SIDS INITIAL ASSESSMENT PROFILE



SUMMARY CONCLUSIONS OF THE SIAR

Human Health

Oral LD₅₀ value of docosanoic acid for rats is greater than 2,000 mg/kg. There are no available data for irritation and sensitization. In an oral study using the OECD combined repeated dose and reproductive/developmental toxicity test [OECD TG 422], docosanoic acid was administered to rats at doses of 0, 100, 300, 1,000 mg/kg/day for at least 42 days. No deaths occurred and also no substance related toxic effects were observed in any parameters. Therefore, the NOAEL is considered to be 1,000 mg/kg/day for both repeated dose toxicity and reproductive/developmental toxicity. The chemical was negative in both a bacterial mutation test [OECD TG 471, 472] and a chromosomal aberration test *in vitro* [OECD TG 473].

Environment

Docosanoic acid is stable in water but inherently biodegradable (OECD TG 301C: 48-56 % (BOD) after 28-day and OECD TG 302C: 79-96% (BOD) after 28 days). It is likely to be easily degraded in air by the reaction with photochemically produced OH radical (half-life time is estimated as 13.7 hours). Fugacity level III calculation shows that the majority of docosanoic acid is likely to be distributed into water and sediment when it is released into water environment.

Acute toxicity values of docosanoic acid on alga (*Selenastrum capricornutum*), aquatic invertebrate (*Daphnia magna*) or fish (*Oryzias latipes*) are greater than its water solubility (0.016 mg/L). The NOEC in a 21-day reproduction test with *Daphnia magna* is also greater than its water solubility. No significant effects are observed in any tests conducted at extremely high concentrations by using dispersant under OECD test guidelines [TG201, 202, 203, 204, or 211]. There is information that some fatty acids with shorter carbon chain caused no mortality at saturated concentration in certain aquatic organisms (gammarus in freshwater; Medaka in seawater condition). Considering from these data and additional information, it is reasonable to assume that docosanoic acid is not toxic to aquatic organisms at the concentration less than its water solubility (0.016 mg/L). A PNEC is not calculated since NOEC values obtained are above the water solubility of the substance.

Exposure

The production volume of docosanoic acid is estimated at 6,440 tonnes (Production; 5,960 tonnes, import; 480

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tonnes) in Japan in 1999. Docosanoic acid is produced in two companies in Japan, and used as an intermediate for the production of its metal salts, docosylamine or higher alkyl esters in the chemical industry. The chemical is approved for use as a cosmetic ingredient in Japan. Docosanoic acid naturally occurs as triglyceride in most seed fats, animal milk fats, marine animal oils and so on.

The chemical seems to be released mainly into water from production and use sites after biological treatment.

Occupational exposures through inhalation as its vapor or dermal absorption are assumed to be negligible because of the low vapor pressure and low water solubility. While this chemical is produced in a closed system in Japan, workers might be exposed by dust during packing process when the chemical is treated as powder. EHE_{inh} is calculated as 0.71 mg/kg/day (8h operation without protection, body weight; 70 kg, respiratory volume; 1.25 m³/h). Workers are recommended to wear protective equipment (dust mask) during the work to avoid the exposure by dust. General population is indirectly exposed to this chemical through food consumption, since docosanoic acid exists naturally in various foods.

Docosanoic acid may be permitted for use in cosmetics in some region (e.g. Japan), however, no information is available on whether cosmetic products are available which contain docosaonic acid. Further information in this regard was not requested due to the low hazard profile identified for this substance.

NATURE OF FURTHER WORK RECOMMENDED

No recommendation.