



EUROPEAN COMMISSION

Institute for Health and Consumer Protection
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SODIUM HYDROXIDE

CAS No: 1310-73-2

EINECS No: 215-185-5

Summary Risk Assessment Report

The mission of the IHCP is to provide scientific support to the development and implementation of EU policies related to health and consumer protection. The IHCP carries out research to improve the understanding of potential health risks posed by chemical, physical and biological agents from various sources to which consumers are exposed.

The Toxicology and Chemical Substances Unit (TCS), commonly known as the European Chemicals Bureau (ECB), provides scientific and technical input and know-how to the conception, development, implementation and monitoring of EU policies on dangerous chemicals including the co-ordination of EU Risk Assessments. The aim of the legislative activity of the ECB is to ensure a high level of protection for workers, consumers and the environment against dangerous chemicals and to ensure the efficient functioning of the internal market on chemicals under the current Community legislation. It plays a major role in the implementation of REACH through development of technical guidance for industry and new chemicals agency and tools for chemical dossier registration (IUCLID5). The TCS Unit ensures the development of methodologies and software tools to support a systematic and harmonised assessment of chemicals addressed in a number of European directives and regulation on chemicals. The research and support activities of the TCS are executed in close co-operation with the relevant authorities of the EU Member States, Commission services (such as DG Environment and DG Enterprise), the chemical industry, the OECD and other international organisations.

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EUR 23040 EN/2

ISSN 1018-5593

Luxembourg: Office for Official Publications of the European Communities, 2008

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Printed in Italy

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SUMMARY RISK ASSESSMENT REPORT

Final report, 2008

Portugal

The Rapporteur for the risk assessment of sodium hydroxide is Portugal. The Rapporteur is responsible for the risk evaluation and subsequently for the contents of this report.

The scientific work on this report has been prepared by the Netherlands Organisation for Applied Scientific Research (TNO) and the National Institute for Public Health and the Environment (RIVM), by order of the rapporteur.

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Date of Last Literature Search:	2003
Review of report by MS Technical Experts finalised:	June 2006
Final report:	2008

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PREFACE

This report provides a summary, with conclusions, of the risk assessment report of the substance sodium hydroxide that has been prepared by Portugal in the context of Council Regulation (EEC) No. 793/93 on the evaluation and control of existing substances.

For detailed information on the risk assessment principles and procedures followed, the underlying data and the literature references the reader is referred to the comprehensive Final Risk Assessment Report (Final RAR) that can be obtained from the European Chemicals Bureau¹. The Final RAR should be used for citation purposes rather than this present Summary Report.

¹ European Chemicals Bureau – Existing Chemicals – <http://ecb.jrc.it>

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GENERAL INTRODUCTION: 'TARGETED RISK ASSESSMENT'

In order to accelerate the EU risk assessment process for existing substances, the European Commission has clearly expressed a wish to perform so-called 'targeted risk assessments' (TRA) for the 4th Priority-list substances, which include NaOH. In this context 'targeted' means that not all endpoints, as defined in the Technical Guidance Documents (TGD), are addressed thoroughly in the risk assessment. In a TRA one deviates therefore from the standard comprehensive risk assessment that covers all possible exposure routes of the chemical and all protection goals. Arguments and requirements for performing a TRA within EC Regulation 793/93 are discussed in the CA discussion paper 'Use of Targeted Risk Assessments in the EU' (CA, 2001).

Based on this and taken into account the data and conclusions in the recent SIDS Initial Assessment Report on NaOH (OECD, 2002), the Rapporteur proposed to perform a targeted risk assessment for NaOH (Portugal, 2003). This proposal was approved by the EU member states at the Technical Meeting in December 2003 (ECB, 2003). For the environmental risk assessment it was agreed to focus solely on the aquatic environment, as the emissions of NaOH in the different life-cycle stages (production and use) mainly apply to (waste) water. The aquatic risk assessment will only deal with the effect on organisms/ecosystems due to possible pH changes related to (OH⁻)- discharges, as the toxicity of the Na⁺ ion is expected to be insignificant compared to the (potential) pH effect. Only the local scale (thus not the regional scale) will be addressed, when applicable including sewage treatment plants (STPs) or waste water treatment plants (WWTPs), both for production and industrial use.

