FOREWORD INTRODUCTION

SODIUM PERCARBONATE

CAS N°: 15630-89-4

SIDS Initial Assessment Report

For

SIAM 20

Paris, France, 19-22 April 2005

1. Chemical Name:	Sodium percarbonate
2. CAS Number:	15630-89-4
3. Sponsor Country:	Poland
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4. Shared Partnership with:	Sodium percarbonate consortium
5. Roles/Responsibilities of the Partners:	
• Name of industry sponsor /consortium	Members of sodium percarbonate consortium: Asahi Denka Co., Ltd; DC Chemical Co., Ltd; Degussa AG; FMC Foret, S.A.; KEMIRA Oyj; Mitsubishi Gas Chemical Company, Inc.; Nippon Peroxide; Shangyu Chemical Industry; Solvay S.A (leader) and Zhejiang Jinke Chemicals Co., Ltd. Contact point: Ir. A.G. Berends Solvay S.A., CC-Health, Safety and Environment Rue de Ransbeek 310 B-1120 Brussels, Belgium Tel. + 32 2 2643398
• Process used	Industry did the literature search, collected all references and prepared the dossier. The sponsor country reviewed the dossier.
6. Sponsorship History	
• How was the chemical or category brought into the OECD HPV Chemicals Programme?	The substance is an ICCA HPV chemical. The sponsor country was contacted by the consortium. A HERA report has already been prepared (http://www.heraproject.com).

7. Review Process Prior to the SIAM:	The dossier was reviewed by Prof. S. Czerczak and Dr. D. Pakulska (Nofer Institute of Occupational Medicine, Poland).
8. Quality check process:	
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10. Date of last Update:	
11. Comments:	

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 g/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.

SIDS Initial Assessment Report

1 IDENTITY

1.1 Identification of the Substance

CAS Number: 15630-89-4
IUPAC Name: Sodium percarbonate
Molecular Formula: $2Na_2CO_3 \cdot 3H_2O_2$
Structural Formula: Not applicable
Molecular Weight: 314.06
Synonyms: Percarbonate; Sodium carbonate peroxyhydrate; Disodium carbonate, compound with hydrogen peroxide; PCS

1.2 Purity/Impurities/Additives

Sodium percarbonate is an addition compound of hydrogen peroxide and sodium carbonate. Based on the molecular formula, the pure substance sodium percarbonate contains 32.5 % hydrogen peroxide and 67.5 % sodium carbonate (based on weight). Sodium percarbonate is a white crystalline powder with a purity of > 85 %. Typical impurities are sodium carbonate (< 15 %), sodium sulphate (< 10 %) and sodium chloride (< 5 %).

1.3 Physico-Chemical properties

Table 1 Summary of physico-chemical properties

Property	Value	Comment/reference
Physical state	White crystalline powder	
Melting point	Not applicable	Decomposes when heated (Bertsch-Frank et al., 1995)
Boiling point	Not applicable	Decomposes when heated (Bertsch-Frank et al., 1995)
Relative density	2.14 g/cm^3	Bertsch-Frank et al. (1995)
Vapour pressure	< 10^{-3} Pa at 25°C	Sodium percarbonate is an ionisable, inorganic compound
Water solubility	140 g/l at 20°C	Bertsch-Frank et al. (1995)
Partition coefficient n-octanol/water	Not applicable	Sodium percarbonate is a simple inorganic salt
pH	About 10.5 at 1% concentration (20°C)	
Average particle size diameter	0.3 – 1.5 mm	

1.4 Justification of the use of analog data

As indicated in section 1.2, sodium percarbonate is an addition compound of hydrogen peroxide and sodium carbonate. It rapidly dissolves in water and dissociates into sodium ions, carbonate ions and hydrogen peroxide and therefore in aqueous media only hydrogen peroxide and sodium carbonate are present. For this reason many endpoints of sodium percarbonate can be assessed based on the available data for hydrogen peroxide and sodium carbonate.

Hydrogen peroxide has been assessed at SIAM 9 (OECD, 1999), while sodium carbonate has been discussed at SIAM 15 (OECD, 2003). Based on Council Regulation 793/93 an EU Risk Assessment has been finalized for hydrogen peroxide (European Commission, 2003a,b).

2 GENERAL INFORMATION ON EXPOSURE

2.1 Production Volumes and Use Pattern

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.

Sodium percarbonate is produced by the reaction of sodium carbonate with hydrogen peroxide, which can be done via dry, spray granulation and crystallization processes. In the dry process aqueous hydrogen peroxide solution is sprayed on solid sodium carbonate; a solid-liquid reaction yields sodium percarbonate. In the spray granulation process sodium percarbonate is produced by a fluid bed process. Solutions of sodium carbonate and hydrogen peroxide are sprayed simultaneously into a drying chamber onto seed crystals whereby the water is evaporated. In the crystallization process sodium percarbonate is usually formed by reacting solutions of sodium carbonate and hydrogen peroxide in a crystallizer possibly in combination with salting out agents.

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. Based on the information from the International Association for Soaps, Detergents and Maintenance Products (AISE, 2002), the concentrations of sodium percarbonate in laundry detergents, laundry additives and machine dishwashing products are 7-24 %, 20-56 % and 3-21 %, respectively. However, higher concentrations are used also. Bleach booster products with a sodium percarbonate concentration between 65 and 85 % are placed on the market. Furthermore the pure product (100 %) is available for consumers as a laundry additive.

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 (FAO/WHO, 1991).

The amount of sodium percarbonate, which is used in household cleaning products in Europe, was estimated to be 100,000 – 150,000 tonnes in 2001 but the amount was expected to increase the coming years (HERA, 2002).

2.2 Environmental Exposure and Fate

2.2.1 Sources of Environmental Exposure

An emission of sodium percarbonate to the environment could potentially occur during production and formulation of sodium percarbonate. In most cases the household cleaning products, which contain sodium percarbonate, are added to tap water during use. After use, the spent washing liquor will be disposed via the drain. However, sodium percarbonate dissociates in water into hydrogen peroxide and sodium carbonate. Hydrogen peroxide is effectively degraded and sodium carbonate will be neutralised to sodium bicarbonate ($NaHCO_3$) and therefore entries of sodium percarbonate into the environment via household cleaning products are unlikely (see sections 2.2.3 and 2.2.5).

2.2.2 Photodegradation

No data on photodegradation are available. However, photodegradation of sodium percarbonate is not applicable because it is an inorganic salt with a negligible vapour pressure. Photodegradation in water is also not applicable because sodium percarbonate rapidly dissolves in water and dissociates into sodium ions, carbonate ions and hydrogen peroxide. For hydrogen peroxide an half-life of 24 hours was chosen to represent the average degradation half-life in the atmosphere (European Commission, 2003a,b).

2.2.3 Stability in Water

Sodium percarbonate rapidly dissolves in water and dissociates into sodium ions, carbonate ions and hydrogen peroxide:

$$2\ Na_2CO_3 \cdot 3H_2O_2 \rightarrow 4\ Na^+ + 2\ CO_3^{2-} + 3\ H_2O_2$$

Hydrogen peroxide

Hydrogen peroxide is a reactive substance in the presence of other substances, elements, radiation, materials or cells. Both biotic and abiotic degradation processes are important routes in removal of hydrogen peroxide in the environment:

$$2\ H_2O_2 \rightarrow 2\ H_2O + O_2$$

Abiotic degradation of hydrogen peroxide is due to either reaction with itself (disproportionation), or reaction with transition metals, organic compounds capable of reacting with hydrogen peroxide, reaction with free radicals, heat or light (European Commission, 2003b). Hydrogen peroxide is normally a short-lived substance in the environment but half-lives vary greatly depending on the circumstances.

Sodium carbonate

Both sodium and inorganic carbonate have a wide natural occurrence (UNEP, 1995; OECD, 2003). The sodium concentration was reported for a total number of 75 rivers in North and South America, Africa, Asia, Europe and Oceania, with a 10^{th} percentile of 1.5 mg/l, mean of 28 mg/l and 90^{th} percentile of 68 mg/l (UNEP, 1995). Also the bicarbonate (HCO_3^-) concentration was reported for a total number of 77 rivers in North-America, South-America, Asia, Africa, Europe and Oceania. The 10^{th} percentile, mean and 90^{th}-percentile were 20, 106 and 195 mg/l, respectively.

An emission of sodium carbonate to water will result in an increase in alkalinity and tendency to raise the pH value:

$CO_3^{2-} + H_2O \rightarrow HCO_3^- + OH^-$

$HCO_3^- + H^+ \rightarrow CO_2 + H_2O$

In water the carbonate ion will re-equilibrate until an equilibrium is established. The increase in pH depends on the buffer capacity of the water, which in most cases is determined by the natural background concentration of bicarbonate. To underline the importance of the buffer capacity, a table is included with the concentration of sodium carbonate needed to increase the pH to a value of 9.0, 10.0 and 11.0 at different bicarbonate concentrations. The data of Table 2 were based on calculations (De Groot et al., 2002).

Table 2 Concentration of sodium carbonate (mg/l) needed to increase the pH to values of 9.0, 10.0 and 11.0 (De Groot et al., 2002)

Buffer capacity[A]	**Final pH**[B]		
	9.0	**10.0**	**11.0**
0 mg/l HCO_3^- (distilled water)	1.1 (0.6)	16 (6.1)	603 (61)
20 mg/l HCO_3^- (10^{th} percentile of 77 rivers)	2.7 (21)	32 (26)	766 (81)
106 mg/l HCO_3^- (mean value of 77 rivers)	9.7 (107)	102 (112)	1467 (167)
195 mg/l HCO_3^- (90^{th} percentile of 77 rivers)	17 (196)	175 (201)	2192 (256)

[A] The initial pH of a bicarbonate solution with a concentration of 15 – 233 mg/l is 8.3 (calculated)
[B] Between brackets the final concentration (mg/l) of bicarbonate is given

2.2.4 Transport between Environmental Compartments

For solid sodium percarbonate no transport to the air is expected because of the negligible vapour pressure. When sodium percarbonate is dissolved in water, it dissociates to sodium carbonate and hydrogen peroxide rather easily. The high water solubility and low vapour pressure indicate that sodium carbonate will be found predominantly in the aquatic environment (OECD, 2003). Volatilisation of hydrogen peroxide from surface waters and moist soil is expected to be very low, while it is expected to be highly mobile in soil (European Commission, 2003b). It can be concluded that the aquatic compartment is the main compartment for sodium carbonate and hydrogen peroxide.

2.2.5 Biodegradation

When sodium percarbonate is dissolved in water, it dissociates to sodium carbonate and hydrogen peroxide. Sodium and carbonate can not be biodegraded, although carbonate can be neutralised to bicarbonate (see section 2.2.3).

Standard ready biodegradation tests are not applicable to the inorganic substances like hydrogen peroxide (European Commission, 2003b). However, the data set available was regarded as sufficient to draw conclusions upon the degradation of hydrogen peroxide. Enzymes produced by aerobic bacteria convert hydrogen peroxide to water and oxygen. Furthermore hydrogen peroxide is rapidly degraded in a biological waste water treatment plant (Groeneveld et al., 1999). Not only a

biological waste water treatment plant but also other domestic clarifiers are able to degrade hydrogen peroxide (Guhl et al., 2001).

2.2.6 Bioaccumulation

When sodium percarbonate is dissolved in water, it dissociates to sodium carbonate and hydrogen peroxide. The sodium ion and carbonate ion will not accumulate in living tissues (OECD, 2003). Hydrogen peroxide is reactive and a short-lived polar substance and no bioaccumulation is expected (European Commission, 2003b; OECD, 1999).

2.3 Human Exposure

2.3.1 Occupational Exposure

During production and formulation possible routes of exposure are direct skin contact and inhalation of dust. Accidental eye exposure of workers could potentially occur if they are not adequately protected by personal protective equipment. No accidental exposures during the production and formulation of sodium percarbonate have been reported in the medical literature. Based on the available information, an Occupation Exposure Limit (OEL) has not been established by authorities.

2.3.2 Consumer Exposure

Sodium percarbonate is used as a bleaching chemical in laundry detergents (tablets or powders), laundry additives and machine dishwashing products and therefore sodium percarbonate is available for consumers. Typical concentrations of sodium percarbonate in these products range between ca. 10 and 60 %. The pure product (100 %) is also available for consumers as a laundry additive (see section 2.1). The following relevant consumer contact scenarios can be identified:

1. *Direct skin contact with the solid*
   Consumers can be exposed directly to sodium percarbonate via skin contact with laundry and dishwash products. Given the very short duration of exposure and the very low levels of material expected to be available for skin absorption, also the exposure can be expected to be negligible.
2. *Skin contact via solutions (hand wash)*
   Consumers can be exposed to sodium percarbonate via hand wash laundry. It is not uncommon that laundry is washed by hand and results in direct contact of detergent solutions with skin of the hands and forearms. In water sodium percarbonate rapidly dissociates to hydrogen peroxide and sodium carbonate. The concentrations are below the irritation limit and hydrogen peroxide will further degrade to water and oxygen.
3. *Inhalation of dust particles*
   The dust formation from products containing sodium percarbonate, is so small that the amount is considered negligible for consumers. Based on the large particle size of the pure sodium percarbonate, which is available as a laundry additive, the inhalation exposure is considered negligible.
4. *Accidental or intentional overexposure*
   Accidental or intentional overexposure to sodium percarbonate may potentially occur via inhalation, oral or eye exposure. No fatal cases arising from oral uptake of sodium percarbonate (solutions) have been found in the literature. The German Federal Institute for Health Protection of Consumers and Veterinary Medicine (BgVV, 1999) published a report on products involved in poisoning cases. No fatal case of poisoning with detergents was reported in this report.

Detergent products were not mentioned as dangerous products with a high incidence of poisoning.

Furthermore sodium percarbonate may be used for preservation of raw milk by use of the lactoperoxidase system, but according to this guideline no hydrogen peroxide is present in the milk (FAO/WHO, 1991).

3 HUMAN HEALTH HAZARDS

3.1 Effects on Human Health

3.1.1 Toxicokinetics, Metabolism and Distribution

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 comes into contact with body fluids it will dissociate into hydrogen peroxide, carbonate ions and sodium ions. All three substances are naturally present in the human body. The substances will be discussed separately below.

Hydrogen peroxide

The toxicokinetics, metabolism and distribution of hydrogen peroxide has been described in detail by ECETOC (1993, 1996) and European Commission (2003a,b). Hydrogen peroxide is a normal metabolite in the aerobic cell. There are a number of different hydrogen peroxide metabolizing systems, among them the enzymes catalase and glutathione peroxidase, which control the hydrogen peroxide concentration at different levels and in different parts of the cell as well as in the blood. Hydrogen peroxide will in part be decomposed by the cells of the tissue of first contact but the remaining part could diffuse into the blood vessels. However, the European Commission (2003b) concluded “In view of the high-degradation capacity for hydrogen peroxide in blood it is however unlikely that the substance is systemically distributed, and therefore the endogenous steady state levels of the substance in tissues are unlikely to be affected“.

