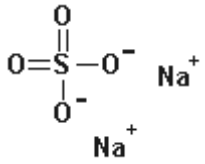
SIDS INITIAL ASSESSMENT PROFILE

CAS No.	7757-82-6
Chemical Name	Sodium sulfate
Structural Formula	

SUMMARY CONCLUSIONS OF THE SIAR

Human Health

Sulfate (and sodium) ions are important constituents of the mammalian body and of natural foodstuffs and there is a considerable daily turnover of both ions (several grams/day expressed as sodium sulfate). Near-complete absorption of dietary sulfates may occur at low concentration, depending on the counter-ion, but absorption capacity can be saturated at higher artificial dosages resulting in cathartic effects. Absorption through skin can probably be ignored since sodium sulfate is fully ionised in solution. One source suggests that very high levels of sulfate in urine may occur due to absorption from dust inhalation. At dietary levels, excretion is mainly in the urine. Sulfates are found in all body cells, with highest concentrations in connective tissues, bone and cartilage. Sulfates play a role in several important metabolic pathways, including those involved in detoxification processes.

The acute toxicity (LD_{50}) of sodium sulfate has not been reliably established but is probably far in excess of 5000 mg/kg. In an inhalation study with an aerosol, no adverse effects were found at 10 mg/m^3. Also human data indicate a very low acute toxicity of sodium sulfate. Human clinical experience indicates that very high oral doses of sodium sulfate, 300 mg/kg bw up to 20 grams for an adult, are well tolerated, except from (intentionally) causing severe diarrhoea. WHO/FAO did not set an ADI for sodium sulfate. There is no data on acute dermal toxicity, but this is probably of no concern because of total ionisation in solution.

Sodium sulfate is not irritating to the skin and slightly irritating to the eyes. Respiratory irritation has never been reported. Based on wide practical experience with sodium sulfate, in combination with the natural occurrence of sulfate in the body, sensitising effects are highly unlikely.

No suitable dermal and inhalation repeated-dose toxicity studies are available. Valid oral repeated dose toxicity studies with 21, 28 and 35 day studies in hens and pigs are available. Toxicity was confined to changes in bodyweight, water and feed intake and diarrhoea. These changes occurred only at very high doses of sodium sulfate. In ruminants, high concentrations of sulfate in food may result in the formation of toxic amounts of sulfites by bacterial reduction the rumen, leading to poly-encephalomalacia. The available data do not allow the derivation of a NOAEL. Based on available consumer data, a daily dose of around 25 mg/kg/day is well tolerated by humans.

There are no data on *in vitro* and *in vivo* genotoxicity, apart from a negative Ames test. There is no valid oral carcinogenicity study. Limited data from experimental studies support the notion that a substance that is abundantly present in and essential to the body is unlikely to be carcinogenic.

Limited data of poor validity did not provide an indication of toxicity to reproduction.

There are considerable data gaps and the data that are available are not all of standard quality or from animals commonly used for toxicity testing. Nevertheless the weight of evidence, combined with previous assessments of both the sodium ion and sulfic ions lead to the conclusion that the identified data gaps need not necessarily be filled.

Environment

Sodium sulphate is a solid inorganic salt well soluble in water (161-190 g/l at 20 ^{o}C) with a melting point of 884 ^{o}C and density of 2.7 g/cm^{3}. In water solutions it is fully dissociated to sodium and sulfate ions.

In water sodium sulfate completely dissociates into sodium and sulfate ions. The ions cannot hydrolyse. In anaerobic environments sulfate is biologically reduced to (hydrogen) sulphide by sulfate reducing bacteria, or incorporated into living organisms as source of sulphur, and thereby included in the sulphur cycle. Sodium sulfate is not reactive in aqueous solution at room temperature. Sodium sulfate will completely dissolve, ionise and distribute across the entire planetary "aquasphere". Some sulfates may eventually be deposited, the majority of sulfates participate in the sulphur cycle in which natural and industrial sodium sulfate are not distinguishable

The BCF of sodium sulfate is very low and therefore significant bioconcentration is not expected. Sodium and sulfate ions are essential to all living organisms and their intracellular and extracellular concentrations are actively regulated. However some plants (e.g. corn and *Kochia Scoparia*), are capable of accumulating sulfate to concentrations that are potentially toxic to ruminants.

Algae were shown to be the most sensitive to sodium sulfate; EC_{50} 120h = 1,900 mg/l. For invertebrates *(Daphnia magna)* the EC_{50} 48h = 4,580 mg/l and fish appeared to be the least sensitive with a LC_{50} 96h = 7,960 mg/l for *Pimephales promelas*. Activated sludge showed a very low sensitivity to sodium sulfate. There was no effect up to 8 g/l. Sodium sulfate is not very toxic to terrestrial plants. *Picea banksiana* was the most sensitive species, an effect was seen at 1.4 g/l. Sediment dwelling organisms were not very sensitive either, with an LC_{50} 96h = 660 mg/l for *Trycorythus sp*. Overall it can be concluded that sodium sulfate has no acute adverse effect on aquatic and sediment dwelling organisms. Toxicity to terrestrial plants is also low.

No data were found for long term toxicity. The acute studies all show a toxicity of sodium sulfate higher than 100 mg/l, no bioaccumulation is expected, therefore it can be considered that no further chronic studies are required.

Exposure

Production: production of sodium sulfate is 4.6 million tonnes/year (1999), of which approximately 50% a by-product of the chemical industry and the remainder is extracted from natural deposits.
Use: The main uses are manufacturing of glass and detergents. Other users are from a wide range of industries, including dyeing technology, electrochemical metal treatment, (animal) feeds, pharmaceuticals, textile, semi-conductors, intermediates, agriculture.
Release: Releases to water come from natural sources as well as from detergents and nearly all industrial sources listed above.
Occupational exposure: Exposure to sodium sulfate-containing dusts or aerosols is possible
Consumer products: Exposure to sodium sulfate occurs via drinking water and through naturally occurring or added amounts in foodstuffs. The maximum acceptable concentration for drinking water is 200 – 500 mg/l sulfate, and is based on taste rather than toxicity.

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

The chemical is of low priority for further work due to its low hazard profile.