SIDS INITIAL ASSESSMENT PROFILE

CAS No.	15630-89-4
Chemical Name	Sodium percarbonate
Structural Formula	$2Na_2CO_3 \cdot 3H_2O_2$

SUMMARY CONCLUSIONS OF THE SIAR

Human Health

Sodium percarbonate is an inorganic, water soluble solid of relatively low molecular weight. Dermal absorption is assumed to be low due to the hydrophilic character and the ionic structure of the substance. When sodium percarbonate is getting into contact with body fluids it will dissociate into hydrogen peroxide, carbonate and sodium ions which are all naturally present in the human body. For hydrogen peroxide a high degradation capacity is present in the blood and tissues, making it unlikely that hydrogen peroxide is systemically available. As carbonate is a part of the natural buffer systems in the organism it is unlikely that it is absorbed through sodium percarbonate exposure in amounts that would disturb the normal acid/base balance of the body. Similarly for sodium percarbonate exposure is not expected to contribute significantly to the sodium load of the body. The mode of action is characterized by the local irritation potential in particular to mucous membranes. No systemic effects are anticipated because it is unlikely that the substance is systemically available.

Acute oral LD50 values ranged between 1034 and 2200 mg/kg bw, while the acute dermal LD50 was > 2000 mg/kg bw. The existing animal data on acute toxicity show that sodium percarbonate has a local effect and that systemic effects are not to be expected. In animal tests a slight irritating effect on the skin was reported for solid sodium percarbonate and it was highly irritating to the rabbit eye (not rinsed). Sodium percarbonate did not have sensitizing properties in a test with guinea pigs. The acute studies indicate that most of the acute and local effects can be explained by the release of hydrogen peroxide.

Although a repeated dose study is not available for sodium percarbonate, an additional repeated dose toxicity study in rats with sodium percarbonate is not necessary because the effects can be predicted based on the release of hydrogen peroxide, carbonate and sodium. As it is expected that repeated dose toxicity of sodium percarbonate will mainly be mediated by hydrogen peroxide, no observed adverse effect levels can be defined on the basis of its hydrogen peroxide content. Based on the 90-day drinking water study according to OECD guidelines and GLP with hydrogen peroxide and catalase deficient mice, the predicted NOAEL of sodium percarbonate would be 308 ppm (81 to 115 mg/kg bw/day for males and females, respectively).

Data on the mutagenicity of sodium percarbonate are not available but it is likely that any test results for sodium percarbonate will be similar to those of hydrogen peroxide due to the release of hydrogen peroxide in aqueous media. The available studies on hydrogen peroxide, most of them, in particular the *in vivo* studies, were performed according to OECD guidelines and GLP, are not in support of significant genotoxicity/mutagenicity under *in vivo* conditions. Therefore sodium percarbonate is also unlikely to have any *in vivo* genotoxic potential. For hydrogen peroxide a wider database in particular with regard to local genotoxicity was however, considered desirable in the EU risk assessment report, once suitable validated methods become available.

Carcinogenicity studies with animals and sodium percarbonate are not available. The only component that could give rise to some concerns with regard to this endpoint is hydrogen peroxide. A local carcinogenic effect was observed in the duodenum of a catalase-deficient mouse strain administered 0.4 % hydrogen peroxide in drinking water. Although

an underlying genotoxic mechanism cannot be excluded, the weight of evidence at this time does not suggest that the carcinogenic properties of hydrogen peroxide should be regarded as practically significant.

Neither an animal study on toxicity to reproduction nor a study on developmental toxicity is available for sodium percarbonate. A developmental toxicity study with sodium carbonate, which was well documented and meets basic scientific principles, revealed no substance related fetotoxic, embryotoxic or teratogenic effects. From the nature of the substance it is to be anticipated that neither sodium percarbonate nor hydrogen peroxide and sodium carbonate will be systemically available under human exposure conditions and are thus unlikely to reach the gonads and the developing embryo or fetus. Therefore the substance is unlikely to have any relevant potential for toxicity to reproduction or developmental toxicity and no further animal testing is warranted for those endpoints.