For the human health risk assessment it was agreed to focus on the risks from acute exposure (local effects, thus not systemic effects), both for workers and consumers. Regarding the environmental and human health effects assessments (hazard identifications) it was concluded that these subjects are covered adequately by the OECD report, thus the effects assessments data from the OECD report will be used without a re-evaluation or update. The same applies to the IUCLID that is included in the OECD evaluation. Thus, the key-issues in this EU Summary Risk Assessment Report are the exposure assessments and the risk characterisations for the aquatic environment (STPs/WWTPs included), workers and consumers.

1 GENERAL SUBSTANCE INFORMATION

1.1 IDENTIFICATION OF THE SUBSTANCE

CAS Number: 1310-73-2
EINECS Number: 215-185-5
IUPAC Name: Sodium hydroxide
Molecular Formula: NaOH
Structural Formula: NaOH
Molecular Weight: 40
Synonyms: Caustic soda (liquid or solid)
Liquid caustic
Lye (liquid)
Caustic flake (solid)
Sodium hydrate

1.2 PURITY/IMPURITIES, ADDITIVES

Sodium hydroxide (NaOH) is a white and deliquescent solid. Impurities are sodium chloride ($\leq 2\%$), sodium carbonate ($\leq 1.0\%$) and sulfate ($\leq 0.2\%$). The concentration of other impurities is less than 0.1%.

1.3 PHYSICO-CHEMICAL PROPERTIES

Table 1.1 Summary of physico-chemical properties

Physico-chemical properties	Results
Melting point	318°C (solid, 100%) 140°C (solution of 80%) 42°C (solution of 60%) 16°C (solution of 40%) -26°C (solution of 20%)
Boiling point	1388°C at 1013 hPa (solid, 100%) 216°C at 1013 hPa (solution of 80%) 160°C at 1013 hPa (solution of 60%) 128°C at 1013 hPa (solution of 40%) 118°C at 1013 hPa (solution of 20%)
Density	2.13 at 20°C (solid, 100%) 1.43 at 20°C (solution of 40%) 1.22 at 20°C (solution of 20%)

Table 1.1 continued overleaf

Table 1.1 continued Summary of physico-chemical properties

Physico-chemical properties	Results
Water solubility	52% (by weight) at 20°C 42% (by weight) at 0°C
Vapour pressure	< 10 ⁻⁵ hPa at 25°C (calculated)
Partition coefficient (log K _{ow})	Not applicable
Oxidising / explosive properties	Not applicable
Autoflammability	Not applicable

NaOH is miscible with water at all proportions but solidifies at 20°C if the concentration is higher than 52% (by weight), which can be considered the maximum water solubility at 20°C. NaOH has a very low vapour pressure (< 10⁻⁵ hPa at 25°C). The octanol water partition coefficient is not relevant for an inorganic substance such as NaOH.

NaOH is a strong alkaline substance that dissociates completely in water into the sodium ion (Na⁺) and hydroxyl ion (OH⁻). The dissolution/dissociation in water is strongly exothermic, so a vigorous reaction occurs when NaOH is added to water.

1.4 CLASSIFICATION AND LABELLING

Sodium hydroxide is included in Annex I of Directive 67/548/EEC.

Classification: C; R35

Label: C

R- phrases: 35

S- phrases: (1/2)-26-37/39-45

Specific concentration limits:

C ≥ 5%: C, R35

2% ≤ C < 5%: C, R34

0.5% ≤ C < 2%: Xi, R36/38

This has remained unchanged since the 12th ATP.

2 GENERAL INFORMATION ON EXPOSURE

2.1 PRODUCTION

The production of sodium hydroxide (NaOH) is based on the electrolysis of NaCl, which can be done via the mercury, diaphragm or membrane process. The distribution of the production routes to chlorine/NaOH in Western Europe is mercury process 46%, diaphragm process 18%, membrane process 33% and other processes 3%. NaOH is mainly commercialised as a solution in water at different concentrations (lye), or as solid (cast, flakes, pearls) or as solutions in water with varying NaOH concentrations (lye). Solid NaOH was produced at 27% of the production sites, but covers only a small percentage (4%) of the total market; the remaining amount (96%) is NaOH in solution. The most important industrial concentration is 50%, NaOH solidifies at a concentration of higher than 52% (by weight) at 20°C.

