Expert Panel for Cosmetic Ingredient Safety first published the Final Report on the Safety Assessment of Hexamidine and Hexamidine Diisethionate in 2007.<sup>1</sup> The Expert Panel concluded that Hexamidine and Hexamidine Diisethionate are safe for use in cosmetics in the practices and concentrations of use as described in the safety assessment if used at concentrations less than or equal to .10%.

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) database,<sup>2</sup> and maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council.<sup>3</sup> The frequency of use of Hexamidine Diisethionate has increased from 38 uses in 2002<sup>1</sup> to 52 uses in 2022. The concentration of use of this ingredient has remained the same ( $\leq 1\%$ ). There were previously, and are currently, no reported uses for Hexamidine. 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>4–9</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 these ingredients in cosmetic products. The Expert Panel noted the clinical studies in which hypersensitivity was observed; however, these studies were

performed in previously determined atopic individuals; therefore, concern for this endpoint was mitigated.

The Expert Panel reviewed 2022 frequency and concentration of use data, in addition to any new, available, relevant safety data, and reaffirmed the 2007 conclusion regarding the safety of Hexamidine and Hexamidine Diisethionate 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.

## Author Contributions

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## Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this

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**Table I.** 2022 and Historical Frequency and Concentration of Use According to Duration and Exposure.

	# of Uses		Max Conc of Use (%)	
	Hexamidine		Diisethionate	
	2022 <sup>2</sup>	2002 <sup>1</sup>	2022 <sup>3</sup>	2004 <sup>1</sup>
<b>Totals</b>	<b>52</b>	<b>38</b>	<b>.036-.1</b>	<b>.03-.1</b>
Duration of use				
Leave-on	34	23	.036-.1	.03-.1
Rinse-off	18	15	NR	.05-.06
Diluted for (bath) use	NR	NR	NR	NR
Exposure type				
Eye area	2	1	NR	NR
Incidental ingestion	NR	NR	NR	NR
Incidental inhalation-spray	9 <sup>a</sup> ; 8 <sup>b</sup>	9 <sup>a</sup> ; 5 <sup>b</sup>	NR	.1 <sup>a</sup> ; .05 <sup>b</sup>
Incidental inhalation-powder	1; 8 <sup>b</sup> ; 3 <sup>c</sup>	5 <sup>b</sup> ; 3 <sup>c</sup>	.036 <sup>c</sup>	.05 <sup>b</sup>
Dermal contact	37	32	.036-.1	.04-.1
Deodorant (underarm)	3 <sup>a</sup>	NR	.05	.1 <sup>a</sup>
Hair – non-coloring	14	5	NR	NR
Hair-coloring	1	NR	NR	NR
Nail	NR	NR	NR	.03
Mucous membrane	1	NR	NR	NR
Baby products	5	5	.036	NR

<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.

NR, no reported use.

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