FOREWORD INTRODUCTION

SODIUM CARBONATE

CAS N°: 497-19-8

SIDS Initial Assessment Report
For
SIAM 15
(Boston, USA, 22-25 October 2002)

Chemical Name: Sodium carbonate

CAS No.: 497-19-8

Sponsor country: Belgium

National SIDS Contact Point:

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Process:

The draft dossier was prepared by a consultant (TNO Chemistry, Zeist, The Netherlands). After a quality check of the IUCLID, SIAR, SIAP and Summary Table by the industry, the dossier was submitted in June 2002 to the sponsor country. On behalf of the sponsor country 2 experts (human health, environment) reviewed the dossier. The sponsor country and the industry consortium leader had been working together already for another ICCA HPV chemical (KOH), which facilitated the process.

History:

The substance is an ICCA HPV chemical. Industry did the literature search and collected all references. The consultant received the literature and prepared the draft dossier. The dossier of sodium bicarbonate (CAS number 144-55-8) was developed in parallel using a similar procedure.

No new SIDS testing conducted (X)

New SIDS Testing conducted ( )

Comments:

Date of first Submission: 6 August 2002

SIDS INITIAL ASSESSMENT PROFILE

CAS No.	497-19-8
Chemical Name	Sodium carbonate
Structural Formula	Na_2CO_3

SUMMARY CONCLUSIONS OF THE SIAR

Sodium carbonate has a melting point of 851°C, it decomposes when heated and therefore a boiling point can not be determined. Sodium carbonate is an inorganic salt and therefore the vapour pressure can be considered negligible. Its water solubility is 215 g/l at 20°C. The average particle size diameter (d_{50}) of light sodium carbonate is in the range of 90 to 150 µm and of dense sodium carbonate is in the range of 250 to 500 µm.

Human Health

Sodium carbonate is an alkaline substance. The acute oral LD_{50} in rats is 2,800 mg/kg bw, while the dermal LD_{50} in rats is >2,000 mg/kg bw. The LC50s for inhalation are 800, 1200 and 2300 mg/m^3 for guinea pig, mice and rat respectively. Sodium carbonate has no or a low skin irritation potential but it is considered irritating to the eyes. Due to the alkaline properties an irritation of the respiratory tract is also possible.

No valid animal data are available on repeated dose toxicity studies by oral, dermal, inhalation or by other routes for sodium carbonate. A repeated dose inhalation study, which was not reported in sufficient detail, revealed local effects on the lungs which could be expected based on the alkaline nature of the compound. Under normal handling and use conditions neither the concentration of sodium in the blood nor the pH of the blood will be increased and therefore sodium carbonate is not expected to be systemically available in the body. It can be stated that the substance will neither reach the foetus nor reach male and female reproductive organs, which shows that there is no risk for developmental toxicity and no risk for toxicity to reproduction. This was confirmed by a developmental study with rabbits, rats and mice. An *in vitro* mutagenicity test with bacteria was negative and based on the structure of sodium carbonate no genotoxic effects are expected.

Environment

The hazard of sodium carbonate for the environment is mainly caused by the pH effect of the carbonate ion. For this reason the effect of sodium carbonate on the organisms depends on the buffer capacity of the aquatic or terrestrial ecosystem. Also the variation in acute toxicity for aquatic organisms may be explained for a significant extent by the variation in buffer capacity of the test medium. In general, mortality of the test organisms was found at concentrations higher than 100 mg/l but for Amphipoda, salmon and trout lethal effects were already observed at 67-80 mg/l although these studies had a low reliability.

Individual aquatic ecosystems are characterized by a specific pH and bicarbonate concentration and the organisms of the ecosystem are adapted to these specific natural conditions. 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 $PNEC_{added}$. To assess the potential environmental effect of a sodium carbonate discharge, the increase in sodium, bicarbonate and pH should be compared with the natural values and their fluctuations and based on this comparison it should be assessed if the anthropogenic addition is acceptable.

The production and use of sodium carbonate could potentially result in an emission of sodium carbonate and it could locally increase the pH in the aquatic environment. However, the pH of effluents is normally measured very frequently and can be adapted easily and therefore a significant increase of the pH of the receiving water is not expected. If emissions of waste water are controlled by appropriate pH limits and/or dilutions in relation to the natural pH and buffering capacity of the receiving water, adverse effects on the aquatic environment are not expected due to production or use of sodium carbonate.

Aquatic sodium emissions originating from uses of sodium carbonate are probably small compared to other sources. It is clear that an environmental hazard assessment of sodium should not only evaluate all natural and anthropogenic sources of sodium but should also evaluate all other ecotoxicity studies with sodium salts, which is beyond the scope of this report.

Exposure

Sodium carbonate is produced on all continents of the world and the global number of production sites is estimated to be 50-70. The total world demand of sodium carbonate in 1999 was 33.4 million metric tonnes.

Sodium carbonate is used for the production of glass, soaps and detergents and other chemicals and it also used by the 'metals and mining' industry and the 'pulp and paper' industry. Sodium carbonate is not only used by industry but is also used by consumers. It may be used directly in solutions of sodium carbonate for soaking of clothes, dishwashing, floor washing and for degreasing operations but it is also present in a large number of consumer products like cosmetics, soaps, scouring powders, soaking and washing powders. Sodium carbonate is also a food additive.

RECOMMENDATION

The chemical is currently of low priority for further work.

RATIONALE FOR THE RECOMMENDATION AND NATURE OF FURTHER WORK RECOMMENDED

This chemical is currently of low priority for further work because of its low hazard potential. However, reversible eye and respiratory tract irritation is noted.

FULL SIDS SUMMARY

CAS N° 497-19-8		PROTOCOL	RESULTS
PHYSICO-CHEMICAL			
2.1	Melting point	No data	851ºC
2.2	Boiling point	No data	Decomposition
2.3	Density	No data	2.532 (at 20ºC)
2.4	Vapour pressure	No data	Negligible, ionizable inorganic compound
2.5	Partition coefficient	No data	Not relevant, ionizable inorganic compound
2.6	Water solubility	No data	215 g/l (at 20ºC)
2.11	Oxidising properties	No data	Not oxidizing
2.12	Additional remarks	Strong alkaline compound with a pH of 11.6 for a 0.1M aqueous solution.	
ENVIRONMENTAL FATE AND PATHWAY			
3.1.1	Photodegradation	Not applicable	
3.1.2	Stability in water	The sodium ion will not adsorb to particulate matter, but remains in the aqueous phase. In water the carbonate ions will re-equilibrate until an equilibrium is established. The main equilibria are: $HCO_3^- \leftrightarrow CO_3^{2-} + H^+$ pKa = 10.35 $CO_2 + H_2O \leftrightarrow HCO_3^- + H^+$ pKa = 6.33 The carbonate will finally be incorporated into the inorganic and organic carbon cycle.	
3.2	Monitoring data	UNEP (1995) reported the bicarbonate concentration 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. 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).	
3.3	Transport and Distribution	Not applicable.	
3.5	Biodegradation	Not applicable, as it is an inorganic compound.	

ECOTOXICOLOGY		SPECIES	PROTOCOL	RESULTS
4.1	Acute/prolonged toxicity to fish	Mosquitofish *Gambusia affinis* Bluegill sunfish *Lepomis macrochirus* Minnows *Notropis a. atherinoides* and spotfin shiners *Notropis spilopterus*	96 hour median tolerance limit test 96 hour exposure, three different size ranges 120 hr exposure	TLm (LC50) 96 hr: 740 mg/l TLm: 300 mg/l for all three sizes Minimum lethal concentrations: 250 mg/l
4.2	Acute toxicity to aquatic invertebrates	Cladoceran *Ceriodaphnia cf. Dubia*	48 hr immobilisation test	EC50 200 and 227 mg/l
4.3	Toxicity to aquatic plants e.g. algae	No data available		
4.5.2	Chronic toxicity to aquatic invertebrates	No data available		
4.6	Toxicity to terrestrial organisms	No data available		

MAMMALIAN TOXICOLOGY		SPECIES	PROTOCOL	RESULTS
5.1.1	Acute Oral	Rat	No data	LD50: 2800 mg/kg bw
5.1.2	Acute Inhalation	Rat Mouse Guinea pig	Dose range tested: 800-4600 mg/m^3 600-3000 mg/m^3 500-3000 mg/m^3 whole-body exposure, 2 hours, aerosols	LC50: 2300 mg/m^3 LC50: 1200 mg/m^3 LC50: 800 mg/m^3
5.1.3	Acute Dermal	Rabbit	EPA 16 CFR 1500.40	LD50: >2000 mg/kg bw
5.2.1	Skin irritation/corrosion	Rabbit Rabbit	EPA 16 CFR 1500.3 Comparable to OECD 404	Not irritating Not irritating
5.2.2	Eye irritation/Corrosion	Rabbit Rabbit Rabbit	EPA 16 CFR 1500.42 Comparable to OECD 405 Comparable to OECD 405	Irritating Conjunctival redness and chemosis Highly irritating
5.3	Sensitisation	No data available		
5.4	Repeated dose	Rat	70 ± 2.9 mg/m^3, 4h/day, 5 days/week for 3.5 months, particle size = 5 µm	Histopathological changes in respiratory tract at 70 mg/m^3; No effects at 10-20 mg/m^3 in preliminary study.
5.5	Genetic Toxicity In vitro	Escherichia coli	Chromotest –S9, 0.11-11000 µg/ml, triplicate	No induction of DNA damage
5.6	Genetic Toxicity In vivo	No data available		
5.7	Reproduction Toxicity	No data available		
5.8	Developmental Toxicity	Mouse Rat Rabbit	Dose range tested: 3.4-340 mg/kg 2.45-245 mg/kg 1.79-179 mg/kg Oral intubation	No effects on implantation, survival of dams/foetuses, or incidence of tissue anomalies.
5.11	Human experience	Some data are available on skin irritation tests with human volunteers. Sodium carbonate was not irritating.		

SIDS Initial Assessment Report

1. IDENTITY

Name: Sodium carbonate

CAS number: 497-19-8

EINECS number: 207-838-8

Molecular formula: Na_2CO_3

Molecular weight: 106

Synonyms:

A synonym, which is widely used, is soda ash. Other synonyms are carbonic acid disodium salt, disodium carbonate, calcined soda (Clayton and Clayton, 1993; The Merck Index, 1983; Johnson and Swanson, 1987).

In addition to the anhydrous form, the monohydrate form (CAS nr. 5968-11-6) and the decahydrate form (CAS nr. 6132-02-1) do exist and are placed on the market in very small quantities (compared to the anhydrous form). Sodium carbonate decahydrate is known as sal soda or washing soda. Although sodium carbonate monohydrate has a different CAS number than anhydrous sodium carbonate, several studies on the sodium carbonate monohydrate have been included in this dossier because the intrinsic properties are expected to be similar to the anhydrate.

1.1 Composition

Sodium carbonate is a white, crystalline and hygroscopic powder with a purity of > 98 %. There are two forms of sodium carbonate available, light soda and dense soda. Impurities of sodium carbonate may include water (< 1.5 %), sodium chloride (< 0.5 %), sulphate (< 0.1 %), calcium (< 0.1 %), magnesium (< 0.1 %) and iron (< 0.004 %). The purity and the impurity profile depends on the composition of the raw materials, the production process and the intended use of the product. For example the purity of the pharmaceutical grade must be higher than 99.5 % in Europe (Pharmacopée Européenne, 1996).

1.2 Physical chemical properties

Sodium carbonate has a melting point of 851°C (CRC Handbook, 1986; The Merck Index, 1983), it decomposes when heated at > 400 °C and therefore a boiling point cannot be determined. Sodium carbonate is an inorganic salt and therefore the vapour pressure can be considered negligible. Its density is 2.532 (20°C) and its water solubility is 71 g/l water at 0°C, 215 g/l water at 20°C and 455 g/l water at 100°C (CRC Handbook, 1986). The octanol water partition coefficient (log Pow) is not relevant for an inorganic substance which dissociates. The average particle size diameter (d_{50}) of light sodium carbonate is in the range of 90 to 150 µm and of dense sodium carbonate is in the range of 250 to 500 µm.
Sodium carbonate is a strong alkaline compound with a pH of 11.6 for a 0.1M aqueous solution (The Merck Index, 1983; Johnson and Swanson, 1987). The pKa of CO_3^{2-} is 10.33, which means that at a pH of 10.33 both carbonate and bicarbonate are present in equal amounts.

2. GENERAL INFORMATION ON EXPOSURE

Sodium carbonate is produced on all continents of the world and the global number of production sites is estimated to be 50-70. The total world demand of sodium carbonate in 1999 was 33.4 million metric tons (Morrin, 2000).

Sodium carbonate can be produced from minerals which contain sodium carbonate. It is present in large deposits in Africa and the United States as either carbonate or trona, a mixed ore of equal molar amounts of the carbonate and bicarbonate. However, about 70 % of the world production capacity of sodium carbonate is manufactured by the Solvay (ammonia soda) process, whereby ammonia is added to a solution of sodium chloride. Carbon dioxide is then bubbled through to precipitate the bicarbonate, $NaHCO_3$. The sodium bicarbonate is decomposed by heat producing sodium carbonate. The traditional Solvay process is utilised in most parts of the world, with the exception of the U.S., where all production is based on the minerals which contain sodium carbonate. Different qualities of the sodium carbonate are produced based on the final use of the substance (Morrin, 2000; Clayton and Clayton, 1993).Technical, food and pharmaceutical grades are placed on the market.

Globally the major end uses for soda ash are (Morrin, 2000):

- container glass (28 %)
- flat glass (16 %)
- chemicals (18 %)
- soaps and detergents (10 %)
- other glass (7 %)
- metals and mining (3 %)
- pulp and paper (2 %)
- others (16 %)

The glass industry is by far the largest single demand sector consuming more than half of the soda ash produced (51%). About 18% of soda ash production is used in the chemical sector, including the production of sodium chromate, sodium silicate and sodium bicarbonate. In the detergent sector, soda ash is used either directly as a builder in detergent formulations, or indirectly in the production of other chemicals used as builders such as sodium tripolyphosphate (STPP) and sodium silicates. Soda ash has environmental applications in effluent and in acid waste neutralisation and is used as a source of alkalinity, in the pulp and paper sectors, in the textiles industry and for brine purification (Morrin, 2000).

The product sodium carbonate is not only used by industry but is also used by consumers. It may be used directly in solutions of sodium carbonate for soaking of clothes, dishwashing, floor washing and for degreasing operations. Furthermore, a large number of consumer products like cosmetics, soaps, scouring powders, soaking and washing powders etc. contain a varying proportion of sodium carbonate. It is also regarded as a ‘Generally Recognised as Safe’ (GRAS) substance in food with no limitation other than current good manufacturing practice (CFR, 1999).

2.1 Environmental Exposure and Fate

The high water solubility and low vapour pressure indicate that sodium carbonate will be found predominantly in the aquatic environment. In water, sodium carbonate dissociates into sodium and carbonate and both ions will not adsorb on particulate matter or surfaces and will not accumulate in living tissues. An emission of sodium carbonate to water will result in an increase in alkalinity and a tendency to raise the pH value.

The carbonate ions will react with water, resulting in the formation of bicarbonate and hydroxide, until an equilibrium is established (McKee et al., 1963). It is obvious that both the sodium and bicarbonate ion have a wide natural occurrence (UNEP, 1995).

Background concentration of carbonate

If carbonate is dissolved in water a re-equilibration takes place according to the following equations:

$HCO_3^- \leftrightarrow CO_3^{2-} + H^+$ pKa = 10.33

$CO_2 + H_2O \leftrightarrow HCO_3^- + H^+$ pKa = 6.35

Only a small fraction of the dissolved CO_2 is present as H_2CO_3, the major part is present as CO_2. The amount of CO_2 in water is in equilibrium with the partial pressure of CO_2 in the atmosphere. The CO_2 / HCO_3^- / CO_3^{2-} equilibria are the major buffer of the pH of freshwater and seawater throughout the world.

Based on the above equations, CO_2 is the predominant species at a pH smaller than 6.35, while HCO_3^- is the predominant species at a pH in the range of 6.35-10.33 and CO_3^{2-} is the predominant species at a pH higher than 10.33.

The natural concentration of CO_2 / HCO_3^- / CO_3^{2-} in freshwater is influenced by geochemical and biological processes. Many minerals are deposited as salts of the carbonate ion and for this reason the dissolution of these minerals is a continuous source of carbonate in freshwater. Carbon dioxide is produced in aquatic ecosystems from microbial decay of organic matter. On the other hand plants utilise dissolved carbon dioxide for the synthesis of biomass (photosynthesis). Because many factors influence the natural concentration of CO_2 / HCO_3^- / CO_3^{2-} in freshwater, significant variations of the concentrations do occur.

If the pH is between 7 and 9 then the bicarbonate ion is the most important species responsible for the buffer capacity of aquatic ecosystems. UNEP (1995) reported the bicarbonate concentration 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.

Background concentration of sodium

The sodium ion is ubiquitously present in the environment and it has been measured extensively in aquatic ecosystems. Sodium and chloride concentrations in water are tightly linked. They both originate from natural weathering of rock, from atmospheric transport of oceanic inputs and from a wide variety of anthropogenic sources. 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).

Anthropogenic addition of sodium carbonate

The use of sodium carbonate could potentially result in an aquatic emission of sodium carbonate and it could locally increase the sodium and carbonate concentration in the aquatic environment. Specific analytical data or other reliable data about the use of sodium carbonate and the related emissions of sodium and carbonate have not been found.

As indicated before, the emission of sodium carbonate to the aquatic environment will increase the pH of the water. 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 1 were based on calculations (De Groot et al., 2002).

Table 1: 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 20 – 195 mg/l is 8.3 (calculated).
[B] Between brackets the final concentration of bicarbonate is given.

2.2 Human exposure

The substance has been used for a long time, but no accidental exposures have been reported in the medical literature. The production and use of sodium carbonate may result in inhalation, dermal and/or oral exposure.

Inhalation
Inhalation of sodium carbonate dust may occur due to occupational exposure to sodium carbonate. Light soda might reach the upper respiratory tract and will then mainly be deposited there, due to the diameter size (see 1.2). It will hardly be able to reach the lower respiratory tract. Dense soda will hardly be able to reach the respiratory tract at all, due to its diameter size and hygroscopic properties. Inhalation is normally considered negligible for consumer applications due to the low exposure duration and due to the negligible dust formation for most of the products which contain sodium carbonate (e.g. cosmetics, liquid cleaning products).

Dermal exposure
Dermal exposure to sodium carbonate may occur during production and use of the (pure) product sodium carbonate. The pure product is also available to consumers. Solutions of sodium carbonate in water may be used by consumers for soaking of clothes, dishwashing, floor washing and for degreasing operations. Furthermore sodium carbonate is present in many household cleaning products and this can result in dermal exposure. It is also used in cosmetics mostly in bath, skin and hair preparations in concentrations from smaller than 0.1% to concentrations in the range of 10 to 25%. These products may be expected to remain in contact with the skin for an hour at most and may be used repeatedly over a period of many years.

Oral exposure
Sodium carbonate is used in many countries (e.g. USA and EU) as a food additive. Sodium carbonate is a 'GRAS' direct human food ingredient, with no limitations other than current good manufacturing practices (CFR, 1999).

3. HUMAN HEALTH HAZARDS

Na_2CO_3 has been used for many applications, in large number of countries and for a long period of time. The major human health hazard (and the mode of action) of Na_2CO_3 is local irritation and therefore a separate section on skin and eye irritation/corrosion was included in the SIAR, although irritation/corrosion is not a SIDS element.

