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Final Report on the Safety Assessment of Stearic Hydrazide

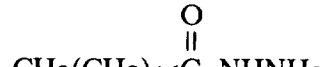
Stearic Hydrazide is reported to be used in 17 cosmetic products at concentrations of use of less than 1.0%. Hydrazides and their salts are prohibited for use in cosmetic products by the European Economic Community. The report concludes that the safety of use of Stearic Hydrazide has not been documented and substantiated and that it is not possible to conclude that the ingredient is safe for use in cosmetic products. The report documents the types of safety test data that are needed to substantiate the safety of use of Stearic Hydrazide in cosmetic products.

INTRODUCTION

Pursuant to Section 30(d)(3) of the Cosmetic Ingredient Review Procedures, the Cosmetic Ingredient Review (CIR) concluded that there was insufficient scientific literature available to justify the preparation of a Scientific Literature Review on Stearic Hydrazide. A Notice of Determination to Proceed With a Review Without the Preparation of a Scientific Literature Review was issued on December 23, 1987. A maximum of 90 days was allowed for the submission of data relevant to the safety of Stearic Hydrazide. No data were received by CIR during this period. Data, available to CIR, concerning the chemistry, use in cosmetic products, and mutagenic potential of Stearic Hydrazide are summarized below.

CHEMISTRY

Stearic Hydrazide, also known as Octadecanoic Acid, Hydrazide, is the organic compound that conforms generally to the formula[1]:



Stearic Hydrazide

Data concerning impurities in Stearic Hydrazide were not available.

COSMETIC USE

Stearic Hydrazide is used as an emollient in cosmetic products.[2]

The Food and Drug Administration (FDA) cosmetic product formulation computer printout[3] is compiled through voluntary filing of such data in accordance with Title 21 Part 720.4 of the Code of Federal Regulations.[4] Ingredients are listed in present concentration ranges under specific product type categories. Since certain cosmetic ingredients are supplied by the manufacturer at less than 100% concentration, the value reported by the cosmetic formulator may not necessarily reflect the actual concentration found in the finished product. The actual concentration would be a fraction of that reported to the FDA. Data submitted within the framework of preset concentration ranges provide the opportunity for overestimation of the actual concentration of an ingredient in a particular product. An entry at the lowest end of a concentration range is considered the same as one entered at the highest end of that range, thus introducing the possibility of a two- to ten-fold error in the assumed ingredient concentration. Stearic Hydrazide is used in cosmetic products at concentrations ranging from ≤ 0.1% to 1.0% (Table 1).

Stearic Hydrazide is not included in the lists of cosmetic ingredients approved for use in cosmetic formulations marketed in Japan.[5–7] Hydrazides and their salts are included in the list of substances that must not be used in cosmetic products marketed in countries of the European Economic Community.[8]

MUTAGENICITY

The mutagenicity of Stearic Hydrazide was evaluated using *Salmonella typhimurium* strains TA98, TA1538, TA1537, TA1535, and TA100. Spot tests were peformed in both the presence and absense of metabolic activation according to the methods of Ames et al.[9] The positive controls were 2-amino-anthracene in DMSO (5 μg/plate), 4-nitro-o-phenylenediamine in DMSO (50 μg/plate), 9-aminoacridine in ethanol (50 μg/plate), and sodium azide in water (50 μg/plate). Untreated cultures, DMSO (100 μl/plate), ethanol (100 μl/plate), and water (100 μl/plate) served as negative controls. There were no significant differences between the reversion rates of the solvent control cultures and the untreated cultures. Reversion rates in positive control cultures were much greater than those in solvent control cultures. Stearic Hydrazide (50 μg/plate) was not mutagenic in any of the strains tested both with and without metabolic activation.[10]

TABLE 1. PRODUCT FORMULATION DATA FOR STEARIC HYDRAZIDE[3]

Product category	*Total no. of formulations in category*	*Total no. containing ingredient*	*No. of product formulations within each concentration range (%)*	
			>0.1–1	*≤0.1*
Eye area cosmetics, skin care preparations, and bath soaps	4150	17	1	16
1988 Totals		17	1	16

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 Stearic Hydrazide were not sufficient for determining whether the ingredient, under relevant conditions of use, was either safe or not safe. The Panel released a Notice of Insufficient Data on January 13, 1989, outlining the data needed to assess the safety of Stearic Hydrazide. The data required included:

1. Genotoxicity data
2. Human skin irritation data
3. Human skin sensitization data
4. Method of synthesis
5. Impurities (particularly free hydrazine)
6. UV absorption spectrum.

No comments regarding the data requested were received during the 90-day public comment period specified in the Notice of Insufficient Data Announcement on Stearic Hydrazide.

CONCLUSION

The safety of Stearic Hydrazide has not been documented and substantiated. The CIR Expert Panel cannot conclude that this ingredient is safe for use in cosmetic products until the appropriate safety data have been obtained and evaluated.

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