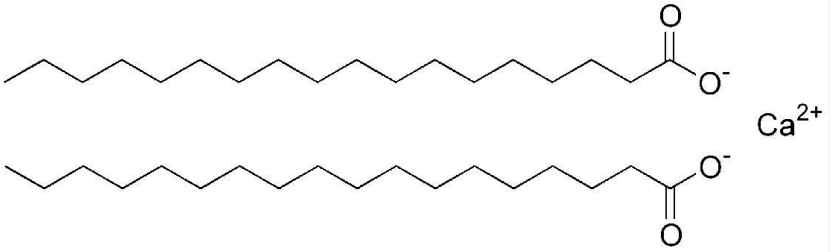
SIDS INITIAL ASSESSMENT PROFILE

CAS No.	1592-23-0
Chemical Name	Calcium distearate
Structural Formula	

SUMMARY CONCLUSIONS OF THE SIAR

Physical and chemical properties

Calcium distearate is a white powder with a melting point of 179-180°C and a calculated boiling point of 661.06°C. It has a bulk density of ≤0.32 g/cm^3 and a calculated vapour pressure of 6×10^{-12} Pa at 25°C. The octanol-water partition coefficient (log K_{ow}) is not applicable for calcium distearate as it has surfactant properties, and it is slightly soluble (≤2 mg/L at 35°C).

Human Health

Stearic acid is a fatty acid that occurs naturally in some animal and vegetable fats and oils and is a normal product of the metabolism of fats. The distribution, metabolism, excretion and storage of radiolabeled ^{14}C-sodium stearate were investigated. Radiolabeled ^{14}C-sodium stearate was administered by stomach tube to rats at a dose of 10Ci 100g of body weight. Negligible amounts (0.1% of the 0.18 mg doses) of the ^{14}C appeared in the urine or feces. Calcium is required for the proper functioning of numerous intracellular and extracellular processes, including muscle contraction, nerve conduction, hormone release and blood coagulation. The calcium ion plays a unique role in intracellular signalling and is involved in the regulation of enzymes and the maintenance of calcium homeostasis is critical.

The oral LD_{50} value of calcium distearate was higher than 2,000 mg/kg bw for female rats [OECD TG 423, Acute Toxic Class Method]. Three animals were dosed with 2,000 mg/kg bw (1st step, no mortality found), following by 2nd step with three additional animals and also 2,000 mg/kg bw dosing. No toxicologically relevant effects were found during necropsy. Loss of body weight, diarrhea and stains around mouth were observed in 1st step. Soiled perineal region, prone position and inanimation were noted in 1st and 2nd step. Those clinical effects were fully recovered at the end of the observation period.

Less reliable studies are available for the skin and eye irritation in animals of calcium distearate. No skin irritation was apparently seen in animal studies in which undisclosed concentrations [probably neat in one case] of calcium stearate were applied to the skin of rats, rabbits and guinea pigs. Also stearic acid showed no evidence of irritation after 24 hours covered application to the intact or abraded skin of rabbits and only mild and temporary effects on the eyes of rabbits. . Calcium stearate has a long history of use in cosmetic and skin pharmaceutical preparations, suggesting that such use is unlikely to cause significant irritation. According to one standard test, the material has been used neat in patch test to identify sensitized individuals. This may suggest that the neat calcium stearate is unlikely to cause irritation in humans.

No data are available for skin sensitization in animals.

In a 28-day repeated dose oral toxicity study in rats following OECD TG 407, the substance was administered

via gavage to 5 animals/sex/dose at 0, 500, 1000 and 2000 mg/kg bw/day for 4 weeks. No death was observed in either sex. There were no treatment-related effects observed for clinical signs, body weight, food consumption, urinalysis, hematology, serum biochemistry, necropsy findings and organ weights at any dose. Based on the results, the NOAEL for repeated dose oral toxicity was considered to be 2000 mg/kg bw/day in both sexes (the highest dose tested).

In a bacterial reverse mutation assay [OECD TG 471] with multiple strains of *Salmonella typhimurium* TA98, TA100, TA1535, TA1537 and *Escherichia coli* WP2*uvr*A, calcium distearate was negative both with and without metabolic activation, when tested up to the limit of solubility. In an *in vitro* chromosomal aberration test [OECD TG 473], it was also negative with and without metabolic activation. Based on these results, calcium distearate is considered to be non genotoxic *in vitro*.