3.1 Toxicokinetics, metabolism and mechanism of action

The major extracellular buffer in the blood and the interstitial fluid of vertebrates is the bicarbonate buffer system, described by the following equation:

$H_2O + CO_2 \leftrightarrow H_2CO_3 \leftrightarrow H^+ + HCO_3$-

Carbon dioxide from the tissues diffuses rapidly into red blood cells, where it is hydrated with water to form carbonic acid. This reaction is accelerated by carbonic anhydrase, an enzyme present in high concentrations in red blood cells. The carbonic acid formed dissociates into bicarbonate and hydrogen ions. Most of the bicarbonate ions diffuse into the plasma. Since the ratio of H_2CO_3 to dissolved CO_2 is constant at equilibrium, pH may be expressed in terms of bicarbonate ion concentration and partial pressure of CO_2 by means of the Henderson-Hasselbach equation:

$pH = pk + \log [HCO_3^-]/aPCO_2$

The blood plasma of man normally has a pH of 7.40. Should the pH fall below 7.0 or rise above 7.8, irreversible damage may occur. Compensatory mechanisms for acid-base disturbances function to alter the ratio of HCO_3^- to PCO_2, returning the pH of the blood to normal. Thus, metabolic acidosis may be compensated for by hyperventilation and increased renal absorption of HCO_3^-. Metabolic alkalosis may be compensated for by hypoventilation and the excess of HCO_3^- in the urine (Johnson and Swanson, 1987). Renal mechanisms are usually sufficient to restore the acid-base balance (McEvoy, 1994). The uptake of sodium, via exposure to sodium carbonate, is much less than the uptake of sodium via food. Therefore, sodium carbonate is not expected to be systemically available in the body. Furthermore it should be realised that an oral uptake of sodium carbonate will result in a neutralisation in the stomach due to the gastric acid.

3.2 Acute toxicity

Oral toxicity

An acute oral toxicity study was performed with Wistar rats and sodium carbonate monohydrate to assess the LD_{50} (Rinehart, 1978a). The rats were dosed with a 20% w/v solution in water by intubation, in concentrations of 1300, 1800, 2600, 3600, and 5000 mg/kg bw. The LD_{50} was 2800 mg/kg bw. For each of the 5 dose levels, there were 5 males and 5 females. The majority of the animals that died showed oral or nasal discharge, lesions in the liver, mottled lungs, mottle d or pale kidney and red or partly gas-filled gastro-intestinal tract. Several of the surviving animals also had mottled livers. It is not stated whether the study was performed according to specific guidelines.

Dermal toxicity

Six New Zealand rabbits were exposed to sodium carbonate monohydrate to assess the dermal LD_{50} (Rinehart, 1978b). Thirty percent of the body surface area was exposed to 2,000 mg/kg bw, administered as an aqueous slurry with concentration 1,000 mg/ml. Three animals had abraded skin

and 3 animals had non-abraded skin. After 24 hrs of occluded exposure, the test area was wiped clean. There was no mortality, but lethargy and hypernea were observed in the animals during the first 24 hrs following compound administration, and well-defined to severe erythema and slight to severe oedema were observed in all six animals 24 hours after compound administration. Three of 6 animals lost or did not gain weight during the observation period. The study was performed according to EPA 16 CFR 1500.40. It can be concluded that the LD_{50} was higher than 2,000 mg/kg bw.

Inhalation toxicity

In an attempt to establish a LC_{50} for sodium carbonate, a series of whole-body inhalation exposures of male rats (Sprague-Dawley and Wistar strains), male mice (Swiss-Webster) and male guinea pigs (Hartley-albino) to varying concentrations were performed (Busch et al., 1983). The animals exhibited respiratory impairment when exposed for 2 hours to aerosols of sodium combustion products (1 µm aerodynamic equivalent diameter), the major constituent of which was shown to be sodium carbonate (rats 91% Na_2CO_3, dose range 800-4600 mg/m^3, mice 95% Na_2CO_3, dose range 600-3000 mg/m^3, guinea pigs 95% Na_2CO_3, dose range 500-3000 mg/m^3). Clinical signs included dyspnoea, wheezing, excessive salivation and distention of abdomen. Mortality occurred mainly in two periods, namely during exposure and within 1-2 hours afterwards or beginning at 1 day after exposure peaking at 5-7 days and continuing to 9-10 days after exposure. Lesions in animals that died during or shortly after exposure were present in the posterior pharynx and larynx and included accumulation of mucus, vesiculation, and mucosal oedema. Other lesions included oedema and vesiculation of the anterior trachea, haemorrhage in the lungs, and severe gastric tympany. For animals that survived, lesions in the respiratory tract were limited to the laryngeal mucosa. The LC_{50}s for guinea pigs, mice and rats were calculated to be 800, 1200 and 2300 mg/m^3, respectively.

Conclusion

An acute oral toxicity study with sodium carbonate monohydrate and rats revealed an LD_{50} of 2,800 mg/kg bw. The acute dermal toxicity of sodium carbonate monohydrate is also low (LD_{50} >2,000 mg/kg bw). These studies were done with sodium carbonate monohydrate but due to the relatively low water content of sodium carbonate monohydrate, the toxicity of sodium carbonate is not expected to be significantly different. The LC_{50}s for guinea pigs, mice and rats were 800, 1200 and 2300 mg/m^3 when male animals were exposed for 2 hours to sodium combustion products containing mainly sodium carbonate.

The low toxicity of sodium carbonate is confirmed by the human experience. Although sodium carbonate has been used widely and for a long time, no cases of acute oral poisoning have been found in the published literature. The low oral toxicity of sodium carbonate can be explained by the neutralisation of sodium carbonate in the stomach.

3.3 Skin irritation

Animal data

In a study performed according to EPA 16 CFR 1500.3 guidelines, the skin irritation potential of sodium carbonate monohydrate was examined in 6 New Zealand White rabbits (Rinehart, 1978c). Each rabbit had two patches clipped for hair, one abraded and one left intact. An amount of 0.5 g was applied as a 1 g/ml aqueous slurry, and covered by an occlusive patch for 24 hrs. It is not reported whether the area was cleaned when the patches were removed. The average erythema and oedema score was 0, and the Primary Dermal Irritation Index 0.

A skin irritation study was performed with six New Zealand White rabbits (Chibanguza, 1985a). A quantity of 0.5 g sodium carbonate was applied to intact and abraded skin (6.25 cm^2) and covered

with an occlusive bandage for 4 hours. After this period the skin was washed. Thirty min, sixty min, 24, 48 and 72 hours after exposure no signs of erythema or oedema were observed. The method used in this study was comparable to OECD guideline 404.

In addition to the 2 valid guideline studies mentioned before, another skin irritation test was done which was not documented in sufficient detail. An aqueous solution of sodium carbonate (50% w/v) was applied to the skin (intact and abraded) of six rabbits and six guinea pigs for 4 hours (Nixon *et al*., 1975). The animals were examined at 4, 24 and 48 hours after application of the solution for erythema and oedema. The abraded skin of the rabbits had slight erythema and oedema, and those of the guinea pigs were negligibly affected. There were no signs of erythema or oedema in the intact skins.

Six New Zealand rabbits were exposed to sodium carbonate monohydrate to assess the dermal LD_{50} (Rinehart, 1978b). Thirty percent of the body surface area was exposed to 2,000 mg/kg bw, administered as an aqueous slurry with concentration 1,000 mg/ml. Three animals had abraded skin and 3 animals had non-abraded skin. After 24 hrs of occluded exposure, the test area was wiped clean. Well-defined to severe erythema and slight to severe oedema were observed in all six animals 24 hours after compound administration.

Human data

A human patch (skin irritation) test with 98% sodium carbonate 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). 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 results showed no reactivity among the volunteers and therefore these solutions of sodium carbonate were not classified as irritant based on the human patch test.

An aqueous solution of sodium carbonate (50% w/v) was applied to the skin (intact and abraded) of six human volunteers for 4 hours (Nixon *et al*., 1975). The volunteers were examined at 4, 24 and 48 hours after application of the solution for erythema and oedema. Categorisation of irritancy to human skin was based on the Primary Irritation Index (PII). The abraded skin had erythema and oedema (mean score > 2) with two subjects having a maximum grade than 4. There were no signs of erythema or oedema in the intact skins (mean PII >1.0).

Conclusion

Skin irritation studies have been performed with solid sodium carbonate and a 50 % solution of sodium carbonate with both animals and human volunteers. Erythema and oedema were not observed for the intact skin and therefore sodium carbonate has no or a low skin irritation potential.

3.4 Ocular irritation

The ocular irritation potential of sodium carbonate monohydrate was assessed in a study performed on 9 New Zealand rabbits (Rinehart, 1978d). A volume of 0.1 ml was instilled in one eye of each animal. After approximately 4 seconds the treated eyes of 3 rabbits were rinsed with 30 ml distilled water, while the remaining rabbit's eyes were not irrigated during the 14 days observation period. Among the animals with unwashed eyes, 2 suffered ruptured eyes and the remaining 4 still had signs of irritation at the termination of the study. One of the animals with washed eyes had signs of irritation at the termination of the study, while the exposed eye appeared normal in the remaining 2 animals from day 2 and 14, respectively. According to the scoring system employed by the authors of the study the responses were either positive or negative. 6/6 animals with unwashed eyes had a positive cornea score, iris score, conjunctivitis (redness and chemosis) score. Among the animals

with washed eyes 1/3 rabbits had a positive cornea score, iris score and conjunctivitis (redness and chemosis) score. Based on the results sodium carbonate was considered irritating for the eyes. The scoring system complied with the EPA 16 CFR 1500.42 guideline.

An eye irritation study was performed with six New Zealand White rabbits (Chibanguza, 1985b). Ocular irritancy was tested by instilling 0.1 g sodium carbonate into the left eye (conjunctival sac) of each animal, the right eye served as the untreated control. After 1 hour, 24, 48 and 72 hours the eyes were examined for observations of the conjunctivae, cornea and iris.
Ocular irritation was scored according to the scale by Draize. The mean Draize intensity score was for conjunctival redness 1.67, for conjunctival chemosis 1.38 and for the iris 0.25. The method used in this study was comparable to OECD guideline 405.

Ocular irritation of sodium carbonate was evaluated in two groups of at least six New Zealand albino rabbits (male and female) based on the methodology of Draize (Murphy's *et al.*, 1982). Sodium carbonate (0.1 ml) was administered to the right eye directly on the central portion of the cornea, the left eye served as the untreated control. The eyes of the first group of rabbits were rinsed for 2 minutes, 30 seconds after instillation (rinsed eyes), the eyes tested in the second group were not rinsed after instillation (unrinsed eyes). Control and treated eyes were scored at 1 h and 1, 2, 3 and 7 days after exposure according to the scale of Draize. Corneal opacities were produced in unrinsed eyes within 1 h after exposure to sodium carbonate and the severest effect was noted by day 3 (mean Draize intensity score 3.8), the severity was maintained through day 7. In rinsed eyes, corneal opacities were observed on day 2 (mean Draize intensity score 0.8) and had disappeared by day 7. Iritis was observed in unrinsed eyes at 1 h after exposure to sodium carbonate and a mean draize score of 2 was reported on days 1, 2, 3 and 7. In rinsed eyes, iritis was observed at 1 hr after exposure (mean Draize intensity score 1.0) and had disappeared by day 3 after exposure. Sodium carbonate produced conjunctivitis which lasted through day 7 in all animals tested. It also produced pannus in 6/12 unrinsed eyes and keratoconus in 2/12 unrinsed eyes. The method used in this study was mainly comparable to OECD guideline 405. Based on the results of the test sodium carbonate was considered highly irritating.

Conclusion
The available eye irritation tests revealed different results. Studies using a dose of 0.1 ml sodium carbonate monohydrate and sodium carbonate (anhydrous) resulted in a classification of irritating and highly irritating, respectively. However, based on a study with a dose of 0.1 g sodium carbonate it was not classified as an ocular irritant. Based on the overall results sodium carbonate is considered irritating to the eyes.

Repeated dose toxicity

Oral and dermal toxicity
No animal data are available on repeated dose toxicity studies by oral or dermal routes for sodium carbonate.

A study on developmental toxicity has been reported by the FDA (1974) but this study provides also some information on repeated dose toxicity (see section 3.7). 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 the survival, body weight, number of implantations and litter size and weight of dams but the reporting of the study was limited. 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).

Inhalation toxicity

A repeated dose inhalation study has been reported by Reshetyuk and Shevchenko (1966) but this study was not reported in sufficient detail. Male rats were exposed to a 2% aqueous sodium carbonate aerosol for 4 h/day, 5 days/week for 3.5 months. The final concentration was reported to be 70 ± 2.9 mg/m^3, whereas particle size was reported not to exceed 5 µm (no further details given). When compared to controls there were no changes in body weight gain, organ weights, body temperature, or several blood parameters. Pulmonary ascorbic acid levels were decreased.

Deviations in lungs were found in control and experimental animals but only experimental animals displayed hyperplasia and desquamination of bronchiolar epithelium, and perivascular oe dema. The upper respiratory tract was not examined. Other pulmonary changes included thickening of alveolar walls, hyperaemia and lymphoid infiltration but these changes were also observed in about 50% of the controls. A preliminary study of unknown duration at a concentration of 10-20 mg/m^3, did not induce toxic effects (Reshetyuk and Shevchenko, 1966).

Although this was a limited reported study, the histopathological changes observed in the lungs are not unexpected, in view of the alkaline nature of the solution (0.1 M (ca. 1%), pH = 11.6). However, in view of the histopathological lesions observed in animals exposed during a single 2 h period, which were almost exclusively confined to the upper respiratory tract (pharynx and larynx; Busch *et al.*, 1983), it may be concluded that changes, likely to be present in the upper respiratory tract, would have been more severe than those observed at the pulmonary level in the above described study of 3.5 months.

Conclusion

A repeated dose inhalation study, which was not reported in sufficient detail, revealed local effects on the lungs which could be expected based on the alkaline nature of the compound. A good quality oral or dermal repeated dose study is not available. However, the long term hazard of sodium for humans is well known and has been focussed 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). Carbonate would be neutralised in the stomach by the low pH of the gastric juice. Furthermore, sodium carbonate is not expected to be systemically available in the body due to neutralisation by gastric acid or by blood. Therefore, additional testing for repeated dose toxicity is considered unnecessary for sodium carbonate. Implicitly this has been recognised in the past, because sodium carbonate is considered 'GRAS' in food with no limitation other than current good manufacturing practice (CFR, 1999).

Genetic toxicity

Olivier and Marzin (1987) examined sodium carbonate for its potential to induce primary DNA damage in the *Escherichia coli* Chromotest. Concentrations of 0.11 – 11,000 µg/ml were incubated with samples of an exponentially growing culture of *Escherichia coli* PQ37 for 2 h without metabolic activation. Toxicity was observed at 1100 µg/ml. It was concluded that sodium carbonate did not induce primary DNA damage in *Escherichia coli* Chromotest without metabolic activation. However, the *Escherichia coli* Chromotest has not been validated for regulatory purposes and therefore it has a limited value.

An Ames test with sodium carbonate is not available but an Ames test with sodium bicarbonate, with and without metabolic activation, has been performed and a negative result was noted (Johnson and Swanson, 1987). Similar results were obtained when sodium sesquicarbonate ($Na_2CO_3.NaHCO_3.2H_2O$) was tested (Blevins et al., 1982).

Conclusion
The available *in vitro* mutagenicity test with sodium carbonate was negative. When the pH will be kept below 8 to have a good functioning biological test system, mainly bicarbonate will be available. Furthermore sodium bicarbonate is naturally present in cells and both the structure of sodium bicarbonate and sodium carbonate do not indicate a genotoxic potential. Therefore there is no reason to evaluate the potential genotoxicity of sodium carbonate further and no genotoxic effects are expected.

Reproduction toxicity

Developmental toxicity
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 foetuses. 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 foetus when exposed to sodium carbonate, as it does not become systemically available.

Reproduction toxicity
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 (see 3.1). As such, it is considered not useful to perform a reproduction study.

4. HAZARDS TO THE ENVIRONMENT

4.1 Aquatic effects

The pH dependent equilibrium between CO_2 , HCO_3^- and CO_3^{2-} that is outlined in paragraph 2.1 should be kept in mind when the aquatic effects of sodium carbonate are evaluated. An addition of sodium carbonate to water will result in an increase of the alkalinity and pH. This means that only the combined effect of carbonate, bicarbonate and pH on organisms can be determined. An overview of EC50 values of aquatic toxicity tests is presented in Table 2.

Effects on fish

A toxicity test with 50 bluegill sunfish (*Lepomis macrochirus*) exposed to sodium carbonate and 10 control fish was performed by Cairns and Scheier (1959). After 24, 48, 72 and 96 hours the mortality was determined. The purpose of the work was to determine the tolerance of three distinct size ranges of the bluegill (small 3.88 cm and 0.96 g, medium 6.09 cm and 2.80 g, large 14.24 cm and 54.26 g). The TL_m or LC_{50}, which is the concentration at which 50 % of organism would be expected to survive, was equal to 300 mg/l for all three sizes.

Another 96 hr median tolerance limit test with sodium carbonate was performed with the mosquitofish (*Gambusia affinis*) by Wallen et al. (1957). The experiments were continued for at least 96 hours with observations after 24, 48, 72 and 96 hours. At 24 hours the TL_m (equal to LC_{50}) was 1200 mg/l, at 48 hours 840 mg/l and at 96 hours 740 mg/l.

The minimum lethal concentration of sodium carbonate to different species of minnows (Lake Emerald (*Notropis a. atherinoides*) and spotfin shiners (*Notropis spilopterus*) was determined by Van Horn et al. (1949). The minimum lethal concentration for sodium carbonate was determined to be 250 mg/l based on an exposure period of 120 hours. A short review of the acute toxicity for fish is described by the California State Water Resources Control Board (McKee et al., 1963). Concentrations of 68-80 mg/l were reported to kill king salmon, silver salmon and cut-throat trout after 5 days of exposure, while other species, like carp, bass, shiners, sunfish and mosquito-fish, were killed at concentrations ranging between 200 and 1200 mg/l with an exposure duration ranging from hours up to five days. The studies reported by Van Horn et al. (1949) and McKee et al. (1963) have a low reliability (Code of Reliability of 4).

Table 2: Overview of LC50 and EC50 values of aquatic toxicity tests

Species	Endpoint	Result (mg/l)	CoR[A]	Reference
Bluegill sunfish	LC_{50}.96h	300	2	Cairns et al. (1959)
Mosquitofish	LC_{50}.96h	740	2	Wallen et al. (1957)
Bluegill sunfish	LC50.24h	385	4	Dowden et al. (1965)
Molly	LC50.50h	297	4	Dowden et al. (1965)
Cladoceran (*C.* cf. *dubia*)	EC_{50}.48h	200-227	2	Warne et al. (1999)

[A] Reliability : 1 = valid without restrictions, 2 = valid with restrictions, 3 = invalid, 4 = not assignable (Klimisch et al., 1997).

Effects on invertebrates

Recently a toxicity test with laundry detergent components and the freshwater cladoceran *Ceriodaphnia* cf. *dubia* was published by Warne et al. (1999). Reported EC_{50} values for 48 hr exposure to sodium carbonate were 200 and 227 mg/l, respectively. The study was well documented and meets the generally accepted scientific principles.

Additional toxicity studies with invertebrates and sodium carbonate were reported by McKee et al. (1963), Anderson (1946) and Dowden et al. (1965). All these studies have a low reliability (Code of Reliability of 3 or 4). The EC_{50} of *Daphnia magna* was reported to be 265 - 524 mg/l. For Amphipoda, *Culex* sp., *Dugesia* sp. and *Lymnea* sp. eggs the EC_{50} values were 67, 600, 341 and 411 mg/l, respectively.

Effects on aquatic plants / algae

Aquatic toxicity studies with plants and algae have not been found. However, it does not seem to be useful to perform a standard OECD guideline study with algae (e.g. *Selenastrum capricornutum*). The results can be predicted based on the increase of the pH of the test solution (see Table 1). An initial pH higher than 9 will reduce the growth and therefore the theoretically calculated NOEC will probably be 1-10 mg/l. The EC50 will probably be in the range of 10-100 mg/l. However, the results will depend on the algal species selected, the composition of the test medium and probably the growth conditions before the start of the test. The results can not be extrapolated directly to aquatic ecosystems because the growth conditions are in many cases not comparable to the laboratory conditions.

