

Final Report on the Safety Assessment of PPG-40 Butyl Ether

ABSTRACT

PPG-40 Butyl Ether is the polypropylene glycol ether of butyl alcohol, which is used as a skin and hair conditioning agent in cosmetic products. The oral LD₅₀ for rats, based on a 14-day observation period, was 34.3 ml/kg. No other safety test data were available on PPG-40 Butyl Ether regarding subchronic and chronic toxicity, dermal or eye irritation and sensitization, mutagenicity, carcinogenicity, and teratogenicity. It cannot be concluded that this ingredient is safe for use in cosmetic products until the needed safety data cited in the report have been obtained and evaluated.

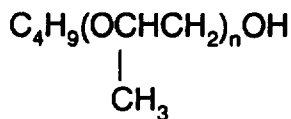
INTRODUCTION

PPG-40 BUTYL ETHER is the polypropylene glycol ether of n-butyl alcohol. It is used in cosmetic formulations as a skin and hair conditioning agent.

CHEMISTRY

Chemical and Physical Properties

PPG-40 Butyl Ether (CAS no. 9003-13-8 [generic]) is the polypropylene glycol ether of butyl alcohol that conforms generally to the formula:



where n has an average value of 40. Other names for PPG-40 Butyl Ether are Ambiflo L-317, Polyoxypropylene (40) Butyl Ether, Polypropylene Glycol (40) Butyl Ether, UCON LB-1715, and Unilube MB-370 (Estrin, 1982).

The molecular weight range of PPG-40 Butyl Ether is 2,400–2,500 (FDA, 1991a).

Impurities

No data were readily available in the scientific literature on the impurities of PPG-40 Butyl Ether.

COSMETIC USE

United States

PPG-40 Butyl Ether is used as a skin and hair conditioning agent (Nikitakis, 1988).

The chemical product formulation data that were submitted to the Food and Drug Administration (FDA) reported that PPG-40 Butyl Ether was used in a total of 46 cosmetic formulations (Table 1) (FDA, 1992). PPG-40 Butyl Ether was used in hair tonics, dressings, grooming aids, dyes, and colors (FDA, 1992).

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 PPG-40 Butyl Ether was used at concentrations up to 50% in tonics, dressings, and other hair grooming aids, and up to 1% in hair dyes and colors (FDA, 1984).

The skin is directly exposed to products containing PPG-40 Butyl Ether, and the potential exists for it to come into contact with the eyes. Products containing this ingredient may be used daily for extended periods of time.

International

PPG-40 Butyl Ether is approved for use as a cosmetic ingredient in Japan (CTFA, 1983).

BIOLOGICAL EFFECTS

No studies were available on the absorption, metabolism, or excretion of PPG-40 Butyl Ether.

ANIMAL TOXICOLOGY

Acute Oral Toxicity

The oral LD₅₀ for rats, based on a 14-day observation period, was 34.3 ml/kg (FDA, 1991).

TABLE 1. COSMETIC PRODUCT FORMULATION DATA FOR PPG-40 BUTYL ETHER*

<i>Product category</i>	<i>Total no. of formulations in category</i>	<i>Total no. of formulations containing ingredient</i>
Tonics, dressings, and other hair grooming aids	548	6
Hair dyes and colors (all types requiring caution statement and patch test)	1112	40
1992 Totals		46

*CIR requests that the cosmetic industry provide current formulation data on each product category.

Source: FDA, 1992.

ASSESSMENT OF SAFETY

No data were available on PPG-40 Butyl Ether regarding subchronic and chronic toxicity, dermal irritation and sensitization, mutagenicity, or carcinogenicity.

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 PPG-40 Butyl Ether were not sufficient for determining whether the ingredient, under relevant conditions of use, was either safe or unsafe. The Panel released a Notice of Insufficient Data on February 12, 1992, outlining the data needed to assess the safety of PPG-40 Butyl Ether. No comments regarding the data requested were received during the 90-day public comment period. The data needed to make a safety assessment are: (1) chemistry (ultraviolet [UV] spectral analysis, pH, impurities, and method of manufacture); (2) 28-day dermal toxicity; (3) ocular irritation (nonanimal studies will be considered); (4) genotoxicity (at least two tests using the commercial product); (5) human irritation and sensitization; (6) carcinogenicity, if the genotoxicity tests are positive.

CONCLUSION

The safety of PPG-40 Butyl Ether 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.

ACKNOWLEDGMENT

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