No data are available for the carcinogenicity of calcium distearate.

The reproductive toxicity of calcium distearate has been investigated in a reproductive and developmental toxicity screening test in rats [OECD TG 421]. In this study, calcium distearate was administered via gavage to 10 animals/sex/dose at 0, 250, 500 and 1000 mg/kg bw/day, to male rats from two weeks prior to mating, during the mating period and, approximately, two weeks post mating, and to female rats from two weeks prior to mating, during the mating period, gestation period and 3 days after lactation. There were no deaths among the treated males and females. There were no treatment related effects on parental animals nor in F1 neonates observed at any dose. Therefore, the NOAEL for reproductive and developmental toxicity was considered to be 1000 mg/kg bw/day in males and females. Based on these results, calcium distearate is considered not to be a reproductive and developmental toxicant.

Calcium distearate has a low hazard profile for human health. Adequate screening-level data are available to characterize the human health hazard for the purposes of the OECD Cooperative Chemicals Assessment Programme.

Environment

Hydrolysis is not expected to occur, as metal salts of fatty acids do not contain functional groups that undergo hydrolysis. In the atmosphere, indirect photo-oxidation by reaction with hydroxyl radicals is predicted to occur with a half-life of 2.99 hours. Several biodegradation tests (OECD TG301B and 301C) showed biodegradation of 55-99%. The weight of evidence indicates that calcium distearate is readily biodegradable under aerobic conditions.

A level III fugacity model calculation for neutral form is considered of no relevance, as at environmentally relevant pH, calcium distearate has surfactant properties. A Henry's law constant of 4.37×10-4 atm.m3/mole suggests that volatilization of calcium distearate from the water phase is expected to be low.

The BCF value based on log K_{ow} is not applicable to calcium distearate as it has surfactant properties.

The following acute toxicity test results have been determined for aquatic species:
Fish [*Oryzias latipes*, OECD TG 203] 96 h LC_{50} > 2.7 mg/L (highest concentration measured in solution, >100 mg/L nominal)
Invertebrate [*Daphnia magna*, OECD TG 202] 48 h EC_{50} >100 mg/L (nominal)
Algae [*P. subcapitata*, OECD TG 201]
72 h E_rC_{50} > 3.5 mg/L (growth rate, highest concentration measured in solution, >100 mg/L , nominal)
72 h E_yC_{50} > 3.5 mg/L (yield, highest concentration measured in solution, >100 mg/L , nominal)

Calcium distearate has a low hazard profile for the environment. Adequate screening-level data are available to characterize the environmental hazard for the purposes of the OECD Cooperative Chemicals Assessment Programme.

Exposure

In the Republic of Korea (sponsor country), the production, use and import volumes of calcium distearate were 9,237, 12,456 and 2,751 tonnes in 2006, respectively. In Sweden, Denmark, Norway and Finland, estimated use volumes of calcium distearate were approx. 2,967, 3,051, 2,795, 2,830 and 2,033 tonnes in 2005, 2006,

2007, 2008 and 2009, respectively.

Calcium distearate is mainly used as stabilizers in plastics additive, lubricants for paper manufacture, paint and ink additives, oxidising agents and synthetic resin in the sponsor country. There is no evidence that calcium distearate is hazardous to the public when it is used as a direct food additive. Food grade calcium distearate is used as flavouring agent and as thickening agent in pharmaceutical products. It is also used as an opacifying agent in shampoos and as a water-in-oil emulsifier in hair grooming products and as an anti-caking agent in dehydrated vegetable products, salt, onion and garlic powder.

The Joint FAO/WHO Expert Committee on Food Additives, reviewing stearic acid and certain of its salts, including calcium stearate, concluded that provided the cation (calcium in this case) 'does not add excessively to the normal body load', these materials need not be considered differently from dietary fatty acids. The committee therefore considered it unnecessary to ascribe a specific acceptable daily intake (ADI) to calcium stearate.

In use facilities of the sponsor country, calcium distearate is handled in closed systems. No monitoring data are available from workplace. Occupational exposure is managed with personal protective equipment such as dust mask, cleanroom garments and gloves.