Mode of action

When sodium carbonate is added to water it results not only in an increase of the sodium and carbonate concentration but also to an increase of the bicarbonate and OH^- concentration (pH) of the water ($CO_3^- + H_2O \rightarrow HCO_3^- + OH^-$).

In theory all ions could contribute to the observed acute toxicity of sodium carbonate, which is found at concentrations of about 100 – 1000 mg/l (1 – 10 mM). However, the addition of sodium cannot explain the toxicity because the acute EC50 values of sodium chloride are an order of magnitude higher (> 1 g/l; Environment Canada, 2000). The concentrations of bicarbonate change only slightly at sodium carbonate additions of 100 – 1000 mg/l (see Table 1) and the acute toxicity of sodium bicarbonate is also too low to explain the effects. The acute EC50 of sodium bicarbonate for daphnids and bluegill sunfish was 4100 and 7100 mg/l, respectively (see SIDS Dossier on sodium bicarbonate; CAS No 144-55-8).

However, the increase of the pH can explain the observed acute toxicity of sodium carbonate. Additions of 100 – 1000 mg/l increase the pH to values of about 10 to 11 and these pH values have been shown to be toxic for aquatic organisms (see SIDS Dossier on NaOH; CAS No 1310-73-2).

Conclusions

In general the available toxicity studies with sodium carbonate were not conducted according to current standard guidelines. In many cases pH, buffer capacity and/or medium composition were not discussed in the publications, although this is essential information for toxicity tests with sodium carbonate. In general, mortality of the test organisms was found at concentrations higher than 100 mg/l but for Amphipoda, salmon and trout lethal effects were already observed at 67-80 mg/l although these studies had a low reliability. The main factor explaining the acute aquatic toxicity of sodium carbonate is most likely the increase of the pH.

The most appropriate parameter to assess the environmental effect of a sodium carbonate discharge is to determine the change in pH. To get an idea about the order of magnitude for acceptable anthropogenic additions, the acceptable sodium carbonate addition will be calculated for 2 representative cases. According to Directive 78/659/EEC (CEE, 1978), the pH of surface water for

the protection of fish should be between 6 and 9. In section 2.1 it has been mentioned that the 10^{th}-percentile and the 90^{th}-percentile of the bicarbonate concentrations of 77 rivers were 20 and 195 mg/l, respectively. If it is assumed that only bicarbonate is responsible for the buffer capacity of the ecosystem and if it is assumed that an increase of the pH to a value of 9.0 would be the maximum accepted value then the acceptable anthropogenic addition of sodium carbonate would be 2.7 and 17 mg/l for bicarbonate concentrations of 20 and 195 mg/l, respectively (see Table 1). This gives an indication of the order of magnitude of the acceptable amount of sodium carbonate which could be discharged to an aquatic ecosystem if there was an emission of a pure sodium carbonate solution. Sodium carbonate concentrations of 2.7 and 17 mg/l are equivalent with the sodium concentrations of 1.2 and 7.4 mg/l. Sodium concentrations of 1.2 to 7.4 have no effect on aquatic organisms because sodium has a low toxicity for aquatic organisms. Reconstituted water of toxicity tests contains for example sodium concentrations which range between 3.3 and 105 mg/l (ASTM, 1996).

Individual aquatic ecosystems are characterized by a specific pH and bicarbonate concentration and the organisms of the ecosystem are adapted to these specific natural conditions. Based on the natural pH and bicarbonate concentration of waters, organisms will have different optimum conditions, ranging from poorly buffered waters with a pH of 6 or less to very hard waters with pH values up to 9 (Bloemendaal et al., 1988). Beause 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 $PNEC_{added}$.

To assess the potential environmental effect of an sodium carbonate discharge, the increase in sodium, bicarbonate and pH should be compared with the natural values and their fluctuations and based on this comparison it should be assessed if the anthropogenic addition is acceptable.

4.2 Terrestrial effects

Toxicity tests which determined the effect of sodium carbonate on terrestrial organisms are not available. Significant exposure to the terrestrial environment is not expected and for this reason there is no need to perform a toxicity test with terrestrial organisms. The results of the tests will depend strongly on the buffer capacity of the soil and can probably be predicted based on the buffer capacity of the soil. Furthermore, carbonates are natural components of soil minerals.

4.3 Other environmental effects

No other environmental effects are expected.

5. Conclusions

5.1 Conclusions

Sodium carbonate is an alkaline substance. The acute oral LD_{50} in rats is 2,800 mg/kg bw, while the dermal LD_{50} in rats is >2,000 mg/kg bw. The LC50s for inhalation are 800, 1200 and 2300 mg/m^3 for guinea pig, mice and rat respectively. Sodium carbonate has no or a low skin irritation potential but it is considered irritating to the eyes. Due to the alkaline properties an irritation of the respiratory tract is also possible.

No valid animal data are available on repeated dose toxicity studies by oral, dermal, inhalation or by other routes for sodium carbonate. A repeated dose inhalation study, which was not reported in sufficient detail, revealed local effects on the lungs which could be expected based on the alkaline nature of the compound. Under normal handling and use conditions neither the concentration of sodium in the blood nor the pH of the blood will be increased and therefore sodium carbonate is not expected to be systemically available in the body. It can be stated that the substance will neither reach the foetus nor reach male and female reproductive organs, which shows that there is no risk for developmental toxicity and no risk for toxicity to reproduction. This was confirmed by a developmental study with rabbits, rats and mice. An *in vitro* mutagenicity test with bacteria was negative and based on the structure of sodium carbonate no genotoxic effects are expected.

The hazard of sodium carbonate for the environment is mainly caused by the pH effect of the carbonate ion. For this reason the effect of sodium carbonate on the organisms depends on the buffer capacity of the aquatic or terrestrial ecosystem. Also the variation in acute toxicity for aquatic organisms may be explained for a significant extent by the variation in buffer capacity of the test medium. In general, mortality of the test organisms was found at concentrations higher than 100 mg/l but for Amphipoda, salmon and trout lethal effects were already observed at 67-80 mg/l although these studies had a low reliability.

Individual aquatic ecosystems are characterized by a specific pH and bicarbonate concentration and the organisms of the ecosystem are adapted to these specific natural conditions. Beause 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 $PNEC_{added}$. To assess the potential environmental effect of an sodium carbonate discharge, the increase in sodium, bicarbonate and pH should be compared with the natural values and their fluctuations and based on this comparison it should be assessed if the anthropogenic addition is acceptable.

The production and use of sodium carbonate could potentially result in an emission of sodium carbonate and it could locally increase the pH in the aquatic environment. However, the pH of effluents is normally measured very frequently and can be adapted easily and therefore a significant increase of the pH of the receiving water is not expected. If emissions of waste water are controlled by appropriate pH limits and/or dilutions in relation to the natural pH and buffering capacity of the receiving water, adverse effects on the aquatic environment are not expected due to production or use of sodium carbonate.

Aquatic sodium emissions originating from uses of sodium carbonate are probably small compared to other sources. It is clear that an environmental hazard assessment of sodium should not only evaluate all natural and anthropogenic sources of sodium but should also evaluate all other ecotoxicity studies with sodium salts, which is beyond the scope of this report.

5.2 Recommendations

This chemical is currently of low priority for further work because of its low hazard potential. However, reversible eye and respiratory tract irritation is noted.

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I U C L I D Data Set

Existing Chemical	:	ID: 497-19-8
CAS No.	:	497-19-8
EINECS Name	:	sodium carbonate
EC No.	:	207-838-8
TSCA Name	:	Carbonic acid disodium salt
Molecular Formula	:	CO3.2Na

Producer related part

Company	:	Solvay S.A.
Creation date	:	02.05.2002

Substance related part

Company	:	Solvay S.A.
Creation date	:	02.05.2002
Status	:	
Memo	:	
Printing date	:	19.02.2003
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Number of pages	**:**	
Chapter (profile)	:	
Reliability (profile)	:	
Flags (profile)	:	

1.0.1 APPLICANT AND COMPANY INFORMATION

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Phone	:	+ 90 212 503647
Telefax	:	+ 90 212 504647
Telex	:	
Cedex	:	
Email	:	eerturk@sisecam.com.tr
Homepage	:	

08.05.2002

Type	:	cooperating company
Name	:	Sodawerk Staßfurt GmbH & Co KG
Contact person	:	Mr. G. Witte
Date	:	
Street	:	An der Löderburger Bahn 4a
Town	:	39418 Staßfurt
Country	:	Germany
Phone	:	+ 49 3925 608260
Telefax	:	+ 49 3925 263379
Telex	:	
Cedex	:	
Email	:	g.witte@sodawerk.de
Homepage	:	

08.05.2002

Type	:	cooperating company
Name	:	Tokuyama Corporation
Contact person	:	Mr. S. Moriyama
Date	:	
Street	:	3-1 Shibya 3-Chome, Shibuya-Ku
Town	:	150-8383 Tokyo
Country	:	Japan
Phone	:	+ 81 3 3499 8478
Telefax	:	+ 81 3 3499 8967
Telex	:	
Cedex	:	
Email	:	s-moriyama@tokuyama.co.jp
Homepage	:	

08.05.2002

1.0.2 LOCATION OF PRODUCTION SITE, IMPORTER OR FORMULATOR

1.0.3 IDENTITY OF RECIPIENTS

1.0.4 DETAILS ON CATEGORY/TEMPLATE

1.1.0 SUBSTANCE IDENTIFICATION

IUPAC Name	:	Sodium carbonate
Smiles Code	:	
Molecular formula	:	Na2CO3
Molecular weight	:	106
Petrol class	:	other: not applicable

16.05.2002

1.1.1 GENERAL SUBSTANCE INFORMATION

Purity type	:	typical for marketed substance

Substance type : inorganic
Physical status : solid
Purity : > 98 % w/w
Colour : white
Odour : no odour
Remark : There are two forms of sodium carbonate available, light soda and dense soda.

31.05.2002

1.1.2 SPECTRA

1.2 SYNONYMS AND TRADENAMES

Calcined soda
08.05.2002

Carbonic acid, disodium salt
08.05.2002

Dense soda
08.05.2002

Disodium carbonate
08.05.2002

Light soda
16.02.1994

Sal soda
Remark : Decahydrate form
08.05.2002

Soda ash
Remark : Anhydrous form
17.07.2001

Soda salt
16.02.1994

Washing soda
Remark : Decahydrate form
14.08.2001

1.3 IMPURITIES

Purity : typical for marketed substance
CAS-No : 7732-18-5
EC-No : 231-791-2
EINECS-Name : water
Molecular formula : H2O
Value : < 1.5 % w/w
31.05.2002

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
31.05.2002

Purity : other: not applicable
CAS-No :
EC-No :
EINECS-Name : sulfate
Molecular formula : SO4
Value : < .1 % w/w
31.05.2002

Purity : other: not applicable
CAS-No : 7440-70-2
EC-No : 231-179-5
EINECS-Name : calcium
Molecular formula : Ca
Value : < .1 % w/w
31.05.2002

Purity : other: not applicable
CAS-No : 7439-95-4
EC-No : 231-104-6
EINECS-Name : magnesium
Molecular formula : Mg
Value : < .1 % w/w
31.05.2002

Purity : typical for marketed substance
CAS-No : 7439-89-6
EC-No : 231-096-4
EINECS-Name : iron
Molecular formula : Fe
Value : < .004 % w/w
31.05.2002

1.4 ADDITIVES

1.5 TOTAL QUANTITY

Remark : The total world demand of sodium carbonate in 1999 was 33.4 million metric tons.

16.05.2002 15)

1.6.1 LABELLING

Labelling : as in Directive 67/548/EEC
Specific limits : yes
Symbols : Xi, , ,
Nota : , ,
R-Phrases : (36) Irritating to eyes
S-Phrases : (2) Keep out of reach of children
(22) Do not breathe dust
(26) In case of contact with eyes, rinseimmediately with plenty of water and seek medical advice

Remark : Labelling for products :
S 2 : only for consumer products
Reference : 011-005-00-2 (XIXth TPA : Directive 93/72/EEC)
08.05.2002

1.6.2 CLASSIFICATION

Classified	:	as in Directive 67/548/EEC
Class of danger	:	irritating
R-Phrases	:	(36) Irritating to eyes
Specific limits	:	yes
1st Concentration	:	>=20%
2nd Concentration	:	
3rd Concentration	:	
4th Concentration	:	
5th Concentration	:	
6th Concentration	:	
7th Concentration	:	
8th Concentration	:	
1st Classification	:	Xi, R36
2nd Classification	:	
3rd Classification	:	
4th Classification	:	
5th Classification	:	
6th Classification	:	
7th Classification	:	
8th Classification	:	
Remark	:	Reference : 011-005-00-2 (XIXth TPA : Directive 93/72/EEC)

08.05.2002

1.6.3 PACKAGING

1.7 USE PATTERN

Type of use	:	
Category	:	Use resulting in inclusion into or onto matrix
Remark	:	The total world soda ash demand in 1999 is 33.4 million metric tons. Total percentage in glass is 51%, whereby 28% is used in container glass, 16% in flat glass and 7% other glass.

08.05.2002 (15)

Type of use	:	industrial
Category	:	Basic industry: basic chemicals
Remark	:	The total world soda ash demand in 1999 is 33.4 million metric tons. Total percentage in chemicals sector is 18%.

08.05.2002 (15)

Type of use	:	industrial
Category	:	Chemical industry: used in synthesis
Remark	:	The total world soda ash demand in 1999 is 33.4 million metric tons. Total percentage in chemicals sector is 18%.

08.05.2002 (15)

Type of use	:	Use
Category	:	Cleaning/washing agents and disinfectants
Remark	:	The total world soda ash demand in 1999 is 33.4 million metric tons. Total percentage in soaps and detergents is 10%.

08.05.2002 (15)

Type of use	:	industrial
Category	:	Metal extraction, refining and processing of metals
Remark	:	The total world soda ash demand in 1999 is 33.4 million metric tons. Total

percentage in metals and mining sector is 3%.
08.05.2002 (15)

Type of use : industrial
Category : Paper, pulp and board industry
Remark : The total world soda ash demand in 1999 is 33.4 million metric tons. Total percentage in pulp and paper sector is 2%.
08.05.2002 (15)
Type of use : use
Category : Absorbents and adsorbents
Remark : The total world soda ash demand in 1999 is 33.4 million metric tons. Total percentage in sectors other than chemical, glass, soaps and detergents, metals and mining and pulp and paper sector is 16%.
08.05.2002 (15)
Type of use : use
Category : Bleaching agents
Remark : The total world soda ash demand in 1999 is 33.4 million metric tons. Total percentage in sectors other than chemical, glass, soaps and detergents, metals and mining and pulp and paper sector is 16%.
08.05.2002 (15)
Type of use : use
Category : Flux agents for casting
Remark : The total world soda ash demand in 1999 is 33.4 million metric tons. Total percentage in sectors other than chemical, glass, soaps and detergents, metals and mining and pulp and paper sector is 16%.
08.05.2002 (15)
Type of use : use
Category : Food/foodstuff additives
08.05.2002 (15)
Type of use : use
Category : Laboratory chemicals
08.05.2002 (15)
Type of use : use
Category : pH-regulating agents
08.05.2002 (15)
Type of use : use
Category : Pharmaceuticals
08.05.2002 (15)
Type of use : use
Category : Softeners
08.05.2002 (15)
Type of use :
Category : Non dispersive use
Remark : The total world soda ash demand in 1999 is 33.4 million metric tons. Total percentage in sectors other than chemical, glass, soaps and detergents, metals and mining and pulp and paper sector is 16%.
08.05.2002 (15)
Type of use :
Category : Use in closed system
Remark : The total world soda ash demand in 1999 is 33.4 million metric tons. Total percentage in sectors other than chemical, glass, soaps and detergents, metals and mining and pulp and paper sector is 16%.
08.05.2002 (15)
Type of use :
Category : Wide dispersive use
Remark : The total world soda ash demand in 1999 is 33.4 million metric tons. To tal percentage in sectors other than chemical, glass, soaps and detergents, metals and mining and pulp and paper sector is 16%.
08.05.2002 (15)

1.7.1 DETAILED USE PATTERN

1.7.2 METHODS OF MANUFACTURE

Origin of substance : Synthesis
Type : Production
Remark : Sodium carbonate can be produced from minerals which contain sodium carbonate. It is present in large deposits in Africa and the United States as either carbonate or trona, a mixed ore of equal molar amounts of the carbonate and bicarbonate. However, about 70 % of the world production capacity of sodium carbonate is manufactured by the Solvay (ammonia soda) process, whereby ammonia is added to a solution of sodium chloride. Carbon dioxide is then bubbled through to precipitate the bicarbonate, NaHCO3. The sodium bicarbonate is decomposed by heat producing sodium carbonate. The traditional Solvay process is utilised in most parts of the world, with the exception of the U.S., where all production is based on the minerals which contain sodium carbonate. Different qualities of the sodium carbonate are produced based on the final use of the substance.

08.05.2002 (6) (15)

1.8 REGULATORY MEASURES

1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES

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

1.11 ADDITIONAL REMARKS

1.12 LAST LITERATURE SEARCH

Type of search : Internal and External
Chapters covered : 3, 4, 5
Date of search : 05.09.2000
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 2000 by Solvay. It covered the period 1994-2000. The following databases were used: AQUIRE, BIODEG, BIOLOG, CCRIS, CHRIS, DART/ETIC, DATALOG, ENVIROFATE, GENETOX, GIABS, HSDB SUBSET, IRIS, MEDLINE TOXICOLOGY SUBSET, NIOSHTIC SUBSET , PHYTOTOX, RISKLINE, RTECS, TERRETOX, TSCATS, TOXCENTER and TOXLINE.

08.01.2003

1.13 REVIEWS

2.1 MELTING POINT

Value	:	= 851 °C
Decomposition	:	yes, at > 400 °C
Sublimation	:	
Method	:	other: no information available
Year	:	
GLP	:	no
Test substance	:	no data
Reliability	:	(2) valid with restrictions Secondary literature, but generally accepted handbooks.

08.05.2002 (7) (25)

2.2 BOILING POINT

Remark	:	Not applicable, as the test substance decomposes upon heating.

08.05.2002 (7) (25)

2.3 DENSITY

Type	:	relative density
Value	:	= 2.532 at 20 °C
Method	:	other: no information available
Year	:	1986
GLP	:	no
Test substance	:	no data
Reliability	:	(2) valid with restrictions Secondary literature, but generally accepted handbooks.

08.05.2002 (7)

2.3.1 GRANULOMETRY

Remark	:	The average particle size diameter (d50) of light sodium carbonate is in the range of 90 to 150 µm and of dense sodium carbonate is in the range of 250 to 500 µm.

31.05.2002

2.4 VAPOUR PRESSURE

Remark	:	Sodium carbonate is an inorganic solid and for this reason the vapour pressure of sodium carbonate is negligible. Furthermore it is technically not possible to determine the vapour pressure due to decomposition (when heated).

14.08.2001

2.5 PARTITION COEFFICIENT

Remark	:	The octanol/water partition coefficient is not relevant for an inorganic substance which dissociates.

