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

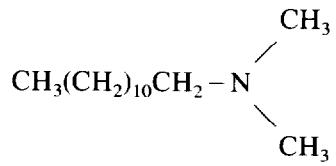
Abstract: Dimethyl Lauramine is a tertiary aliphatic amine intended for use in cosmetics as an antistatic agent, but no actual uses were reported in 1993. The antimicrobial and fungicidal properties of Dimethyl Lauramine are well documented. Because of a lack of other data, however, the safety of Dimethyl Lauramine for use in cosmetic formulations has not been substantiated. The data needed to make a safety assessment include the basic chemistry (pH, impurities, and UV spectral analysis), 28-day dermal toxicity, ocular irritation, human dermal irritation and sensitization, human photosensitization if the material absorbs in the UVA or UVB region of the spectrum, genotoxicity evaluated in two different assays, and carcinogenicity tests if the genotoxicity tests are positive. It cannot be concluded that this ingredient is safe for use in cosmetic products until these safety data have been obtained and evaluated.
Key Words: Dimethyl Lauramine—Cosmetics—Antistatic agent.

Dimethyl Lauramine is a tertiary aliphatic amine. The following report reviews the safety data on this compound as a cosmetic ingredient.

CHEMISTRY

Definition and Structure

Dimethyl Lauramine (CAS No. 112-18-5) is a tertiary aliphatic amine that conforms generally to the following formula (Estrin et al., 1982):



Synonyms for Dimethyl Lauramine are *N,N*-Dimethyl-1-Dodecanamine; 1-Dodecanamine, *N,N*-Dimethyl-; Dimethyl Laurylamine; and Lauryl Dimethyl Amine (Estrin et al., 1982).

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[1]Reviewed by the Cosmetic Ingredient Review Expert Panel.

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Properties

Dimethyl Lauramine is a clear liquid with a molecular weight of 213.46 (Sweet, 1987; Armak, 1978). It has a density of 0.775 (Aldrich, 1992) and is soluble in methanol, ethanol, acetone, isopropanol, chloroform, toluene, carbon tetrachloride, kerosene, white mineral oil, and ethyl ether (Armak, 1978). Dimethyl Lauramine has a melting range of −4 to +5°F and a flash point of 245°F (COC) (Armak, 1978). The boiling point of Dimethyl Lauramine at 3 mm of pressure ranges from 110 to 112°C (Aldrich, 1992).

Dimethyl Lauramine has the potential to form carcinogenic nitrosamines when it is ingested with nitrite. A mixture of Dimethyl Lauramine and nitrite given orally to rats induces neoplasms of the urinary bladder and nonglandular stomach (Lijinsky and Taylor, 1975, 1977; Lijinsky, 1982).

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 (Armak, 1978).

COSMETIC USE

Dimethyl Lauramine is an antistatic agent (Nikitakis, 1988). No data on the formulation or frequency of use for this ingredient were reported to the Food and Drug Administration (FDA) in 1993 (FDA, 1993).

BIOLOGY

Dimethyl Lauramine has antimicrobial, antibacterial, and fungicidal properties (Hueck et al., 1966). Its ability to inhibit is dependent on pH and temperature. In a study with *Streptococcus agalactiae* and *Escherichia coli,* the antimicrobial activity was greater at pH 7 than at pH 8, and at pH 6 a large decrease occurred in the ability of Dimethyl Lauramine to inhibit bacterial growth. Increasing the temperature from 20 to 40°C increased antimicrobial activity (Turck et al., 1982). Dimethyl Lauramine also inhibited the growth of *Streptococcus faecalis* (Bass et al., 1976).

DISCUSSION

Section 1, paragraph (p), of the *CIR Procedures* states that "A lack of information about an ingredient shall not be sufficient 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 Lauramine were not sufficient for determining whether the ingredient, under relevant conditions of use, was safe or unsafe. The Panel released a "Notice of Insufficient Data" on December 4, 1992, outlining the data needed to assess the safety of Dimethyl Lauramine.

No comments regarding the requested data were received during the 90-day public comment period. The following data are necessary to make a safety assessment:

1. Chemistry (pH, impurities, and UV spectral analysis)
2. 28-Day dermal toxicity
3. Ocular irritation
4. Human dermal irritation and sensitization
5. Human photosensitization (only if Dimethyl Lauramine absorbs in the UVA or UVB range)
6. Genotoxicity (at least two different assays)
7. Carcinogenicity, only if the genotoxicity tests are positive.

The Expert Panel issues the final report in accordance with Section 45 of the *CIR Procedures*. When 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 data available on Dimethyl Lauramine are insufficient to support the safety of this ingredient as used in cosmetic products.

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REFERENCES

Aldrich Chemical Co. (1992) *Catalog Handbook of Fine Chemicals: 1992–1993*. Milwaukee, WI: Aldrich Chemical Company, 500.

Armak Co. (1978) Physical and chemical characteristics of Armeen aliphatic amines. Product data bulletin no. 78-5, 1978. NTIS No. OTS0526854.

Bass GE, Powers LJ, Dillingham EO. (1976) Inhibition of *Streptococcus faecalis* by long chain aliphatic monoamines: quantitative structure-activity studies. *J Pharm Sci* 65:1525–7.

Estrin NF, Crosley PA, Haynes CR, eds. (1982) *CTFA Cosmetic Ingredient Dictionary*. 3rd ed. Washington, D.C.: Cosmetic, Toiletry and Fragrance Association, 84, 153, 301.

Food and Drug Administration (FDA). (1993) Cosmetic product formulation data: ingredient use by product category. Computer printout. Washington, D.C.:FDA.

Hueck HJ, Adema DMM, Wiegmann JR. (1966) Bacteriostatic, fungistatic, and algistatic activity of fatty nitrogen compounds. *Appl Microbiol* 34:308–19.

Lijinsky W. (1982) Carcinogenesis by exposure to nitrites and amines. In: Magee PN, ed. *Banbury Report*, vol 12. *Nitrosamines and Human cancer*. Meeting XVI. Cold Spring Harbor, NY: Cold Spring Harbor Laboratory, 257–70.

Lijinsky W, Taylor HW. (1977) Feeding tests in rats on mixtures of nitrite with secondary and tertiary amines of environmental importance. *Food Cosmet Toxicol* 15:269–74.

Lijinsky W, Taylor HW. (1975) Induction of urinary bladder tumors in rats by administration of nitrosomethyldodecylamine. *Cancer Res* 35:958–61.

Nikitakis JM. (1988) *CTFA Cosmetic Ingredient Handbook*. Washington, D.C.: Cosmetic, Toiletry, and Fragrance Association.

Sweet DV, ed. (1987) Registry of toxic effects of chemical substances (RTECS). Cincinnati: National Institute of Occupational Safety and Health (DHHS Publication No. (NIOSH), 87-114.

Turck PA, Bitman J, Thompson MJ. (1982) Mastitis: effect of pH, temperature, and emollients on disinfecting action of *N,N*-dimethyldodecanamine. *J Dairy Sci* 65:2987–92.