# *N*,*N*-BIS(2-HYDROXYETHYL)-*p*-PHENYLENEDIAMINE SULFATE

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report on the Safety Assessment of *N*,*N*-Bis(2-Hydroxyethyl)-*p*-Phenylenediamine Sulfate in 1992.[1] The Panel concluded that this ingredient is safe as a cosmetic ingredient in present practices of use and concentration, as described in the safety assessment.

Because it has been at least 15 years since the final report was published, in accordance with CIR Procedures, the Panel determined whether the safety assessment should be reopened. At the June 2022 meeting, the Panel considered updated information regarding product types and ingredient use frequencies as reported in the US Food and Drug Administration (FDA) Voluntary Cosmetic Registration Program (VCRP) database, and the maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council (Council). When the report was published, the number of reported uses in hair dye formulations was 183.[1] The FDA reported that 119 uses were reported at concentrations of $\leq$ 0.1%, 55 uses were reported at concentrations of 0.1% to 1%, and 9 uses were reported at concentrations of 1% to 5%. The FDA VCRP database in 2022 has reported an increase in uses to a total of 193.[2] A survey performed by the Council in 2022 reported the maximum use concentration range to be 0.006% to 1.3% in hair dye formulations.[3] 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 1992 forward, and new data were found.[4-6] The Panel agreed, however, that 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 majority of the new data were summarized in the European Union's Scientific Committee on Consumer Products (SCCP) opinion from 2006, in which the SCCP concluded that *N*,*N*-Bis(2-Hydroxyethyl)-*p*-Phenylenediamine Sulfate did not pose a risk to the health of the consumer (apart from its sensitizing potential) when use as an oxidative hair dye substance at up to a maximum concentration of 2.5% after mixing with hydrogen peroxide.[6] Along with the SCCP. the Panel noted that *N,N*-Bis(2-Hydroxyethyl)-*p*-Phenylenediamine Sulfate is a tertiary amine; the Panel cautions that this ingredient should not be used in cosmetic products in which *N*-nitroso compounds can be formed.

After reviewing updated frequency and concentration of use data and toxicity and safety data, the Panel determined to not reopen this safety assessment on *N,N*-Bis(2-Hydroxyethyl)-*p*-Phenylenediamine Sulfate, and reaffirmed the original conclusion.

**Table 1. Current and historical frequency and concentration of use according to duration and exposure**

| | ***N*,*N*-Bis(2-Hydroxyethyl)-*p*-Phenylenediamine Sulfate** | | | |
|---|---|---|---|---|
| | **# of Uses** | | **Max Conc of Use (%)** | |
| | **2022[2]** | **1984[1]** | **2022[3]** | **1984[1]** |
| **Totals*** | **193** | **183** | **0.006-1.3** | **≤ 5‡** |
| *Leave-On* | *NR* | *NR* | *NR* | *NR* |
| *Rinse-Off* | *193* | *183* | *0.006-1.3* | *< 5‡* |
| *Diluted for (Bath) Use* | *NR* | *NR* | *NR* | *NR* |
| Eye Area | NR | NR | NR | NR |
| Incidental Ingestion | NR | NR | NR | NR |
| Incidental Inhalation-Spray | NR | NR | NR | NR |
| Incidental Inhalation-Powder | NR | NR | NR | NR |
| Dermal Contact | NR | NR | NR | NR |
| Deodorant (underarm) | NR | NR | NR | NR |
| Hair - Non-Coloring | NR | NR | NR | NR |
| Hair-Coloring | 193 | 183 | 0.006-1.3 | < 5‡ |
| Nail | NR | NR | NR | NR |
| Mucous Membrane | NR | NR | NR | NR |
| Baby Products | NR | NR | NR | NR |

*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.
‡ The concentration of use data were presented in range groups at the time this report was written. For *N*,*N*-Bis(2-Hydroxyethyl)-*p*-Phenylenediamine Sulfate, 119 uses were reported at concentrations < 0.1%, 55 uses were reported between 0.1%-1%, and 9 uses were reported between 1%-5%.
NR – not reported

## REFERENCES


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2. U.S. Food and Drug Administration Center for Food Safety & Applied Nutrition (CFSAN). 2022. Voluntary Cosmetic Registration Program - Frequency of Use of Cosmetic Ingredients. College Park, MD.

3. Personal Care Products Council. 2022. Concentration of Use by FDA Product Category - *N*,*N*-Bis(2-Hydroxyethyl)-*p*-Phenylenediamine Sulfate. [Unpublished data submitted by the Personal Care Products Council on January 10, 2022].

4. European Commission. 2022. Cosing database; following Cosmetic Regulation (EC) No. 1223/2009. http://ec.europa.eu/growth/tools-databases/cosing/. Date Accessed: April 20, 2022.

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6. Scientific Committee on Consumer Products (SCCP). 2006. Opinion on N,N-bis(2-hydroxyethyl)-*p*-phenylenediamine sulfate: COLIPA No. A50. SCCP/0983/06. https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_065.pdf. Date Accessed: April 20, 2022.