Carbonate

The toxicokinetics, metabolism and distribution of carbonate has been described by the OECD (2003). Carbonate could potentially increase the pH of the blood. The blood plasma of man normally has a pH of 7.4. Should the pH fall below 7.0 or rise above 7.8, irreversible damage may occur. Compensatory mechanisms for acid-base disturbances return the pH of the blood to normal. If carbonate is absorbed its concentration will be regulated and therefore elevated amounts of carbonate are not expected to be available in the body. Furthermore it should be realised that an oral uptake of sodium percarbonate results in a neutralisation of carbonate in the stomach by the gastric acid. Significant amounts of gastric acids are present in the stomach (pH about 2) which will result in a formation of bicarbonate and/or carbon dioxide. Therefore it is very unlikely that an oral uptake of sodium percarbonate will result in a pH increase of the blood.

Sodium

Sodium ions are readily absorbed throughout the small intestine and are subject to rapid exchange by the large majority of cells in the body. Exposure to sodium percarbonate is not expected to contribute significantly to the sodium load of the body (compared to dietary uptake) and therefore elevated amounts of sodium are not expected to be available in the body.

Conclusion

Dermal absorption of sodium percarbonate is assumed to be low and after getting into contact with body fluids it will dissociate into hydrogen peroxide, carbonate ions and sodium ions. All three components are 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, sodium percarbonate exposure is not expected to contribute significantly to the sodium load of the body.

3.1.2 Acute Toxicity

Oral

A number of oral acute toxicity studies have been carried out in rats using solutions with different concentrations of sodium percarbonate.

An acute oral study has been conducted with rats according to EPA test guidelines and EPA GLP guidelines (Glaza, 1990a). An LD_{50} of 1034 mg/kg bw (body weight) was calculated when groups of 5 rats/sex were given aqueous suspensions containing 700, 1000 or 1500 mg/kg bw orally. Toxic effects included depressed activity, poor co-ordination, diarrhoea, facial staining (red), laboured breathing, absence of pain reflex, excessive salivation and, in the glandular portion of the stomach, coloration changes with occasional thickening of the wall.

Rats were dosed with sodium percarbonate, as a 10 % suspension in maize oil, at dose levels of 1000, 1700, 2900 and 5000 mg/kg bw (Chater, 1978). This study was not performed according to GLP or standard test guidelines. A total number of 24 rats was used in this study (3/sex/dose) and the observation period was 14 days. The LD_{50} was 2000 mg/kg bw and the clinical signs of the surviving animals were raised hair, incontinence, dehydration and atrophy of the testes (further details of clinical signs not available). Necropsy findings indicated that an effect was present in the stomach. Inflammation and necrosis were observed. Death was always found to be associated with the stomach and intestine being enlarged and filled with gas.

Another acute oral study has been conducted with mice and sodium percarbonate (Momma et al., 1986). This study was not performed according to GLP or standard test guidelines. A total number of 130 female and male mice were dosed with a solution of 4 % sodium percarbonate in water at dose levels of 1500 – 3040 mg/kg bw. The LD_{50} value was 2050 mg/kg for the males and 2200 mg/kg for the females. Observed effects were decreased activity, swollen abdomen, diarrhoea, unspecified "behavioural symptoms". At necropsy, dead animals presented a slight degree of congestion or blood spots in the stomach mucosa, and blood was mixed with the stomach contents. Furthermore distension of the gastro-intestinal tract was observed and, in high-dose animals that died, slight congestion of the brain and lungs was found.

The results of these studies are in accordance with results obtained from acute oral studies with hydrogen peroxide at comparable concentration levels (European Commission, 2003a).

Dermal

A single dose of 2000 mg/kg bw sodium percarbonate was administered to the intact skin of 10 New Zealand White rabbits according to EPA test guidelines and EPA GLP guidelines (Glaza, 1990b). The rabbits were exposed to the test substance for 24 hours under occluded conditions. No mortality and no treatment-related overt systemic toxicity were observed during the study and therefore the LD_{50} in rabbits was > 2000 mg/kg bw. The level of dermal irritation was severe. No other macroscopic findings were observed at necropsy.

The results of this study are in accordance with results obtained from acute dermal studies with hydrogen peroxide at a comparable concentration level (European Commission, 2003a).

Inhalation

A reliable acute inhalation toxicity study was not available. The following data was reported without any quality assessment: LC_0 rat > 4.58 mg/l at an exposure time of 1 hour (ICI, 1977). The original reference was not available but the study was reported in the IUCLID published by the ECB (2000). An acute respiratory irritation study has been conducted with male mice (Janssen, 2001). No clinical signs and no indication of treatment related effect was observed at necropsy and no indication of a treatment effect on lung weight was obtained. This study has been described in detail in section 3.1.3.

Conclusion

Standard acute oral and dermal toxicity studies with a high reliability are available. Acute oral LD_{50} values ranged between 1034 and 2000 mg/kg bw, while the acute dermal LD_{50} 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.

3.1.3 Irritation

Skin Irritation

A skin irritation study was conducted with 6 New Zealand White rabbits according to EPA test guidelines and EPA GLP guidelines (Glaza, 1990c). Sodium percarbonate (0.5 g) was moistened with physiological saline (0.9 %) and the rabbits were exposed for 4 hours under semi-occluded conditions. The scoring system for erythema and edema was done according to the Draize method (highest score of 4) and examinations were made at 0.5, 24, 48, 72 and 96 hours and days 7 and 14 after patch removal. Sodium percarbonate resulted in slight to moderate erythema and edema reactions. The highest erythema and edema score was 2 and this score was observed up to 7 days after patch removal. No reaction was discernible anymore after 14 days.

Another skin irritation study was conducted with rats exposed to repeated applications (12 days) of sodium percarbonate, either as solid or as a 1 % aqueous solution (Chater, 1978). This study was not performed according to GLP or standard test guidelines. The powder caused slight to mild irritation to rat skin. Slight erythema and desquamation developed by the 4th application but this did not progress during the remainder of the test period. The 1 % aqueous solution appeared to be practically non-irritant to rat skin, slight erythema and desquamation only becoming apparent during the last 2 days of the test.

During an acute dermal toxicity test with New Zealand White rabbits dermal irritation consisted of slight to severe erythema and edema and slight to marked atonia, desquamation, coriaceousness (“leathery appearance”) and fissuring (Glaza, 1990b) (see section 3.1.2).

A human patch (skin irritation) test with sodium percarbonate was performed using 26 human volunteers and exposing them for 15, 30 or 60 minutes through to 2, 3 and 4 hours (York et al., 1996). Only one out of 26 volunteers (4 %) was considered to have demonstrated a "positive" irritant reaction.

The small irritant effect of sodium percarbonate can be explained by the presence and formation of hydrogen peroxide. Sodium carbonate (solid) and sodium carbonate solutions are essentially non-irritant for the skin (OECD, 2003). Sodium percarbonate itself is only slightly irritant to the skin, which is consistent with the hydrogen peroxide content being just below the irritation limit of

hydrogen peroxide (European Commission, 2003a,b). In the European Union solutions of hydrogen peroxide with concentrations ≥ 35 % are labelled as irritating to skin, while concentrations ≥ 50 % are labelled as corrosive (European Commission, 2005).

Eye Irritation

The eye irritation studies conducted with sodium percarbonate powders and sodium percarbonate solutions are summarized in Table 3.

The eyes of 6 rabbits were exposed to 100 mg sodium percarbonate in powder form according to EPA test guidelines and GLP (Glaza, 1990d). The eyes were exposed for 96 hours and not rinsed. Pain response, blanching of the conjunctivae, petite haemorrhaging of the conjunctivae and corneal peeling of the epithelium was reported. Necrosis of the conjunctivae was seen in one animal at 48 hours and in six animals at 72 and 96 hours (study termination). Sodium percarbonate was considered highly irritating.

Three different eye irritation studies, all reported by Driscoll (1995a,b,c), were done according to OECD Guidelines and GLP. A dose of 100 mg sodium percarbonate was instilled in the eye of a female rabbit (Driscoll, 1995a). The eye was exposed for 24 hours without washing. The eye was examined after 1 and 24 hours. A similar study was conducted in which 100 mg sodium percarbonate was instilled in the eye of a male rabbit without washing (Driscoll, 1995b). The study was stopped after 5 hours and the eye was examined after 1 and 5 hours. In both studies translucent corneal opacity, iridial inflammation, moderate to severe conjunctival irritation and haemorrhage of the nictitating and conjunctival membrane was observed. Sodium percarbonate was considered to be highly irritating.

Amounts of 10 and 50 mg sodium percarbonate were instilled into the eyes of rabbits (Driscoll, 1995c). At the 10 mg dose level observations were made 1, 24, 48 and 72 hours following treatment. Additional observations were made on day 7, 14 and 21 to assess the reversibility of the ocular effects. At the 50 mg dose level observations were made 1, 24 and 48 hours following treatment and this study was stopped after 48 hours. A single 10 mg application of the test material to the non-irrigated eye of three rabbits produced translucent corneal opacity, irridial inflammation, moderate conjunctival irritation and vascularisation of the cornea. Two treated eyes appeared normal 7 days after treatment. Corneal opacity and vascularisation persisted in one treated eye at the 21-day observation and these effects were considered to be irreversible. A single 50 mg application of sodium percarbonate to the non-irrigated eye of one rabbit produced translucent corneal opacity, irridial inflammation and moderate to severe conjunctival irritation. Sodium percarbonate (10 mg) was considered to be corrosive to the eye due to irreversible effects noted in one treated eye.

Table 3 *In vivo* eye irritation tests with sodium percarbonate

Species	Protocol	Concentrations	Result	Reference[A]
Rabbit	Dose of 100 mg, observation for 96 hours, not rinsed, EPA OPP 81-4	powder	Highly irritating	Glaza (1990d) CoR 1
Rabbit	Dose of 100 mg, observation for 24 hours, not rinsed, OECD Guideline 405	powder	Highly irritating	Driscoll (1995a) CoR 1
Rabbit	Dose of 100 mg, observation for 5 hours, not rinsed, OECD Guideline 405	powder	Highly irritating	Driscoll (1995b) CoR 1
Rabbit	Dose of 10 and 50 mg, observation for 21 days and 48 hours, respectively, not rinsed, OECD Guideline 405	powder	Highly irritating Corrosive (one animal, dose of 10 mg)	Driscoll (1995c) CoR 1
Rabbit	Dose of 100 mg, rinsed (after 4 and 30 s) and unrinsed eyes	powder	Without rinse: severe irritation Rinsed after 4 s: no irritation Rinsed after 30 s: mild irritation	Momma et al. (1986) CoR 2
Rabbit	Sodium percarbonate was tested either as 1 % aqueous solution or in powder form	1 % and powder	1 %: no irritation powder: severe irritation	Chater (1978) CoR 2

[A] CoR = Code of Reliability
Reliability : 1 = valid without restrictions, 2 = valid with restrictions, 3 = invalid and 4 = not assignable

An eye irritation study was conducted which was comprised of three groups of three rabbits (Momma et al., 1986). This study was not performed according to GLP or standard test guidelines. Furthermore the test substance several per cent of non-ionic surfactant. Quantities of 100 mg of the solid test substance were instilled in the rabbit left eyes and the eyes were submitted to three different treatments. One group's eye was left unrinsed, one group's left eye was rinsed after 4 seconds and the third group's eye was rinsed after 30 seconds. Severe irritation was observed in the eye of the group of animals which had not been rinsed. When the eyes had been rinsed after 4 seconds no lesion in the cornea and iris was observed. Redness, edema of conjunctiva disappeared after 7 days. When the eyes had been rinsed after 30 seconds no effect on the iris was observed. Redness, edema of conjunctiva persisted up to day 7.

An eye irritation study was performed with New Zealand White rabbits (Chater, 1978). Ocular irritancy was tested by introducing sodium percarbonate into the rabbit eye, either in powder form, or as 1 % aqueous solution (3 animals per group). The powder resulted in moderate initial pain, and severe irritation of cornea, iris and conjunctiva was observed and these effects were still apparent at the end of the 7 days observation period. The 1 % aqueous solution was considered not irritant while the powder was considered a severe irritant.

The eye irritation potential of sodium percarbonate is in accordance with the eye irritation potential of hydrogen peroxide. Sodium percarbonate contains 32.5 % hydrogen peroxide and such a hydrogen peroxide concentration is highly irritating and causes irreversible effects in the rabbit eye (European Commission, 2003b). In the European Union solutions of hydrogen peroxide with concentrations ≥ 5 % are labelled as irritating to eyes, concentrations ≥ 8 % are labelled with "risk of serious damage to eyes" and concentrations ≥ 50 % are labelled as corrosive (European Commission, 2005). However, sodium carbonate is also irritating to the eyes (OECD, 2003) and

therefore the alkaline properties of sodium carbonate could contribute to the eye irritation potential of sodium percarbonate.

It is important to realize that in order to perform eye irritation studies, the material had to be ground to a fine powder or dissolved. The product that is actually handled has a much larger particle size and thus the possibility of eye contact and irritation reactions is smaller under normal conditions.

Respiratory Tract Irritation

The acute respiratory irritation was studied by a single treatment of male mice with sodium percarbonate (Janssen, 2001). This study was not performed according to GLP or standard test guidelines. Mice were exposed nose-only for 20 minutes to sodium percarbonate concentrations of 309, 330, 354, 698, 764 and 805 mg/m³ (4 mice per exposure level). Respiratory rates and volumes were evaluated before, during and after exposure at intervals of 5 minutes. Observations of clinical symptoms were made between 1 and 4 hours and 1 day after exposure. At necropsy external appearance and macroscopic changes in the abdominal and thoracic cavities were evaluated and lungs and tracheas were removed and weighed. Treatment related decreased respiratory rates and minute volumes were observed in all exposure groups. In the 309 mg/m³ exposure group the respiratory rate was only decreased at the end of the exposure period but in the other groups the respiratory rate was decreased throughout the whole exposure period. No full recovery was observed in the 764 mg/m³ group during the post-exposure period. No other clinical signs were observed, and there was no indication of a treatment related effect at necropsy. Lung weight was unaffected by treatment. From the findings it was concluded that the test material is a respiratory irritant with an RD_{50} of approximately 700 mg/m³.

Conclusion

For skin and eye irritation, GLP and standard guideline studies are available. Sodium percarbonate is only slightly irritating to the skin of rats and rabbits. Sodium percarbonate (in the form of a finely ground powder) is highly irritating to the eyes of rabbits and can produce an irreversible corrosive effect if not rinsed. In a well reported, non-GLP study with mice, sodium percarbonate appeared to be a respiratory irritant at relatively high aerosol concentrations. The RD_{50} was approximately 700 mg/m³ of respirable particles.

3.1.4 Sensitization

A skin sensitization test was conducted on 24 guinea pigs according to EPA test guidelines and EPA GLP guidelines (Buehler method) (Glaza, 1990e). A naive control group of 10 animals was included. The animals received one application (0.4 ml of a 75 % w/v mixture) per week for 3 weeks but the naive control animals were not treated during this phase. Applicataions were occluded. Two weeks following the third induction dose, a challenge dose (0.4 ml of a 25 % w/v mixture) was administered to the test animals and the naive control animals. Application sites were examined and scored for erythema and edema at 24 and 48 hours following the induction and challenge applications. Very faint to faint dermal reactions were elicited from all test animals during the induction phase. None of the test or naive control animals reacted to the challenge application of the test. Sodium percarbonate was not a skin sensitiser.

Conclusion

A valid GLP guideline study was conducted with guinea pigs in which sodium percarbonate was not a skin sensitiser.

3.1.5 Repeated Dose Toxicity

No animal data are available for sodium percarbonate on repeated dose toxicity studies by oral, dermal or inhalation exposure routes. However, repeated dose toxicity data are available for hydrogen peroxide, carbonate and sodium. Based on the composition of the material and the acute toxicity data it is likely that the toxicity of sodium percarbonate after repeated exposure is driven by hydrogen peroxide.

