

Final Report on the Safety Assessment of PPG-9, -25, and -40 Diethylmonium Chloride¹

PPG-9, -25, and -40 Diethylmonium Chloride are quaternary ammonium salts that function as antistatic agents in cosmetic formulations. Only PPG-9 and -25 Diethylmonium Chloride are reported to be used. Neither animal test data nor clinical test results were available. No data were provided in response to requests of interested parties to supply the needed data. Accordingly, the available data are insufficient to support the safety of these ingredients in cosmetics. The additional data needed include: (1) current concentration of use; (2) dermal absorption using PPG-9 Diethylmonium Chloride; if significantly absorbed, then a 28-day dermal toxicity study will be needed; (3) two genotoxicity assays, at least one in a mammalian system, of PPG-9 Diethylmonium Chloride; if positive, then a 2-year dermal carcinogenicity study using NTP methods may be needed; (4) human skin sensitization and irritation at concentration of use; and (5) impurities data, especially nitrosamines. Depending on the findings in these studies, additional data such as reproductive and developmental toxicity may be needed.

INTRODUCTION

PPG-9, -25, and -40 Diethylmonium Chloride are quaternary ammonium salts that function as antistatic agents in cosmetic formulations. This report is a summary of the available safety data on PPG-9, -25, and -40 Diethylmonium Chloride.

CHEMISTRY

Definition and Structure

PPG-9 (CAS No. 9042-76-6), -25, and -40 (CAS No. 9076-43-1) Diethylmonium Chloride are quaternary ammonium salts that generally conform to the formula shown in Figure 1, where *n* averages 9, 25, and 40, respectively (Wenninger and McEwen 1997). PPG-9 Diethylmonium Chloride is also known as Polyoxypylene (9) Methyl Diethyl Ammonium Chloride; Quaternium-6 (Wenninger and McEwen 1997); *N*-Polyoxypylene (9) *N*-Methyl *N,N*-Diethyl Ammonium Chloride (Rempe and Santucci 1992) and Methyl Diethyl Polypropoxyethoxy Ammonium Chloride (Brinker et al. 1993). Other names for PPG-25 Diethylmonium Chloride are Polyoxypylene (25) Me-

thyl Diethyl Ammonium Chloride; *N*-Polyoxypylene (25) *N*-Methyl *N,N*-Diethyl Ammonium Chloride (Rempe and Santucci 1992), and Quaternium-20; whereas PPG-40 Diethylmonium Chloride is also known as Polyoxypylene (40) Methyl Diethyl Ammonium Chloride; Quaternium-21 (Wenninger and McEwen 1997) and *N*-Polyoxypylene (40) *N*-Methyl *N,N*-Diethyl Ammonium Chloride (Rempe and Santucci 1992).

Physical and Chemical Properties

PPG-25 Diethylmonium Chloride is a yellow to straw-colored oily liquid. It is insoluble in mineral oil, but is soluble in water and most organic solvents. The compound has an amine type odor. In a 10% *w/v* solution, PPG-25 Diethylmonium Chloride has a pH of 5.0–7.0, and is neutralized in a 10:6 isopropanol and water solution (Nikitakis and McEwen 1990).

Method of Manufacture

PPG-25 Diethylmonium Chloride is produced by heating diethylamine and propylene oxide in the presence of base. The by-product of the resulting tertiary aminopolyether alcohol polymer, polypropylene glycol, forms when the propylene oxide self-condenses in water. PPG-25 Diethylmonium Chloride results when the mixture of the polymer and polypropylene glycol is quaternized with methyl chloride (Kalish, Weintraub, and Kowblansky 1972).

Analytical Methods

PPG-25 Diethylmonium Chloride can be determined by gas chromatography, nuclear magnetic resonance, mass spectroscopy, gel permeation chromatography, high-speed liquid chromatography, and infrared spectroscopy (Kalish, Weintraub, and Kowblansky 1972).