14.08.2001

2.6.1 SOLUBILITY IN DIFFERENT MEDIA

Solubility in	:	Water
Value	:	= 71 g/l at 0 °C
pH value	:	
concentration	:	at °C
Temperature effects	:	
Examine different pol.	:	
pKa	:	at 25 °C
Description	:	
Stable	:	
Reliability	:	(2) valid with restrictions Secondary literature, but generally accepted handbooks.
01.05.2002		(7)

Solubility in	:	Water
Value	:	= 215 g/l at 20 °C
pH value	:	
concentration	:	at °C
Temperature effects	:	
Examine different pol.	:	
pKa	:	at 25 °C
Description	:	
Stable	:	
Source	:	TNO Voeding AJ Zeist
Reliability	:	(2) valid with restrictions Secondary literature, but generally accepted handbooks.
28.08.2001		(7)

Solubility in	:	Water
Value	:	= 455 g/l at 100 °C
pH value	:	
concentration	:	at °C
Temperature effects	:	
Examine different pol.	:	
pKa	:	at 25 °C
Description	:	
Stable	:	
Source	:	TNO Voeding AJ Zeist
Reliability	:	(2) valid with restrictions Secondary literature, but generally accepted handbooks.
28.08.2001		(7)

Solubility in	:	Organic Solvents
Value	:	at °C
pH value	:	
concentration	:	at °C
Temperature effects	:	
Examine different pol.	:	
pKa	:	at 25 °C
Description	:	
Stable	:	
Remark	:	Slightly soluble in ethanol and insoluble in acetone.
Source	:	TNO Voeding AJ Zeist
Reliability	:	(4) not assignable Only secondary literature
06.09.2001		(11) (13)

2.6.2 SURFACE TENSION

2.7 FLASH POINT

Remark : Not applicable.
14.08.2001

2.8 AUTO FLAMMABILITY

Remark : Not flammable. Not a fire hazard.
14.08.2001

2.9 FLAMMABILITY

Remark : Not flammable. Not combustible.
16.05.2002

2.10 EXPLOSIVE PROPERTIES

Result : not explosive
17.07.2001

2.11 OXIDIZING PROPERTIES

Result : no oxidizing properties
17.07.2001

2.12 DISSOCIATION CONSTANT

Remark : $HCO_3^- \leftrightarrow CO_3^{2-} + H^+$ pKa = 10.33
$CO_2 + H_2O \leftrightarrow HCO_3^- + H^+$ pKa = 6.35
30.07.2002

2.13 VISCOSITY

2.14 ADDITIONAL REMARKS

Memo : Sodium carbonate is a strong alkaline substance with a pH of 11.6 for a 0.1 M aqueous solution.
14.08.2001 (11) (25)

3.1.1 PHOTODEGRADATION

Remark : Not applicable
08.05.2002

3.1.2 STABILITY IN WATER

Remark : In water, sodium carbonate dissociates into sodium and carbonate.

Carbonate re-equilibrates according to the following equations:
HCO_3^- <--> CO_3^{2-} + H^+ pKa = 10.33
$CO_2 + H_2O$ <--> HCO_3^- + H^+ pKa = 6.35

Only a small fraction of the dissolved CO_2 is present as H_2CO_3, the major part is present as CO_2. The amount of CO_2 in water is in equilibrium with the partial pressure of CO_2 in the atmosphere. The CO_2 / HCO_3^- / CO_3^{2-} equilibria are the major buffer of the pH of freshwater throughout the world.

Based on the above equations, CO_2 is the predominant species at a pH smaller than 6.35, while HCO_3^- is the predominant species at a pH in the range of 6.35-10.33 and CO_3^{2-} is the predominant species at a pH higher than 10.33.

30.07.2002

3.1.3 STABILITY IN SOIL

3.2.1 MONITORING DATA

Type of measurement : background concentration
Media : surface water
Concentration :
Method :
Remark : The sodium and bicarbonate ion are both naturally occuring in the environment.

UNEP (1995) reported the sodium concentration for a total number of 75 rivers in North-America, South-America, Asia, Africa, Europe and Oceania. The 10th-percentile, mean and 90th-percentile were 1.5, 28 and 68 mg/l, respectively.

UNEP (1995) reported the bicarbonate concentration for a total number of 77 rivers in North-America, South-America, Asia, Africa, Europe and Oceania. The 10th-percentile, mean and 90th-percentile were 20, 106 and 195 mg/l, respectively.

16.05.2002 (26)

3.2.2 FIELD STUDIES

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Remark : Sodium carbonate is an inorganic substance and therefore standard computer models can not be used to determine the transport or distribution between environmental compartments.

Solid sodium carbonate has a negligible vapour pressure and for this reason it will not be distributed to the atmosphere.

If sodium carbonate is emitted to water it will remain in the water phase. If the pH is decreased then carbonic acid (H_2CO_3 or CO_2) can be formed. If the concentration of carbon dioxide water is above the water solubility limit, the carbon dioxide will distribute to the atmosphere.

If sodium carbonate is emitted to soil it can escape to the atmosphere as CO_2 (see above), precipitate as a metal carbonate, form complexes or stay in solution.

08.05.2002

3.3.2 DISTRIBUTION

Remark : See 3.1.2 and 3.3.1 .
16.05.2002

3.4 MODE OF DEGRADATION IN ACTUAL USE

08.05.2002

3.5 BIODEGRADATION

Remark : Sodium carbonate is a inorganic substance which can not be oxidized or biodegraded by microorganisms. A biodegradation test would not generate valid or useful data.

08.05.2002

3.6 BOD5, COD OR BOD5/COD RATIO

Remark : Not applicable, see 3.5.
08.05.2002

3.7 BIOACCUMULATION

Remark : Not bioaccumulable. Log Po/w is not applicable for an inorganic compound which dissociates.

08.05.2002

3.8 ADDITIONAL REMARKS

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type	:	static
Species	:	*Lepomis macrochirus* (Fish, fresh water)
Exposure period	:	96 hour(s)
Unit	:	mg/l
LC50	:	= 300
Limit test	:	no
Analytical monitoring	:	no
Method	:	other
Year	:	1959
GLP	:	no
Test substance	:	other TS: sodium carbonate
Method	:	METHOD FOLLOWED: Recommendations of the Committee on Research, Submcomitttee on Toxicity, Section III, Federation of Sewage and Industrial Wastes Associations were followed. GLP: No STATISTICAL METHODS: None METHOD OF CALCULATION: Not reported. ANALYTICAL METHODS: Not reported.
Result	:	RESULTS: EXPOSED - Nominal/measured concentrations: No measured concentrations reported. - Effect data (Mortality): LC50 96hr=300 mg/l. - Concentration / response curve: Not reported. - Effect concentration vs. test substance solubility: Not reported. - Other effects: not reported. RESULTS: CONTROL - Number/percentage of animals showing adverse effects: A control aquarium was always maintained with 10 fishes. Nothing further reported. RESULTS: TEST WITH REFERENCE SUBSTANCE - Not reported.
Test condition	:	TEST ORGANISMS - Strain: common blue gill, Lepomis macrochirus Raf - Wild caught: From various sources, private fish hatchery in Pennsylvania and Pennsylvania Fish Commission. - Age/size/weight/loading: three different sizes tested; small, 3.88 cm and 0.96 grams (average); medium, 6.09 cm and 2.80 grams (average); large, 14.24 cm and 54.26 grams (average). - Feeding: daily with chopped, freshly cooked shrimp. - Pretreatment: seven days acclimatisation to test conditions. - Feeding during test: No feeding during the test. STOCK AND TEST SOLUTION AND THEIR PREPARATION - Concentrated stock solution. STABILITY OF THE TEST CHEMICAL SOLUTIONS: Not reported. REFERENCE SUBSTANCE: Not reported. DILUTION WATER - Source: reconstituted water - Aeration: open jar - Alkalinity: 40 mg/l of $NaHCO_3$ - Hardness: - Salinity: Not reported. - TOC: Not reported. - TSS: Not reported. - pH: measured but results not reported. - Oxygen content: not reported. - Conductance: Not reported. TEST SYSTEM - Concentrations: Not reported.

- Dosing rate: Not reported.
- Exposure vessel type: 5 gallon glass jars with cork stoppers immersed in a constant temperature water bath.
- Number of replicates, fish per replicate: 5 to 10 fish in each jar, depending on fish size.
- Test temperature: 19-21 C
- Dissolved oxygen: 5-9 ppm
- pH: measured but not further described.
- Adjustment of pH: Not reported.
- Intensity of irradiation: Not reported.
- Photoperiod: Not reported.

DURATION OF THE TEST: 96 hr.
TEST PARAMETER: Death = cessation of gill movement and lack of response to a mechanical stimulus for a period of 5 minutes.
SAMPLING: Not reported.
MONITORING OF TEST SUBSTANCE CONCENTRATION: Not reported.

Test substance : SOURCE: Baker analyzed
PURITY: "Chemically pure".
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.

Reliability : (2) valid with restrictions
Well documented publication. However results of all test concentrations not given and no analysis of test solutions.

14.02.2003 (3)

Type : static
Species : *Gambusia affinis* (Fish, fresh water)
Exposure period : 96 hour(s)
Unit : mg/l
NOEC : = 550
LC50 : = 740
Limit test : no
Analytical monitoring : no data
Method : other: Recommendations of Committee on Research were followed (Doudoroff et al., 1951)
Year : 1957
GLP : no
Test substance : other TS: sodium carbonate
Method : METHOD FOLLOWED: A 96 hr median tolerance limit test with female fish (N=10). The experiments were continued for at least 96 hours with checks made of the 24, 48, 72 and 96 hour survivors.
GLP: No
STATISTICAL METHODS: None
METHOD OF CALCULATION: Plotting of survival against concentration of sodium carbonate on logarithmic paper
ANALYTICAL METHODS: Not reported.

Result : RESULTS: EXPOSED
- Nominal/measured concentrations: No measured concentrations reported.
- Effect data (Mortality): LC50 24hr=1200 mg/l. LC50 48hr=840 mg/l.
- Concentration / response curve: Not reported, but a median tolerance limit was plotted on logarithmic paper (not shown in report).
- Effect concentration vs. test substance solubility: Not reported.
- Other effects: At 560 mg/l and below all fishes were normal for 96 hr. At 1000 mg/l 3 were dead in 24 hr, 4 others at 48 hr, 2 others at 96 hr. The one remaining was in poor condition at the end of the test.

RESULTS: CONTROL
- Number/percentage of animals showing adverse effects: A control aquarium was always maintained with 10 fishes. Nothing further reported.

RESULTS: TEST WITH REFERENCE SUBSTANCE
- Not reported.

Test condition : TEST ORGANISMS
- Strain: Not reported.
- Supplier: Not reported.
- Wild caught: From Stillwater Creek in Payne County.
- Age/size/weight/loading: Adult females selected based on difference in size between males and females.
- Feeding: Plankton and detritus, along with various artificial foods.
- Pretreatment: 2-3 weeks acclimatization period.
- Feeding during test: Not fed.

STOCK AND TEST SOLUTION AND THEIR PREPARATION
- No details reported.

STABILITY OF THE TEST CHEMICAL SOLUTIONS: Not reported.
REFERENCE SUBSTANCE: Not reported.
DILUTION WATER
- Source: Two farm ponds containing water with high turbidity.
- Aeration: Artificial aeration
- Alkalinity: Low.
- Hardness: Not reported.
- Salinity: Not reported.
- TOC: Not reported.
- TSS: Not reported.
- pH: 7.8-8.3
- Oxygen content: Maintained through aeration.
- Conductance: Not reported.
- Holding water: Not reported.

TEST SYSTEM
- Concentrations: 10, 18, 32, 56, 1000, 180, 320, 560, 1000 ppm (=mg/l)
- Dosing rate: Not reported.
- Renewal of test solution: Not relevant.
- Exposure vessel type: Cylindrical pyrex jars containing 15 L water.
- Number of replicates, fish per replicate: In total 10 fish used.
- Test temperatu re: 18-25ºC
- Dissolved oxygen: Level maintained through aeration.
- pH: Slightly increased to 8.6-9.2
- Adjustment of pH: No.
- Intensity of irradiation: Not reported.
- Photoperiod: Not reported.
- Turbidity: Remained nearly constant 105-160 mg/l

DURATION OF THE TEST: 96 hr
TEST PARAMETER: Mortality
SAMPLING: Not reported.
MONITORING OF TEST SUBSTANCE CONCENTRATION: Not reported.

Test substance : SOURCE: Not reported.
PURITY: "Chemically pure".
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.

Reliability : (2) valid with restrictions
Well documented publication, executed according to national standards of that time (1951), but with several shortcomings to today's standard methods.

14.02.2003 (27)

Type : static
Species : *Lepomis macrochirus* (Fish, fresh water)
Exposure period : 24 hour(s)
Unit : mg/l
LC50 : = 385
Limit test :
Analytical monitoring : no data
Method : other: according to Freeman (1953).

Year : 1965
GLP : no
Test substance : other TS: sodium carbonate
Method : METHOD FOLLOWED: According to Freeman (1953)
GLP: No
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.
Result : RESULTS: EXPOSED
No details reported.
RESULTS: CONTROL
No details reported.
RESULTS: TEST WITH REFERENCE SUBSTANCE
No details reported.
Test condition : TEST ORGANISMS
- Strain: Not reported.
- Supplier: State and federal fish hatcheries.
- Age/size/weight/loading: Not reported.
- Feeding: Not reported.
- Pretreatment: Not reported.
- Feeding during test: Not reported.
STOCK AND TEST SOLUTION AND THEIR PREPARATION
No details reported.
STABILITY OF THE TEST CHEMICAL SOLUTIONS: Not reported.
REFERENCE SUBSTANCE: Not reported.
DILUTION WATER
- Source: University Lake Water filtered through glass wool.
No further details reported.
TEST SYSTEM
No details reported.
DURATION OF THE TEST: 24 hr.
TEST PARAMETER: Death
SAMPLING: Not reported.
MONITORING OF TEST SUBSTANCE CONCENTRATION: Not reported.
Test substance : SOURCE: Not reported.
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.
Reliability : (4) not assignable
Documentation insufficient for complete assessment.

14.02.2003 (8)

Type : static
Species : other: *Mollienesia latipinna*
Exposure period : 50 hour(s)
Unit : mg/l
LC50 : = 297
Limit test :
Analytical monitoring : no data
Method : other: according to Freeman (1953)
Year : 1965
GLP : no
Test substance : other TS: sodium carbonate
Method : METHOD FOLLOWED: According to Freeman (1953).
GLP: No
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.
Result : RESULTS: EXPOSED
- Effect data (mortality): LC50 25 hr is 405 mg/l.

No further details reported.
RESULTS: CONTROL
No details reported.
RESULTS: TEST WITH REFERENCE SUBSTANCE
No details reported

Test condition : TEST ORGANISMS
- Strain: Not reported.
- Supplier: Local pet shop.
- Age/size/weight/loading: Not reported.
- Feeding: Not reported.
- Pretreatment: Not reported.
- Feeding during test: Not reported.

STOCK AND TEST SOLUTION AND THEIR PREPARATION
No details reported.
STABILITY OF THE TEST CHEMICAL SOLUTIONS: Not reported.
REFERENCE SUBSTANCE: Not reported.
DILUTION WATER
- Source: Standard Reference water, prepared in a laboratory, comparable to mean surface water in US. No further details reported.

TEST SYSTEM
No details reported.
DURATION OF THE TEST: 50 hr.
TEST PARAMETER: Death
SAMPLING: Not reported.
MONITORING OF TEST SUBSTANCE CONCENTRATION: Not reported.

Test substance : SOURCE: Not reported.
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.

Reliability : (4) not assignable
Documentation insufficient for complete assessment.

14.02.2003 (8)

Remark : A short review of the acute toxicity for fish is described by the California State Water Resources Control Board (McKee et al., 1963). Concentrations of 68-80 mg/l were reported to kill king salmon, silver salmon and cut-throat trout after 5 days of exposure, while other species, like carp, bass, shiners, sunfish and mosquito-fish, were killed at concentrations ranging between 200 and 1200 mg/l with an exposure duration ranging from hours up to five days. Furthermore, exposure for 5 days to concentrations of 33-58 mg/l to king salmon, silver salmon and cut-throat trout has not been harmful. Exposure for 7 days to 100-200 mg/l to bass and sunfish and to 200-500 mg/l to goldfish was not harmful.

Reliability : (4) not assignable
Only secondary literature

31.07.2002 (14)

Type : static
Species : *Notropis atherinoides*
Exposure period : 5 day(s)
Unit : mg/l
Limit test :
Analytical monitoring : no data
Method : other
Year : 1949
GLP : no
Test substance : other TS: sodium carbonate

Method : METHOD FOLLOWED: Modification of that employed by Powers (1917) which has been described previously by Van Horn (1943). Determination of

minimum lethal concentration, defined as the lowest concentration of a toxic material which would kill any of the test animals within a period of 120 hours. Observations were made hourly. No further description given.
GLP: No
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.

Result : RESULTS: EXPOSED
- Nominal/measured concentrations: Not reported.
- Effect data (Mortality): Minimal lethal effect level: 250 mg/l
- Concentration / response curve: Not reported.
- Effect concentration vs. test substance solubility: Not reported.
- Other effects: Not reported.

RESULTS: CONTROL
- Number/percentage of animals showing adverse effects: zero
- Nature of adverse effects: 100% survival of controls was required.

RESULTS: TEST WITH REFERENCE SUBSTANCE
- Concentrations: Not reported.
- Results: Not reported.

Test condition : TEST ORGANISMS
- Strain: Not reported.
- Wild caught: From various sources in the vicinity of Appleton, Wisconsin.
- Age/size/weight/loading: Not reported.
- Feeding: Not reported.
- Pretreatment: Not reported.
- Feeding during test: Not reported.

STOCK AND TEST SOLUTION AND THEIR PREPARATION
- No details reported.

STABILITY OF THE TEST CHEMICAL SOLUTIONS: Not reported.
REFERENCE SUBSTANCE: Not reported.
DILUTION WATER
- Source: Fox River water.
- Aeration: Open battery jars.
- Alkalinity: 140 to 160 ppm.
- Hardness: Relatively hard.
- Salinity: Not reported.
- TOC: Not reported.
- TSS: Not reported.
- pH: 7.6 to 7.8.
- Oxygen content: >4 ppm
- Conductance: Not reported.
- Holding water: Not reported.

TEST SYSTEM
- Concentrations: Not reported.
- Dosing rate: Not reported.
- Exposure vessel type: 2 litres of test solution were placed in open battery jars immersed in a constant temperature water bath.
- Number of replicates, fish per replicate: 1 to 5 fish in each jar, depending on the oxygen resources.
- Test temperature: 18ºC
- Dissolved oxygen: >4 ppm
- pH: Checked and within limits favorable to fish life, but not further described.
- Adjustment of pH: Not reported.
- Intensity of irradiation: Not reported.
- Photoperiod: Not reported.

DURATION OF THE TEST: 120 hr.
TEST PARAMETER: Death
SAMPLING: Not reported.
MONITORING OF TEST SUBSTANCE CONCENTRATION: Not reported.

Test substance	:	SOURCE: Not reported. PURITY: Not reported. IMPURITY/ADDITIVE/ETC.: Not reported. ANY OTHER INFORMATION: Not reported.
Reliability	:	(4) not assignable Documentation insufficient for complete assessment.
14.02.2003		(10)
Type	:	Static
Species	:	other: *Notropis spilopterus* (spotfin shiner)
Exposure period	:	5 day(s)
Unit	:	mg/l
Limit test	:	
Analytical monitoring	:	no data
Method	:	other
Year	:	1949
GLP	:	no data
Test substance	:	other TS: sodium carbonate
Method	:	METHOD FOLLOWED: Modification of that employed by Powers (1917) which has been described previously by Van Horn (1943). Determination of minimum lethal concentration, defined as the lowest concentration of a toxic material which would kill any of the test animals within a period of 120 hours. Observations were made hourly. No further description given. GLP: No STATISTICAL METHODS: Not reported. METHOD OF CALCULATION: Not reported. ANALYTICAL METHODS: Not reported.
Result	:	RESULTS: EXPOSED - Nominal/measured concentrations: Not reported. - Effect data (Mortality): Minimal lethal effect level: 250 mg/l - Concentration / response curve: Not reported. - Effect concentration vs. test substance solubility: Not reported. - Other effects: Not reported. RESULTS: CONTROL - Number/percentage of animals showing adverse effects: zero, 100% survival of controls was required. - Nature of adverse effects: Not reported. RESULTS: TEST WITH REFERENCE SUBSTANCE - Concentrations: Not reported. - Results: Not reported.
Test condition	:	TEST ORGANISMS - Strain: Not reported. - Wild caught: From various sources in the vicinity of Appleton, Wisconsin. - Age/size/weight/loading: Not reported. - Feeding: Not reported. - Pretreatment: Not reported. - Feeding during test: Not reported. STOCK AND TEST SOLUTION AND THEIR PREPARATION - No details reported. STABILITY OF THE TEST CHEMICAL SOLUTIONS: Not reported. REFERENCE SUBSTANCE: Not reported. DILUTION WATER - Source: Fox River water. - Aeration: Open battery jars. - Alkalinity: 140 to 160 ppm. - Hardness: Relatively hard. - Salinity: Not reported. - TOC: Not reported. - TSS: Not reported. - pH: 7.6 to 7.8.