Hydrogen peroxide

A number of repeated dose studies by the oral route are available and they were described in detail by the European Commission (2003a). One 90-day study with catalase deficient mice was identified as the key study and is therefore reviewed below in more detail.

During this 90-day study, catalase deficient C57BL/6NCrlBR mice were given hydrogen peroxide in drinking water in concentrations between 100 and 3000 ppm (Freeman et al., 1997). A 6-week recovery period was included in the study. Both males and females receiving 3000 ppm exhibited significant reductions in body weight and food and water consumption. Animals receiving 300 and 1000 ppm displayed intermittent reductions in food and water consumption. No biologically significant differences in haematology parameters were noted among treated animals relative to controls. Males receiving 3000 ppm displayed significant reductions in total protein and globulin levels in the blood possibly attributed to reduced food consumption or reduced protein absorption caused by mucosal hyperplasia observed in the duodenum of these animals. No treatment-related significant differences in absolute or relative organ weights were noted. Necropsy revealed no treatment-related gross lesions. Microscopical analysis revealed treatment related changes only in the duodenum of male and female mice treated with 1000 and 3000 ppm of hydrogen peroxide and a single 300 ppm group male. They consisted of an increase in cross sectional diameter and a larger mucosal area with broader, more substantial villi compared to controls, while the general architecture of the duodenum was normal. The changes were assessed as mucosal hyperplasia because of the increase in mucosal thickness and size of the villi.

In the recovery period increased water consumption was observed in males and females of the 3000 ppm group and females of the 300 and 1000 ppm groups. No treatment related pathological or histopathological changes were observed in the recovery group indicating the reversibility of the findings in the duodenal mucosa.

Based on dose-related reductions in food and water consumption, and the observation of duodenal mucosal hyperplasia, the Lowest Observed Adverse Effect Level (LOAEL) was 300 ppm and the No Observed Adverse Effect Level (NOAEL) was 100 ppm (26 and 37 mg/kg/day for males and females, respectively).

If the lowest NOAEL of the study in catalase deficient mice, a very sensitive animal model is considered, the dose of 26 or 37 mg/kg/day of hydrogen peroxide is equivalent to a sodium percarbonate dose of 81 to 115 mg/kg/day. As the local effect is not only dependent on the administered dose but also dependent on the concentration. The no effect concentration of 100 ppm for hydrogen peroxide would be equivalent to a concentration of 308 ppm of sodium percarbonate.

In addition to the 90-day drinking water study, a 28-day range finding inhalation study in rats has been performed with hydrogen peroxide vapours (European Commission, 2003a). The results showed a respiratory tract irritation and concentration related inflammatory changes in the anterior nasal cavity of the rats from 14.6 mg/m^3, but not at 2.9 mg/m^3. However, it should be realized that this study was done with vapours, while sodium percarbonate is a solid, which can release hydrogen peroxide when it comes into contact with the moist surface of the respiratory tract.

Carbonate

An oral uptake of carbonate will result in a neutralization in the stomach by the low pH of the gastric juice and therefore neither local nor systemic effects are expected after oral exposure. Also via other exposure routes (inhalation, dermal exposure) carbonate is not expected to be systemically available in the body due to the limited uptake and the neutralization capacity of the blood. A detailed assessment has been presented by the OECD (2003).

Sodium

The effect of repeated exposure of humans to sodium has been studied extensively and has mainly focused on the effects of sodium on the prevention and control of hypertension. Recommendations on daily dietary sodium intake were reported to be 2.0-3.0 g for a moderately restricted intake and 3.1-6.0 g was considered to be a normal intake (Fodor et al., 1999).

Conclusion

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).

3.1.6 Mutagenicity

Studies with 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.

Hydrogen peroxide

The mutagenicity of hydrogen peroxide has been tested extensively. A review has been presented for example by ECETOC (1996), European Commission (2003a,b) and OECD (1999). The summary report of the European Commission (2003b) concluded: "H_2O_2 is a mutagen and genotoxicant in a variety of *in vitro* test systems. Regarding *in vivo* genotoxicity, studies have explored DNA repair in liver cells of rats, as well as micronucleus formation in mice, all with a negative outcome. At low concentrations (0.2-3.2 % solutions), and with a low application frequency on the skin of mice, H_2O_2 did not induce local genotoxicity or mutagenicity. The available studies are not in support of significant genotoxicity/mutagenicity of H_2O_2 under *in vivo* conditions."

Sodium carbonate

Also for sodium carbonate there was no concern with regard to a possible genotoxicity. An *in vitro* mutagenicity test with bacteria was negative and based on the structure of sodium carbonate no genotoxic effects are expected (OECD, 2003).

Conclusion

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.

3.1.7 Carcinogenicity

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 that has been intensively studied for possible carcinogenic effects (ECETOC, 1996; European Commission, 2003a,b; OECD, 1999).

For hydrogen peroxide several studies show that long-term oral administration of 0.1-0.4 % hydrogen peroxide causes an inflammatory response in gastroduodenal tissue of mice, which may progress to duodenal hyperplasia and localised duodenal carcinomas (Ito et al., 1981a,b). The response is limited to the glandular stomach and, to a lesser extent, to the peri-pyloric and proximal portion of the duodenum. No inflammatory response was observed in the oral cavity, forestomach or distal intestinal tract. The incidence was higher in strains of mice with a low catalase activity. Studies by Ito et al. (1982) revealed that cessation of hydrogen peroxide administration causes a regression of lesions including tumors induced by prolonged (up to 180d) administration of hydrogen peroxide in drinking water.

The investigations by Ito et al. (1981a,b) suggest that this inflammatory response may progress to carcinogenic changes in mice that are catalase deficient. In rats, hydrogen peroxide induced only papillomas; no malignant tumours of the forestomach were seen, even at nearly lethal concentrations (1-1.5% hydrogen peroxide in drinking water). Initiation-promotion studies suggest that hydrogen peroxide is not an initiator in skin, but may be a weak promoter of tumours in the rat at high (> 15%) concentrations on the skin, or nearly lethal concentrations (1.5%) in drinking water.

In the 90-day study performed on catalase-deficient, C57BL/6NCrlBR mice that received constant concentrations of 0, 100, 300, 1000, or 3000 ppm of hydrogen peroxide in distilled drinking water for approximately 90 days, microscopically, no evidence of cellular atypia or architectural disruptions nor any other indications of neoplastic changes were observed (FMC, 1997). Therefore, the treatment-related mucosal hyperplasia noted in this study is not considered to be a neoplastic lesion. This reinforces the conclusion from the data of Ito (1981a,b; 1982) suggesting that only inflammatory changes seen at nearly lethal concentrations in particularly catalase-deficient species or individuals could possibly lead to local tumours.

In vivo genotoxicity data currently point strongly to the fact that hydrogen peroxide is not an *in vivo* genotoxin. The induction of carcinogenicity by a non-genotoxic mechanism has been proposed (Troll and Wiesner, 1985). The fact that tumours were induced only at the sites where high concentrations of H_2O_2 came directly into contact with the tissues and that the tumours were associated with persistent local inflammation supports a non-genotoxic mechanism for the gastrointestinal tract tumours. It can be underlined also here that three recent studies demonstrated the lack of genotoxicity of hydrogen peroxide when administered *in vivo* at the maximally tolerated dose by different routes (intra-peritoneal, oral, i.v.) (CEFIC, 1995 and 1997).

Based on the available data the European Commission (2003a) concluded:

„Although 0.1-0.4% H_2O_2 in drinking water showed potential to induce local carcinogenic effects in the duodenum of a sensitive, catalase-deficient mouse strain, it is notable that the lesions showed a marked tendency of regression and even disappearance after the cessation of treatment. The mechanism of the carcinogenic effect is unclear. In rats, administration of H_2O_2 in drinking water

was not associated with the occurrence of tumours. In another study, however, 1% H_2O_2 in drinking water induced squamous cell papillomas in the forestomach of rats. Tumour promotion studies with H_2O_2 revealed equivocal results. The special nature of the demonstrated carcinogenicity of H_2O_2, an endogenous reactive oxygen species, the existing biological defense mechanisms, and the overall evidence available, cast some doubt on whether H_2O_2 is a carcinogen of practical significance and the evidence is considered to be insufficient to trigger classification."

All recent evaluations have concluded that hydrogen peroxide is of no concern with regard to a possible carcinogenicity in humans (ACGIH, 1995; US FDA, 1991; IARC, 1999; Desesso et al., 2000; European Commission, 2003a,b; EPA, 2002; OECD, 1999).

Conclusion

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.

3.1.8 Toxicity for Reproduction

Neither an animal study on toxicity to reproduction nor a study on developmental toxicity are available for sodium percarbonate. However, under normal handling and use conditions, sodium percarbonate will not reach the male and female reproductive organs or the foetus, as it does not become available systemically (see section 3.1.1). For this reason the substance is neither considered toxic to reproduction nor toxic to the foetus and it is considered not useful to perform additional studies with animals.

Hydrogen peroxide

No appropriate animal studies were available for a complete evaluation of the reproductive and developmental toxicity of hydrogen peroxide. However, these studies were not required because hydrogen peroxide is not expected to be systemically available in the body (European Commission, 2003a,b; OECD, 1999).

Sodium carbonate

A reproduction toxicity test is not available for sodium carbonate. However, the substance will usually not reach the foetus or the male and female reproductive organs when exposed orally, dermally or by inhalation, as it does not become available systemically (OECD, 2003).

A developmental toxicity study was reported in OECD (2003): "Aqueous solutions of sodium carbonate were administered daily via oral intubation to pregnant mice at doses ranging from 3.4 to 340 mg/kg bw during days 6-15 of gestation. The test substance did not affect implantation nor the survival of dams and fetuses. Soft and skeletal tissue anomalies were noted in the experimental group, but the incidence of these findings did not differ from that of sham-treated controls. Similar negative results were reported for rats and rabbits for daily doses from 2.45-245 mg/kg bw and 1.79-179 mg/kg bw, respectively (FDA, 1974). This study confirms in three species that there is no concern with regard to developmental toxicity, which supports the general consideration that the substance will usually not reach the fetus when exposed to sodium carbonate, as it does not become systemically available."

Conclusion

Neither an animal study on toxicity to reproduction nor a study on developmental toxicity are available for sodium percarbonate. A developmental toxicity study with sodium carbonate revealed no substance related fetotoxic, embrytoxic 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.

3.2 Initial Assessment for 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 comes 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 LD_{50} values ranged between 1034 and 2200 mg/kg bw, while the acute dermal LD_{50} 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.

4 HAZARDS TO THE ENVIRONMENT

4.1 Aquatic Effects

Acute Toxicity Test Results

A semi-static acute toxicity study with fathead minnow (*Pimephales promelas*) and sodium percarbonate has been conducted according to EPA (Environmental Protection Agency) test guidelines (Shurtleff, 1989a). The fathead minnow is a freshwater fish species. Test solutions were renewed daily and the hydrogen peroxide concentration was determined before and after renewal using a titration with potassium permanganate. The measured hydrogen peroxide concentration was used to calculate mean measured sodium percarbonate concentrations. Fish were exposed for 96 hours to mean measured sodium percarbonate concentrations of 0; 1.1; 7.4; 34; 81; 465 and 937 mg/l and observations were made after 24, 48, 72 and 96 hours. The LC_{50} and NOEC (No Observed Effect Concentration, based on mortality) of sodium percarbonate were 71 and 7.4 mg/l, respectively. No control mortality was observed.

The effects of sodium percarbonate on the water flea *Daphnia pulex* have been studied by Shurtleff (1989b) according to EPA guidelines. Daphnids were exposed for 48 hours and they were transferred to fresh test solutions daily. The hydrogen peroxide concentrations were measured before and after each renewal using a titration with potassium permanganate. The measured hydrogen peroxide concentration was used to derive mean measured sodium percarbonate concentrations. Mean measured test concentrations were 0; 2.0; 12; 46; 89; 416 and 835 mg/l. Based on mortality the EC_{50} and NOEC of sodium percarbonate were 4.9 and 2.0 mg/l, respectively. No control mortality was observed.

The results of ecotoxicity tests with sodium percarbonate, hydrogen peroxide and sodium carbonate are compared in Table 4. The results are expressed as sodium percarbonate, hydrogen peroxide and sodium carbonate concentrations, if applicable. The data of Table 4 show that the amount of hydrogen peroxide, which is released at EC_{50} concentrations of the fish and invertebrates tests with sodium percarbonate, is sufficient to explain the acute toxicity of sodium percarbonate. However, the amount of sodium carbonate, which is released at EC_{50} concentrations of the fish and invertebrates tests with sodium percarbonate, is not sufficient to explain the acute toxicity of sodium percarbonate. Based on the results of Table 4, the acute toxicity of sodium percarbonate can be explained by the formation of hydrogen peroxide.

Table 4 Comparison of acute toxicity of sodium percarbonate, hydrogen peroxide and sodium carbonate

Test substance	Species	EC_{50} (mg/l)			Reference
		SPC [A]	H_2O_2 [A]	SC [A]	
Sodium percarbonate	Fathead minnow	50-100	16-33	34-68	Shurtleff (1989a)
Hydrogen peroxide	Fathead minnow		13-21		Shurtleff (1989a)
Sodium carbonate	Freshwater fish			300-740	OECD (2003)
Sodium percarbonate	*Daphnia pulex*	2-12	0.7-3.8	1.4-8.0	Shurtleff (1989b)
Hydrogen peroxide	*Daphnia pulex*		1.0-5.5		Shurtleff (1989b)
Sodium carbonate	*Ceriodaphnia dubia*			200-227	OECD (2003)

[A] LC_{50} values are expressed as 95 % confidence intervals.
SPC = sodium percarbonate, H_2O_2 = hydrogen peroxide and SC = sodium carbonate.

Algal studies have been reported by Clarke (1991) but these studies were not performed according to GLP or standard guidelines. In these studies three green algae, *Chlamydomonas eugametos*, *Chlorella emersonii* and *Scenedesmus quadricauda* and three cyanobacteria, *Anabaena variabilis*, *Anabaena* A_4 and *Synechococcus leopoliensis* were used. The algae were incubated in microtitre plates (300 µl). Analytical measurements were not available. Reported EC_{50} values ranged between 8-160 mg/l but these high values are not reliable. Hydrogen peroxide probably degraded because of the duration of the test period (between 140 and 240 hours). A significant recovery of the algal growth was seen in most cases during the test, which indicates a lack of exposure at the end of the test.

An algal study with *Chlorella vulgaris* has been conducted with hydrogen peroxide under standard test conditions (Degussa, 1991). The EC_{50} and NOEC of this study were 2.5 and 0.1 mg/l, respectively. Based on the study of Degussa (1991) predicted EC_{50} and NOEC values for a study with *C. vulgaris* and sodium percarbonate are 7.7 and 0.3 mg/l, respectively. Although a standard and valid guideline study is not available for algae, the toxicity of sodium percarbonate for algae can be predicted from an algal test with hydrogen peroxide. For this reason there is no need to do a standard algal toxicity test with sodium percarbonate.

Chronic Toxicity Test Results

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 and sodium carbonate.

