

## Final Report on the Safety Assessment of Adipic Acid Dihydrazide

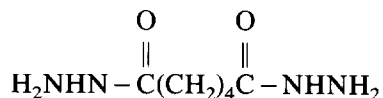
**Summary:** Adipic Acid Dihydrazide has been used as a chemical additive in a variety of cosmetic products. The ingredient was previously reported to be used; however, there are no reported uses of Adipic Acid Dihydrazide during 1992. The available safety test data were insufficient to judge the safety of use of Adipic Acid Dihydrazide in cosmetic products. The types of data required before an evaluation on the safety of use of this cosmetic ingredient include: metabolism (stability of compound in vivo, with respect to hydrolysis to hydrazine); stability and impurities (specifically, data on hydrazine content is necessary); concentration of use in cosmetic formulations. If the interpretation of the preceding requested data indicates that this ingredient could be safely used in cosmetic formulations, the following additional safety test data must be available and evaluated before it can be determined whether this compound may be safely used in cosmetic products. The needed data include: chemistry (including pH, method of manufacture, and UV spectrum); ocular irritation; dermal irritation; dermal sensitization; dermal photosensitization (only if the compound absorbs in the UV spectrum); 28-day dermal toxicity; genotoxicity (at least two assays); carcinogenicity may be requested if genotoxicity assays are positive. **Key Words:** Safety assessment—Adipic Acid Dihydrazide.

The following is a summary of data available to Cosmetic Ingredient Review (CIR) concerning the chemistry and cosmetic use of Adipic Acid Dihydrazide.

### CHEMISTRY

#### Definition and Structure

Adipic Acid Dihydrazide (CAS No. 29659-38-9) is adipic acid reacted with hydrazine, conforming to the formula:



Another name for this compound is hexanedioic acid dihydrazide (Nikitakis et al., 1991).

### USE

#### Cosmetic

Adipic Acid Dihydrazide is used as a chemical additive in a variety of cosmetic products (Nikitakis, 1988). As of 1991, there were two reported uses of Adipic

Acid Dihydrazide listed (product category not stated) (FDA, 1991). As of 1992, there were no reported uses of Adipic Acid Dihydrazide listed (FDA, 1992). Data submitted in 1984 indicated that Adipic Acid Dihydrazide was used at concentrations <0.1% (Table 1) in sachets and other fragrance preparations (FDA, 1984).

### International

The European Economic Community (EEC) Cosmetic Directive (1986) prohibits the use of hydrazides and their salts in cosmetic products. CIR was advised by COLIPA that the use of Adipic Acid Dihydrazide would probably come under the general ban on all hydrazides in cosmetic products (Elder, 1992).

### 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 CIR Procedures, the Expert Panel informed the public of its decision that the data on Adipic Acid Dihydrazide are insufficient to determine whether this ingredient, under each relevant condition of use, is either safe or unsafe. The Panel released a Notice of Insufficient Data Announcement on May 14, 1992 outlining the data needed to assess the safety of Adipic Acid Dihydrazide. The types of data required include:

1. Metabolism (stability of compound in vivo, with respect to hydrolysis to hydrazine);
2. Stability and impurities (especially hydrazine);
3. Concentration of use in cosmetic formulations.

The data received will be reviewed by the Panel. Based on the results of the stability and impurities studies, the Panel has indicated a need for the following additional data:

4. Chemistry (including pH, method of manufacture, and UV spectrum);
5. Ocular irritation;
6. Dermal irritation;
7. Dermal sensitization;

TABLE 1. *Product formulation data (FDA, 1984)*

Product category	Total no. containing ingredient	No. of product formulations within each concentration range (%)	
		>0.1-1	<0.1
Sachets	2	—	2
Other fragrance preparations	2	—	2
1984 totals	4	—	4

8. Dermal photosensitization (only if the compound absorbs in the UVA or UVB range);
9. Twenty-eight-day dermal toxicity;
10. Genotoxicity (at least two assays);
11. Carcinogenicity may be requested if genotoxicity assays are positive.

No offer to supply the preceding safety test data was received. In accordance with Section 45 of the CIR Procedures, the Expert Panel issues a Final Safety Evaluation Report—Insufficient Data. When the requested new data are available, the 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 Adipic Acid Dihydrazide as used in cosmetic products.

**Acknowledgment:** Lynn Willis, Scientific Analyst and Writer, prepared this report.

### REFERENCES

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