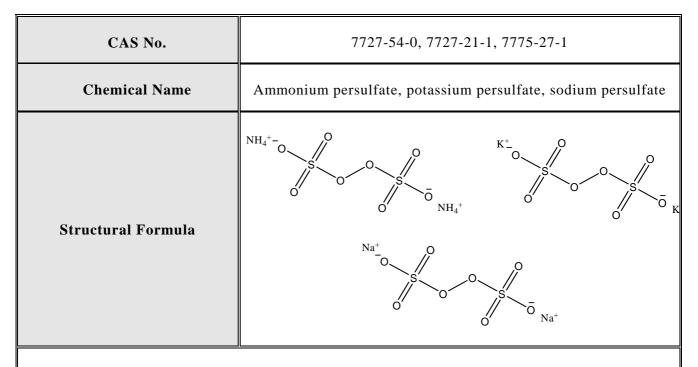
SIDS INITIAL ASSESSMENT PROFILE



SUMMARY CONCLUSIONS OF THE SIAR

Category Rationale

The persulfates category includes molecules with similar chemical structure and similar physical-chemical properties. The inorganic substances differ only by the cationic portion of the salt, which is not expected to influence the hazardous properties of the molecule. The anionic part is identical and, therefore, the three salts are expected to display the same environmental, ecotoxicological and toxicological behaviour based on the available data.

Human Health

Toxicokinetics and dynamics of the salts will be influenced mainly by the persulfate anion. This anion is likely to decompose to hydrogen peroxide and the sulfate ion. The hydrogen peroxide will be rapidly converted to oxygen and water by catalase and peroxidase enzymes.

The acute oral LD_{50} in rats, for the three salts, ranged from 495 mg/kg bw for the ammonium salt to 895 mg/kg bw for the sodium salt to 1130 mg/kg bw for the potassium salt. The acute dermal LD_{50} in rats and rabbits, for all three salts, was greater than 2000 mg/kg bw for the ammonium salt to greater than 10,000 mg/kg bw for the potassium and sodium salts. In acute inhalation studies in rats, the 4-hour LC_{50} was generally greater than the maximum attainable concentration (>5,100 mg/m³ for sodium persulfate and >2,950 mg/m³ for ammonium persulfate). Clinical signs in the inhalation studies included ocular and nasal discharge and respiratory distress.

Ammonium persulfate is slightly irritating to eyes and skin in rabbits. Older eye and skin irritation studies on the potassium and sodium salts produced little irritation in rabbits. Studies in humans indicate that aqueous solutions of 5% persulfate or higher can cause skin irritation. Persulfates also can be irritating to skin and the respiratory track of occupationally exposed individuals (hairdressers).

Results of animal skin sensitization tests (Buehler Test and Maximization Test) were negative when persulfate was applied topically and positive when persulfate was injected intradermally in induction and challenge phases in a non-

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standard Maximization Test. Numerous dermal challenge tests indicate that all three persulfates are dermal and respiratory sensitizers in humans occupationally exposed to persulfates in hairdressing salons and, in one case, in a production facility. In controlled clinical trials with non-occupationally exposed-subjects (NH_4 & Na salts), no sensitization reactions were observed.

In repeated-dose studies, local effects to the gastro-intestinal tract and the airways were reported. Administration of sodium persulfate to rats in the diet for 13 weeks resulted in a LOAEL of 3000 ppm (225 mg/kg bw/day) based on gastrointestinal lesions and reduced body weights. In a subchronic inhalation study in male and female rats, adverse effects at a high dose of 25 mg/m³ ammonium persulfate aerosol consisted of inflammation of the trachea, bronchi, bronchioles, increased lung weight, decreased body weights, rales and increased respiratory rate. A NOAEL of 10.3 mg/m³ was established. Pulmonary function tests of workers in a persulfate production plant (cation not identified) indicated that there were no short- or long-term effects on pulmonary function at levels in the plant (0.5 mg/m³).

None of the three persulfates cause gene mutations or chromosomal effects *in vitro*. *In vivo* tests on sodium persulfate (micronucleus test and UDS test) were negative.

A 51 week dermal study in female SENCAR mice exposed to 0.2 ml of a 200 mg/ml solution of ammonium persulfate showed that ammonium persulfate is neither a tumor promoter nor a complete carcinogen when applied to the skin.

In a developmental/reproduction study with ammonium persulfate in rats (OECD TG 421), no effects on reproductive performance, fertility, fetal anomalies, fetal viability, spermatogenesis, spermatogenic cycle were reported up to 250 mg/kg-bw/day. Dose levels were chosen based on the acute lethality studies for the ammonium salt and on a 90-day repeat-dose study in rats with the sodium salt (high dose: 225 mg/kg-bw/day). In the developmental/reproduction study, animals were dosed prior to and during mating through gestation until lactation day 4. There was a transient depression in pup body weight at the 250 mg/kg dose level on lactation day 0 which resolved by day 4. This effect was not considered adverse. Based on the available data, the persulfates do not show evidence of reproductive or developmental toxicity. The NOAEL is 250 mg/kg bw/day.

Environment

Because they decompose below their melting and boiling points, persulfate decomposition temperatures are reported in their stead as 120, ~100, and >180°C for the ammonium, potassium and sodium persulfates, respectively. The inorganic persulfates are soluble in water (≥ 60 g/L) and their vapour pressures are negligible.

The three persulfate salts will be distributed into the water compartment in the ionic form of the cation, $(NH_4, Na \text{ or } K)$ and persulfate anion. Aqueous persulfates are expected to degrade in the environment mainly via hydrolysis, but metal catalyzed decomposition, and reactions with organic chemicals in the soil or water also are possible.

Persulfates are not expected to adsorb to soil due to their dissociation properties, instability (hydrolysis) and high water solubility. They should behave as free ions or decompose into sulfate ions. In soils, upon decomposition, the cation could form more stable sulfate or bisulfate salts.

Persulfates are not expected to bioaccumulate in the soil or in aqueous solution. They will decompose into inorganic sulfate or bisulfate.

The LC₅₀ values for acute toxicity to fish ranged between 76 and 323 mg/L for ammonium persulfate and from 163 to 771 mg/L for sodium persulfate. The acute toxicity EC_{50} -values for invertebrates were between 120 and 391 mg/L for ammonium persulfate and between 133 and 519 for sodium persulfate. In algae the EC_{50} for ammonium persulfate was 83.7 mg/L and for sodium persulfate 116 mg/L. For potassium persulfate, non-GLP data on fish and daphnia toxicity fell within the range of the other two category members.

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Exposure

For the year 2003 the global market for persulfate salts was estimated to be ca. 76,000 tonnes. The substances are used in polymerization reactions and printed circuit manufacturing. Persulfates also are used as oxidants in hair-bleaching products.

Occupational exposure occurs during manufacturing and during use as hair dyes. The dermal and inhalation routes will be the most important routes of exposure.

During end-use, consumers may be exposed to these substances (e.g., hair dyes may come into contact with the scalp and the hands).

There is potential for environmental exposure during production and processing; however, solid and liquid wastes will be treated to decompose the material or discharged properly as hazardous waste.

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

Human Health: The chemicals in this category possess properties indicating a hazard for human health (eye and skin irritation and skin and respiratory sensitisation). Based on data presented by the Sponsor country, adequate risk management measures (MSDS's and labelling) are being applied and therefore the chemicals in this category are currently of low priority for further work. Other countries may wish to consider their own risk management measures.

Environment: Some chemicals in this category possess properties indicating a hazard for the environment (acute toxicity for fish and algae). However, they are of low priority for further work due to rapid degradation and the absence of bioaccumulation.

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