A chronic toxicity study with invertebrates (zebra mussels) and hydrogen peroxide revealed a NOEC of 2 mg/l. Algae were regarded the most sensitive species for hydrogen peroxide based on one study with a NOEC of 0.1 mg/l. The NOEC value of 0.1 mg/l and an assessment factor of 10 were used to derive a PNEC (Predicted No Effect Concentration) of 10 µg/l for hydrogen peroxide. However, it has to be considered that natural background concentrations (without anthropogenic influence) were reported to range from <1 to 30 µg/l (European Commission, 2003a,b; OECD, 1999).

Because the natural pH, bicarbonate and also the sodium concentration (and their fluctuations in time) varies significantly between aquatic ecosystems, it is not considered useful to derive a generic PNEC or $PNEC_{added}$ for sodium carbonate (OECD, 2003). The increase in pH (to a value of 9.0) of the receiving water was used to obtain an idea of the acceptable amount of sodium carbonate which can be added to aquatic ecosystems. Depending on the buffer capacity of the aquatic ecosystem, an estimate of the acceptable amount ranges between 2.7 and 17 mg/l (see also Table 2). The PNEC of

hydrogen peroxide is much lower (10 µg/l) and this confirms that hydrogen peroxide is the component which is responsible for the toxicity of sodium percarbonate. There is no need to derive a PNEC of sodium percarbonate for risk characterization because the risk characterization should be based on the separate risk characterizations of hydrogen peroxide and sodium carbonate.

Toxicity to Microorganisms

Toxicity tests, which determine the effects of sodium percarbonate on microorganisms, are not available. However, some data on the toxicity of hydrogen peroxide to microorganisms are available. An 18-hour cell multiplication test with *Pseudomonas putida* revealed an EC_{10} of 11 mg/l, while an activated sludge respiration inhibition test with hydrogen peroxide resulted in an EC_{50} value of 466 mg/l (European Commission, 2003a,b).

4.2 Terrestrial Effects

Toxicity tests, which determine the effects of sodium percarbonate on terrestrial organisms, are not available. Significant exposure of the terrestrial environment is not expected and for this reason there is no need to perform toxicity test with terrestrial organisms.

4.3 Other Environmental Effects

No other environmental effects are expected.

4.4 Initial Assessment for the 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 LC_{50} 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 EC_{50} 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 EC_{50} 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.

5 RECOMMENDATIONS

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.

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S I D S

Dossier

Existing Chemical	:	ID: 15630-89-4
CAS No.	:	15630-89-4
EINECS Name	:	disodium carbonate, compound with hydrogen peroxide (2:3)
EC No.	:	239-707-6
TSCA Name	:	Carbonic acid disodium salt, compd. with hydrogen peroxide (H2O2) (2:3)
Molecular Formula	:	2Na2CO3.3H2O2

Producer related part

Company	:	Solvay Interox S.A.
Creation date	:	31.05.1994

Substance related part

Company	:	Solvay Interox S.A.
Creation date	:	31.05.1994
Status	:	
Memo	:	JPE
Printing date	:	21.02.2006
Revision date	:	
Date of last update	:	21.02.2006
Number of pages	:	78
Chapter (profile)	:	
Reliability (profile)	:	
Flags (profile)	:	

1.0.1 APPLICANT AND COMPANY INFORMATION

Type : lead organisation
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Telefax : + 32 2 264 2990
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Homepage : www.solvay.com

11.09.2003

Type : cooperating company
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21.02.2006

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Homepage :

09.09.2003

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09.09.2003

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Cedex :
Email : luis_peri@fmc.com
Homepage : www.fmcforet.com

13.02.2004

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Town : SE-251 09 Helsingborg
Country : Sweden
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Telefax : + 46 42 18 76 35
Telex :
Cedex :
Email : Katarina.Fridh@kemira.com
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04.02.2004

Type : cooperating company
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Contact person : T. Hamaguchi
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Town : 100-8324 Tokyo
Country : Japan
Phone : + 81 3 3283 4869
Telefax : + 81 3 3287 2649
Telex :
Cedex :
Email : hamaguchi@mgc.co.jp
Homepage :

16.01.2006

Type : cooperating company
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Phone : + 81 24 941 0066
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Telex :
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Homepage :

21.10.2003

Type : cooperating company
Name : Shangyu Chemical Industry
Contact person : Susan Zhang
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Phone : + 86 575 2219080
Telefax : + 86 575 2211434
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Cedex :
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Homepage :

04.10.2004

Type : cooperating company
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Telefax : + 86-571-85812333
Telex :
Cedex :
Email : bright@jinke-chem.com
Homepage : www.jinke-chem.com

09.09.2003

1.0.2 LOCATION OF PRODUCTION SITE, IMPORTER OR FORMULATOR

Remark : Globally sodium percarbonate is produced at 12 - 24 production sites and about half of them are located in Europe.

Sodium percarbonate is produced in:

- Austria
- China
- Germany
- Italy
- Japan

- Russian Federation
- South Korea
- Spain
- Sweden
- United Kingdom
- United States of America

The produced amount of sodium percarbonate in 2003 was estimated to be 300,000 - 500,000 tonnes (estimation by Solvay).

18.01.2006

1.0.3 IDENTITY OF RECIPIENTS

1.0.4 DETAILS ON CATEGORY/TEMPLATE

1.1.0 SUBSTANCE IDENTIFICATION

IUPAC Name	:	Sodium Percarbonate
Smiles Code	:	[Na]OC(O[Na])=O OO
Molecular formula	:	2Na2CO3·3H2O2
Molecular weight	:	314.06
Petrol class	:	other: Not applicable

12.09.2003

1.1.1 GENERAL SUBSTANCE INFORMATION

Purity type	:	typical for marketed substance
Substance type	:	inorganic
Physical status	:	solid
Purity	:	> 85 % w/w
Colour	:	white
Odour	:	no specific odour

25.02.2003

1.1.2 SPECTRA

1.2 SYNONYMS AND TRADENAMES

Disodium carbonate, compound with hydrogen peroxide

06.02.2002

PCS

27.10.2003

Percarbonate

09.04.2002

Sodium carbonate peroxyhydrate

27.10.2003

Sodium percarbonate

06.02.2002

1.3 IMPURITIES

Purity : typical for marketed substance
CAS-No : 497-19-8
EC-No : 207-838-8
EINECS-Name : sodium carbonate
Molecular formula : Na2CO3
Value : < 15 % w/w

27.10.2003

Purity : typical for marketed substance
CAS-No : 7757-82-6
EC-No : 231-820-9
EINECS-Name : sodium sulphate
Molecular formula : Na2SO4
Value : < 10 % w/w

27.10.2003

Purity : typical for marketed substance
CAS-No : 7647-14-5
EC-No : 231-598-3
EINECS-Name : sodium chloride
Molecular formula : NaCl
Value : < 5 % w/w

27.10.2003

Remark : In addition to the typical impurities mentioned above, sodium silicates, sodium phosphates, magnesium sulphate and borates can be present in sodium percarbonate in low concentrations.

16.01.2006

1.4 ADDITIVES

Remark : Several of the inorganic salts, which are mentioned in section 1.3 of this IUCLID, can also be used as coatings to improve the stability of sodium percarbonate in formulated products.

The maximum concentrations will comply with the concentrations mentioned in section 1.3.

04.03.2003

1.5 TOTAL QUANTITY

Quantity : = 300000 - 500000 tonnes produced in 2003

Remark : The estimated world-wide demand of sodium percarbonate was 300,000 - 500,000 tonnes in 2003 (estimation by Solvay S.A.).

11.01.2006

1.6.1 LABELLING

Labelling : provisionally by manufacturer/importer
Specific limits : no
Symbols : O, Xn, ,
Nota : , ,
R-Phrases : (8) Contact with combustible material may cause fire
(22) Harmful if swallowed
(41) Risk of serious damage to eyes
S-Phrases : (3) Keep in a cool place
(8) Keep container dry
(17) Keep away from combustible material
(24/25) Avoid contact with skin and eyes
(26) In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

11.01.2006 (35)

1.6.2 CLASSIFICATION

Classified : provisionally by manufacturer/importer
Class of danger : harmful
R-Phrases : (22) Harmful if swallowed
Specific limits : no

10.01.2006 (35)

Classified : provisionally by manufacturer/importer
Class of danger : irritating
R-Phrases : (41) Risk of serious damage to eyes
Specific limits : no

16.01.2006 (35)

Classified : provisionally by manufacturer/importer
Class of danger : oxidizing
R-Phrases : (8) Contact with combustible material may cause fire
Specific limits : no

16.01.2006 (35)

1.6.3 PACKAGING

1.7 USE PATTERN

Type of use : type
Category : Wide dispersive use

Remark : 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.

10.09.2003

Type of use : industrial
Category : Personal and domestic use

Remark : 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 or for denture cleansing.

Furthermore the pure product (100 %) is available for consumers as a laundry additive.

10.09.2003

Type of use : use
Category : Bleaching agents

Remark : When sodium percarbonate is used on textiles, it brightens whites and colours and is an effective deodorizer.

21.11.2003

Type of use : use
Category : Oxidizing agents

Remark : Applications for sodium percarbonate include treatment of biological upsets in ponds, treatment of sludges, municipal sewage treatment, dechlorination and water softening.

11.02.2002

1.7.1 DETAILED USE PATTERN

1.7.2 METHODS OF MANUFACTURE

Origin of substance : Synthesis
Type : Production

Remark : Sodium percarbonate is formed by the reaction of sodium carbonate with hydrogen peroxide:
$Na_2CO_3 + 1.5\ H_2O_2 \rightarrow Na_2CO_3 \cdot 1.5H_2O_2$
The following processes are used to produce sodium percarbonate:

Dry Process
The so-called dry process essentially involves spraying an aqueous

stabilized hydrogen peroxide solution on solid sodium carbonate with continuous agitation. A solid-liquid reaction yields sodium percarbonate. Completion of the reaction is followed by cooling and finally a dry, free-flowing powder is obtained.

Spray Granulation Process
Solutions of sodium carbonate and aqueous stabilized hydrogen peroxide are sprayed onto a bed of sodium percarbonate nuclei in a fluid-bed granulator. The product bed is kept in movement by a stream of heated air. Product is continuously withdrawn from the dryer and the desired grain-size fraction is obtained by classification. The fines and ground oversize are recycled to the fluid-bed granulator as nuclei.

Crystallization Process
Because sodium percarbonate is highly soluble, it is usually prepared by salting out of aqueous solutions with sodium chloride. A sodium carbonate/NaCl suspension is reacted with stabilized hydrogen peroxide under stirring and cooling. The crystallized sodium percarbonate is separated from the mother liquor by centrifugation, then dried in a fluid-bed dryer.

11.01.2006 (5)

1.8 REGULATORY MEASURES

1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES

Type of limit : MAC (NL)
Limit value : 10 mg/m3

Remark : For sodium percarbonate no MAC value has been established. The general limit value for fine inhalable dust is 10 mg/m³.

06.02.2002 (26)

Type of limit : MAK (DE)
Limit value : 6 mg/m3

Remark : General limit value for fine dust
06.02.2002

Type of limit : other: ACGIH
Limit value : 10 mg/m3

Remark : General limit value for inert dust
06.02.2002 (1)

1.8.2 ACCEPTABLE RESIDUES LEVELS

1.8.3 WATER POLLUTION

1.8.4 MAJOR ACCIDENT HAZARDS

1.8.5 AIR POLLUTION

1.8.6 LISTINGS E.G. CHEMICAL INVENTORIES

1.9.1 DEGRADATION/TRANSFORMATION PRODUCTS

1.9.2 COMPONENTS

1.10 SOURCE OF EXPOSURE

Remark : 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. Based on the information from the International Association for Soaps, Detergents and Maintenance Products (AISE, 2002), the concentrations of sodium percarbonate in laundry detergents, laundry additives and machine dishwashing products are 7 24 %, 20 56 % and 3 21 %, respectively. However, higher concentrations are used also. Bleach booster products with a sodium percarbonate concentration between 65 and 85 % are placed on the market. Furthermore the pure product (100 %) is available for consumers as a laundry additive.

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 (FAO/WHO, 1991).

The amount of sodium percarbonate, which is used in household cleaning products in Europe, was estimated to be 100,000 - 150,000 tonnes in 2001 but the amount was expected to increase the coming years (HERA, 2002).

18.01.2006 (2) (15) (22)

1.11 ADDITIONAL REMARKS

Remark : Sodium percarbonate rapidly dissociates to hydrogen peroxide and sodium carbonate.

Hydrogen peroxide was listed on the second priority list of Council Regulation 793/93 on the evaluation and control of the risks of existing substances. Finland was rapporteur country for hydrogen peroxide. The Finnish authorities in cooperation with the CEFIC Peroxygen Sector Group have assessed the risks of production, formulation and all uses

of hydrogen peroxide in the EU. An extensive Risk Assessment Report has been prepared. This can be found on internet (http://ecb.jrc.it/existing-chemicals/).

In June 1999, the SIDS dossier of hydrogen peroxide has been discussed at the 9th SIAM. Finland was sponsor country for this chemical.

In October 2002, a SIDS dossier of sodium carbonate was submitted to OECD. Belgium was sponsor country for this chemical. The dossier has been published on internet (http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html).

11.01.2006 (8) (14) (29) (30)

1.12 LAST LITERATURE SEARCH

Type of search : Internal and External
Chapters covered : 3, 4, 5
Date of search :

Remark : A literature search has been done in 1994 by the industry to prepare the IUCLID in the context of 'Council Regulation (EEC) No. 793/93 on the Evaluation and Control of the Risks of Existing Substances'. This IUCLID has been published by the European Chemicals Bureau.

An additional literature search has been done in March 2002 by Solvay. It covered the period 1994-2002. The following databases were used: AQUIRE, BIODEG, BIOLOG, CCRIS, CHRIS, DART/ETIC, DATALOG, EMIC, ENVIROFATE, GENETOX, GIABS, HSDB SUBSET, IRIS, MEDLINE, NIOSHTIC SUBSET , PHYTOTOX, RTECS, TERRETOX, TSCATS, TOXCENTER and TOXLINE.

16.01.2006

1.13 REVIEWS

2.1 MELTING POINT

Remark : A melting point can not be determined because sodium percarbonate decomposes when heated.
Reliability : (2) valid with restrictions
Flag : Critical study for SIDS endpoint
11.01.2006 (5) (35)

2.2 BOILING POINT

Remark : A boiling point can not be determined because sodium percarbonate decomposes when heated.
Reliability : (2) valid with restrictions
Flag : Critical study for SIDS endpoint
11.01.2006 (5) (35)

2.3 DENSITY

Type : density
Value : = 2.14 g/cm³ at °C
Method : other: not described
Year : 1995
GLP : no
Test substance : no data

Reliability : (2) valid with restrictions
Flag : Critical study for SIDS endpoint
11.01.2006 (5)

Type : bulk density
Value : = 900 - 1100 kg/m3 at °C
Method : other: not described
Year : 1995
GLP : no
Test substance : no data

Reliability : (2) valid with restrictions
Flag : Critical study for SIDS endpoint
11.01.2006 (5)

2.3.1 GRANULOMETRY

Remark : The average particle size diameter of sodium percarbonate is in the range of 0.3 - 1.5 mm. The particle size distribution showed that 95 % has a particle size greater than 0.15 mm and less than 1.4 mm.
10.09.2003 (35)

2.4 VAPOUR PRESSURE

Remark : The vapour pressure of sodium percarbonate at 25°C will be very low (< 10-3 Pa) as sodium percarbonate is an ionic substance. An experimental method can not be applied because sodium percarbonate decomposes when heated.

