SIDS INITIAL ASSESSMENT PROFILE



SUMMARY CONCLUSIONS OF THE SIAR

Human Health

No data is available regarding toxicokinetics, metabolism or distribution of 4,4'-Oxybis(benzenesulfonyl hydrazide) (OBSH). The acute oral toxicity of OBSH was studied by two different groups according to OECD TG 401, under GLP. Based on the results of these studies, the LD50 is considered to be higher than 1000 mg/kg bw. No reliable skin/eye irritation and sensitisation studies were available.

In a combined repeated dose toxicity study with the reproduction/development toxicity screening test (OECD TG 422), OBSH was given orally to Sprague-Dawley rats at concentrations of 0, 5, 15, and 45 mg/kg bw/day. The LOAEL for male rats was 5 mg/kg bw/day and the NOAEL for female rats was 15 mg/kg bw/day. These values were based on the increase in salivation and the enlargement of adrenal glands in all male treatment groups and the increase in liver and kidney weights in females and males dosed with 45 mg/kg bw/day, respectively. In another available 28-day repeated dose toxicity study (OECD TG 407), the main target organs were the kidney and the liver. The NOAELs in rats were 10 mg/kg bw/day for both sexes based on the increases in kidney weights for males and decreases in protein contents in urine for females at 30 mg/kg bw/day.

In *in vitro* bacterial reverse mutation tests (OECD TG 471), OBSH showed positive results in *Salmonella typhimurium* strains TA 98, TA 100, TA 1535 and/or *Escherichia coli* (WP2 *uvrA*) with or without S9 mix. In a chromosomal aberration test (OECD TG 473) with CHL cells and in a DNA repair test with rat and mouse hepatocytes, OBSH elicited positive results. However, in an *in vivo* mammalian erythrocyte micronucleus assay (OECD TG 474), OBSH did not exhibit mutagenic effects in mouse bone marrow cells at doses ranging from 375 to 1,500 mg/kg bw.

No data on carcinogenicity is available.

The reproductive and development toxicities were evaluated using OECD TG 421 and OECD TG 422 in rats. Non-specific signs of intoxication were observed at the highest dose tested. Consideration of the results of these two studies indicates that the NOAEL for reproductive and developmental toxicity is 45 mg/kg bw/day.

Environment

OBSH is an odorless fine white crystalline powder with a melting point of 150 ~ 160 °C. At the melting point, OBSH is decomposed. An experimental water solubility value is 62.5 mg/l at 20 °C. The measured vapor pressure was $\leq 5.43 \times 10^{-6}$ hPa at 80 °C. The vapor pressure and octanol-water partition coefficient (log K_{ow}) were estimated as 8.89 x 10⁻¹⁰ Pa at 25 °C and 0.08, respectively.

The atmospheric half-life of OBSH based on photodegradation (i.e., reaction with hydroxyl radical) is 5.1 days. OBSH is not readily biodegradable (10.9%, TG301C), however, is rapidly hydrolyzed in water. Half-lives of OBSH in water (TG111, 25 °C) were reported as 9.2 hours at pH 4, 7.2 hours at pH 7 and 5.8 hours at pH 9. Identified major degradation products were 4,4'-oxybis(benzenesulfonic acid) and hydrazine (CAS No. 302-01-

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2). A bioaccumulation study (TG305) was performed and BCF values ranged from 0.3 to 3.

Following equal releases to air, water, and soil, the fugacity model level III (EQC model) predicts that OBSH will mainly partition to soil (Air = 7.90 x 10^{-5} %; Soil = 98.6%; Water = 1.41%; Sediment = 2.83 x 10^{-3} %). If OBSH is emitted to air or soil, it will mainly partition to soil (99%). If it is released to water, OBSH will remain in water (99.8%). From the estimated soil adsorption coefficient (K_{oc} = 8182) and Henry's law constant (1.28 x 10^{-12} Pa m³/mole), OBSH has a low potential of mobility in soil and is non-volatile from water. OBSH is not readily biodegradable under aerobic condition. This substance has low bioaccumulation potential (Measured BCF = 0.3 ~ 3 and Calculated BCF = 3.162).

The following toxicity data for aquatic organisms are available for OBSH (n = nominal concentration; m = measured concentration). It should be noted that these values may reflect toxic effects of degradation products as well as the parent compound.

Fish [Oryzias latipes]:	$LC_{50} (96 \text{ hrs}) = 74 \text{ mg/L} (n)$ $LC_{50} (96 \text{ hrs}) > 6.6 \text{ mg/L} (m)$
Invertebrates [Daphnia magna]:	$EC_{50} (48 \text{ hrs}) = 15 \text{ mg/L} (n)$ $EC_{50} (48 \text{ hrs}) = 2.9 \text{ mg/L} (m)$
Algae [Pseudokirchneriella subcapitata]:	EC_{50} (72 hrs) = 6.7 mg/L (Growth rate); (n) EC_{50} (72 hrs) = 2.2 mg/L (Biomass) (n) EC_{50} (72 hrs) = 3.0 mg/L (Growth rate) (m)

Exposure

In Korea, the production volume of OBSH was 711, 735, and 806 tonnes in 2002, 2003, and 2004, respectively. In the United States, the production volume of OBSH was 453 tonnes in 2000. OBSH is produced at volumes below 100 tonnes/year in the EU, Sweden, and Japan.

OBSH is manufactured by the reaction of 4,4'-oxybis(benzenesulfonyl chloride) and hydrazine in China. OBSH is mainly used as a blowing agent in the manufacturing process of sponge rubber and expanded plastics.

Environmental release to atmosphere may occur during the manufacturing or processing such as drying, handling, mixing, and pulverizing processes. Dusts from manufacturing and processing are controlled by local and general ventilation systems. Monitoring results for total dust containing OBSH in air ranged from 5.2 to 8.0 mg/m³, which were under the emission limit value of 100 mg/m³.

In the production and processing facilities of Korea, workers might be exposed to OBSH dust by inhalation during drying, mixing, pulverizing, and packaging the raw material. Occupational exposure is controlled with personal protective equipments such as dust masks, gloves, glasses, and with ventilation. The 8hr-TWA concentrations of dust for workplace in OBSH were $0.4 \sim 2.0 \text{ mg/m}^3$. These values were less than occupational exposure limit of 10 mg/m³ as total dust.

In the sponsor country, a direct consumer exposure is not likely to occur. During the foaming process OBSH decompose into nitrogen and 4,4'-oxybis(benzenesulfonic acid). 4,4'-Oxybis (benzenesulfonic acid) is further transformed into polydithiophenyl ether and polymetric thiosulfonate. Therefore, there are no direct use or consumer products containing this substance.

RECOMMENDATION AND RATIONALE FOR THE RECOMMENDATION AND NATURE OF FURTHER WORK RECOMMENDED

Human Health: This chemical is to be a candidate for further work. The chemical possesses properties indicating hazards for human health (acute repeated dose and *in vitro* but not *in vivo* genetic toxicity). An exposure assessment and, if then indicated, a health risk assessment is recommended.

Environment: The chemical is a candidate for further work. The chemical possesses properties indicating a hazard to the environment (acute aquatic toxicity). Therefore, an exposure assessment and, if then indicated, an environmental risk assessment is recommended.

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