- Oxygen content: >4 ppm
- Conductance: Not reported.
- Holding water: Not reported.

TEST SYSTEM
- Concentrations: Not reported.
- Dosing rate: Not reported.
- Exposure vessel type: 2 litres of test solution were placed in open battery jars immersed in a constant temperature water bath.
- Number of replicates, fish per replicate: 1 to 5 fish in each jar, depending on the oxygen resources.
- Test temperature: 18ºC
- Dissolved oxygen: >4 ppm
- pH: Checked and within limits favorable to fish life, but not further described.
- Adjustment of pH: Not reported.
- Intensity of irradiation: Not reported.
- Photoperiod: Not reported.

DURATION OF THE TEST: 120 hr.
TEST PARAMETER: Death
SAMPLING: Not reported.
MONITORING OF TEST SUBSTANCE CONCENTRATION: Not reported.

Test substance : SOURCE: Not reported.
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.

Reliability : (4) not assignable
Documentation insufficient for complete assessment.

14.02.2003 (10)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type	:	semistatic
Species	:	*Ceriodaphnia sp.* (Crustacea)
Exposure period	:	48 hour(s)
Unit	:	mg/l
EC50	:	= 200 - 227
Analytical monitoring	:	no data
Method	:	other: method developed by NSW Environment Protection Authority (Warne & Julli, 1999)
Year	:	1999
GLP	:	no
Test substance	:	other TS: sodium carbonate
Method	:	METHOD FOLLOWED: 48-h immobilisation test using methods developed by the NSW Environment Protection Authority (Warne and Julli, 1999). Immobilisation was defined as the absence of visible movement by the cladocera within 15 sec of a gentle agitation of the test solution (ASTM, 1988). Chemical was tested in a range-finder and definitive test, with a second definitive test when the results were markedly different. GLP: No. STATISTICAL METHODS: Trimmed Spearman-Karber method. METHOD OF CALCULATION: Toxicity of the chemical was expressed in three different units, mg/L, mmol/L and toxic units (TU). ANALYTICAL METHODS: Not reported.
Result	:	RESULTS: EXPOSED - Nominal/measured concentrations: Values based on nominal concentrations. - Effect data (Immobilisation): 95% confidence limits: 166.9-298.9 mg/l, 156.6-198.3 mg/lg, 192.4-267.4 mg/l.

- Concentration / response curve: Not reported.
- Cumulative immobilisation: Not reported.
- Effect concentration vs. test substance solubility: Not reported.
- Other effects: Not reported.

RESULTS CONTROL: Test was considered invalid w hen more than 10% of the control neonates were immobilized.

RESULTS: TEST WITH REFERENCE SUBSTANCE
- Concentrations: Not reported.
- Results: Not reported.

Test condition : TEST ORGANISMS
- Strain: Not reported.
- Source/supplier: Not reported.
- Breeding method: Cultures maintained in 2-L glass beakers and transferred to fresh water 3 times weekly.
- Age: Neonates less than 24 hr old.
- Feeding: After water renewal at a concentration of 25,000 cell/ml of each of the unicellular algae *Pseudokirchneriellia subcapitata Printz* and *Ankistrodesmus sp*.
- Pretreatment: Not reported.
- Feeding during test: Not fed.
- Control group: Yes.

STOCK AND TEST SOLUTION AND THEIR PREPARATION
- Dispersion: The appropriate amount of the chemical was dissolved in 1 or 2 litre water, gently stirred for 12 hr in the dark using Teflon magnetic stirrers.
- Vehicle, solvent: Dechlorinated Sydney mains water
- Concentration of vehicle/ solvent: Not reported.
- Other procedures: Not reported.

STABILITY OF THE TEST CHEMICAL SOLUTIONS: Stock solutions were diluted to appropriate concentrations immediately prior to commencement of the test.

REFERENCE SUBSTANCE: Not reported.

DILUTION WATER
- Source: Dechlorinated Sydney mains water filtered, aged and adjusted to 500 microS/cm with seawater.
- Aeration: Not reported.
- Alkalinity: Not reported.
- Hardness: Not reported.
- Salinity: Not reported.
- TOC: Not reported.
- Ca/Mg ratio: Not reported.
- Na/K ratio: Not reported.
- TSS: Not reported.
- pH: Measured, not described.
- Oxygen content: Measured, not described.
- Conductance: Measured, not described.
- Holding water: Not reported.

TEST SYSTEM
- Concentrations: The bioassay consisted of five concentrations of sodium carbonate or soda ash in geometric series plus a control.
- Renewal of test solution: No.
- Exposure vessel type: 250 ml glass beakers which held 200 ml of the test solution or control solution.
- Number of replicates, individuals per replicate: For each concentration triplicates of five cladocera per beaker glass were used.
- Test temperature: 22-24°C
- Dissolved oxygen: Measured, not described.
- pH: Measured, not described.
- Adjustment of pH: Not reported.
- Intensity of irradiation: Below 1000 1x at the surface of the solution.

- Photoperiod: 16:8 h light:dark
DURATION OF THE TEST: 48 hr
TEST PARAMETER: immobilization
SAMPLING: Immobile cladocera counted.
MONITORING OF TEST SUBSTANCE CONCENTRATION: Not reported.

Test substance : SOURCE: Not reported.
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.

Reliability : (2) valid with restrictions
Acceptable, well documented publication which meets basic scientific principles. Method developed by Australian government authority.
Acceptable, well documented publication which meets basic scientific principles. Method developed by Australian government authority.

16.05.2002 (28)

Type :
Species : *Daphnia magna* (Crustacea)
Exposure period :
Unit : mg/l
Analytical monitoring : no data
Method : other: not indicated
Year : 1963
GLP : no
Test substance : other TS: sodium carbonate
Method : METHOD FOLLOWED: Not reported.
GLP: No
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.
Remark : In Lake Erie wtaer at 25 degrees Celsius 424 mg/l, 300 mg/l, at 17 degrees Celsius 300 mg/l and at 800 mg/l all animals were killed. The 100 hr EC50 at 23 degrees Celsius in doudble distilled water has been reported at 524 mg/l, pH 9.5. Furthermore, at 23 degrees Celsius for a 100-hr exposure the EC50 was 552 mg/l at a dissolved oxygen tension of 6.5 mg/l, but the EC50 was only 267 mg/l when the dissolved oxyg en tension dropped to 1.53 mg/l.
Result : RESULTS: EXPOSED
No details reported.
RESULTS: CONTROL
No details reported.
RESULTS: TEST WITH REFERENCE SUBSTANCE
No details reported.
Test condition : TEST ORGANISMS
No details reported.
STOCK AND TEST SOLUTION AND THEIR PREPARATION
No details reported.
STABILITY OF THE TEST CHEMICAL SOLUTIONS: No details reported.
REFERENCE SUBSTANCE: No details reported.
DILUTION WATER
No details reported.
TEST SYSTEM
No details reported.
TEST PARAMETER: Mortality.
SAMPLING: No details reported.
MONITORING OF TEST SUBSTANCE CONCENTRATION: No details reported.
Test substance : SOURCE: Not reported.
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.

Reliability : (4) not assignable Only secondary literature.
Only secondary literature.
14.02.2003 (14)

Type :
Species : *Daphnia magna* (Crustacea)
Exposure period : 48 hour(s)
Unit : mg/l
EC50 : < 424
Analytical monitoring : no data
Method : other: according to Anderson et al. (1944)
Year : 1946
GLP : no data
Test substance : other TS: sodiumcarbonate
Method : METHOD FOLLOWED: According to Anderson et al. (1944).
GLP: No
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Immobilization time-concentration curves were constructed on the basis of 48-hour observaion, from which the threshold concentrations were estimated.
ANALYTICAL METHODS: Not reported.
Result : RESULTS: EXPOSED
- Nominal/measured concentrations: Not reported.
- Effect data (Immobilisation): EC50 48 hr <424 mg/l.
- Concentration / response curve: For several chemicals described, not for sodium carbonate.
- Cumulative immobilisation: Not reported.
- Effect concentration vs. test substance solubility: Not reported.
- Other effects: pH 9.2 at EC50, therefore toxicity due alkalinity.

RESULTS: CONTROL
Number/percentage of animals showing adverse effects:
80-100% remained alive and active.
Nature of adverse effects: Death and reduced activity.
RESULTS: TEST WITH REFERENCE SUBSTANCE
- Concentrations: Not reported.
- Results: Not reported.

Test condition : TEST ORGANISMS
No details reported.
STOCK AND TEST SOLUTION AND THEIR PREPARATION
No details reported.
STABILITY OF THE TEST CHEMICAL SOLUTIONS: Not reported.
REFERENCE SUBSTANCE: Not reported.
DILUTION WATER
- Source: Centrifuged Lake Erie water.

No further details reported.
TEST SYSTEM
pH: Determined, only reported at threshold level, 9.2.
No further details reported.
DURATION OF THE TEST: 48 hr
TEST PARAMETER: Death.
SAMPLING: Not reported.
MONITORING OF TEST SUBSTANCE CONCENTRATION: Not reported.
Test substance : SOURCE: Not reported.
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.
Reliability : (3) invalid Documentation insufficient for assessment.
Documentation insufficient for assessment.
14.02.2003 (1)

Type	:	
Species	:	*Daphnia magna* (Crustacea)
Exposure period	:	48 hour(s)
Unit	:	mg/l
EC50	:	= 265
Analytical monitoring	:	no data
Method	:	other: according to Anderson et al. (1948)
Year	:	1965
GLP	:	No
Test substance	:	other TS: sodium carbonate
Method	:	METHOD FOLLOWED: According to Anderson et al. (1948). GLP: No STATISTICAL METHODS: Not reported. METHOD OF CALCULATION: Not reported. ANALYTICAL METHODS: Not reported.
Result	:	RESULTS: EXPOSED - Nominal/measured concentrations: Not reported. - Effect data (Immobilisation): LC50 24 hr 347 mg/l. - Concentration / response curve: Not reported. - Cumulative immobilisation: Not reported. - Effect concentration vs. test substance solubility: Not reported. - Other effects: Not reported. RESULTS CONTROL: Not reported. RESULTS: TEST WITH REFERENCE SUBSTANCE - Concentrations: Not reported. - Results: Not reported.
Test condition	:	TEST ORGANISMS - Strain: Not reported. - Source/supplier: Cultured in laboratory, starting culture obtained from Put-In-Bay, Ohio. No further details reported. STOCK AND TEST SOLUTION AND THEIR PREPARATION No further details reported. STABILITY OF THE TEST CHEMICAL SOLUTIONS: Not reported. REFERENCE SUBSTANCE: Not reported. DILUTION WATER - Source: University Lake Water filtered through glass-wool. No further details reported. TEST SYSTEM No details reported. DURATION OF THE TEST: 48 hr TEST PARAMETER: Death. SAMPLING: Not reported. MONITORING OF TEST SUBSTANCE CONCENTRATION: Not reported.
Test substance	:	SOURCE: Not reported. PURITY: Not reported. IMPURITY/ADDITIVE/ETC.: Not reported. ANY OTHER INFORMATION: Not reported.
Reliability	:	(4) not assignable Documentation insufficient for complete assessment. Documentation insufficient for complete assessment.

14.02.2003 (8)

Type	:	
Species	:	*Daphnia magna* (Crustacea)
Exposure period	:	96 hour(s)
Unit	:	mg/l
EC50	:	= 524
Analytical monitoring	:	no data
Method	:	other: according to Anderson et al. (1948)

Year : 1965
GLP : No
Test substance : other TS: sodium carbonate
Method : METHOD FOLLOWED: According to Anderson et al. (1948).
GLP: No
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.
Result : RESULTS: EXPOSED
- Nominal/measured concentrations: Not reported.
- Effect data (Immobilisation): LC50 25 hr 607 mg/l, LC50 48 hr 565 mg/l.
- Concentration / response curve: Not reported.
- Cumulative immobilisation: Not reported.
- Effect concentration vs. test substance solubility: Not reported.
- Other effects: Not reported.
RESULTS CONTROL: Not reported.
RESULTS: TEST WITH REFERENCE SUBSTANCE
- Concentrations: Not reported.
- Results: Not reported.
Test condition : TEST ORGANISMS
- Strain: Not reported.
- Source/supplier: Cultured in laboratory, starting culture obtained from Put-In-Bay, Ohio.
No further details reported.
STOCK AND TEST SOLUTION AND THEIR PREPARATION
No further details reported.
STABILITY OF THE TEST CHEMICAL SOLUTIONS: Not reported.
REFERENCE SUBSTANCE: Not reported.
DILUTION WATER
- Source: Standadard Reference Water which is prepared in a laboratory, free from organics, containing all the major ions in concentrations and proportions of a mean surface water of the United States.
No further details reported.
TEST SYSTEM
No details reported.
DURATION OF THE TEST: 96 hr
TEST PARAMETER: Death.
SAMPLING: Not reported.
MONITORING OF TEST SUBSTANCE CONCENTRATION: Not reported.
Test substance : SOURCE: Not reported.
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.
Reliability : (4) not assignable Documentation insufficient for complete assessment.
Documentation insufficient for complete assessment.

14.02.2003 (8)

Type :
Species : other: Amphipoda
Exposure period : 96 hour(s)
Unit : mg/l
EC50 : = 67
Analytical monitoring : No data
Method : other: according to Anderson et al. (1948)
Year : 1965
GLP : No
Test substance : other TS: sodium carbonate
Method : METHOD FOLLOWED: According to Anderson et al. (1948).
GLP: No

STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.

Result : RESULTS: EXPOSED
- Nominal/measured concentrations: Not reported.
- Effect data (Immobilisation): LC50 24 hr 360 mg/l, 48 hr 176 mg/l, 72 hr 67 mg/l.
- Concentration / response curve: Not reported.
- Cumulative immobilisation: Not reported.
- Effect concentration vs. test substance solubility: Not reported.
- Other effects: Not reported.

RESULTS CONTROL: Not reported.
RESULTS: TEST WITH REFERENCE SUBSTANCE
- Concentrations: Not reported.
- Results: Not reported.

Test condition : TEST ORGANISMS
- Strain: Not reported.
- Wild caught: Obtained from University Lake on the campus of the University.

No further details reported.
STOCK AND TEST SOLUTION AND THEIR PREPARATION
No further details reported.
STABILITY OF THE TEST CHEMICAL SOLUTIONS: Not reported.
REFERENCE SUBSTANCE: Not reported.
DILUTION WATER
- Source: University Lake Wter filetered through glass-wool.

No further details reported.
TEST SYSTE M
No details reported.
DURATION OF THE TEST: 96 hr
TEST PARAMETER: Death.
SAMPLING: Not reported.
MONITORING OF TEST SUBSTANCE CONCENTRATION: Not reported.

Test substance : SOURCE: Not reported.
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.

Reliability : (4) not assignable Documentation insufficient for complete assessment.
Documentation insufficient for complete assessment.

14.02.2003 (8)

Type :
Species : other: *Culex sp.*
Exposure period : 48 hour(s)
Unit : Mg/l
EC50 : = 600
Analytical monitoring : No data
Method : other: according to Andreson et al. (1948)
Year : 1965
GLP : No
Test substance : other TS: sodium carbonate
Method : METHOD FOLLOWED: According to Anderson et al. (1948).
GLP: No
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.

Result : RESULTS: EXPOSED
- Nominal/measured concentrations: Not reported.

- Effect data (Immobilisation): LC50 24 hr 1820 mg/l.
- Concentration / response curve: Not reported.
- Cumulative immobilisation: Not reported.
- Effect concentration vs. test substance solubility: Not reported.
- Other effects: Not reported.

RESULTS CONTROL: Not reported.
RESULTS: TEST WITH REFERENCE SUBSTANCE
- Concentrations: Not reported.
- Results: Not reported.

Test condition : TEST ORGANISMS
- Strain: Not reported.
- Wild caught: Obtained during the summer in mixed culture of mostly Culex pipiens from puddles in a ditch on the campus.

No further details reported.
STOCK AND TEST SOLUTION AND THEIR PREPARATION
No further details reported.
STABILITY OF THE TEST CHEMICAL SOLUTIONS: Not reported.
REFERENCE SUBSTANCE: Not reported.
DILUTION WATER
- Source: Reference Dilution Water which is a more easily formulated organic-free medium which will support aquatic animals longer than other artificial media.

No further details reported.
TEST SYSTEM
No details reported.
DURATION OF THE TEST: 48 hr
TEST PARAMETER: Death.
SAMPLING: Not reported.
MONITORING OF TEST SUBSTANCE CONCENTRATION: Not reported.

Test substance : SOURCE: Not reported.
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.

Reliability : (4) not assignable Documentation insufficient for complete assessment.
Documentation insufficient for complete assessment.

14.02.2003 (8)

Type :
Species : other: *Dugesia sp*.
Exposure period : 96 hour(s)
Unit : Mg/l
EC50 : = 341
Analytical monitoring : No data
Method : other: according to Anderson et al. (1948)
Year : 1965
GLP : No
Test substance : other TS: sodium carbonate
Method : METHOD FOLLOWED: According to Anderson et al. (1948).
GLP: No
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.

Result : RESULTS: EXPOSED
- Nominal/measured concentrations: Not reported.
- Effect data (Immobilisation): LC50 24 hr 384 mg/l, 48 hr 360 mg/l, 72 hr 360 mg/l.
- Concentration / response curve: Not reported.
- Cumulative immobilisation: Not reported.
- Effect concentration vs. test substance solubility: Not reported.

- Other effects: Not reported.
RESULTS CONTROL: Not reported.
RESULTS: TEST WITH REFERENCE SUBSTANCE
- Concentrations: Not reported.
- Results: Not reported.

Test condition : TEST ORGANISMS
- Strain: Not reported.
- Wild caught: Obtained from University Lake on the campus of the University.
No further details reported.
STOCK AND TEST SOLUTION AND THEIR PREPARATION
No further details reported.
STABILITY OF THE TEST CHEMICAL SOLUTIONS: Not reported.
REFERENCE SUBSTANCE: Not reported.
DILUTION WATER
- Source: University Lake Water filtered through glass wool.
No further details reported.
TEST SYSTEM
No details reported.
DURATION OF THE TEST: 96 hr
TEST PARAMETER: Death.
SAMPLING: Not reported.
MONITORING OF TEST SUBSTANCE CONCENTRATION: Not reported.

Test substance : SOURCE: Not reported.
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.

Reliability : (4) not assignable Documentation insufficient for complete assessment.
Documentation insufficient for complete assessment.

14.02.2003 (8)

Type :
Species : other: *Lymnaea sp.* eggs
Exposure period : 96 hour(s)
Unit : Mg/l
EC50 : = 411
Analytical monitoring : no data
Method : other: according to Anderson et al. (1948)
Year : 1965
GLP : No
Test substance : other TS: sodium carbonate
Method : METHOD FOLLOWED: According to Anderson et al. (1948).
GLP: No
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.

Result : RESULTS: EXPOSED
- Nominal/measured concentrations: Not reported.
- Effect data (Immobilisation): LC50 24 hr 403 mg/l, 48 hr 403 mg/l, 72 hr 395 mg/l.
- Concentration / response curve: Not reported.
- Cumulative immobilisation: Not reported.
- Effect concentration vs. test substance solubility: Not reported.
- Other effects: Not reported.
RESULTS CONTROL: Not reported.
RESULTS: TEST WITH REFERENCE SUBSTANCE
- Concentrations: Not reported.
- Results: Not reported.

