

MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

December 6, 2000

TO: File for Palmitic Acid (CAS #57-10-3)

FROM: Marco Bianchi, Toxics Unit, Air Quality Division

SUBJECT: Initial Threshold Screening Level

The initial threshold screening level (ITSL) for palmitic acid is 50 microgram per cubic meter ($\mu\text{g}/\text{m}^3$) based on an annual averaging time.

The following references or databases were searched to identify data to determine the ITSL: Integrated Risk Information System, Health Effects Assessment Summary Table, National Toxicology Program (NTP) Management Status Report-Online, Registry of Toxic Effects of Chemical Substances, Environmental Protection Bureau (EPB) Chemical Criteria Database, EPB library, Chemical Abstract Service-Online, National Library of Medicine-Online, International Agency for Research on Cancer (IARC), National Institute for Occupational Safety and Health (NIOSH) Pocket Guide, and American Conference of Governmental Industrial Hygienists Guide (ACGIH).

According to Patty's Industrial Hygiene and Toxicology (1994), palmitic acid is a naturally occurring fatty acid component of animal fats and vegetable oils and fats, including olive oil. It is produced commercially by the hydrolysis and fractionation of palm oil, tallow oil, coconut oil, and spermaceti. The major uses of this acid are in the manufacture of soaps, lubricating oils, and waterproofing materials, and in the synthesis of metal palmitates and food-grade additives. Palmitic acid is generally recognized as safe (GRAS — Food and Drug Administration) for use as a direct food additive and is exempt from tolerance requirements for use as diluent for pesticide chemicals. Based on the available data from studies in animals and humans, the Cosmetic, Toiletry, and Fragrance Association concluded that palmitic acid is a nonirritant and safe toward skin in present practice of use and concentration in cosmetics.

RTECS listed an oral rat LD50 of >10 mg/kg, while a study sponsored by the Cosmetic, Toiletry, and Fragrance Association, and published in the Journal of the American College of Toxicology (1987) showed similar results. In this study, no deaths and no significant gross lesions were noted in rats dosed up to 10 milliliters per kilogram (ml/kg), or 8520 mg/kg of commercial grade palmitic acid. Palmitic acid produced no irritation of the eyes of albino rabbits and, applied as the commercial product or as formulations, produced slight or no irritation of rabbit skin.

Tove (1964), observed that when diets containing 5-40% palmitic acid were fed as the monoglyceride for three weeks to weanling mice, depression of growth was observed at all dietary levels. No information was found in the literature assessing reproductive, developmental, or genotoxic effects. However, palmitic acid was administered subcutaneously to Swiss-Webster mice at a dose of 1.0 mg, three times/week for a total of 10 injections to assess tumorigenicity. After a post observation period of 12 to 18 months, one subcutaneous sarcoma was found, and two pulmonary neoplasms were found at 19 to 22 months. It is

unknown if control animals were used in this study. In humans, palmitic acid is a mild irritant to the skin. It is rapidly metabolized, primarily by β -oxidation. In addition to oxidative breakdown, palmitic acid undergoes a variety of conversion reactions in the liver and intestinal mucosa to stearic, oleic, palmitoleic, and myristic acids. After oxidation, the carbon skeleton of palmitic acid is stored in the form of esterified cholesterol or returned to the plasma.

From the data presented above, palmitic acid appears to be relatively non-toxic. It is a naturally occurring fatty acid that is used in the cosmetics industry, and used as a direct food additive. Only when ingested in excessively high concentrations does palmitic acid appear to alter metabolic processes leading to depression in growth. No mention was made in any of the studies that palmitic acid affected the respiratory system of test animals. Since the melting temperature of palmitic acid is 144°F, it appears this compound is a particulate at standard temperature and pressure. Therefore, in order to protect against pulmonary irritation from particulates, it seems appropriate to use the National Ambient Air Quality Standard for particulates of 50 $\mu\text{g}/\text{m}^3$ annual averaging as an ITSL for palmitic acid. The ITSL for palmitic acid = 50 $\mu\text{g}/\text{m}^3$ based on annual averaging.

References:

1. Patty's Industrial Hygiene and Toxicology, 4th Edition, Volume 11(1994). Aliphatic Carboxylic Acids. Editors, George D. and Florence E. Clayton. John Wiley & Sons, Inc. New York. Chapter 36; pgs. 3566-3567.
2. "Final Report on the Safety Assessment of Oleic Acid, Lauric Acid, Palmitic Acid, Myristic Acid, and Stearic Acid," Cosmetic Ingredient Review. Cosmetic, Toiletry and Fragrance Assoc., Washington, J. Am. Coll. Toxicol., 6, 321 (1987).
3. Tove SB., 1964. Journal of Nutrition. 84, 237.

MB:SLB

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