31.05.1994 (28)

2.5 PARTITION COEFFICIENT

Remark : Not applicable. Sodium percarbonate is a simple inorganic salt.

10.09.2003

2.6.1 SOLUBILITY IN DIFFERENT MEDIA

Solubility in	:	Water
Value	:	ca. 140 g/l at 20 °C
pH value	:	= 10.4 - 10.6
concentration	:	1 vol% at 20 °C
Temperature effects	:	
Examine different pol.	:	
pKa	:	at 25 °C
Description	:	
Stable	:	no
Deg. product	:	yes
Method	:	other: not described
Year	:	1995
GLP	:	no
Test substance	:	no data
Deg. products	:	497-19-8 207-838-8 sodium carbonate 7722-84-1 231-765-0 hydrogen peroxide
Reliability	:	(2) valid with restrictions
Flag	:	Critical study for SIDS endpoint

11.01.2006 (5)

Remark : Based on a technical data sheet of Solvay Chemicals the water solubility is 120 g/l at 20 °C.

04.10.2005 (34)

Remark : Based on a technical data sheet of DCC Basic Chemicals the water solubility is 12, 14 and 18.5 g/100 gram water at temperatures of 5, 20 and 40 °C, respectively.

04.10.2005 (9)

2.6.2 SURFACE TENSION

2.7 FLASH POINT

Remark : not applicable
31.05.1994

2.8 AUTO FLAMMABILITY

Remark : not applicable
31.05.1994

2.9 FLAMMABILITY

Result : non flammable

31.05.1994

2.10 EXPLOSIVE PROPERTIES

Remark : not applicable
31.05.1994

2.11 OXIDIZING PROPERTIES

Result : other: The product sodium percarbonate should be classified in Division 5.1
Method : other: UN Test O.1
Year : 2001
GLP : no
Test substance : no data

Reliability : (2) valid with restrictions
11.01.2006 (38)

2.12 DISSOCIATION CONSTANT

Remark : Not applicable
09.01.2002

2.13 VISCOSITY

2.14 ADDITIONAL REMARKS

Remark : Sodium percarbonate is a metastable substance and the bond between the peroxygen atoms can be broken giving rise to a decomposition producing sodium carbonate, steam or water, oxygen and heat:
2Na2CO3.3H2O2 --> 2Na2CO3 + 3H2O + 1.5 O2 + Heat

Under normal circumstances the rate of decomposition is low. The rate of decomposition and the associated heat output rate can significantly increase as a result of temperature increase, added water, contamination by organic materials, bases, transition metal ions and reducing agents.

09.01.2002

3.1.1 PHOTODEGRADATION

Remark : No data on photodegradation are available. However, photodegradation of sodium percarbonate is not applicable because it is an inorganic salt with a negligible vapour pressure. Photodegradation in water is also not applicable because sodium percarbonate rapidly dissolves in water and dissociates into sodium ions, carbonate ions and hydrogen peroxide. For hydrogen peroxide an half-life of 24 hours was chosen to represent the average degradation half-life in the atmosphere (European Commission, 2003).

11.01.2006 (14)

3.1.2 STABILITY IN WATER

Type : abiotic
t1/2 pH4 : at °C
t1/2 pH7 : at °C
t1/2 pH9 : at °C

Remark : Sodium percarbonate dissolves rapidly in water dissociating to sodium carbonate and hydrogen peroxide. For hydrogen peroxide a degradation of 3.0 - 30 % within 24 hours was reported in aquatic toxicity tests. Hydrogen peroxide is an unstable substance and the fate has been studied extensively (ECETOC, 1993; European Commission, 2001). The carbonate ion can be neutralized to bicarbonate (HCO3). Both sodium and inorganic carbonate have a wide natural occurrence (UNEP, 1995)

11.01.2006 (13) (14) (32) (33) (39)

Type : abiotic
t1/2 pH4 : at °C
t1/2 pH7 : at °C
t1/2 pH9 : at °C
Deg. product :
Method : other: not described
Year : 1994
GLP : no
Test substance : no data

Remark : The stability of a 0.5 % sodium percarbonate solution in water was determined using regular tap water, deionized water and filtered tap water. Sodium percarbonate proved to be very stable in deionized water with an active oxygen loss (AvOx) of 4.4 % after 11 days. For tap water and filtered tap water the AvOx loss observed was 58 and 47.5 %, respectively after 24 hours. Under the conditions of the test the AvOx loss is similar to the loss of hydrogen peroxide (other chemicals which contain active oxygen are not expected to be present).

Reliability : (2) valid with restrictions

11.01.2006 (16)

3.1.3 STABILITY IN SOIL

Remark : In contact with soil, sodium percarbonate will rapidly decompose into

hydrogen peroxide and sodium carbonate. Hydrogen peroxide decomposes into water and oxygen. The carbonate ion can be neutralized to bicarbonate (HCO3). Both sodium and inorganic carbonate have a wide natural occurrence (UNEP, 1995).

21.10.2003 (39)

3.2.1 MONITORING DATA

3.2.2 FIELD STUDIES

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Remark : For solid sodium percarbonate no transport is expected. When sodium percarbonate is dissolved in water, it dissociates to sodium carbonate and hydrogen peroxide rather easily. Both substances are very water soluble and will therefore remain in the water phase.

28.10.2003

3.3.2 DISTRIBUTION

Remark : As a man-made solid, sodium percarbonate will not partition between compartments. When dissolved in water it will decompose into hydrogen peroxide and sodium carbonate. Both substances are very water soluble and will therefore remain in the water phase.

27.02.2003

3.4 MODE OF DEGRADATION IN ACTUAL USE

Remark : When the formulated product, containing sodium percarbonate (e.g. laundry detergent), is added to water, the sodium percarbonate will dissociate directly into sodium ions, carbonate ions and hydrogen peroxide. The hydrogen peroxide will be further degraded. Carbonate will be neutralised to bicarbonate if the solution is further diluted with water.

11.01.2006

3.5 BIODEGRADATION

Remark : When sodium percarbonate is dissolved in water, it dissociates to sodium carbonate and hydrogen peroxide rather easily. Sodium and carbonate can not be biodegraded, although carbonate can be neutralised to bicarbonate. Hydrogen peroxide can be degraded by micro-organisms (e.g. bacteria) or other higher organisms.

27.02.2003

3.6 BOD5, COD OR BOD5/COD RATIO

Remark : Not applicable as sodium percarbonate is an inorganic compound.
07.02.2002

3.7 BIOACCUMULATION

Remark : When sodium percarbonate is dissolved in water, it dissociates to sodium carbonate and hydrogen peroxide rather easily. Also in contact with soil, sodium percarbonate will rapidly decompose into hydrogen peroxide and sodium carbonate.

Both sodium carbonate and hydrogen peroxide are inorganic chemicals which do not bioaccumulate. Furthermore hydrogen peroxide is not stable.

09.04.2002

3.8 ADDITIONAL REMARKS

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type : semistatic
Species : Pimephales promelas (Fish, fresh water)
Exposure period : 96 hour(s)
Unit : mg/l
LC50 : = 70.7
NOEC (mortality) : = 7.4
Limit test : no
Analytical monitoring : yes
Method : other: EPA guidelines
Year : 1989
GLP : no
Test substance : other TS

Method : DEVIATIONS FROM GUIDELINE: not described
ANALYTICAL MONITORING: The concentration of hydrogen peroxide was determined by titration with potassium permanganate within 30 minutes before and after renewal of test solutions. This means that the concentration percarbonate was derived from the measured concentration hydrogen peroxide.
STATISTICAL METHOD: The LC50 and its 95 % confidence limits was calculated using the Trimmed Spearman-Karber statistical method. The LC50 was calculated using the average titrimetrically-determined concentrations.

Result : RESULTS EXPOSED

Nom conc (mg/l)	Meas conc (mg/l)	Mortality (Cum. no. dead) 24h	48h	72h	96h
1.0	1.1	0	0	0	0
10	7.4	0	0	0	0
50	33.5	2	4	4	4
100	80.5	6	12	12	12
500	465.0	20	20	20	20
1000	936.5	20	20	20	20

At a concentration of > 50 mg/l, fish were affected within minutes. The fish exposed to 500 and 1000 mg/l exhibited severe problems with respiration, and all died within 12 hours. At 100 mg/l the fish showed various symptoms of intoxication (gulping air and twitching at the bottom) but 8 of 20 fish did survive 96 hours.
RESULTS CONTROL
No control mortality was observed.
ANALYTICAL RESULTS
Sometimes a significant decrease of the measured hydrogen peroxide concentration was found between start of the exposure and renewal (daily). In 2 cases the measured concentration after one day was less than 10 % of the initial measured concentration.

Test condition : TEST ORGANISMS
- Source/supplier: fish have been cultured by Burlington Research for 6 years. Starter organisms were obtained from the Aquatic Toxicology Group (Divison of Environmental Management, North Carolina)
- Age/size/loading: 6-8 weeks/13.7 ± 1.2 mm/0.25 ± 0.08 g/l
- Feeding: fish are fed brine shrimp for two months after which they are fed fish flakes
- Pretreatment: fish are removed from their maturation

tanks for acclimation to the dilution water and temperature conditions four weeks before use in tests
- Feeding during test: no
STOCK AND TEST SOLUTION AND THEIR PREPARATION
- Vehicle/solvent: 1 % w/v stock solutions were prepared in reconstituted water
REFERENCE SUBSTANCE
- monthly quality control bioassays with reference toxicants
DILUTION WATER
- Source: moderately hard reconstituted water
- Alkalinity: not described
- Hardness: 50-250 mg/l CaCO3
TEST SYSTEM
- Nominal concentrations: 0, 1, 10, 50, 100, 500, 1000 mg/l
- Renewal of test solutions: daily
- Exposure vessel type: borosilicate glass dishes (diameter 20 cm; depth 8.0 cm) containing 1 liter test solution
- Number of replicates/fish per replicate: 2 / 10
- Test temperature: 20 ± 1°C
- Dissolved oxygen: > 9.2 mg/l, at 500 and 1000 mg/l DO levels of 14-16 mg/l were measured
- pH: 7.3-9.8
- Intensity of radiation/photoperiod: not described
TEST PARAMETER: mortality

Test substance : TEST SUBSTANCE
- Test substance: Sodium percarbonate
- Source: Solvay Interox S.A.
- Purity: > 88 %

Reliability : (1) valid without restriction
Test procedure in accordance with generally accepted scientific standards and described in sufficient detail.

Flag : Critical study for SIDS endpoint

11.01.2006 (32)

Type : static
Species : other: hamachi (yellow tail)
Exposure period : 3 minute(s)
Unit : mg/l
NOEC : >= 500
Limit test :
Analytical monitoring : no data
Method : other: not described
Year : 1989
GLP : no data
Test substance : no data

Method : METHOD USED
The test was performed on fish infected with skin parasites. 1000 hamachi (average bodyweight of 550 g) were treated twice on a 2-week interval. Growth and survival rate were investigated.

Result : Result:
No mortality was found. Growth was increased as compared to control group.

Reliability : (4) not assignable
Original reference not available

27.02.2003 (37)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type : semistatic
Species : Daphnia pulex (Crustacea)
Exposure period : 48 hour(s)
Unit : mg/l
NOEC : = 2
EC50 : = 4.9
Limit Test : no
Analytical monitoring : yes
Method : other: EPA guidelines
Year : 1989
GLP : no
Test substance : other TS

Method : DEVIATIONS FROM GUIDELINE: not described
ANALYTICAL MONITORING: The concentration of hydrogen peroxide was determined by titration with potassium permanganate within 30 minutes on fresh and 24-h old solutions. This means that the concentration percarbonate was derived from the measured hydrogen peroxide concentration
STATISTICAL METHOD: The LC50 and its 95 % confidence limits was calculated using the Trimmed Spearman-Karber statistical method. The LC50 was calculated using the average titrimetrically-determined concentrations.

Result : RESULTS EXPOSED

nom conc (mg/l)	meas conc (mg/l)	Mortality (no. dead/no. tested) 24h	48h
1.0	2.0	0/20	0/20
10	11.8	20/20	20/20
50	45.5	20/20	20/20
100	88.7	20/20	20/20
500	415.5	20/20	20/20
1000	834.6	20/20	20/20

RESULTS CONTROL
No control mortality was observed.
ANALYTICAL RESULTS
At nominal concentrations of 1 and 10 mg/l, the measured initial concentrations were 2.0 and 11.8 mg/l, respectively. The measured concentrations did not decrease between start of the exposure and renewal (24 h) for these 2 concentrations.

Test condition : TEST ORGANISMS
- Source/Supplier: Brood stocks have been maintained by Burlington Research for 6 years. The starting culture was obtained from the Aquatic Toxicology Group (Divison of Environmental Management, North Carolina)
- Breeding method: daphnids are cultured at a temperature of 20 ± 1°C in a static system in 2000 ml Pyrex borosilicate glass beakers without aeration. The light intensity was approximately 500 lux with a light-dark cycle of 16h:8h. Solutions are renewed on Monday, Wednesday and Friday of each week.
- Age: 12-24 hours
- Feeding: suspension of Selenastrum capricornutum and digested salmon chow, yeast and Cerophyll®
- Feeding during test: no

STOCK AND TEST SOLUTION AND THEIR PREPARATION

- Vehicle, solvent: 1 % w/v stock solutions were prepared in reconstituted water

REFERENCE SUBSTANCE
- Biweekly quality control bioassays with reference toxicants

DILUTION WATER
- Source: reconstituted dilution water based on a 1:1 mixture of Triton® distilled and lake water (Lake Cammack, North Carolina)
- Alkalinity: not described
- Hardness: 50-250 mg/l CaCO3

TEST SYSTEM
- Concentrations: 0, 1, 10, 50, 100, 500 and 1000 mg/l
- Renewal of test solution: daily
- Exposure vessel type: Falcon brand 250 ml polyprolylene cups with polypropylene lids containing 200 ml test solution
- Number of replicates/individuals per replicate: 2 / 10
- Test temperature: 20 ± 1°C
- Dissolved oxygen: > 96 % saturation
- pH: 6.8-9.9
- Adjustment of pH: the pH of solutions with concentrations of 500 and 1000 mg/l was adjusted below 9.0 with 1.2N HCl
- Intensity of irradiation: 500 lux
- Photoperiod: 16h light: 8h dark

TEST PARAMETER: mortality

Test substance : TEST SUBSTANCE
- Test substance: Sodium percarbonate
- Source: Solvay Interox S.A.
- Purity: > 88 %

Reliability : (1) valid without restriction
Test procedure in accordance with generally accepted scientific standards and described in sufficient detail.

Flag : Critical study for SIDS endpoint

11.01.2006 (33)

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

Species	:	Anabaena sp. (Algae)
Endpoint	:	other: optical density
Exposure period	:	140 hour(s)
Unit	:	mg/l
EC50	:	= 8
Limit test	:	no
Analytical monitoring	:	no
Method	:	other
Year	:	1991
GLP	:	no
Test substance	:	other TS

Method : STATISTICAL METHOD
The optical density was plotted against concentration. The EC50 value was determined from the dose/response curve.

Result : RESULTS
Concentrations of 3 and 6 mg/l had relatively little effect on the optical density. Growth suppresion occurred for 48 h in 9 mg/l, however subsequent rapid growth re-established the population at 46 % of control density at 140 hours. Inhibition occurred throughout the experiment at 12 mg/l.