Test condition : TEST ORGANISMS

- Strain: Not reported.
- Wild caught: The snails from which eggs were obtained, were found in a ditch near Fountainebleau State Park.
No further details reported.
STOCK AND TEST SOLUTION AND THEIR PREPARATION
No further details reported.
STABILITY OF THE TEST CHEMICAL SOLUTIONS: Not reported.
REFERENCE SUBSTANCE: Not reported.
DILUTION WATER
- Source: University Lake Water filtered through glass wool.
No further details reported.
TEST SYSTEM
No details reported.
DURATION OF THE TEST: 96 hr
TEST PARAMETER: Death.
SAMPLING: Not reported.
MONITORING OF TEST SUBSTANCE CONCENTRATION: Not reported.

Test substance : SOURCE: Not reported.
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.

Reliability : (4) not assignable Documentation insufficient for complete assessment.
Documentation insufficient for complete assessment.

14.02.2003 (8)

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

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

5.1.1 ACUTE ORAL TOXICITY

Type	:	LD50
Value	:	= 2800 mg/kg bw
Species	:	rat
Strain	:	Wistar
Sex	:	male/female
Number of animals	:	50
Vehicle	:	water
Doses	:	1.3, 1.8, 2.6, 3.6, 5.0 g/kg
Method	:	other
Year	:	1978
GLP	:	no
Test substance	:	other TS: sodium carbonate monohydrate
Method	:	METHOD FOLLOWED: Not reported. DEVIATIONS FROM GUIDELINE: Not reported. GLP: No STATISTICAL METHODS: Not reported. METHOD OF CALCULATION: Not reported. ANALYTICAL METHODS: Not reported.
Result	:	MORTALITY: - Time of death: The time of death is listed by dose. 1.8 g/kg: day 8. 2.6 g/kg: day 1-2. 3.6 g/kg: day 1. 5.0g/kg: day 1. - Number of deaths at each dose: 1.3 g/kg: 0/10. 1.8 g/kg: 1/10. 2.6 g/kg: 4/10. 3.6 g/kg: 7/10. 5.0 g/kg: 10/10. CLINICAL SIGNS: All animals that died during the observation period had reduced body weight or no body weight gain. The animals that survived until the study termination, gained weight compared to the initial weight at study start. Signs of effects observed included: ataxia, muscle tremors, red nasal discharge, urinary staining of the abdomen, soft stool, piloerection, prostration, lethargy, faecal staining of the abdomen and dyspnoea. All animals surviving the study were clear of signs of effect by day 5. NECROPSY FINDINGS: The necropsy findings are listed by dose. 1.3 g/kg: 4/10 rats had a mottled liver only. 1.8 g/kg: 5/10 rats hands a mottled liver, one of these had air filled intestines. 2.6 g/kg: 2/10 had a mottled liver. 4/10 had a mottled liver, mottled or pale kidneys, nasal or oral discharge, red intestines, stomach with a red pyloric region or containing red fluid. 3.6 g/kg: 2/10 had a mottled liver only. The remaining animals, with one exception, had most of the following lesions: mottled or pale kidneys, nasal or oral discharge, red intestines, stomach with a red pyloric region or containing red fluid, mottled or dark red lungs, mottled liver. 5.0 g/kg: The animals in this dosing group all had most of the following lesions: mottled or pale kidneys, nasal or oral discharge, intestines filled with fluid, stomach with a red pyloric region or containing red fluid, mottled or dark red lungs, mottled liver, air in the intestines. POTENTIAL TARGET ORGANS: Not reported. SEX-SPECIFIC DIFFERENCES: Not reported.
Test condition	:	TEST ORGANISMS: Wistar albino rats. - Source: Marland Breeding Farms, Inc., Hewitt, NJ. - Age: Not reported. - Weight at study initiation: 187-296 g. - Controls: Not reported. ADMINISTRATION: Oral, by intubation. - Doses: 1.3, 1.8, 2.6, 3.6 and 5.0 g/kg. - Doses per time period: One dosing only. - Volume administered or concentration: The test material was administered

by oral intubation as a 20% w/v solution in tap water.
- Post dose observation period: 14 days.
EXAMINATIONS: Following dosing the rats were observed for mortality and overt signs of effects at 0-2 and 4-6 hrs following dosing and daily thereafter for 14 days. Body weight was recorded initially and terminally.

Test substance : SOURCE: Not reported.
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: The test substance was sodium carbonate monohydrate.

Reliability : (1) valid without restriction
Comparable to guideline study

17.02.2003 (22)

Type : LD50
Value : = 4090 mg/kg bw
Species : Rat
Strain :
Sex :
Number of animals :
Vehicle :
Doses :
Method : other
Year : 1972
GLP : No
Test substance : other TS: sodium carbonate
Method : METHOD FOLLOWED: Not reported.
GLP: No
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.
Result : MORTALITY:
No details reported.
CLINICAL SIGNS: Not reported.
NECROPSY FINDINGS: Not reported.
POTENTIAL TARGET ORGANS: Not reported.
SEX-SPECIFIC DIFFERENCES: Not reported.
Source : TNO Voeding AJ Zeist
Test condition : TEST ORGANISMS:
No details reported.
ADMINISTRATION:
No details reported.
EXAMINATIONS: Not reported.
Test substance : SOURCE: Not reported.
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.
Reliability : (4) not assignable
Only stated in secondary literature.

14.02.2003 (13) (20)

5.1.2 ACUTE INHALATION TOXICITY

Type : LC50
Value : = 2300 mg/m³
Species : Rat
Strain : other: Wistar and Sprague-Dawley
Sex : Male
Number of animals : 60

Vehicle	:	no data
Doses	:	800-4600 mg/m³
Exposure time	:	2 hour(s)
Method	:	other
Year	:	1983
GLP	:	No
Test substance	:	other TS: sodium carbonate
Method	:	METHOD FOLLOWED: More or less comparable to OECD guideline 403. In addition cellular immunity was assessed using mitogen-induced lymphocyte activation assays and T-cell distribution assays in rats killed at 3-4 days and at 12-13 days after inhalation. The mitogens used were concanavalin A, phytohemagglutinin, pokeweed mitogen, and lipopolysaccharide. T-cell distribution was based on uptake of [3H]uridine. DEVIATIONS FROM OECD GUIDELINE 403: 2h exposure instead of 4h exposure; only males used; reporting less elaborate and complete; assays of cellular immunity were included. GLP: No STATISTICAL METHODS: Not reported. METHOD OF CALCULATION: LC50 were calculated from acute death (those occurring from beginning of the exposure to 2 hr after exposure) data from three trials. In other trials, acute deaths were scattered over all dose ranges. In no trial was LC50 calculable from overall death data (i.e., from beginning of exposure to 14 days after exposure). ANALYTICAL METHODS: Not reported.
Result	:	MORTALITY: - Time of death: During and within 1-2 hr after exposure, or beginning at 1 day after exposure, peaking at 5-7 days, and continuing to 9-10 days after exposure. - Number of deaths at each dose: Not reported. CLINICAL SIGNS: Signs of respiratory impairment immediately after exposure. Dyspnea, wheezing, excessive salivation, and distention of the abdomen. In many animals, excessive salivation and repeated swallowing continued during the first 2 hr following exposure. Signs subsided within 3-4 hr after exposure. Beginning at about 5 hr after exposure, many animals exhibited inappetence. At the same time, both inspiratory and expiratory dyspnea appeared in some animals. NECROPSY FINDINGS: Lesions in respiratory tract in animals that died limited to the posterior pharynx, larynx, anterior trachea, and in approximately 3% of the animals, lungs. POTENTIAL TARGET ORGANS: Respiratory tract. SEX-SPECIFIC DIFFERENCES: Not relevant. OTHER OBSERVATIONS: A transitory immunologic repression. This may be, at least in part, contributory to bacteremia.
Test condition	:	SOURCE: sodium combustion products, formed by sodium in combination with oxygen. PURITY: 91% IMPURITY/ADDITIVE/ETC.: 9.0% NaOH and 0.0% NaHCO3 ANY OTHER INFORMATION: Not reported.
Test substance	:	TEST ORGANISMS: - Source: Not reported. - Age: Adult - Weight at study initiation: Average weight 365 g. - Number of animals: 6 trials of each 10 animals. - Controls: Not reported. ADMINISTRATION: - Type of exposure: Whole body inhalation to aerosols of sodium combustion products. - Concentrations: 17 concentrations between 800-4600 mg/m3.

- Particle size: median aerodynamic diametre ± GSD: 1.04±1.97 micrometre
- Type or preparation of particles: Sodium combines with oxygen to form combustion products. These react subsequently and rapidly with atmospheric components. In a typical atmosphere the predominant reactions proceed rapidly from the oxide forms to NaOH, then to Na2CO3. They all form in the atmosphere without appreciable settling and produce an aerosol in the order of 1 micrometre aerodynamic equivalent diameter.
EXAMINATIONS: mortality, clinical signs, necroscopy, assay for cellular immunity.

Reliability : (2) valid with restrictions
Acceptable, well documented publication which meets basic scientific principles. Comparable to guideline study with acceptable restrictions.

17.02.2003 (2)

Type : LC50
Value : = 1200 mg/m³
Species : mouse
Strain : Swiss Webster
Sex : male
Number of animals : 40
Vehicle : no data
Doses : 600-3000 mg/m³
Exposure time : 2 hour(s)
Method : other
Year : 1983
GLP : no
Test substance : other TS: sodium carbonate
Method : METHOD FOLLOWED: More or less comparable to OECD guideline 403.
DEVIATIONS FROM
OECD GUIDELINE 403: 2h exposure instead of 4h exposure; only males used; reporting less elaborate and complete.
GLP: No
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: LC50 were calculated from acute death (those occurring from beginning of the exposure to 2 hr after exposure) data from three trials. In other trials, acute deaths were scattered over all dose ranges. In no trial was LC50 calculable from overall death data (i.e., from beginning of exposure to 14 days after exposure).
ANALYTICAL METHODS: Not reported.

Result : MORTALITY:
- Time of death: During and within 1-2 hr after exposure, or beginning at 1 day after exposure, peaking at 5-7 days, and continuing to 9-10 days after exposure.
- Number of deaths at each dose: Not reported.

CLINICAL SIGNS: Signs of respiratory impairment immediately after exposure. Dyspnea, wheezing, excessive salivation, and distention of the abdomen. In many animals, excessive salivation and repeated swallowing continued during the first 2 hr following exposure. Signs subsided within 3-4 hr after exposure. Beginning at about 5 hr after exposure, many animals exhibited inappetence. At the same time, both inspiratory and expiratory dyspnea appeared in some animals.

NECROPSY FINDINGS: Lesions in respiratory tract in animals that died limited to the posterior pharynx, larynx, anterior trachea, and in approximately 3% of the animals, lungs.
POTENTIAL TARGET ORGANS: Respiratory tract.
SEX-SPECIFIC DIFFERENCES: Not relevant.

Test condition : SOURCE: sodium combustion products, formed by sodium in combination with oxygen.
PURITY: 95%

IMPURITY/ADDITIVE/ETC.: 2.5% NaOH and 2.5% NaHCO3
ANY OTHER INFORMATION: Not reported.

Test substance : TEST ORGANISMS:
- Source: Not reported.
- Age: Adult
- Weight at study initiation: Average weight 30 g.
- Number of animals: 2 trial each of 20 animals.
- Controls: Not reported.

ADMINISTRATION:
- Type of exposure: Whole body inhalation to aerosols of sodium combustion products.
- Concentrations: 8 concentrations between 600-3000 mg/m3.
- Particle size: median aerodynamic diametre ± GSD: 0.77 ± 2.10 micrometre
- Type or preparation of particles: Sodium combines with oxygen to form combustion products. These react subsequently and rapidly with atmospheric components. In a typical atmosphere the predominant reactions proceed rapidly from the oxide forms to NaOH, then to Na2CO3. They all form in the atmosphere without appreciable settling and produce an aerosol on the order of 1 micrometre aerodynamic equivalent diameter.

EXAMINATIONS: mortality, clinical signs, necroscopy.

Reliability : (2) valid with restrictions
Acceptable, well documented publication which meets basic scientific principles. Comparable to guideline study with acceptable restrictions.

17.02.2003 (2)

Type : LC50
Value : = 800 mg/m³
Species : guinea pig
Strain : Hartley
Sex : Male
Number of animals : 10
Vehicle : no data
Doses : 500-3000
Exposure time : 2 hour(s)
Method : other
Year : 1983
GLP : no
Test substance : other TS: sodium carbonate
Method : METHOD FOLLOWED: More or less comparable to OECD guideline 403.
DEVIATIONS FROM
OECD GUIDELINE 403: 2h exposure instead of 4h exposure; only males used; reporting less elaborate and complete.
GLP: No
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: LC50 were calculated from acute death (those occurring from beginning of the exposure to 2 hr after exposure) data from three trials. In other trials, acute deaths were scattered over all dose ranges. In no trial was LC50 calculable from overall death data (i.e., from beginning of exposure to 14 days after exposure).
ANALYTICAL METHODS: Not reported.

Result : MORTALITY:
- Time of death: During and within 1-2 hr after exposure, or beginning at 1 day after exposure, peaking at 5-7 days, and continuing to 9-10 days after exposure.
- Number of deaths at each dose: Not reported.

CLINICAL SIGNS: Signs of respiratory impairment immediately after exposure. Dyspnea, wheezing, excessive salivation, and distention of the abdomen. In many animals, excessive salivation and repeated swallowing continued during the first 2 hr following exposure. Signs subsided within 3-4

hr after exposure. Beginning at about 5 hr after exposure, many animals exhibited inappetence. At the same time, both inspiratory and expiratory dyspnea appeared in some animals.

NECROPSY FINDINGS: Lesions in respiratory tract in animals that died limited to the posterior pharynx, larynx, anterior trachea, and in approximately 3% of the animals, lungs.
POTENTIAL TARGET ORGANS: Respiratory tract.
SEX-SPECIFIC DIFFERENCES: Not relevant.

Test condition : SOURCE: sodium combustion products, formed by sodium in combination with oxygen.
PURITY: 95%
IMPURITY/ADDITIVE/ETC.: 4.5% NaOH and 0.5% NaHCO3
ANY OTHER INFORMATION: Not reported.

Test substance : TEST ORGANISMS:
- Source: Not reported.
- Age: Adult
- Weight at study initiation: Average weight 320 g.
- Number of animals: 1 trial of 10 animals.
- Controls: Not reported.

ADMINISTRATION:
- Type of exposure: Whole body inhalation to aerosols of sodium combustion products.
- Concentrations: 11 concentrations between 500-3000 mg/m3.
- Particle size: median aerodynamic diametre ± GSD: 0.74±1.82 micrometre
- Type or preparation of particles: Sodium combines with oxygen to form combustion products. These react subsequently and rapidly with atmospheric components. In a typical atmosphere the predominant reactions proceed rapidly from the oxide forms to NaOH, then to Na2CO3. They all form in the atmosphere without appreciable settling and produce an aerosol on the order of 1 micrometre aerodynamic equivalent diameter.

EXAMINATIONS: mortality, clinical signs, necroscopy.

Reliability : (2) valid with restrictions
Acceptable, well documented publication which meets basic scientific principles. Comparable to guideline study with acceptable restrictions.

17.02.2003 (2)

5.1.3 ACUTE DERMAL TOXICITY

Type	:	LD 50
Value	:	> 2000 mg/kg bw
Species	:	Rabbit
Strain	:	New Zealand white
Sex	:	no data
Number of animals	:	6
Vehicle	:	Water
Doses	:	2000 mg/kg bw as a 1000 mg/ml aqueous slurry.
Method	:	other: EPA 16 CFR 1500.40
Year	:	1978
GLP	:	No
Test substance	:	other TS: sodium carbonate monohydrate
Method	:	METHOD FOLLOWED: EPA 16 CFR 1500.40 DEVIATIONS FROM GUIDELINE: Not reported. GLP: No STATISTICAL METHODS: Not reported. METHOD OF CALCULATION: Not reported. ANALYTICAL METHODS: Not reported.
Result	:	MORTALITY: No deaths occurred during the experiment. CLINICAL SIGNS: 3/6 animals gained weight during the 14 days the

experiment lasted. 3/6 animals lost weight or did not gain weight. Well-defined to severe erythema and slight to severe oedema were observed in all six animals at the 24-hour dermal observations. The severity of the lesions did not vary significantly between the animals with abraded or non-abraded skin. Lethargy and hypernea were observed in each animal during the first 24 hrs following compound administration.
NECROPSY FINDINGS: Not reported.
POTENTIAL TARGET ORGANS: Skin.
SEX-SPECIFIC DIFFERENCES: Not reported.

Test condition : TEST ORGANISMS: New Zealand White Albino Rabbits.
- Source: Marland Breeding Farms, Inc., Hewitt, NJ.
- Age: Not reported.
- Weight at study initiation: 2.50-3.40 kg.
- Controls: Not reported. 3 animals had abraded skin, and 3 animals had non-abraded skin.

ADMINISTRATION: The hair of each rabbit was clipped from the trunk so as to expose at least 30% of the body surface area. The skin of half the animals was abraded longitudinally every two or 3 cm over the area of exposure. The operations were deep enough so as to penetrate the stratum corneum, but not so deep as to disturb the derma or produced bleeding.
- Area covered: The test material was administered to the clipped area.
- Occlusion: The test material was held in contact with the skin by a sleeve made of impervious plastic sheeting designed to contain the dose without leakage or undue pressure.
- Vehicle: Water.
- Concentration in vehicle: the test material was administered as a 1000 mg/ml aqueous slurry.
- Total volume applied: Not reported.
- Doses: 2000 mg/kg.
- Removal of test substance: After 24 hrs of exposure, the exposed area was wiped free of excess test material.

EXAMINATIONS: Observations for mortality and overt signs of effect were made at 0-2 and 4-6 hrs following dosing and daily thereafter for 14 days. The exposed area was observed for oedema, erythema and eschar formation after 24 hrs. Body weight was recorded initially and terminally.

Test substance : SOURCE: Not reported.
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: The test substance was sodium carbonate monohydrate.

Reliability : (1) valid without restriction
Guideline study

14.02.2003 (21)

Type : LD50
Value : = 2210 mg/kg bw
Species : mouse
Strain :
Sex :
Number of animals :
Vehicle :
Doses :
Method : other
Year : 1970
GLP : no
Test substance : other TS: sodium carbonate
Method : METHOD FOLLOWED: Not reported.
GLP: No
STATISTIC AL METHODS: Not reported.

METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.

Result : MORTALITY:
No details reported.
CLINICAL SIGNS: Not reported.
NECROPSY FINDINGS: Not reported.
POTENTIAL TARGET ORGANS: Not reported.
SEX-SPECIFIC DIFFERENCES: Not reported.

Test condition : TEST ORGANISMS:
No details reported.
ADMINISTRATION:
No details reported.
EXAMINATIONS: Not reported.

Test substance : SOURCE: Not reported.
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.

Reliability : (4) not assignable
Only stated in secondary literature.

14.02.2003 (13) (20)

5.1.4 ACUTE TOXICITY, OTHER ROUTES

5.2.1 SKIN IRRITATION

Species : rabbit
Concentration : .5 g
Exposure : Occlusive
Exposure time : 4 hour(s)
Number of animals : 6
Vehicle : other
PDII : 0
Result : not irritating
Classification : not irritating
Method : Directive 84/449/EEC, B.4 "Acute toxicity (skin irritation)"
Year : 1985
GLP : no
Test substance : other TS: sodium carbonate
Method : METHOD FOLLOWED: According OECD guideline 404, with two main deviations, and several minor ones.
DEVIATIONS FROM
OECD GUIDELINE 404: Test substance was not moistened with water to ensure good contact between skin and test substance; patch was occlusive instead of semi-occlusive.
Minor deviations included small differences in housing conditions and no other toxic effects have been observed.
GLP: A Quality Assurance Unit statement was included
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.

Result : AVERAGE SCORE
- Erythema: 0
- Edema: 0
REVERSIBILITY: Not relevant
OTHER EFFECTS: No

Test condition : TEST ANIMALS:
- Strain: White New Zealand
- Sex: Not reported.

