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Final Report on the Safety Assessment of Dimethyl Stearamine[1]

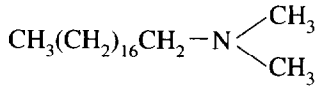
Abstract: Dimethyl Stearamine is a tertiary aliphatic amine that is used as an antistatic agent in cosmetics at concentrations up to 5%. Bacterial studies suggest antibacterial action at concentrations as low as 3.6 moles per 10^6. Mutagenicity testing was negative, even though the ingredient can act as a biocide. Additional safety test data are needed, including concentration of use, impurities, inhalation toxicity (or information on particle size), ocular irritation, dermal irritation and sensitization, and a 28-day dermal toxicity study (possibly followed by absorption, distribution, and metabolism studies). Additionally, if significantly absorbed, reproduction and developmental toxicity (including teratogenicity) data and two genotoxicity assays, one using a mammalian system, are needed. If the mutagenesis data are positive, then a dermal carcinogenesis study may be needed. In the absence of this further information, the available data are insufficient to support the safety of Dimethyl Stearamine in cosmetics. **Key Words:** Dimethyl Stearamine—Mutagenicity—Ocular irritation—Dermal irritation.

Dimethyl Stearamine is a tertiary aliphatic amine that is used as an antistatic agent in cosmetic formulations. This report reviews the safety data on this ingredient.

CHEMISTRY

Definition and Structure

Dimethyl Stearamine (CAS No. 124-28-7) is the tertiary aliphatic amine that conforms generally to the formula (Wenninger and McEwen, 1993):



Other names for this ingredient are: *N,N*-Dimethyl-1-Octadecanamine; Dimethyl Stearylamine; 1-Octadecanamine, *N,N*-Dimethyl-; Stearyl Dimethyl Amine (Wenninger and McEwen, 1993); and *N,N*-Dimethyloctadecylamine (RTECS,

[1] Reviewed by the Cosmetic Ingredient Review Expert Panel.
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1993). Trade names for Dimethyl Lauramine are: Adogen MA-108, Armeen DM18D, and Kemamine T-9902 (Wenninger and McEwen, 1993).

Chemical and Physical Properties

Dimethyl Stearamine is a clear liquid (NTIS, 1978) that has a molecular weight of 297.64 (RTECS, 1993). It has a melting range of 68–73°F and a flash point of 330°F. Dimethyl Stearamine is very soluble in white mineral oil and ethyl ether; is soluble in methanol, ethanol, acetone, isopropanol, chloroform, and toluene; and is slightly soluble in carbon tetrachloride. It is not soluble in water (NTIS, 1978).

As a tertiary amine, Dimethyl Stearamine has the potential to form carcinogenic nitrosamines in the presence of N-nitrosating agents. When 19 hair-care products were analyzed for the presence of *N*-nitroso-*N*-methyloctadecylamine, no detectable levels (detection limit: 20 ppb) of this nitrosamine were found in any of the products. However, the authors cautioned that the number of products tested was small and could not be considered representative of Dimethyl Stearamine in general (Morrison et al., 1983).

Method of Manufacture

In general, tertiary amines are formed by reacting a secondary amine with additional nitrile, imine, or alcohol at high temperatures and under hydrogenated conditions. They can also be produced by methylating primary or secondary fatty amines (NTIS, 1978).

Analytical Methods

Dimethyl Stearamine can be determined using gas chromatography (Suzuki et al., 1986).

COSMETIC USE

Dimethyl Stearamine is used as an antistatic agent in cosmetic formulations (Wenninger and McEwen, 1992). The product formulation data submitted to the Food and Drug Administration (FDA) in 1994 reported that Dimethyl Stearamine was used in a total of 55 cosmetic product formulations (Table 1) (FDA, 1994). Concentration of use values are no longer reported to the FDA by the cosmetic industry (Federal Register, 1992). However, product formulation data submitted to the FDA in 1984 stated that Dimethyl Stearamine was used at concentrations up to 5% in rinses (non-coloring) and up to 1% in hair conditioners, sprays, and straighteners and other hair preparations (FDA, 1984).