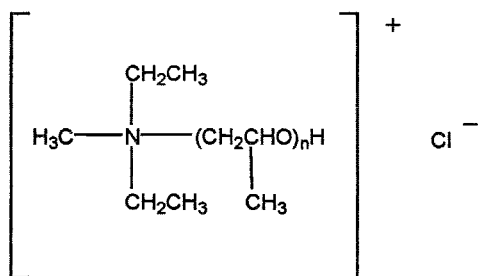
USE

Cosmetic

PPG-9, -25, and -40 Diethylmonium Chloride serve as antistatic agents in cosmetic formulations, and PPG-9 also functions as a hair conditioning agent (Wenninger and McEwen 1997). As detailed in Table 1, PPG-9 Diethylmonium Chloride was used in 18 cosmetic formulations, whereas PPG-25 and -40 Diethylmonium Chloride were reportedly not used (Food and Drug

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**FIGURE 1**

Chemical formula for PPGs Diethylmonium Chloride.

Administration [FDA] 1997). Concentration of use values are no longer reported to the FDA, but product formulation data submitted in 1984 stated that PPG-9 Diethylmonium Chloride was used at concentrations up to 5% (FDA 1984).

International

PPG-9, -25, and -40 Diethylmonium Chloride are listed in the *Comprehensive Licensing Standards of Cosmetics by Category* (CLS) and must conform to the standards of the *Japanese Cosmetic Ingredient Codex* (JCIC) (Yakuji Nippo, Ltd. 1994). They can be used in nail creams, nail enamels, and nail makeup removers without restriction.

Noncosmetic

PPG-9 Diethylmonium Chloride is a surfactant that can be utilized to screen soil contaminated by diesel fuel, other hydrocarbons, and pesticides (Rickabaugh, Clement, and Lewis 1987; Peters et al. 1991; 1992). In horticulture, airblast application of PPG-9 Diethylmonium Chloride reduces fruit set and increases fruit size of Redhaven peaches (Byers and Lyons 1985). Additionally, 15% (*w/w*) PEG-9 Diethylmonium Chloride or 10% PEG-9 Diethylmonium Chloride blended with 5% of a second

surfactant functions as a herbicide to control the spread of warm and cool climate grasses (Brinker et al. 1993).

SUMMARY

PPG-9, -25, and -40 Diethylmonium Chloride are quaternary ammonium salts that function as antistatic agents in cosmetic formulations. In 1996, PPG-9 and -25 Diethylmonium Chloride were reportedly used in 28 and 2 cosmetic formulations, respectively. PPG-40 Diethylmonium Chloride was not used.

PPG-25 Diethylmonium Chloride is produced by autoclaving diethylamine and propylene oxide in the presence of a base. The resulting mixture of a tertiary aminopolyether alcohol polymer and polypropylene glycol is quaternized with methyl chloride to form PPG-25 Diethylmonium Chloride.

Data on animal and clinical toxicology, general biology, and mutagenicity of the PPGs Diethylmonium Chloride were not available.

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-9, -25, and -40 Diethylmonium Chloride were not sufficient for determining whether the ingredients, under relevant conditions of use, were either safe or unsafe. The Panel released an Insufficient Data Announcement on June 4, 1996, outlining the data needed to assess the safety of the PPGs Diethylmonium Chloride. No comments were received during the 90-day public comment period. Additional data needed to make a safety assessment are: (1) current concentration of use; (2) dermal absorption using PPG-9 Diethylmonium Chloride; if significantly absorbed, then a 28-day dermal toxicity study will be needed; (3) two

TABLE 1
Cosmetic formulation data on PPGs Diethylmonium Chloride (FDA 1997)

Product category	Total no. of formulations in product category	Total no. of formulations containing ingredient
Other bath preparations	141	1
Hair sprays (aerosol fixatives)	255	5
Rinses (noncoloring)	42	1
Shampoos (noncoloring)	825	2
Tonics, dressings, and other hair grooming aids	512	3
Wave sets	55	1
Other hair preparations	311	2
Bath soaps and detergents	341	2
Other personal cleanliness products	262	1
1997 total		18

genotoxicity assays, at least one in a mammalian system, on PPG-9 Diethylmonium Chloride; if positive, then a 2-year dermal carcinogenicity study using National Toxicology Program (NTP) methods will be needed; (4) dermal sensitization and irritation in humans at concentration of use; and (5) impurities data, especially nitrosamines. Depending on the findings in these studies, additional data such as reproductive and developmental toxicity may be needed.

CONCLUSION

The Cosmetic Ingredient Review (CIR) Expert Panel concludes that the available data are insufficient to support the safety of PPG-9, -25, and -40 Diethylmonium Chloride for use in cosmetic products.

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