- Source: Harald Schriever, Rabbit farm, Germany.
- Age: Not reported.
- Weight at study initiation: 2.4 - 2.6 kg
- Number of animals: 6
- Controls: Included but not described.

ADMINISTRATION/EXPOSURE
- Preparation of test substance: No preparation
- Area of exposure: Shaved backskin 2.5 x 2.5 cm.
- Occlusion: Yes
- Vehicle: Not reported.
- Concentration in vehicle: Not reported.
- Total volume applied: 0.5 g
- Postexposure period: Up to 72 hr.
- Removal of test substance: Washed with water.

IN VITRO TEST SYSTEM
Not relevant.
EXAMINATIONS
- Scoring system: Draize scheme
- Examination time points: 30 and 60 min, 24, 48, and 72 hr.

Test substance : SOURCE: Chem . Fabrik Kalk GmbH, Köln, Germany
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Name (in german) of test substance: "Leichte calc. Soda" (Eng.: Light calcined soda)

Reliability : (1) valid without restriction
Guideline study with minor deviations.

17.02.2003 (5)

Species : rabbit
Concentration : .5 g
Exposure : Occlusive
Exposure time : 24 hour(s)
Number of animals : 6
Vehicle : other: none
PDII : 0
Result : not irritating
Classification : not irritating
Method : other: EPA 16 CFR 1500.3
Year : 1978
GLP : no
Test substance : other TS: The test substance was sodium carbonate monohydrate.
Method : METHOD FOLLOWED: 16 CFR 1500.3
DEVIATIONS FROM GUIDELINE: Not reported.
GLP: No
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.
Result : AVERAGE SCORE
- Erythema: 0.
- Edema: 0.

REVERSIBILITY: Not reported.
OTHER EFFECTS: Not reported.
The primary dermal irritation index was 0.
Test condition : TEST ANIMALS: Rabbits.
- Strain: New Zealand White Albino.
- Sex: Not reported.
- Source: Not reported.
- Age: Not reported.
- Weight at study initiation: 2.2-2.7 kg.
- Number of animals: 6.

- Controls: Not reported.
ADMINISTRATION/EXPOSURE
- Preparation of test substance: The test material was administered as an aqueous slurry.
- Area of exposure: The rabbits were closely clipped over the back and sides. There were to test sites for rabbit, each site 1 inch by 1 inch in area. The site to the left of the spinal column was abraded, while the sites to the right of the spinal column was left intact. The abrasions were sufficiently deep so as to penetrate the stratum corneum, but not so deep as to disturb the derma or produce bleeding.
- Occlusion: A surgical gauze square a 1 inch by 1 inch, 8 single layers thick, was based on directly on the test site and secured with Dermicel tape. The animals were then wrapped with plastic sheeting secured with masking tape.
- Vehicle: Water.
- Concentration in vehicle: 1 gram/ml.
- Total volume applied: 0.5 ml
- Postexposure period: The animals were observed for 72 hrs after application.
- Removal of test substance: After 24 hrs the sheeting and gauze patches were removed. It is not reported whether the test substance was cleaned from the application area.
EXAMINATIONS
- Scoring system: The Draize method.
- Examination time points: Observations for signs of dermal irritation or systemic toxicity were recorded at 24 and 72 hrs after application. All treated sides were scored for erythema, eschar, and oedema formation.

Test substance : SOURCE: Not reported.
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: The test substance was sodium carbonate monohydrate.

Reliability : (1) valid without restriction
Guideline study

14.02.2003 (23)

Species : human
Concentration : .2 g
Exposure : no data
Exposure time : 4 hour(s)
Number of animals : 26
Vehicle : water
PDII :
Result : not irritating
Classification :
Method : other: human patch test
Year : 1996
GLP : yes
Test substance : other TS: sodium carbonate
Method : METHOD FOLLOWED: Human patch test procedure slightly modified from that described earlier (Basketter et al. 1994). Developed for humans to replace method described by OECD guideline 404. Volunteers were exposed for 15, 30 or 60 minutes, or up to 2, 3 or 4 hours using patches with Hill Top Chambers. Solids were moistened. Scores were assessed 24, 48 and 72 hours after patch removal using a 4-point scale.
GLP: Yes.
STATISTICAL METHODS: Fisher's exact test was used to compare overall rectivity.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.

Result : AVERAGE SCORE
- Total reactivity: 0%
REVERSIBILITY: Not relevant
OTHER EFFECTS: 81% SDS (20%) reactivity.

Test condition : TEST ANIMALS:
- Sex: Not standardized.
- Age: Between 18-65 years
- Number of animals: 26
- Controls: Positive control SDS (20%) included.
ADMINISTRATION/EXPOSURE
- Preparation of test substance: Moistened
- Area of exposure: 25 mm Plain Hill Top C hamber
- Occlusion: Not reported.
- Vehicle: Not reported.
- Concentration in vehicle: Not reported.
- Total volume applied: 0.2 g
- Postexposure period: Up to 72 hr.
- Removal of test substance:
IN VITRO TEST SYSTEM
Not relevant.
EXAMINATIONS
- Scoring system: The reactions were scored using the following criteria: 0 = no reaction, + = weakly positive reaction (usually characterised by mild erythema across most of the treatment site, ++ = moderately positive reaction (usually distinct erythema possibly spreading beyond the treatment site, +++ = strongly positive reaction (strong, often spreading erythema with oedema).
- Examination time points: 24, 48, and 72 hr.

Test substance : SOURCE: Solvay
PURITY: 98%
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.

Reliability : (1) valid without restriction
Acceptable, well documented publication which meets basic scientific principles.

17.02.2003 (30)

Species : rabbit
Concentration : 50 %
Exposure : no data
Exposure time : 4 hour(s)
Number of animals : 6
Vehicle : water
PDII : 0
Result : not irritating
Classification : not irritating
Method : other: revis ed FHSA procedure proposed by FDA (1972)
Year : 1975
GLP : no
Test substance : other TS: sodium carbonate
Method : METHOD FOLLOWED: Probably comparable to OECD guideline 404, as FHSA procedure proposed by FDA was used. However, description was too short to make a full comparison.
DEVIATIONS FROM
OECD GUIDELINE 404: Test substance was suspended in water in stead of being moistened with water; scores done at 4, 24 and 48h, instead of 1, 24, 48 and 72h; most subjects were reexamined after one month; intact skin and abraded skin was used instead of only intact skin; reporting less elaborate than guideline demands.
GLP: No

METHOD OF CALCULATION: A primary irritation index was calculated by averageing the scores for abraded and intact skin with respect to e rythema and oedema at 4, 24 and 48 h.
STATISTICAL METHODS: Not reported.
ANALYTICAL METHODS: Not reported.

Result : AVERAGE SCORE
- Erythema: 0
- Edema: 0

For abraded skin a mean score of 1.5
REVERSIBILITY: Not relevant
OTHER EFFECTS: No tissue destruction.

Test condition : TEST ANIMALS:
No details reported.
ADMINISTRATION/EXPOSURE
- Preparation of test substance: No preparation
- Area of exposure: Intact and abraded skin.
- Occlusion: Semi-occlusive or occlusive patches used.
- Vehicle: Not reported.
- Concentration in vehicle: Not reported.
- Total volume applied: 0.5 ml
- Postexposure period: Up to 48 h, and reexamination after one month.
- Removal of test substance: Not reported.

IN VITRO TEST SYSTEM
Not relevant.
EXAMINATIONS
- Scoring system: Primary irritation indices
- Examination time points: 4, 24, and 48 hr.

Test substance : SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Not reported

Reliability : (4) not assignable
Description too short and only referenced method, therefore no assessment can be made.

17.02.2003 (17)

Species : guinea pig
Concentration : 50 %
Exposure : no data
Exposure time : 4 hour(s)
Number of animals : 6
Vehicle : water
PDII : 0
Result : not irritating
Classification : not irritating
Method : other: revised FHSA procedure proposed by FDA (1972)
Year : 1975
GLP : no
Test substance : other TS: sodium carbonate
Method : METHOD FOLLOWED: Probably comparable to OECD guideline 404, as FHSA procedure proposed by FDA was used. However, description was too short to make a full comparison.
DEVIATIONS FROM
OECD GUIDELINE 404: Test substance was suspended in water in stead of being moistened with water; scores done at 4, 24 and 48h, instead of 1, 24, 48 and 72h; most subjects were reexamined after one month; intact skin and abraded skin was used instead of only intact skin; reporting less elaborate than guideline demands.
GLP: No
METHOD OF CALCULATION: A primary irritation index was calculated by

averageing the scores for abraded and intact skin with respect to erythema and oedema at 4, 24 and 48 h.
STATISTICAL METHODS: Not reported.
ANALYTICAL METHODS: Not reported.

Result : AVERAGE SCORE
- Erythema: 0
- Edema: 0
For abraded skin a mean score of 0.1
REVERSIBILITY: Not relevant
OTHER EFFECTS: No tissue destruction.

Test condition : TEST ANIMALS:
- Strain: Hartley
- Age: Young adults.
No further details reported.
ADMINISTRATION/EXPOSURE
- Preparation of test substance: No preparation
- Area of exposure: Intact and abraded skin.
- Occlusion: Semi-occlusive or occlusive patches used.
- Vehicle: Not reported.
- Concentration in vehicle: Not reported.
- Total volume applied: 0.5 ml
- Postexposure period: Up to 48 h, and reexamination after one month.
- Removal of test substance: Not reported.
IN VITRO TEST SYSTEM
Not relevant.
EXAMINATIONS
- Scoring system: Primary irritation indices
- Examination time points: 4, 24, and 48 hr.

Test substance : SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Not reported

Reliability : (4) not assignable
Description too short and only referenced method, therefore no assessment can be made.

17.02.2003 (17)

Species : Human
Concentration : 50 %
Exposure : no data
Exposure time : 4 hour(s)
Number of animals : 6
Vehicle : water
PDII : 0
Result : not irritating
Classification : not irritating
Method : other: revised FHSA procedure proposed by FDA (US)
Year : 1975
GLP : no
Test substance : other TS: sodium carbonate
Method : METHOD FOLLOWED: Probably comparable to OECD guideline 404, as FHSA procedure proposed by FDA was used. However, description was too short to make a full comparison.
DEVIATIONS FROM
OECD GUIDELINE 404: Test substance was suspended in water in stead of being moistened with water; scores done at 4, 24 and 48h, instead of 1, 24, 48 and 72h; most subjects were reexamined after one month; intact skin and abraded skin was used instead of only intact skin; reporting less elaborate than guideline demands.

GLP: No
METHOD OF CALCULATION: A primary irritation index was calculated by averageing the scores for abraded and intact skin with respect to erythema and oedema at 4, 24 and 48 h.
STATISTICAL METHODS: Not reported.
ANALYTICAL METHODS: Not reported.

Result : AVERAGE SCORE
- Erythema: 0
- Edema: 0

For abraded skin a mean score of >2.0 with 2 out of 6 humans having tissue destruction greater than grade 4.0.
REVERSIBILITY: Not relevant
OTHER EFFECTS: No tissue destruction.

Test condition : TEST ANIMALS:
No details reported.
ADMINISTRATION/EXPOSURE
- Preparation of test substance: No preparation
- Area of exposure: Intact and abraded skin.
- Occlusion: Semi-occlusive or occlusive patches used.
- Vehicle: Not reported.
- Concentration in vehicle: Not reported.
- Total volume applied: 0.5 ml
- Postexposure period: Up to 48 h, and reexamination after one month.
- Removal of test substance: Not reported.

IN VITRO TEST SYSTEM
Not relevant.
EXAMINATIONS
- Scoring system: Primary irritation indices
- Examination time points: 4, 24, and 48 hr.

Test substance : SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Not reported

Reliability : (4) not assignable
Description too short and only referenced method, therefore no asses sment can be made.

17.02.2003 (17)

5.2.2 EYE IRRITATION

Species	:	Rabbit
Concentration	:	Undiluted
Dose	:	.1 other: g
Exposure time	:	72 hour(s)
Comment	:	not rinsed
Number of animals	:	6
Vehicle	:	none
Result	:	not irritating
Classification	:	not irritating
Method	:	Directive 84/449/EEC, B.5 "Acute toxicity (eye irritation)"
Year	:	1985
GLP	:	yes
Test substance	:	other TS: sodium carbonate

Method : METHOD FOLLOWED: Comparable to OECD guideline 405 with minor deviations.
DEVIATIONS FROM
OECD GUIDELINE 405: Minor deviations included housing conditions.
GLP: Only a Quality Assurance Unit statement was included.
STATISTICAL METHODS: Not reported.

METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.

Result : AVERAGE SCORE
- Cornea: 0
- Iris: 0.25
- Conjuntivae (Redness): 1.67
- Conjuntivae (Chemosis): 1.38
- Overall irritation score: Not irritant

DESCRIPTION OF LESIONS: Not reported.
REVERSIBILITY: All effects were reversible, only one animal showed conjunctival redness and chemosis after 72 hr (score 1), but this score was decreasing.
OTHER EFFECTS: No.

Test condition : TEST ANIMALS:
- Strain: White New Ze aland
- Sex: Not reported.
- Source: Harald Schriever, Rabbit farm, Germany.
- Age: Not reported.
- Weight at study initiation: 2.4 - 2.6 kg
- Number of animals: 6
- Controls: Right eye.

ADMINISTRATION/EXPOSURE
- Preparation of test substance: No preparation
- Amount of substance instilled: 0.1 g in left eye
- Vehicle: Right eye not treated.
- Postexposure period: Up to 72 hr.

IN VITRO TEST SYSTEM
Not relevant.
EXAMINATIONS
- Ophtalmoscopic examination: Yes.
- Scoring system: Draize scheme
- Observation period: 1, 24, 48, and 72 hr.
- Tool used to assess score: Two independent persons using grade system as described in OECD 405.

Test substance : SOURCE: Chem. Fabrik Kalk GmbH, Köln, Germany
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Name (in german) of test substance: "Leichte calc. Soda" (Eng.: Light calcined soda)

Reliability : (1) valid without restriction
Guideline study with minor deviations

17.02.2003 (4)

Species : rabbit
Concentration : undiluted
Dose : .1 ml
Exposure time :
Comment : other: The eyes were either rinsed 4 seconds after instillation or not rinsed during the test period.
Number of animals : 9
Vehicle : none
Result : irritating
Classification :
Method : other: EPA 16 CFR 1500.42
Year : 1978
GLP : no
Test substance : other TS: Sodium carbonate monohydrate
Method : METHOD FOLLOWED: 16 CFR 1500.42
DEVIATIONS FROM GUIDELINE: Yes, but not reported in detail by the authors.

GLP: No
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.

Result : AVERAGE SCORE
- Cornea: According to the scoring system employed, the responses were positive (+) or negative (-). 6/6 animals with unwashed eyes had a positive score. 1/3 animals with washed eyes had a positive score.
- Iris: According to the scoring system employed, the responses were positive (+) or negative (-). 6/6 animals with unwashed eyes had a positive score. 1/3 animals with washed eyes had a positive score.
- Conjuntivae (Redness): According to the scoring system employed, the responses were positive (+) or negative (-). 6/6 animals with unwashed eyes had a positive score.1/3 animals with washed eyes had a positive score.
- Conjuntivae (Chemosis):According to the scoring system employed, the responses were positive (+) or negative (-). 6/6 animals with unwashed eyes had a positive score. 1/3 animals with washed eyes had a positive score. The incidence of necrosis or ulceration was also registered. 6/6 animals with unwashed eyes had a positive score, and 2/3 animals with washed eyes had a positive score.
- Overall irritation score: The maximum Draize scores in the animals with unwashed eyes were: 88, 108, 104,110, 110, 108; the mean was 105. The maximum Draize scores in the animals with washed eyes were: 30, 6, 4; the mean was 13.

DESCRIPTION OF LESIONS: All six unwashed eyes were assigned positive scores for corneal opacity. Five eyes were assigned positive scores for ulceration. Pannus was observed in the 4 intact eyes beginning on day 7 of the study (2 eyes ruptured on day 7). Iritis was evident in all six eyes. Each unwashed eye had conjunctival redness, chemosis and necrosis/ulceration. Alopecia was observed around 1 treated eye. Bleeding was noted on one eyelid while the eyelids of two different eyes were observed to be healing closed by day 14. Signs of irritation were evident in the four intact unwashed eyes at the termination of the study.
Corneal opacity and ulceration were observed in one of three eyes washed at 4 seconds. One eye was assigned positive scores for conjunctival redness and chemosis, and 2 eyes were assigned positive scores for conjunctival ulceration. Signs of irritation were evident in one eye at the termination of the study.
REVERSIBILITY: Among the animals with unwashed eyes, 2 suffered ruptured eyes and the remaining 4 still had signs of irritation at the termination of the study. One of the animals with washed eyes had signs of irritation at the termination of the study, while the eye appeared normal in the remaining two animals on day 2 and 14, respectively.
OTHER EFFECTS: Not reported.

Test condition : TEST ANIMALS: Rabbits.
- Strain: New Zealand white.
- Sex: Not reported.
- Source: Marland Breeding Farms, Inc., Hewitt, NJ.
- Age: Not reported.
- Weight at study initiation: Not reported.
- Number of animals: 9.
- Controls: The test substance was not administered in one eye of each animal, this eye served as a control.

ADMINISTRATION/EXPOSURE
- Preparation of test substance: Not reported.
- Amount of substance instilled: 0.1 ml.
- Vehicle: None.
- Postexposure period: The treated eyes of three rabbits were rinsed with 30 ml of distilled water, 4 seconds following compound administration. The

remaining six animals received no further treatment. Animals were observed until 14 days after exposure.
EXAMINATIONS
- Ophtalmoscopic examination: The eyes were examined and scored for ocular reactions on days 1,2,3, 4,7,10 and 14 following installation of the test compound, or until the eyes were determined to be free of ocular irritation for two consecutive observations.
- Scoring system: The Draize method was employed.
- Observation period: 14 days.
- Tool used to assess score: A fluorescein wash was used when necessary in scoring ocular reactions.

Test substance : SOURCE: Not reported.
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: The test substance was sodium carbonate monohydrate.

Reliability : (1) valid without restriction
Guideline study

14.02.2003 (24)

Species : rabbit
Concentration : undiluted
Dose : .1 ml
Exposure time : 24 hour(s)
Comment : other: Of six animals the eyes were washed for 2 minutes, 30 seconds after instillation. Of 12 animals the eyes were not washed.
Number of animals : 18
Vehicle : none
Result : highly irritating
Classification : risk of serious damage to eyes
Method : Draize Test
Year : 1982
GLP : no
Test substance : other TS: sodium carbonate
Method : METHOD FOLLOWED: Based on the methodology of Draize et al. (1944) and the FHSAR (1973) with slight modifications. Comparable to OECD guideline 405. Scoring system seems to be identical, but evaluation/classification was different. The ocular reactions were rated as follows:
(1) severe: Corneal opacity, iritis and conjunctivitis-positive at 24h, one or more of the treated eyes still exhibit opacity, iritis, and conjunctivitis at the 7th day. (2) Moderate: Corneal opacity and/or iritis and conjunctivitis-positive at 24-72h, iritis and conjunctivitis remaining at the 7th day. (3) Irritant: Corneal opacity and/or iritis and conjunctivitis-positive at 24h, eyes normal at 3rd day. (4) Non-irritant: No positive responses in any of the test animals at 24h. Washed eyes were stained with 1 drop of 2% fluorescein, 1, 24 and 72h after instillation. Unwashed eyes 24 and 72h after instillation. The stain was removed after 15-20 seconds by rinsing with 5-10 ml of sterile isotonic saline.
DEVIATIONS FROM
OECD GUIDELINE 405: The test material was placed directly on the central portion of the cornea (right eye) instead of placing it in a cup formed by the conjunctival sac. Evaluation system different.
GLP: No
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.