BIOLOGY

Antibacterial Properties

Dimethyl Stearamine has antibacterial activity against *Streptococcus faecalis*. A concentration of 3.6 mol/L $\times$ 10^6 caused 50% growth inhibition. The most active compound in this study was heptadecylamine, which inhibited growth by

TABLE 1. *Cosmetic product formulation data on Dimethyl Stearamine (FDA, 1994)*

Product category	Total no. of formulations in category	Total no. of formulations containing ingredient
Baby lotions, oils, powders, and creams	45	1
Hair conditioners	614	6
Hair sprays (aerosol fixatives)	306	29
Hair straighteners	61	1
Rinses (non-coloring)	58	2
Tonics, dressings, and other hair grooming aids	563	12
Other hair preparations	376	4
1994 Totals		55

50% at a concentration of 1.9 mol/L $\times 10^6$. When structure–activity analyses were conducted, the authors noted that for tertiary amines, the bulk of the ammonium head along with the overall hydrophobic properties of the molecule appeared to determine activity (Bass et al., 1975).

Absorption, Distribution, and Metabolism

Published data on the absorption, distribution, and metabolism of Dimethyl Stearamine were not found.

ANIMAL TOXICOLOGY

Acute Oral Toxicity

The oral LD_{50} for Dimethyl Stearamine was 780 mg/kg for rats (Cutler and Drobeck, 1970).

REPRODUCTION AND DEVELOPMENTAL TOXICITY

Published data on the teratogenicity of Dimethyl Stearamine were not found.

MUTAGENICITY

Dimethyl Stearamine was tested for mutagenicity using the paper-disk method. Nutrient agar was seeded with streptomycin-dependent Sd-4-73 *Escherichia coli* and filter-paper disks containing Dimethyl Stearamine were placed on the surface of the cultures. The frequency of reversion from streptomycin dependence to independence was used as the measure of mutagenicity. Dimethyl Stearamine was negative in this test (Szybalski, 1958).

CARCINOGENICITY

Published data on the carcinogenicity of Dimethyl Stearamine were not found.

CLINICAL ASSESSMENT OF SAFETY

Published clinical data on Dimethyl Stearamine were not found.

SUMMARY

Dimethyl Stearamine is an antistatic agent used in a variety of hair care and baby products. The limited safety data on this ingredient indicate that Dimethyl Stearamine has antibacterial properties and that its oral LD_{50} is 780 mg/kg for rats. Negative results were obtained in a paper-disk mutagenicity assay.

DISCUSSION

Section 1, paragraph (p), of the CIR Procedures states that "A lack of information about an ingredient shall not be enough to justify a determination of safety." In accordance with Section 30(j)(2)(A) of the Procedures, the Expert Panel informed the public of its decision that the data on Dimethyl Stearamine are insufficient to determine whether Dimethyl Stearamine, under each relevant condition of use, is either safe or unsafe. The Expert Panel released a 'Notice of Insufficient Data Announcement' on May 27, 1994, outlining the data needed to assess the safety of Dimethyl Stearamine. The types of data required included:

1. Concentration of use.
2. Impurities.
3. Inhalation toxicity or information on particle size.
4. Ocular irritation data.
5. Dermal irritation and sensitization.
6. 28-day dermal toxicity.
7. Depending on the results of the 28-day dermal toxicity test, dermal absorption, distribution, and metabolism data may be needed.
8. If significantly absorbed, then teratogenicity data* *and* two genotoxicity assays (one using a mammalian system); if positive, a dermal carcinogenicity assay by NTP standards may be required.

No offer to supply the data was received. In accordance with Section 45 of the CIR Procedures, the Expert Panel issued a Final Report—Insufficient Data. When the requested new data are available, the Expert Panel will reconsider the Final Report in accordance with Section 46 of the CIR Procedures, Amendment of a Final Report.

CONCLUSION

The CIR Expert Panel concludes that the available data are insufficient to support the safety of Dimethyl Stearamine and its hydrochloride salt as used in cosmetics.

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* While the possibility that teratogenicity data might be needed is specifically stated, the reader should also include the potential need for overall reproduction and developmental toxicity data.

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