In the European Union (EU), 50 companies at 84 sites in 20 countries produce chlorine and the vast majority of them simultaneously produce NaOH. The total EU production capacity of chlorine was 12.4 million tonnes in 2003. Sodium hydroxide is produced in a fixed ratio of 1.128 tonnes (as 100% NaOH) per tonne chlorine produced and therefore the EU production capacity of NaOH was 14 million tonnes in 2003. The Western European consumption of sodium hydroxide was 9.7 million tonnes in 2003

2.2 USES

NaOH is used for different purposes in a variety of industrial sectors. The sector with the largest use of NaOH is the production of other chemicals, both organics (28%) and inorganics (16%). Other uses are in the sectors pulp and paper industry (12%), aluminium and metal industry (6%), food industry (3%), water treatment (3%) and textile (3%). The remainder is used in the production of soaps, mineral oils, bleach, phosphates, cellulose, rubber and others.

2.3 TRENDS

The global demand for NaOH is expected to grow with 3.1% per year.

2.4 LEGISLATIVE CONTROLS

There are several EU Directives with quality standards for surface waters, aimed at the protection of human health or aquatic wildlife, depending on the function of the surface water (98/83/EC, 75/440/EEC, 76/160/EEC, 78/659/EEC and 79/923/EEC). These EU Directives include a quality standard for the pH and should have been implemented in national legislation of the 'old' EU Member States or be implemented in the near future in the 'new' EU Member States.

Taking into account the existing EU Directives for pH control for surface water and the data of many Member States on additional national regulations to control the pH of waste waters (STP influents) and surface waters it is concluded that STPs and surface waters are sufficiently protected with regard to pH changes.

3 ENVIRONMENT

3.1 EXPOSURE

3.1.1 General Discussion

The exposure assessment for the aquatic environment will only deal with the possible pH changes in STP effluent and surface water related to the OH⁻ discharges at the local scale.

The emissions of NaOH mainly apply to (waste) water. Furthermore, the high water solubility and very low vapour pressure indicate that NaOH will be found predominantly in water. In water (including soil or sediment pore water), NaOH is present as the sodium ion (Na⁺) and hydroxyl ion (OH⁻), as solid NaOH rapidly dissolves and subsequently dissociates in water. If emitted to soil, sorption to soil particles will be negligible. Depending on the buffer capacity of the soil, OH⁻ will be neutralised in the soil pore water or the pH may increase.

Bioaccumulation in organisms is not relevant for NaOH.

3.1.2 Environmental releases

The emissions of NaOH during production and use mainly apply to the aquatic environment. For sodium, other anthropogenic sources are for instance mining and the use of road salt (sodium chloride). In water (including pore water of sediment and soil), NaOH dissociates into the sodium ion (Na⁺) and hydroxyl ion (OH⁻), both having a wide natural occurrence.

3.1.2.1 Releases from production

The production of NaOH can potentially result in an aquatic emission and locally increase the sodium concentration and pH in the aquatic environment. When the pH of the influent is not neutralised, the discharge of effluent from NaOH production sites may cause an increase in pH in the receiving water. The pH of effluents is normally measured very frequently and can be neutralised easily.

Industry submitted actual data on pH values in effluent and receiving surface waters at NaOH production sites, based on the results of a questionnaire that was sent to a broad cross section of NaOH producers in the EU. The results of this questionnaire provided effluent and receiving water data for 43 out of 84 production sites, indicating that the pH of waste water discharges is controlled and that almost always proper regulations are in place.