Test condition : TEST ORGANISMS
- Strain: Anabaena A4
- Source/supplier: University of Dundee
- Method of cultivation: working cultures maintained in 100 ml medium in 250 ml glass conical flasks at 25°C. Sub-culturing was carried out weekly
- Pretreatment: established liquid cultures (140 h) were centrifuged at 3,000 rpm for 15 min. The pellet was resuspended in fresh, sterile, growth medium
- Controls: yes
- Initial cell concentration: 1,000,000 cells/ml

REFERENCE SUBSTANCE: not described
TEST MEDIUM CHEMISTRY
- Test medium: BG 11 medium
- Dilution water: distilled water

TEST SYSTEM
- Concentrations: 0, 3, 6, 9, 12, 15, 18, 21, 24 and 27 mg/l
- Renewal of test solutions: no
- Exposure vessel type: microtitre plates (12 x 8 cm), with 96 cylindrical flat-bottomed wells of 300 µl capacity containing 200 µl test solution (170 µl medium and 30 µl inoculum)
- Number of replicates: 6
- Test temperature: 25°C
- pH: pH of stock solutions was adjusted to pH 7.0
- Intensity of irradiation: fluorescent illumination (28 µmol/m2/s)
- Photoperiod: continuous illumination

TEST PARAMETER: Total growth inhibition
MEASUREMENTS: optical density at 630 nm was determined at 24 h intervals

Test substance : TEST SUBSTANCE
- Test substance: sodium carbonate peroxyhydrate (PCS)
- Source: Solvay Interox S.A.
- Purity: approximately 90 %

Reliability : (3) invalid
At the high concentrations (without growth recovery) there is probably continuous exposure and therefore these results could be considered valid. A significant recovery at lower concentrations is probably related with a degradation of hydrogen peroxide during the test period and therefore these results are invalid. Because there is no guarantee for exposure during the test, the overall results (EC50 and NOEC) are considered invalid and therefore a reliability of (3) was assigned.

16.01.2006 (7)

Species : Anabaena variabilis (Algae)
Endpoint : other: optical density
Exposure period : 140 hour(s)
Unit : mg/l
EC50 : = 19
Limit test : no
Analytical monitoring : no
Method : other
Year : 1991
GLP : no
Test substance : other TS

Method : STATISTICAL METHOD
The optical density was plotted against concentration. The EC50 value was determined from the dose/response curve.

Result : RESULTS:
Concentrations up to and including 24 mg/l were moderately inhibitory but a small increase in concentration e.g. to 27 mg/l, produced complete inhibition.

Test condition : TEST ORGANISMS
- Source/supplier: University of Warwick
- Method of cultivation: working cultures maintained in 100 ml medium in 250 ml glass conical flasks at 25°C and 80 oscillations per minute. Sub-culturing was carried out weekly
- Pretreatment: established liquid cultures (140 h) were centrifuged at 3,000 rpm for 15 min. The pellet was resuspended in fresh, sterile, growth medium
- Controls: yes
- Initial cell concentration: 1,000,000 cells/ml

REFERENCE SUBSTANCE: not described
TEST MEDIUM CHEMISTRY
- Test medium: BG 11 medium
- Dilution water: distilled water

TEST SYSTEM
- Concentrations: 0, 3, 6, 9, 12, 15, 18, 21, 24 and 27 mg/l
- Renewal of test solutions: no
- Exposure vessel type: microtitre plates (12 x 8 cm), with 96 cylindrical flat-bottomed wells of 300 µl capacity containing 200 µl test solution (170 µl medium and 30 µl inoculum)
- Number of replicates: 6
- Test temperature: 25°C
- pH: pH of stock solutions was adjusted to pH 7.0
- Intensity of irradiation: fluorescent illumination (28 µmol/m2/s)
- Photoperiod: continuous illumination

TEST PARAMETER: Total growth inhibition
MEASUREMENTS: optical density at 630 nm was determined at 24 h intervals

Test substance : TEST SUBSTANCE
- Test substance: sodium carbonate peroxyhydrate (PCS)
- Source: Solvay Interox S.A.
- Purity: approximately 90 %

Reliability : (3) invalid
At the high concentrations (without growth recovery) there is probably continuous exposure and therefore these results could be considered valid. A significant recovery at lower concentrations is probably related with a degradation of hydrogen peroxide during the test period and therefore these results are invalid. Because there is no guarantee for exposure during the test, the overall results (EC50 and NOEC) are considered invalid and therefore a reliability of (3) was assigned.

16.01.2006 (7)

Species : Chlamydomonas sp. (Algae)
Endpoint : other: optical density
Exposure period : 240 hour(s)
Unit : mg/l
EC50 : = 100 - 200
Limit test : no
Analytical monitoring : no
Method : other
Year : 1991
GLP : no
Test substance : other TS

Method : STATISTICAL METHOD
The optical density was plotted against concentration. The EC50 value was determined from the dose/response curve.

Result : RESULTS
Growth was arrested for 65 h by 100 mg/l, after which time growth proceeded at a rate similar to that of the control culture. Total growth inhibition was maintained at 200 mg/l.

Test condition : TEST ORGANISMS
- Strain: Chlamydomonas eugametos
- Source/supplier: Culture centre of algae and protozoa (Cambridge)
- Method of cultivation: working cultures maintained in 100 ml medium in 250 ml glass conical flasks at static conditions at 25°C and 80. Sub-culturing was carried out weekly
- Pretreatment: established liquid cultures (96 h) were centrifuged at 3,000 rpm for 15 min. The pellet was resuspended in fresh, sterile, growth medium
- Controls: yes
- Initial cell concentration: 300,000 cells/ml

REFERENCE SUBSTANCE: not described
TEST MEDIUM CHEMISTRY
- Test medium: Volvox medium
- Dilution water: distilled water

TEST SYSTEM
- Concentrations: 0, 100, 200, 300, 400, 500, 600, 700, 800 and 850 mg/l
- Renewal of test solutions: no
- Exposure vessel type: microtitre plates (12 x 8 cm), with 96 cylindrical flat-bottomed wells of 300 µl capacity containing 200 µl test solution (170 µl medium and 30 µl inoculum)
- Number of replicates: 6
- Test temperature: 25°C
- pH: pH of stock solutions was adjusted to pH 7.0
- Intensity of irradiation: fluorescent illumination (28 µmol/m2/s)
- Photoperiod: continuous illumination

TEST PARAMETER: Total growth inhibition
MEASUREMENTS: optical density at 630 nm was determined at 24 h intervals

Test substance : TEST SUBSTANCE
- Test substance: sodium carbonate peroxyhydrate (PCS)
- Source: Solvay Interox S.A.
- Purity: approximately 90 %

Reliability : (3) invalid
At the high concentrations (without growth recovery) there is probably continuous exposure and therefore these results could be considered valid. A significant recovery at lower concentrations is probably related with a degradation of hydrogen peroxide during the test period and therefore these results are invalid. Because there is no guarantee for exposure during the test, the overall results (EC50 and NOEC) are considered invalid and therefore a reliability of (3) was assigned.

16.01.2006 (7)

Species : Chlorella emersonii (Algae)
Endpoint : other: optical density
Exposure period : 240 hour(s)
Unit : mg/l
EC50 : = 100 - 200

Limit test : no
Analytical monitoring : no
Method : other
Year : 1991
GLP : no
Test substance : other TS

Method : STATISTICAL METHOD
The optical density was plotted against concentration. The EC50 value was determined from the dose/response curve.

Result : RESULTS
Reduction of the optical density occurred in medium containing 100 and 200 mg/l for up to 90 h. After this time the optical density rose slightly, but extensive inhibition was still maintained.

Test condition : TEST ORGANISMS
- Source/supplier: Culture centre of algae and protozoa (Cambridge)
- Method of cultivation: working cultures maintained in 100 ml medium in 250 ml glass conical flasks at 25°C. Sub-culturing was carried out weekly
- Pretreatment: established liquid cultures (96 h) were centrifuged at 3,000 rpm for 15 min. The pellet was resuspended in fresh, sterile, growth medium
- Controls: yes
- Initial cell concentration: 300,000 cells/ml

REFERENCE SUBSTANCE: not described
TEST MEDIUM CHEMISTRY
- Test medium: Volvox medium
- Dilution water: distilled water

TEST SYSTEM
- Concentrations: 0, 100, 200, 300, 400, 500, 600, 700, 800 and 850 mg/l
- Renewal of test solutions: no
- Exposure vessel type: microtitre plates (12 x 8 cm), with 96 cylindrical flat-bottomed wells of 300 µl capacity containing 200 µl test solution (170 µl medium and 30 µl inoculum)
- Number of replicates: 6
- Test temperature: 25°C
- pH: pH of stock solutions was adjusted to pH 7.0
- Intensity of irradiation: fluorescent illumination (28 µmol/m2/s)
- Photoperiod: continuous illumination

TEST PARAMETER: Total growth inhibition
MEASUREMENTS: optical density at 630 nm was determined at 24 h intervals

Test substance : TEST SUBSTANCE
- Test substance: sodium carbonate peroxyhydrate (PCS)
- Source: Solvay Interox S.A.
- Purity: approximately 90 %

Reliability : (3) invalid
At the high concentrations (without growth recovery) there is probably continuous exposure and therefore these results could be considered valid. A significant recovery at lower concentrations is probably related with a degradation of hydrogen peroxide during the test period and therefore these results are invalid. Because there is no guarantee for exposure during the test, the overall results (EC50 and NOEC) are considered invalid and therefore a reliability of (3) was assigned.

16.01.2006 (7)

Species : Scenedesmus quadricauda (Algae)
Endpoint : other: optical density

Exposure period	:	240 hour(s)
Unit	:	mg/l
LOEC	:	= 100
EC50	:	ca. 150
Limit test	:	no
Analytical monitoring	:	no
Method	:	other
Year	:	1991
GLP	:	no
Test substance	:	other TS
Method	:	STATISTICAL METHOD The optical density was plotted against concentration. The EC50 value was determined from the dose/response curve.
Result	:	RESULTS At 100 mg/l the optical density fell initially and barely significant inhibition followed. Both 200 and 300 mg/l caused an initial drop in optical density, however in 200 mg/l slow growth occurred later.
Test condition	:	TEST ORGANISMS - Source/supplier: Culture Centre of Algae and Protozoa (Cambridge) - Method of cultivation: Working cultures maintained in 100 ml medium in 250 ml glass conical flasks at 25°C and 30 µmol/m2/s. Sub-culturing was carried out weekly - Pretreatment: established liquid cultures (96 h) were centrifuged at 3,000 rpm for 15 min. The pellet was resuspended in fresh, sterile, growth medium - Controls: yes - Initial cell concentration: 300,000 cells/ml REFERENCE SUBSTANCE: not described TEST MEDIUM CHEMISTRY - Test medium: Volvox medium - Dilution water: distilled water TEST SYSTEM - Concentrations: 0, 100, 200, 300, 400, 500, 600, 700, 800 and 850 mg/l - Renewal of test solutions: no - Exposure vessel type: microtitre plates (12 x 8 cm), with 96 cylindrical flat-bottomed wells of 300 µl capacity containing 200 µl test solution (170 µl medium and 30 µl inoculum) - Number of replicates: 6 - Test temperature: 25°C - pH: pH of stock solutions was adjusted to pH 7.0 - Intensity of irradiation: fluorescent illumination (28 µmol/m2/s) - Photoperiod: continuous illumination TEST PARAMETER: Total growth inhibition MEASUREMENTS: Optical density at 630 nm was determined at 24 h intervals
Test substance	:	TEST SUBSTANCE - Test substance: sodium carbonate peroxyhydrate (PCS) - Source: Solvay Interox S.A. - Purity: approximately 90 %
Reliability	:	(3) invalid At the high concentrations (without growth recovery) there is probably continuous exposure and therefore these results could be considered valid. A significant recovery at lower concentrations is probably related with a degradation of hydrogen peroxide during the test period and therefore these results are invalid. Because there is no guarantee for exposure during the test, the overall results (EC50 and NOEC) are considered invalid

and therefore a reliability of (3) was assigned.

16.01.2006 (7)

Species	:	other algae: Synechococcus leopoliensis
Endpoint	:	other: optical cell density
Exposure period	:	160 hour(s)
Unit	:	mg/l
LOEC	:	= 100
EC50	:	ca. 160
Limit test	:	no
Analytical monitoring	:	no
Method	:	other
Year	:	1991
GLP	:	no
Test substance	:	other TS

Method : STATISTICAL METHOD
The optical density was plotted against concentration. The EC50 value was determined from the dose/response curve.

Result : RESULTS
At 100 mg/l there was a short growth delay effect. In 200 mg/l growth was inhibited for 48 h, after which moderate growth proceeded. Throughout the experiment 300 mg/l was inhibitory.

Test condition : TEST ORGANISMS
- Source/supplier: Culture centre of algae and protozoa (Cambridge)
- Method of cultivation: Method of cultivation: working cultures maintained in 100 ml medium in 250 ml glass conical flasks at 25°C and 25 µmol/m2/s P.A.R. Sub-culturing was carried out weekly
- Pretreatment: established liquid cultures (140 h) were centrifuged at 3,000 rpm for 15 min. The pellet was resuspended in fresh, sterile, growth medium25 µmol/m2/s P.A.R.
- Controls: yes
- Initial cell concentration: 1,000,000 cells/ml

REFERENCE SUBSTANCE: not described
TEST MEDIUM CHEMISTRY
- Test medium: BG11 medium
- Dilution water: distilled water

TEST SYSTEM
- Concentrations: 0, 100, 200, 300, 400, 500, 600, 700, 800 and 850 mg/l
- Renewal of test solutions: no
- Exposure vessel type: microtitre plates (12 x 8 cm), with 96 cylindrical flat-bottomed wells of 300 µl capacity containing 200 µl solution (170 µl medium and 30 µl inoculum)
- Number of replicates: 6
- Test temperature: 25°C
- pH: pH of stock solutions was adjusted to pH 7.0
- Intensity of irradiation: fluorescent illumination (28 µmol/m2/s)
- Photoperiod: continuous illumination

TEST PARAMETER: Total growth inhibition
MEASUREMENTS: Optical density at 630 nm was determined at 24 h intervals

Test substance : TEST SUBSTANCE
- Test substance: sodium carbonate peroxyhydrate (PCS)
- Source: Solvay Interox S.A.
- Purity: approximately 90 %

Reliability : (3) invalid
At the high concentrations (without growth recovery) there is probably continuous exposure and therefore these results could be considered valid. A significant recovery at lower concentrations is probably related with a degradation of hydrogen peroxide during the test period and therefore these results are invalid. Because there is no guarantee for exposure during the test, the overall results (EC50 and NOEC) are considered invalid and therefore a reliability of (3) was assigned.

16.01.2006 (7)

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

4.5.1 CHRONIC TOXICITY TO FISH

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANISMS

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS

4.6.4 TOX. TO OTHER NON MAMM. TERR. SPECIES

4.7 BIOLOGICAL EFFECTS MONITORING

4.8 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

Remark : Conclusion from SIAR, section 3.1.1:

Dermal absorption of sodium percarbonate is assumed to be low and after getting into contact with body fluids it will dissociate into hydrogen peroxide, carbonate ions and sodium ions. All three components are 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, sodium percarbonate exposure is not expected to contribute significantly to the sodium load of the body.

