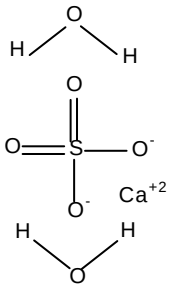
SIDS INITIAL ASSESSMENT PROFILE

CAS No.	10101-41-4
Chemical Name	Calcium sulfate, dihydrate
Structural Formula	

SUMMARY CONCLUSIONS OF THE SIAR

Human Health

There is no information on toxicokinetics, metabolism and distribution.

The acute oral toxicity study [OECD TG 420, Fixed dose procedure] of calcium sulfate, dihydrate showed that this chemical did not cause any changes even at 2,000 mg/kg b.w. Therefore, the oral LD_{50} value was more than 2,000 mg/kg b.w. for female rats without specific clinical signs.

Calcium sulfate, dihydrate was not irritating to the skin of rabbits at 1, 24, 48 and 72 hours after removal of the patches [OECD TG 404]. There is no indication of skin sensitisation in guinea pigs [OECD TG 406].

In a Combined Repeated Dose and Reproduction/Developmental Toxicity Screening Test in rats [OECD TG 422], calcium sulfate, dihydrate was administered by gavage at the dose levels of 0, 100, 300 and 1,000 mg/kg bw/day for more than 35 days and 41 ~ 45 days for male and female animals, respectively. Calcium sulfate, dihydrate had no critical influence on test items such as mortality, body weights (organ weight), food consumption, necropsy, reflex action, grip strength and behaviour of the animals. However, the values of total protein, albumin, blood urea nitrogen, aspartate aminotransferase, alanine aminotransferase and creatinine were decreased at 300 mg/kg bw/day and 1,000 mg/kg bw/day treatment for male animals showing that the test substance might affect the excretion process, distribution or metabolism of test substance in relation to the kidney. Based on these results, the LOAEL and NOAEL were determined to be 300 mg/kg bw/day and 100 mg/kg bw/day for male rats. In case of female rats, no effects were observed at the top dose tested (1,000 mg/kg bw/day).

In the above mentioned reproduction/developmental toxicity screening test [OECD TG 422], male and female rats, were dosed for 35 days and 41 ~ 45 days respectively and the pre-mating exposure period was 14 days. No adverse effects were observed in terms of fertility, delivery and nursing in parent animals during the test period. There were no signs of reproduction/developmental toxicity on the body weight, gestation index, sex ratio, clinical signs or viability up to 1,000 mg/kg/day (highest dose tested).
Bacterial gene reverse mutation tests in *Salmonella typhimurium* (strains TA98, TA100, TA1535 and TA1537) and *Escherichia coli* WP2 *uvr*A with and without metabolic activation gave negative results. An i*n vivo* mammalian erythrocyte micronucleus assay using male ICR mice [OECD TG 474], tested at the dose levels of 1,250, 2,500 and 5,000 mg/kg b.w, gave negative results. Accordingly calcium sulfate, dihydrate was not mutagenic *in vivo* and *in vitro.*

According to mutagenicity data, this substance would not be expected to be carcinogenic. There is no data available on carcinogenicity.

Environment

Calcium sulfate, dihydrate is a colorless solid inorganic substance with monoclinic and hygroscopic properties. It has a water solubility of 2.05 g/L at 20 °C. Vapor pressure, n-octanol/water partition coefficient and stability in water are not applicable for the salt of an inorganic substance. Photodegradation, environmental fate modeling and biodegradation are not relevant for an inorganic compound. Bioaccumulation is not expected.

The following studies for aquatic organisms are available:
Green algae (*Selenastrum capricornutum)*: EC_{g50} (72 h) > 100 mg/L (growth rate),
EC_{b50} (72 h) > 100 mg/L (biomass)
Invertebrates (*Daphnia magna):* EC_{50} (48 h) > 100 mg/L.
Fish (*Oryzias latipes*): LC_{50} (96 h) > 100 mg/L.

No data are available on terrestrial organisms. Data from limit tests of 100 mg/L in fish, invertebrates and algae show no harmful effects..

Exposure

In Korea, the estimated production amounts of calcium sulfate, dihydrate were 1,447,000 tonnes in 2002. The total estimated amounts of import were about 59.1 tonnes from four countries in 2002 such as 46 tonnes from China, 3.6 tonnes from Nauru, 1.5 tonnes from South Africa and 8 tonnes from Morocco.

Calcium sulfate, dihydrate is produced in two companies as a waste-solid in the phosphatic fertilizer industry in Korea and this chemical is used as a primary material in gypsum industry, in which residues of calcium sulfate, dihydrate are recycled. Calcium sulfate, dihydrate is used in portland-cement retarders, tiles, polishing powders, paints, paper, dyes, metallurgy, wallboard, food additives and desiccants.

Releases of calcium sulfate, dihydrate into environment might be considered to be significant. As for human exposure, there is a potential for exposure to workers via dust inhalation and dermal routes at the manufacturing or using process. No data were available for workplace measurement of calcium sulfate, dihydrate but measured monitoring data for total dust in workplace was below the exposure limit value TWA of 15 mg/m^3.

RECOMMENDATION

The chemical is currently of low priority for further work.

RATIONALE FOR THE RECOMMENDATION AND NATURE OF FURTHER WORK RECOMMENDED

This substance is currently of low priority for further work because of its low hazard profile.