3.1.2.2 Releases from use

To estimate the environmental releases from the uses of NaOH a questionnaire was organised by industry, in cooperation with the Portuguese and Dutch authorities, focussing on the major downstream uses. Because the exposure assessment focussed on possible pH changes in the local aquatic environment, data were requested on the pH control at user sites. The results from the questionnaires for the use sites demonstrate that in most cases the final effluents did not contain

NaOH anymore. Usually, the pH of waste water discharges is controlled and almost always proper regulations are in place. Nevertheless, for some use sites, emitting their effluents to the environment, it cannot be excluded that they do not neutralise their effluents and have no legal obligation to neutralise.

3.2 EFFECTS

3.2.1 Aquatic compartment

The results of single-species acute toxicity tests with NaOH include tests with fish and invertebrates; all but one test were performed with freshwater species. The tests with fish resulted in acute LC₅₀ values and toxic / lethal concentrations ranging from 35 to 189 mg/l. The results for invertebrates are very similar, with a range of 33 to 450 mg/l. There are no data for algae and higher aquatic plant species. For chronic toxicity of NaOH only one limited study is available, with fish (guppy) *Lebistes reticulatus*. This study clearly showed effects on survival, growth and reproduction of fish at long-term exposure to NaOH concentrations of 25 mg/l and higher. The available data indicate that NaOH concentrations of 20 to 40 mg/l may be acutely toxic to fish and invertebrates. Data on pH-increases due to the addition of these amounts of NaOH in the used test waters are lacking. In waters with a relatively low buffering capacity, NaOH concentrations of 20-40 mg/l may result in a pH increase with one to several pH units.

The data on the pH tolerance of fish show that an increase in pH value from around 8.5 to 9.5-10.5. i.e. an increase with 1 to 2 pH units results in acute lethality in fish that were not acclimatized to intermediate values. The data further show that pH values of 9-10 may be toxic or lethal to some fish species and above a pH value of 10 mortalities may be expected for many species exposed for a prolonged period.

3.2.2 Effects on microorganisms

In a test system with the freshwater ciliated protozoan *Tetrahymena thermophila*, NaOH is used as a positive control. At the NOEC (EC₁₀) of 167 mg/l the calculated pH value was 11.6, assuming that the dilution medium has no buffer capacity.

The inhibition of the bioluminescence of the marine bacterium *Photobacterium phosphoreum* by NaOH has been measured with the Microtox test system, resulting in a 15-minutes EC₅₀ of 22 mg/l.

3.2.3 Predicted No Effect Concentration (PNEC)

A generic PNEC cannot be derived from single-species toxicity data for NaOH, as the pH of natural waters as well as the buffer capacity of natural waters show considerable differences and aquatic organisms/ecosystems are adapted to these specific natural conditions, resulting in different pH optima and pH ranges that are tolerated. There is a lot of information available about the relationship between pH and ecosystem structure and also natural variations in pH of aquatic ecosystems have been quantified and reported extensively.

3.3 RISK CHARACTERISATION

3.3.1 Aquatic compartment

Production

Based on the results from a questionnaire among producers, it is concluded that discharges of NaOH from production sites to STPs/WWTPs and receiving waters are well controlled in all investigated cases. Taking into account the existing EU Directives for pH control for surface water and the data of many Member States on (additional) national regulations to control the pH of waste waters (STP influents) and surface waters it is concluded that STPs and surface waters are sufficiently protected with regard to pH changes.

Conclusion (ii).

Use

The results from a questionnaire among users indicate that in most cases the final effluent did not contain NaOH anymore, so it is concluded that discharges of NaOH from the various downstream applications rarely occur. If discharges do occur they are well controlled in all investigated cases and are often covered by EU and/or national regulations.

Conclusion (ii).

It should be noted that for a few sites it cannot be excluded that NaOH will be discharged to the aquatic environment, resulting in significant pH changes and effects on biological STPs/WWTPs or receiving surface waters. However, the available data clearly indicate that neutralisation of NaOH containing waste waters and effluents is common practice, either from a legal point of view (legislation for surface waters) or from a practical point of view (protection of the functioning of biological STPs/WWTPs).

3.3.2 PBT assessment

Persistence

NaOH will rapidly dissolve and dissociate in water. Therefore, NaOH does not fulfil the P criterion.