16.01.2006 (14) (29) (30)

5.1.1 ACUTE ORAL TOXICITY

Type : LD50
Value : = 1034 mg/kg bw
Species : rat
Strain : other: Crl: CD®BR
Sex : male/female
Number of animals : 30
Vehicle : water
Doses : 700, 1000 and 1500 mg/kg
Method : other: EPA guidelines
Year : 1990
GLP : yes
Test substance : other TS

Method : DEVIATIONS FROM GUIDELINE: not described
STATISTICAL METHOD: The LD50 value for males, females and the sexes combined was determined by a computer program utilizing a Modified Behrens-Reed-Muench Cumulant Method. No other statistical methods were performed.

Result : MORTALITY

Sex	Dose level (mg/kg)	Mortality (number Dead/number dosed)
Male	700	0/5
	1000	1/5
	1500	5/5
Female	700	1/5
	1000	3/5
	1500	5/5

The estimated oral LD50 was determined to be 1164; 893 and 1034 mg/kg of body weight for males, females and the combined sexes, respectively. All mortality occurred within 3 days of test material administration.
CLINICAL SIGNS
Hypoactivity, ataxia, diarrhea, red-stained face, dyspnea, absence of pain

reflex, excessive salivation, brown-stained urogenital area, prostration, and death. Animals surviving until the end of the observation period exhibited weight gain.
NECROPSY FINDINGS
Coloration changes in the glandular portion of the stomach. The wall of these stomachs were occasionally thickened as well.

Test condition : TEST ORGANISMS
- Source: Charles River Laboratories, Inc., Portage MI
- Age: Young adult (approximately 8 weeks old)
- Weight at study initiation: 201 - 282 g
- Acclimation: at least 7 days
- Controls: no

ADMINISTRATION
- Doses per time period: single dose
- Volume administered or concentration: An individual dose was calculated for each animal based upon its fasted body weight and administered by gavage using a dose volume of 10.0 ml/kg

EXAMINATIONS
- Animals were observed for clinical signs and mortality at 1, 2.5 and 4 hours after test material administration. These animals were observed daily thereafter for 14 days for clinical signs and twice daily for mortality.

Test substance : TEST SUBSTANCE
- Test substance: Sodium Percarbonate
- Source: Solvay Interox s.a.
- Purity: > 88 %

Reliability : (1) valid without restriction
GLP Guideline study

Flag : Critical study for SIDS endpoint

28.10.2003 (18)

Type : LD50
Value : = 2000 mg/kg bw
Species : rat
Strain : other: Alderley Park albino
Sex : male/female
Number of animals : 24
Vehicle : other: maize oil
Doses : 1000, 1700, 2900 and 5000 mg/kg
Method : other: general methods manual No 2
Year : 1978
GLP : no
Test substance : no data

Method : DEVIATIONS FROM GUIDELINE: not described
STATISTICAL METHOD: not described

Result : MORTALITY

Sex	Dose level (mg/kg)	Mortality (number Dead/number dosed)
Male	1000	0/3
	1700	1/3
	2900	3/3
	5000	3/3
Female	1000	0/3
	1700	1/3
	2900	3/3
	5000	3/3

CLINICAL SIGNS

Piloerection, incontinence, dehydration and atrophy of the testis
NECROPSY FINDINGS
Necropsy findings indicated that an effect was present in the stomach. The stomach had undergone inflamation and necrosis. Death was always found to be associated with the stomach and intestine being gas filled and enlarged.

Test condition : TEST ORGANISMS
- Source: not described
- Age: not described
- Weight at study initiation: 150-200 g
- Acclimation: not described
- Controls: no

ADMINISTRATION
- Doses per time period: single dose
- Volume administered or concentration: rats were dosed with the material, as a 10% suspension in maize oil

EXAMINATIONS
- Animals were observed for death or clinical signs of toxicity for a period of 14 days following dosing. A second group dosed at 1700 mg/kg were sacrificed at 48 hours for histopathological examination.

Reliability : (2) valid with restrictions
Materials and methods are not described in sufficient detail. Results and histopathology findings following the oral administration are described in sufficient detail.

27.10.2003 (6)

Type : LD50
Value : = 2050 - 2200 mg/kg bw
Species : mouse
Strain : other: ddY
Sex : male/female
Number of animals : 130
Vehicle : water
Doses : 1500-2420 mg/kg for males and 1740-3040 mg/kg for females
Method : other
Year : 1986
GLP : no
Test substance : other TS

Method : DEVIATIONS FROM GUIDELINE: not described
STATISTICAL METHOD: The LD50 value was calculated using the Litchfield-Wilcoxon method.

Result : MORTALITY

Dose level (mg/kg)	Mortality (no. Dead/no.dosed)	Dose level (mg/kg)	Mortality (no. Dead/no.dosed)
MALE		FEMALE	
cont.	0/10	cont.	0/10
1500	0/10	1740	0/10
1650	1/10	2000	0/10
1820	1/10	2300	2/10
2000	4/10	2650	9/10
2200	8/10	3040	10/10
2420	10/10		

Death of the animals, both male and female, occurred starting from the 3rd hour after application and ending on the 3rd day after application. The LD50 value was 2050 mg/kg (with 95 % confidence limit of 1880-2230) for the males and 2200 mg/kg (1980-2440) for the females.

CLINICAL SIGNS
Clinical signs appeared from 5 minutes after dosing and were depression of spontaneous movement and abdomen distension, diarrhea, various behavioural symptoms.
NECROPSY FINDINGS
At necropsy, dead animals presented a slight degree of congestion or blood spots in the stomach mucosa, and blood was mixed with the stomach contents. Furthermore distention of the GI tract was observed. Slight congestion in the brain and lungs in the high-dose group. Few signs of congestion in animals that survived for 14 days.

Test condition : TEST ORGANISMS
- Source: Shizuoka Experimental Animal Agricultural Cooperative
- Age: 5 weeks
- Weight at study initiation: not described
- Acclimation: one week
- Controls: yes, a volume of solvent (= water) equal to the maximum dose of test substance was applied

ADMINISTRATION
- Doses per time period: single dose
- Volume administered or concentration: a 4 % aqueous solution was prepared and an oral dose was applied swiftly using the injection tube of a metal stomach probe for mice.

EXAMINATIONS
- The general condition of the animals was observed over a period of 14 days. Animals that died during this period were autopsied immediately after death and animals that survived to the end of the test were killed and autopsied.

Test substance : TEST SUBSTANCE
- Source: Kao Sekken [Peony Soup] Co.
- Purity: white granules containing 80 % sodium percarbonate

Reliability : (2) valid with restrictions
Study well documented, control group included. Animal weight at test initiation not described.

11.01.2006 (27)

Type : other
Value : = 300 mg/kg bw
Species : dog
Strain :
Sex :
Number of animals :
Vehicle :
Doses :

Remark : Vomiting within 5 minutes
Reliability : (4) not assignable
Original reference not available

27.02.2003 (25)

5.1.2 ACUTE INHALATION TOXICITY

Type : LC0
Value : > 4.58 mg/l
Species : rat
Strain :

Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Exposure time	:	1 hour(s)
Method	:	other: no data
Year	:	1977
GLP	:	no data
Test substance	:	no data
Remark	:	No signs of toxicity or irritation
Reliability	:	(4) not assignable Original reference not available

23.04.2002 (23)

5.1.3 ACUTE DERMAL TOXICITY

Type	:	LDLo
Value	:	> 2000 mg/kg bw
Species	:	rabbit
Strain	:	New Zealand white
Sex	:	male/female
Number of animals	:	10
Vehicle	:	other: 0.9 % saline
Doses	:	2000 mg/kg
Method	:	other: EPA Guidelines
Year	:	1990
GLP	:	yes
Test substance	:	other TS
Method	:	DEVIATIONS FROM GUIDELINE: not described STATISTICAL METHOD: No statistical method was performed.
Result	:	MORTALITY - No mortality was observed during the test CLINICAL SIGNS - No mortality or test material related clinical signs were observed. The level of dermal irriation was severe. Body weight losses of 10 to 128 g were noted for four animals at day 7 and in one animal at day 14. Dermal irriation consisted of slight to severe erythema and oedema and slight to marked atonia, desquamation, coriaceousness ("leathery appearance") and fissuring. NECROPSY FINDINGS - Test material related lesions observed at necropsy were limited to comments concerning crusted areas of the treated skin. SEX-SPECIFIC DIFFERENCES: - No sex-specific differences were observed.
Test condition	:	TEST ORGANISMS - Source: Hazleton Research Products, Inc., Denver PA - Age: Young adult (approximately 14 weeks old) - Weight at study initiation: 2510 - 2894 g - Acclimation: at least 7 days - Controls: no ADMINISTRATION - Area covered: not described - Occlusion: 10 cm x 10 cm gauze patch secured with paper tape - Concentration in vehicle: not described - Total volume of vehicle applied: not described

- Removal of test substance: 24-hours after test material application the bandages were removed and the residual test material was removed with lukewarm tap water

EXAMINATIONS
- Animals were observed for clinical signs and mortality at 1, 2.5 and 4 hours after test material administration. The animals were observed daily for clinical signs and twice daily (morning and afternoon) for mortality.

Test substance : TEST SUBSTANCE
- Test substance: Sodium Percarbonate
- Source: Solvay Interox s.a.
- Purity: > 88 %

Reliability : (1) valid without restriction
GLP guideline study

Flag : Critical study for SIDS endpoint

11.01.2006 (17)

5.1.4 ACUTE TOXICITY, OTHER ROUTES

5.2.1 SKIN IRRITATION

Species : rabbit
Concentration : .5 g
Exposure : Semiocclusive
Exposure time : 4 hour(s)
Number of animals : 6
Vehicle : physiol. saline
PDII :
Result : slightly irritating
Classification : not irritating
Method : EPA OPP 81-5
Year : 1990
GLP : yes
Test substance : other TS

Result : AVERAGE SCORE

Observation Period	Average Score
4 hours	2.2
24 hours	1.2
48 hours	1.2
72 hours	1.2
96 hours	1.0
Day 7	0.0
Day 14	0.0

Application of sodium percarbonate to rabbits under 4-hour semioccluded conditions resulted in slight to moderate erythema and oedema reactions. The highest erythema and edema score was 2 and this score was observed up to 7 days after patch removal. No reaction was discernible anymore after 14 days.

Test condition : TEST ANIMALS
- Strain: New Zealand White
- Sex: male (3)/female (3)
- Source: Hazleton Research Products, Inc.

- Age: Adult
- Weight at study initiation: 2608 - 2914 g
- Controls: intact skin of each animal

ADMINISTRATION/EXPOSURE
- Preparation of test substance: dosed as received
- Area of exposure: approximately 6.25 cm²
- Occlusion: the area of application will be covered with a 2.5 cm x 2.5 cm gauze patch secured with paper tape and loosely overwrapped
- Postexposure period: 14 days

EXAMINATIONS
- Scoring system: the degree of erythema and oedema was read according to the Draize method, the highest possible score is 4.
- Examination time points: examinations were made at 0.5, 24, 48, 72 and 96 hours and days 7 and 14 after patch removal.

Test substance : TEST SUBSTANCE
Test substance: Sodium percarbonate
Source: Solvay Interox s.a.
Purity: > 88 %

Reliability : (1) valid without restriction
GLP Guideline study

Flag : Critical study for SIDS endpoint

10.01.2006 (20)

Species : rat
Concentration :
Exposure :
Exposure time : 12 day(s)
Number of animals :
Vehicle : no data
PDII :
Result : slightly irritating
Classification : not irritating
Method : other: not described
Year : 1978
GLP : no
Test substance : no data

Result : DESCRIPTION OF EFFECTS
Powder: slight/mild irritant to rat skin. Slight erythema and desquamation developed by the 4th application but this did not progress during the remainder of the test period.
1 % Aqueous solution: practically non-irritant to rat skin, slight erythema and desquamation only becoming apparent during the last 2 days of the test.

Test condition : TEST ANIMALS
- Strain: Alderley Park albino
- Sex: female
- Source: not described
- Age: not described
- Weight at study initiation: 150 - 200 g
- Number of animals: not described
- Controls: not described

ADMINISTRATION/EXPOSURE
- Preparation of test substance: rats were exposed to repeated applications of the test material, either as solid or as a 1 % aqueous solution
- Area of exposure/occlusion: not described
- Total volume applied: not described
- Postexposure period: application repeated for 12 days

EXAMINATIONS
- Scoring system: not described
- Examination time points: not described

Reliability : (3) invalid
Documentation insufficient for assessment. Several essential test parameters (number of animals, application of test substance etc.) not described

10.01.2006 (6)

Remark : A human patch (skin irritation) test with 88-92% sodium percarbonate (source: Interox) was performed using 26 human volunteers and exposing them for 15, 30 or 60 minutes through to 2, 3 and 4 hours. The patch test involved the application of 0.2 g on to a plain Hill Top Chamber and treated sites were assessed 24, 48 and 72 hours after patch removal. The upper outer arm was used as the treatment site for all experiments.

Only one out of 26 volunteers (4 %) was considered to have demonstrated a "positive" irritant reaction. Based on the results of the human patch test the authors concluded that sodium percarbonate should not be classified for skin irritation in the European Union.

Reliability : (2) valid with restrictions
16.01.2006 (3) (4) (40)

5.2.2 EYE IRRITATION

Species : rabbit
Concentration : .1 g
Dose :
Exposure time : 96 hour(s)
Comment : not rinsed
Number of animals : 6
Vehicle : none
Result : highly irritating
Classification : risk of serious damage to eyes
Method : EPA OPP 81-4
Year : 1990
GLP : yes
Test substance : other TS

Result : AVERAGE SCORE

Observation period (hour)	Average Score
1	19.3
24	103.0
48	108.5
72	47.6
96	36.0

DESCRIPTION OF LESIONS
pain response, blanching of the conjuctivae, petite hemorrhaging of the conjunctivae, corneal peeling of
epithelium. Necrosis of the conjunctivae was seen in one animal at 48 hours and in six animals at 72 and 96 hours.

Test condition : TEST ANIMALS
- Strain: New Zealand White
- Source: Hazleton Research Products, Inc.

- Sex: male and female
- Age: young adult
- Weight at study initiation: 2536 - 2810 g
- Controls: the contralateral eye served as untreated control

ADMINISTRATION/EXPOSURE
- Preparation of the test substance: An individual dose of 0.10 g was weighed out for each animal

EXAMINATIONS
- Ophtalmoscopic examination: changes of the cornea, iris and conjunctiva. Sodium fluorescein was used to aid in revealing possible corneal injury.
- Scoring system: Draize method
- Observation period: observations were made 1, 24, 48, 72 and 96 hours after treatment. The study was stopped after 96 hours.

Test substance : TEST SUBSTANCE
- Test substance: Sodium Percarbonate
- Source: Solvay Interox s.a.
- Purity: not described

Reliability : (1) valid without restriction
GLP Guideline study

Flag : Critical study for SIDS endpoint

10.01.2006 (21)

Species : rabbit
Concentration : 100 mg
Dose :
Exposure time : 24 hour(s)
Comment : not rinsed
Number of animals : 1
Vehicle : none
Result : highly irritating
Classification : risk of serious damage to eyes
Method : OECD Guide-line 405 "Acute Eye Irritation/Corrosion"
Year : 1995
GLP : yes
Test substance : other TS

Result : AVERAGE SCORE

	Score 1 hour	Score 24 hours
Cornea	20	40
Iris	5	5
Conjunctivae	14	16
Total score	39	61

DESCRIPTION OF LESIONS
Translucent corneal opacity, iridial inflammation and moderate conjunctival irritation.
OTHER EFFECTS
Haemorrhage of the upper and lower conjunctival membranes and nictitating membrane and the presence of white areas on the lower conjunctival membrane.