Result : AVERAGE SCORE
- Cornea: 3.1 (0.4 in unwashed eyes)
- Iris: 2.0 (0.6 in unwashed eyes)

- Conjuntivae (Redness): Not reported.
- Conjuntivae (Chemosis): Not reported.
- Overall irritation score: Not reported.
DESCRIPTION OF LESIONS: Conjunctivitis was observed in all animals and lasted through day 7. Pannus was observed in 6/12 unwashed eyes and keratoconus in 2/12 unwashed eyes.
REVERSIBILITY: Effects were reversible in washed eyes, but not in unwashed eyes.
OTHER EFFECTS: No.

Test condition : TEST ANIMALS:
- Strain: New Zealand albino
- Sex: Unselected
- Source: Zartman Farms, P.A. Animals
- Age: Not reported.
- Weight at study initiation: 2.0-2.5 kg
- Number of animals: 6 with washed eyes and 12 with unwashed eyes.
- Controls: Left eye.
ADMINISTRATION/EXPOSURE
- Preparation of test substance: Concentration 100% w/v
- Amount of substance instilled: 0.1 ml
pH=11.3 (saturated solution)
- Vehicle: No.
- Postexposure period: Up to 7 days.
IN VITRO TEST SYSTEM
Not relevant.
EXAMINATIONS
- Ophtalmoscopic examination: Eyes were examined grossly a nd grades of damage recorded.
- Scoring system: Draize
- Observation period: At 1 hr, 1, 2, 3 and 7 days after installation.
- Tool used to assess score: 2% fluorescein.

Test substance : SOURCE: Fisher Scientific Company
PURITY: reagent grade
IMPURITY/AD DITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.

Reliability : (2) valid with restrictions
Acceptable, well documented publication, comparable to guideline but with acceptable restrictions.

17.02.2003 (16)

5.3 SENSITIZATION

5.4 REPEATED DOSE TOXICITY

Type	:	
Species	:	rat
Sex	:	male
Strain	:	other: not indicated
Route of admin.	:	inhalation
Exposure period	:	3.5 months
Frequency of treatm.	:	4 h/d, 5 d/wk
Post exposure period	:	
Doses	:	70 +/- 2.9 mg/m3
Control group	:	yes, concurrent no treatment
LOAEL	:	= 70 mg/m³
Method	:	other
Year	:	1966

GLP : no
Test substance : other TS: sodium carbonate
Method : METHOD FOLLOWED: Not reported.
GLP: No
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.
Result : LOAEL: 70 mg/m3, from preliminary experiment, NOAEL 10-20 mg/m3
TOXIC RESPONSE/EFFECTS BY DOSE LEVEL:
- Body weight gain: Increased regularly, but the experimental animals lagged behind the controls. No difference with the controls at the end of the test.
- Clinical chemistry: Concentration of ascorbic acid in lungs decreased compared to controls. No other changes.
- Haematology: Blood characteristics did not differ from controls.
- Organ weights: No changes in relative weight and dry residue of internal organs.
- Histopathology: Deviations in lungs were found in control and experimental animals. But experimental animals displayed hyperplasia and desquamation of bronchial epithelium, alveolar lumina often contained free "dust cells" without any visible foreign inclusions, perivascular oedema was more frequent.
- Other: Body temperature did not differ from controls.
STATISTICAL RESULTS: Histopathological results statistically different.
Test condition : TEST ORGANISMS
- Age: Young
- Weight at study initiation: 140 g
- Number of animals: 12 males/group
ADMINISTRATION / EXPOSURE
- Duration of test/exposure: 4 hr/day
- Type of exposure: whole body, aerosols
- Post exposure period: No
- Doses: 2% soda ash solution = 70 mg/m3, 2% soda ash solution with the addition of 0.2% sulfonol = 42 mg/m3 soda, controls.
- Particle size: <= 5 microm.
- Type or preparation of particles: Not reported.
- Vehicle: No treatment.
- Concentration in vehicle: Not relevant.
SATELLITE GROUPS AND REASONS THEY WERE ADDED: No.
OBSERVATIONS AND FREQUENCY:
- Clinical signs: Not reported.
- Mortality: Not reported.
- Body weight: Measured regularly, but frequency not reported.
- Body temperature
- Food consumption: Not reported.
- Water consumption: Not reported.
- Ophthalmoscopic examination: Not reported.
- Haematology: Measured several times, but frequency not reported.
- Biochemistry: Measured several times, but frequency not reported.
- Urinalysis: Not reported.
ORGANS EXAMINED AT NECROPSY (MACROSCOPIC AND MICROSCOPIC):
- Macroscopic: Organs weighted
- Microscopic: Lungs examined, no investigation of upper respiratory tract.
OTHER EXAMINATIONS: The same authors did a preliminary experiment of unknown duration with 10-20 mg/m3 test substance.
STATISTICAL METHODS: Not reported.
Test substance : SOURCE: Not reported.
PURITY: N ot reported.

IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.

Reliability : (3) invalid
Documentation insufficient for assessment.

17.02.2003 (19)

5.5 GENETIC TOXICITY 'IN VITRO'

Type : other: *Escherichia coli* Chromotest
System of testing : PQ37 (uvrB-)
Test concentration : 0.11-11000 microg/ml
Cycotoxic concentr. : 1100 microg/ml
Metabolic activation : Without
Result : Negative
Method : other: SOS chromotest
Year : 1987
GLP : No
Test substance : other TS: sodium carbonate
Method : METHOD FOLLOWED: SOS Chromotest as described by Quillardet et al. (1982) and adapted by Marzin et al. (1986).
GLP: No
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.
Result : GENOTOXIC EFFECTS:
- With metabolic activation: Not done.
- Without metabolic activation: Negative.
FREQUENCY OF EFFECTS: Not relevant.
PRECIPITATION CONCENTRATION: Not reported.
MITOTIC INDEX: Not relevant.
CYTOTOXIC CONCENTRATION:
- With metabolic activation: Not relevant.
- Without metabolic activation: 1100 migrog/ml (10000 nM/ml).
TEST-SPECIFIC CONFOUNDING FACTORS: Not reported.
STATISTICAL RESULTS: Not reported.
Test condition : SYSTEM OF TESTING
- Species/cell type: *E. coli* PQ37
- Deficiences/Proficiences: uvrB-, sensitive to Cr(VI)
- Metabolic activation system: Not used.
- No. of metaphases analyzed: Not reported.
ADMINISTRATION:
- Dosing: 1-100000 nM/ml (approx. 0.11-11000 microg/ml).
- Number of replicates: Three
- Application: 100 microlitre of solution in L-medium or 30 microlitre in DMSO.
- Positive and negative control groups and treatment:
- Pre-incubation time: 2 hr
DESCRIPTION OF FOLLOW UP REPEAT STUDY: Not reported.
CRITERIA FOR EVALUATING RESULTS: Induction of the baterial gene sfiA was determined using a colorimetric assay. sfiA expression is induced after DNA damage as part of the SOS system. sfiA expression is monitored by assaying Beta-galactosidase activity by kinetic measurement.
Test substance : SOURCE: Merck
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.
Reliability : (2) valid with restrictions
Acceptable, well documented publication which meets basic scientific

principles.

14.02.2003 (18)

5.6 GENETIC TOXICITY 'IN VIVO'

5.7 CARCINOGENICITY

5.8.1 TOXICITY TO FERTILITY

5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

Species	:	rat
Sex	:	female
Strain	:	Wistar
Route of admin.	:	gavage
Exposure period	:	d 6-15
Frequency of treatm.	:	daily
Duration of test	:	
Doses	:	2.45, 11.4, 52.9 and 245 mg/kg
Control group	:	other: yes, sham-treated
NOAEL maternal tox.	:	>= 245 mg/kg bw
NOAEL teratogen.	:	>= 245 mg/kg bw
Method	:	other: no data
Year	:	1974
GLP	:	no
Test substance	:	other TS: sodium carbonate
Method	:	METHOD FOLLOWED: Not reported, well described, see TC. GLP: No STATISTICAL METHODS: Not reported. METHOD OF CALCULATION: Not reported. ANALYTICAL METHODS: Not reported.
Result	:	NOAEL: >= 245 mg/kg bw (maternal and developmental) TOXIC RESPONSE/EFFECTS BY DOSE LEVEL: - Parental data and F1: No effects. - Body weight: No effects. - Mortality: No effects. - Number of implantations: No effects. - Litter size and weights: No effects. - Other observations: No effects on resorptions, live fetuses, visceral and skeletal effects. STATISTICAL RESULTS: Not reported.
Test condition	:	ADMINISTRATION / EXPOSURE - Type of exposure: oral - Duration of test/exposure: day 6-15 of gestation - Control group and treatment: Including positive control of 250 mg/kg aspirin (active ingredient: acetylsalicylic acid) - Vehicle: water - Concentration in vehicle: 0 mg/kg - Doses: 2.45, 11.4, 52.9 and 245 mg/kg - Concentrations: 10 ml/kg bodyweight, administered as a water solution MATING PROCEDURES: 21-25 female rats were mated with young adult males, observation of the vaginal sperm plug was considered day 0 of gestation. EXAMINATIONS: Body weights were recorded on days 0, 6, 11, 15 and 20 of gestation, observed daily for appearance and behaviour. On day 20 all dams were subjected to caesarean section under anesthesia, numbers of

implantation sites, resorption sites, and live and dead fetuses were recorded. Body weight of live fetuses were recorded. The urogenital tract of each dam was examined in detail for anatomical normality. All fetuses were examined grossly for the presence of external congenital abnormalities. 1/3 of fetuses of each litter underwent detailed visceral examinations employing the Wilson technique. The remaining 2/3 were examined for skeletal defects.
STATISTICAL METHODS: Not reported.

Test substance : SOURCE: Not reported.
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.

Reliability : (2) valid with restrictions
Acceptable, well documented study which meets basic scientific principles.

17.02.2003 (9)

Species : Mouse
Sex : Female
Strain : CD-1
Route of admin. : Gavage
Exposure period : d 6-15 of gestation
Frequency of treatm. : Daily
Duration of test :
Doses : 3.4 to 340 mg/kg
Control group : other: yes, sham treated
NOAEL maternal tox. : >= 340 mg/kg bw
NOAEL teratogen. : >= 340 mg/kg bw
Method : other
Year : 1974
GLP : No
Test substance : other TS: sodium carbonate
Method : METHOD FOLLOWED: Not reported, well described, see TC.
GLP: No
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.

Result : NOAEL: >= 340 mg/kg bw (maternal and developmental)
TOXIC RESPONSE/EFFECTS BY DOSE LEVEL:
- Parental data and F1: No effects.
- Body weight: No effects.
- Mortality: No effects.
- Number of implantations: No effects.
- Litter size and weights: No effects.
- Other observations: No effects on resorptions, live fetuses, visceral and skeletal effects.

STATISTICAL RESULTS: Not reported.

Test condition : ADMINISTRATION / EXPOSURE
- Type of exposure: oral
- Duration of test/exposure: day 6-15 of gestation
- Control group and treatment: Including positive control of 150 mg/kg aspirin (active ingredient: acetylsalicylic acid)
- Vehicle: water
- Concentration in vehicle: 0 mg/kg
- Doses: 3.4, 15.8, 73.4 and 340 mg/kg
- Concentrations: 10 ml/kg bodyweight, administered as a water solution.

MATING PROCEDURES: 25 females were mated with young adult males, observation of the vaginal sperm plug was considered day 0 of gestation.
EXAMINATIONS: Body weights were recorded on days 0, 6, 11, 15 and 17 of gestation, observed daily for appearance and behaviour. On day 17 all dams were subjected to caesarean section under anesthesia, numbers of

implantation sites, resorption sites, and live and dead fetuses were recorded. Body weight of live fetuses were recorded. The urogenital tract of each dam was examined in detail for anatomical normality. All fetuses were examined grossly for the presence of external congenital abnormalities. 1/3 of fetuses of each litter underwent detailed visceral examinations employing the Wilson technique. The remaining 2/3 were examined for skeletal defects.
STATISTICAL METHODS: Not reported.

Test substance : SOURCE: Not reported.
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.

Reliability : (2) valid with restrictions
Acceptable, well documented study which meets basic scientific principles.

17.02.2003 (9)

Species : rabbit
Sex : female
Strain : Dutch
Route of admin. : gavage
Exposure period : d 6-18 of gestation
Frequency of treatm. : daily
Duration of test :
Doses : 1.79, 8.31, 38.6, 179 mg/kg
Control group :
NOAEL maternal tox. : >= 179 mg/kg bw
NOAEL teratogen. : = 179 mg/kg bw
Method : other
Year : 1974
GLP : no
Test substance : other TS: sodium carbonate

Method : METHOD FOLLOWED: Not reported, well described, see TC.
GLP: No
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.

Result : NOAEL: >= 179 mg/kg bw (maternal and developmental)
TOXIC RESPONSE/EFFECTS BY DOSE LEVEL:
- Parental data and F1: No effects.
- Body weight: No effects.
- Mortality: No effects.
- Number of implantations: No effects.
- Litter size and weights: No effects.
- Other observations: No effects on resorptions, live fetuses, visceral and skeletal effects.

STATISTICAL RESULTS: Not reported.

Test condition : ADMINISTRATION / EXPOSURE
- Type of exposure: oral
- Duration of test/exposure: day 6-18 of gestation
- Control group and treatment: Including positive control of 150 mg/kg aspirin (active ingredient: acetylsalicylic acid)
- Vehicle: water
- Concentration in vehicle: 0 mg/kg
- Doses: 1.79, 8.31, 38.6 and 179 mg/kg
- Concentrations: 10 ml/kg bodyweight

MATING PROCEDURES: 10-15 Females were inseminated artificially.
EXAMINATIONS: Body weights were recorded on days 0, 6, 12, 18 and 29 of gestation, observed daily for appearance and behaviour. On day 29 all dams were subjected to caesarean section under anesthesia, numbers of implantation sites, resorption sites, and live and dead fetuses were

recorded. Body weight of live fetuses were recorded. The urogenital tract of each dam was examined in detail for anatomical normality. All fetuses were examined grossly for the presence of external congenital abnormalities. All fetuses of each litter underwent detailed visceral examinations employing the Wilson technique. All fetuses were examined for skeletal defects.
STATISTICAL METHODS: Not reported.

Test substance : SOURCE: Not reported.
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.

Reliability : (2) valid with restrictions
Acceptable, well documented study which meets basic scientific principles.

17.02.2003 (9)

5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

5.9 SPECIFIC INVESTIGATIONS

Endpoint	:	other: nasal toxicity
Study descr. in chapter	:	
Reference	:	
Type	:	
Species	:	rat
Sex	:	male
Strain	:	Wistar
Route of admin.	:	inhalation
No. of animals	:	
Vehicle	:	
Exposure period	:	
Frequency of treatm.	:	once
Doses	:	
Control group	:	yes, concurrent vehicle
Observation period	:	
Result	:	No nasal toxicity
Method	:	
Year	:	2000
GLP	:	no data
Test substance	:	other TS: sodium carbonate
Remark	:	Aim of the study: determine whether changes in biochemical parameters in the in vitro model system could predict the pathological changes in the nasal cavities of rats.
Result	:	IN VITRO: OLFACTORY EPITHELIUM -ATP concentrations reduced to 60% of control values by 4 hr. No further loss of ATP when longer incubated, nor any evidence of recovery during incubation in fresh medium. -Intracellular potassium was less affected, only significantly decreased when incubated for 24 hr, or 4 hr followed by 20 hr incubation in fresh medium. RESPIRATORY EPITHELIUM - No significant decrease in ATP or intracellular potassium. IN VIVO: - Clinical signs: No adverse clinical signs. - No morphological changes in any region of the nasal cavity. SENSITIVITY OF IN VITRO SYSTEM: -Concentration dependent decreases in ATP, with the first significant loss of ATP occuring at 0.1 mM. Estimated EC50 2.57 mM. With increasing concentration sodium carbonate, the pH increased from 8-10.

Test condition : TEST ORGANISMS
- Age: 2-4 months old
- Weight at study initiation: Not reported.
- Number of animals: 5/dose
- Standard controlled housing conditions
ADMINISTRATION / EXPOSURE IN VIVO
- Duration of test/exposure: 4 hr
- Type of exposure: nose-only, aerosols
- Post exposure period: 24 hr after start of exposure animals were killed.
- Doses: Target chamber concentration 250 or 750 microg/l
- Particle size: <= 5 microm.
- Type or preparation of particles: Aerosols were generated using either a Wright dust feed machinism or a System 22 nebuliser. Chamber aerosol concentrations were determined by drawing a measured volume of air through either a glass fibre filer or a g lass bubbler system.
- Vehicle: high purity water
- Control: Air
ADMINISTRATION / EXPOSURE IN VITRO
- Duration of test/exposure: 4 hr, 24 hr, or 4 hr followed by fresh medium incubation for 20 hr.
- Doses: In vivo dose level estimated and an equivalent dose per turbinate given, medium concentration 35.4 in distilled water.
- In vitro cells exposed: Olfactory and respiratory turbinates (n=6 and n=3, resp.) were exposed.
SENSITIVITY OF IN VITRO SYSTEM:
- olfactory turbinates were exposed to 0-100 mM test substance for 4 hr and ATP concentrations were determined.
OBSERVATIONS IN VIVO:
- Clinical signs: Reported.
- Microscopic: Nasal cavity.
OBSERVATIONS IN VITRO:
- ATP, intracellular potassium and protein concentrations of turbinates.
STATISTICAL METHODS: ANOVA or Students's t-test was used.

Test substance : SOURCE: Sigma, Poole, UK
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.

Conclusion : It is possible that acidic mucopolysaccharides in the nasal mucous are able to protect the nose against sodium carbonate in vivo, but that in vitro the buffering capacity of the OE becomes overwhelmed. Furthermore, the loss of ATP with pH changes suggested that the observed toxicity was due to exposure of the tissue to relatively extreme alkalinity.

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Endpoint : other: screen for respiratory toxins
Study descr. in chapter :
Reference :
Type :
Species : other: Human bronchial cell line (16HBE14o-)
Sex :
Strain :
Route of admin. :
No. of animals :
Method :
Year : 1999
GLP : no data
Test substance : other TS: sodium carbonate
Remark : This cell line appears to be a suitable cell line for future use in the development of in vitro assays for respiratory toxicity.
Result : -TER measurements: Time and concentration dependent decrease in TER.

Also a marked increase in pH of treatment solutions > 500 microg./ml. However, a similar decrease in TER was seen when the pH was adjusted to neutral pH using 1 M hydrochloric acid. Some recovery of TER by 24 hr.
-Cytotoxicity: MTT and NRU measurements showed toxicity, IC50s being 4770 and 3840 microg./ml resp.

Test condition : CELL C ULTURE:
- Under controlled culturing conditions
ADMINISTRATION / EXPOSURE IN VITRO
- Duration of test/exposure: 0.25, 0.5, 1, 2, 4, 6 or 24 hr.
- Doses: 0, 1000, 3000, 5000 microg/ml
OBSERVATIONS IN VITRO:
- TER = transepithelial resistance was measured, prior to treatment and after treatment in triplicate
- Cytotoxicity was measured by NRU (neutral red uptake) and MTT measurements, 8 times after 20 hr of treatment. This was repeated three times.
STATISTICAL METHODS: ANOVA or Students's t-test was used.

Test substance : SOURCE: Not reported.
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Not reported.

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5.10 EXPOSURE EXPERIENCE

5.11 ADDITIONAL REMARKS

6.1 ANALYTICAL METHODS

6.2 DETECTION AND IDENTIFICATION

7.1 FUNCTION

7.2 EFFECTS ON ORGANISMS TO BE CONTROLLED

7.3 ORGANISMS TO BE PROTECTED

7.4 USER

7.5 RESISTANCE

8.1 METHODS HANDLING AND STORING

8.2 FIRE GUIDANCE

8.3 EMERGENCY MEASURES

8.4 POSSIB. OF RENDERING SUBST. HARMLESS

8.5 WASTE MANAGEMENT

8.6 SIDE-EFFECTS DETECTION

8.7 SUBSTANCE REGISTERED AS DANGEROUS FOR GROUND WATER

8.8 REACTIVITY TOWARDS CONTAINER MATERIAL

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