Environment

The water solubility of sodium percarbonate is 140 g/l at 20 ºC. Sodium percarbonate rapidly dissolves in water and dissociates into sodium ions, carbonate ions and hydrogen peroxide. Sodium carbonate and hydrogen peroxide are very water soluble and will therefore remain in the water phase. Hydrogen peroxide is a naturally occurring substance (typical background concentrations < 1 - 30 µg/l). Almost all cells with the exception of anaerobic bacteria produce it in their metabolism. Hydrogen peroxide is a reactive substance in the presence of other substances, elements, radiation, materials and can be degraded by micro-organisms or higher organisms. Hydrogen peroxide is rapidly degraded in a biological waste water treatment plant. Hydrogen peroxide adsorbs poorly to sediment particles and is rapidly degraded, thus accumulation in the sediment is also not expected.

A standard guideline study has been done with a freshwater fish species and sodium percarbonate and this study revealed an acute LC50 value of 71 mg/l for fathead minnow (*Pimephales promelas*). A standard guideline study has been done also with a water flea (*Daphnia pulex*) and in this case an acute EC50 value of 4.9 mg/l was found. Based on a comparison of the results of acute toxicity tests with sodium carbonate, hydrogen peroxide and sodium percarbonate, the acute toxicity of sodium percarbonate can be explained by the formation of hydrogen peroxide. Chronic toxicity studies with sodium percarbonate are not available. However, the chronic toxicity of sodium percarbonate can be predicted from the chronic toxicity of hydrogen peroxide. A chronic toxicity study with invertebrates (zebra mussels) and hydrogen peroxide revealed a NOEC of 2 mg/l. The PNEC of hydrogen peroxide is equal to 10 µg/l and algae are the most sensitive species for hydrogen peroxide. The algal EC50 of hydrogen peroxide was 1.6-5 mg/l, while the NOEC was 0.1 mg/l. Both sodium carbonate and hydrogen peroxide (log Kow < -1) are inorganic chemicals which do not bioaccumulate.

Exposure

The estimated world-wide demand of sodium percarbonate was 300,000 – 500,000 tonnes in 2003. Globally sodium percarbonate is produced at 12 – 24 production sites and about half of them are located in Europe.

The main user of sodium percarbonate is the household cleaning products industry, which is expected to use more than 95 % of the global sodium percarbonate demand. Sodium percarbonate is mainly used as a bleaching chemical in laundry detergents (tablets, compact or regular powders), laundry additives and machine dishwashing products. Minor amounts of sodium percarbonate may be used in products for drain cleaning, multipurpose cleaning, denture cleansing and tooth whitening. Furthermore sodium percarbonate may be used for preservation of raw milk by use of the lactoperoxidase system, when cooling facilities of raw milk are not available. The pure product (100 %) is available for consumers as a laundry additive.

During production and formulation possible routes of exposure for workers are direct skin contact and inhalation of dust. Consumer exposure may occur through direct skin contact with the solid, through skin contact with solutions (e.g. hand wash) and via inhalation of dust particles. Furthermore accidental or intentional overexposure may occur in certain cases for consumers and/or workers.

An emission of sodium percarbonate to the environment could potentially occur during production, formulation and use of the substance. However, hydrogen peroxide is rapidly degraded in a biological waste water treatment plant, while sodium carbonate will be neutralised by such a treatment.

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

The chemical is currently of low priority for further work. The chemical possesses properties indicating a hazard for human health and the environment. These hazards do not warrant further work as they are related to reversible effects (irritation) and acute toxicity which may become evident at high exposure level. They should nevertheless be noted by chemical safety professionals and users.

Note: Member states assessing the exposure of hydrogen peroxide should take into account the sources from the use of sodium percarbonate.