Test condition : TEST ANIMALS
- Strain: New Zealand White
- Source: David Percival Ltd., Moston, Sandbach, Cheshire,

UK
- Sex: female
- Age: 12 - 16 weeks
- Weight at study initiation: 2.82 kg
- Control: the left eye remained untreated

ADMINISTRATION/EXPOSURE
- Preparation of the test substance: the test material was ground to a fine powder before use

EXAMINATIONS
- Ophtalmoscopic examination: ocular damage and irritation
- Scoring system: Draize method, maximum total score possible = 110
- Observation period: observations were made 1 and 24 hours following treatment. The study was stopped after 24 hours.

Test substance : TEST SUBSTANCE
- Test substance: Sodium carbonate peroxyhydrate
- Source: Solvay Interox s.a.
- Purity: > 88 %

Reliability : (1) valid without restriction
GLP guideline study

Flag : Critical study for SIDS endpoint

10.01.2006 (10)

Species : rabbit
Concentration : 100 mg
Dose :
Exposure time : 24 hour(s)
Comment : not rinsed
Number of animals : 1
Vehicle : none
Result : highly irritating
Classification : risk of serious damage to eyes
Method : OECD Guide-line 405 "Acute Eye Irritation/Corrosion"
Year : 1995
GLP : yes
Test substance : other TS

Result : AVERAGE SCORE

	Score 1 hour	Score 5 hours
Cornea	40	40
Iris	5	5
Conjunctivae	14	16
Total score	59	61

DESCRIPTION OF LESIONS
Translucent corneal opacity, iridial inflammation and moderate to severe conjunctival irritation.
OTHER EFFECTS
Petechial haemorrhage of the nictitating membrane and haemorrhage of the conjunctival membrane and nictitating membrane.

Test condition : TEST ANIMALS
- Strain: New Zealand White
- Source: David Percival Ltd., Moston, Sandbach, Cheshire, UK
- Sex: male
- Age: 12 - 17 weeks
- Weight at study initiation: 2.78 kg
- Control: the left eye remained untreated

ADMINISTRATION/EXPOSURE
- Preparation of the test substance: the test material was ground to a fine powder before use

EXAMINATIONS
- Ophtalmoscopic examination: ocular damage and irritation
- Scoring system: Draize method, maximum total score possible = 110
- Observation period: observations were made 1 and 5 hours following treatment. The study was stopped after 5 hours.

Test substance : TEST SUBSTANCE
- Test substance: Sodium carbonate peroxyhydrate
- Source: Solvay Interox s.a.
- Purity: > 88 %

Reliability : (1) valid without restriction
GLP Guideline study

Flag : Critical study for SIDS endpoint

10.01.2006 (12)

Species : rabbit
Concentration :
Dose :
Exposure time :
Comment : not rinsed
Number of animals : 4
Vehicle : none
Result : corrosive
Classification : risk of serious damage to eyes
Method : OECD Guide-line 405 "Acute Eye Irritation/Corrosion"
Year : 1995
GLP : yes
Test substance : other TS

Result : AVERAGE SCORE
10 mg Dose Level: 18.7
50 mg Dose Level: 61
DESCRIPTION OF LESIONS
10 mg Dose Level: translucent corneal opacity, irridial inflammation and moderate conjunctival irritation. Other effects were petechial haemorrhage of the nictitating membrane and vascularisation of the cornea.
50 mg Dose Level: translucent corneal opacity, irridial inflammation and moderate to severe conjunctival irritation. Other effects were petechial haemorrhage of the nictitating membrane and haemorrhage of the nictitating and conjuntival membranes.
REVERSIBILITY
10 mg Dose Level: Two treated eyes appeared normal 7 days after treatment. Corneal opacity and vascularisation persisted in one treated eye at the 21-day observation and these effects were considered to be irreversible.

Test condition : TEST ANIMALS
- Strain: New Zealand White
- Source: David Percival Ltd., Moston, Sandbach, Cheshire, UK
- Sex: male/female
- Age: 12 - 16 weeks
- Weight at study initiation: 2.73 - 3.05 kg
- Controls: the left eyes remained untreated

ADMINISTRATION/EXPOSURE
- Preparation of the test substance: the test material was ground to a fine powder before use
- Amount of substance instilled: 10 mg (3 animals) and 50 mg (1 animal)

EXAMINATIONS
- Ophtalmoscopic examination: ocular damage and irritation
- Scoring system: Draize method, maximum total score possible = 110
- Observation period:
10 mg Dose Level: observations were made 1, 24, 48 and 72 hours following treatment. Additional obervations were made on day 7, 14 and 21 to assess the reversibility of the ocular effects.
50 mg Dose Level: observations were made 1, 24 and 48 hours following treatment. The study was stopped after 48 hours.

Test substance : TEST SUBSTANCE
- Test substance: Sodium carbonate peroxyhydrate
- Source: Solvay Interox s.a.
- Purity: > 88 %

Reliability : (1) valid without restriction
GLP Guideline study

Flag : Critical study for SIDS endpoint

10.01.2006 (11)

Species : rabbit
Concentration : 100 mg
Dose :
Exposure time :
Comment : other: see freetext
Number of animals : 9
Vehicle :
Result :
Classification :
Method :
Year :
GLP : no
Test substance : other TS

Result : AVERAGE SCORE
- Group without washing: Lachrymation, clouding of the cornea, pupil contraction, redness and oedema of nictitating membrane. Loss of light reflex. Redness, oedema of cornea. No recovery after 21 days. Max. score was 90.6 on 14th day (MAX = 110)
- Group with washing after 4 seconds: No lesion in the cornea, iris. Redness, oedema of conjunctiva disappeared after 7 days. Max. score was 8.7 after 3 hours (MAX = 110)
- Group with washing after 30 seconds: No effect on iris. Redness, oedema of conjunctiva persisting up to day 7. Max score was 20.0 after 48 hours (MAX = 110).

Test condition : TEST ANIMALS
- Strain: Japanese white
- Source: Nippon Seibutsu Kenkyusho (Japan Biological laboratories)
- Sex: male
- Age: not described
- Weight at study initiation: 2.0-3.0 kg
- Controls: the right eye was an untreated control

ADMINISTRATION/EXPOSURE
- Method of administration: 3 groups with 3 animals, each group submitted to the following treatment.
Group 1: not washed after placing the substance in the eye

Group 2: washed 4 sec after placing in the eye (5 min with 300 ml of warm water)
Group 3: washed 30 sec after placing in the eye (5 min with 300 ml of warm water)
EXAMINATIONS
- Ophtalmoscopic examination: changes of the cornea, iris and conjunctiva
- Scoring system: Draize method
- Observation period: observations were made 1, 3, 6, 24 and 48 hours and then 4, 7, 14 and 21 days after instillation.

Test substance : TEST SUBSTANCE
- Source: Kao Sekken [Peony Soup] Co.
- Purity: white granules containing 80 % sodium percarbonate, several per cent of non-ionic surfactant and other carbonates

Reliability : (2) valid with restrictions
Test substance contains surfactant. Study not done according to GLP or test guidelines but study well documented.

10.01.2006 (27)

Species : rabbit
Concentration :
Dose :
Exposure time :
Comment : no data
Number of animals : 3
Vehicle : water
Result :
Classification :
Method : other: not described
Year : 1978
GLP : no
Test substance : no data

Result : AVERAGE SCORE (Powder)
Moderate initial pain, severe irritation of cornea, iris, conjunctiva for 7 days, pannus reaction from day 3
Score: 7 (max=8), severe irritant
AVERAGE SCORE (1% aqueous solution)
No initial pain scoring. Slight irritation in 1 rabbit during the first 2 hours, no signs of irritancy were observed throughout the seven days of the test
Score: 1 (max=8), non-irritating

Test condition : TEST ANIMALS
- Strain: New Zealand White
- Sex: not described
- Source: not described
- Age: not described
- Weight at study initiation: 2-2.5 kg
- Number of animals: 3 for each group
- Controls: no

ADMINISTRATION/EXPOSURE
- Preparation of test substance: The material was introduced into the rabbit eye, either in powder form, or as 1% aqueous solution
- Amount of substance instilled: not described

EXAMINATIONS
- Ophtalmoscopic examination: changes of the cornea, iris and conjunctiva
- Scoring system: the degree of irritancy was scored by the method of Draize and interpreted using the scale of Kay and Calandra

- Observation period: initial pain and irritancy over a period of 7 days were recorded.

Reliability : (2) valid with restrictions
Materials and methods are not described in sufficient detail. Results and findings following the instillation are described in sufficient detail.

11.01.2006 (6)

5.3 SENSITIZATION

Type : Patch-Test
Species : guinea pig
Number of animals : 24
Vehicle : water
Result : not sensitizing
Classification : not sensitizing
Method : other: EPA guidelines
Year : 1990
GLP : yes
Test substance : other TS

Result : RESULTS OF THE TEST
- Sensitization reaction: Very faint to faint dermal reactions were elicited from all ten test animals during the induction phase. None of the test or naive control animals reacted to the challenge application of the test material.
- Positive control: All four of the guinea pigs receiving the positive control material reacted during the induction and challenge phases of the study.

Test condition : TEST ANIMALS
- Strain: (DH)SPF
- Sex: male (12)/female (12)
- Source: Hazleton Research Products, Inc.
- Age: young adult
- Weight at study initiation: 420-550 g
- Controls: naive control group of 10 animals

ADMINISTRATION/EXPOSURE
- Induction schedule: the animals received one application per week for 3 weeks for a total of three applications, the naive control animals were not treated during this phase
- Concentrations used for induction: 0.4 ml of a 75 % w/v mixture
- Challenge schedule: two weeks following the third induction dose, a challenge dose was administered to the test animals and the naive control animals
- Concentrations used for challenge: 25 % w/v mixture
- Positive control: 4 animals. Induction phase, 0.4 ml (0.3 % w/v DNCB in 80 % ethanol/deionized water) was administered in the same manner as for the test group. Challenge phase, 0.4 ml was administered at a concentration of 0.1 % w/v in acetone.

EXAMINATIONS
- Observations: application sites were examined and scored for erythema and oedema at 24 and 48 hours following the induction and challenge applications. General behaviour and appearance once daily during the entire study period.
- Grading system: Bühler scoring scale. Grades of 1 or greater in the test animals indicate evidence of sensitization, provided grades of < 1 are seen

in the naive controls animals.

Test substance : TEST SUBSTANCE
- Test substance: Sodium Percarbonate
- Source: Solvay Interox s.a.
- Purity: not described

Reliability : (1) valid without restriction
GLP Guideline study

Flag : Critical study for SIDS endpoint

28.10.2003 (19)

5.4 REPEATED DOSE TOXICITY

Remark : Conclusion from SIAR, section 3.1.5:

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).

21.02.2006 (14) (29) (30)

5.5 GENETIC TOXICITY 'IN VITRO'

5.6 GENETIC TOXICITY 'IN VIVO'

Remark : Conclusion from SIAR, section 3.1.6:

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.

16.01.2006 (14) (29) (30)

5.7 CARCINOGENICITY

Remark : Conclusion from SIAR, section 3.1.7:

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.

16.01.2006 (14) (29) (30)

5.8.1 TOXICITY TO FERTILITY

Remark : Conclusion from SIAR, section 3.1.8:

Neither an animal study on toxicity to reproduction nor a study on developmental toxicity are available for sodium percarbonate. A developmental toxicity study with sodium carbonate revealed no substance related fetotoxic, embrytoxic 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.

16.01.2006 (14) (29) (30)

5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

5.9 SPECIFIC INVESTIGATIONS

Endpoint	:	other: Acute respiratory irritation
Study descr. in chapter	:	5.9 Specific Investigations
Reference	:	Reliability = 1 Test procedure in accordance with generally accepted scientific standard procedures and described in sufficient detail
Type	:	other
Species	:	mouse
Sex	:	male
Strain	:	Swiss
Route of admin.	:	inhalatory exposure
No. of animals	:	24
Vehicle	:	
Exposure period	:	20 minute(s)
Frequency of treatm.	:	single treatment
Doses	:	0.309, 0.330, 0.354, 0.698, 0.764 and 0.805 g/m³
Control group	:	no
Observation period	:	between 1 and 4 hours and 1 day after exposure
Result	:	The test material is a respiratory irritant with an RD50 of approximately 0.7 g/m³
Method	:	other
Year	:	2001

GLP : no
Test substance : other TS

Result : RESPIRATORY RATES
- Mainly the nose and upper respiratory tract were exposed to the test material. Treatment related decreased respiratory rates and minute volumes were observed in all exposure groups. In the 0.309 g/m³ exposure group the respiratory rate was only decreased at the end of the exposure group. In the other groups the respiratory rate was decreased throughout the whole exposure period. No full recovery was observed in the 0.764 g/m³ group during the post-exposure period. From the findings it was concluded that the test material is a respiratory irritant with an RD50 of approximately 0.7 g/m³.
CLINICAL SIGNS
- No clinical signs were observed after exposure.
NECROPSY FINDINGS
- No indication of treatment related effect was observed at necropsy. No indication of a treatment effect on lung weight was obtained.

Test condition : TEST ORGANISMS
- Strain: HSD/CPB:SE Swiss mice
- Source: Harlan, Austerlitz, The Netherlands
- Age: not described
- Weight at study initiation: 23.5 - 28.6 g
- Number of animals: 4 per exposure level
ADMINISTRATION/EXPOSURE
- Type of exposure: nose-only
- Particle size: The mass median aerodynamic diameter ranged from 5.0 to 7.2 µm
- Type of preparation of particles: The test material was fed from a reservoir with a motor driven helix to a stream of fresh air into an air mover. The concentration was measured during each exposure (gravimetrical analysis)
EXAMINATIONS
- Respiratory rates and volumes: Respiratory rates and volumes were evaluated before, during and after exposure at intervals of 5 minutes
- Clinical symptoms: Between 1 and 4 hours and 1 day after exposure
- Necropsy: External appearance and macroscopic changes in the abdominal and thoracic cavities were evaluated. Lungs and tracheas were removed and weighed.

Test substance : TEST SUBSTANCE
- Test substance: Sodium carbonate peroxyhydrate
- Source: Solvay Interox s.a.
- Purity: > 88 %

11.01.2006 (24)

5.10 EXPOSURE EXPERIENCE

5.11 ADDITIONAL REMARKS

6.1 FUNCTION

6.2 EFFECTS ON ORGANISMS TO BE CONTROLLED

Remark : Sodium percarbonate was tested as 1 % solution against poliovirus type I. Sodium percarbonate produced a reduction rate of 10,000 of the infectivity level after 15 minutes.

27.10.2003 (31) (36)

Remark : Sodium percarbonate was used to activate the lactoperoxidase (LP)-system of raw milk. In contact with water the percarbonate decomposes into carbonate and hydrogen peroxide. The activation of the LP-system in combination with moderate cooling could be a useful alternation to extend the keeping quality of raw milk.

27.10.2003 (41) (42)

6.3 ORGANISMS TO BE PROTECTED

6.4 USER

6.5 RESISTANCE

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