Bioaccumulation

Bioaccumulation is not relevant for NaOH, therefore, NaOH does not meet the B criterion of the PBT criteria.

Toxicity

The lowest LC₅₀ for freshwater and marine organisms were found to be 40 and 33 mg/l, respectively. This is clearly above the cut-off value of 0.1 mg/l. Therefore, NaOH does not meet the T criterion in the PBT assessment.

Conclusion

NaOH, does not fulfil the criteria for persistency, bioaccumulation and toxicity as laid down in the TGD. Therefore, this substance is not considered a PBT or vPvB substance.

4 HUMAN HEALTH

4.1 EXPOSURE

4.1.1 Occupational exposure

NaOH is produced as solutions, generally of 50% or lower, or as solid flakes, pearls or casts. NaOH has mainly industrial uses in the production of organic and inorganic chemicals, the pulp and paper industry, soap and detergent industry, textile industry, aluminium industry, water treatment and neutralisation, rayon and cellophane production, gasoline refining and for the cleaning of non-disposable bottles in the food industry. Several other (minor) uses also exist. Although major quantities are used by the industry (large enterprises) it is also widely used by small and medium sized enterprises.

Dermal contact is the most obvious route of exposure to workers because of the low vapour pressure of NaOH. Some inhalation exposure is possible to dust when handling solid NaOH and to aerosols, e.g. when handling products by spraying (e.g. cleaning products). Ocular exposure is possible due to hand-eye contact or splashes. NaOH is a labelled corrosive substance. For the handling of corrosive substances and formulations, it is assumed that daily dermal exposure can be neglected because workers are protected from dermal exposure and immediate dermal contacts occur only accidentally. Techniques and equipment (including PPE) are used that provide a high level of protection from direct dermal contact. Repeated dermal exposure cannot be neglected for preparations and products containing NaOH that have no corrosive labelling (dilutions containing < 2% NaOH, according to EU classification and labelling, Annex 1 of Dir 67/548/EEC).

Measured exposure data on inhalation exposure are available for production of NaOH and several use scenarios. Also, the EASE model is used to estimate exposure for situations with too limited measured data. Full shift inhalation exposure levels are generally below 3.4 mg/m³, with the highest levels measured in the textile industry. The highest dermal exposures due to the use of diluted products are estimated to be up to 84 mg/day in the use of oven cleaner sprays.

Table 4.1 Summary of worst-case exposures to workers

Exposure scenario	Industry/activity	Inhalation exposure			Dermal exposure		
		Duration [#]	Reasonable worst case (mg/m ³)	Method	Exposure level (mg/cm ² /day)	Reasonable worst case (mg/day)	Method
Production	Drumming liquid NaOH	Full shift	0.33	Modelled	--	--	--
	Bagging NaOH	Full shift	1.8	Measured	--	--	--
Formulation	Formulating cleaning products	Full shift	0.08	Modelled	--	--	--

Table 4.1 continued overleaf

Table 4.1 continued Summary of worst-case exposures to workers

Exposure scenario	Industry/activity	Inhalation exposure			Dermal exposure		
		Duration [#]	Reasonable worst case (mg/m ³)	Method	Exposure level (mg/cm ² /day)	Reasonable worst case (mg/day)	Method
End use formulated products	Oven cleaner liquid	Full shift	--	--	0.1	42	Modelled
	Oven cleaner spray	Full shift	0.13	Modelled	0.1	84	Modelled
	Hair straightening products	Full shift	--	--	0.002	1.68	Modelled
Uses	Organic/ inorganic	Full shift	0.08	Modelled	--	--	--
	Aluminium	Full shift	0.14	Measured	--	--	--
		Short term	1.1	Measured	--	--	--
	Pulp/paper	Full shift	0.08	Modelled	--	--	--
	De-inking waste paper	> 1hour/ day*	1.2	Measured	--	--	--
Textile	Full shift	3.4	Measured	0.002	0.84	Modelled	

[#] Frequency was not estimated for most scenarios; reasonable worst case assumption is daily exposure

* Assuming 8-hour TWA as reasonable worst case

-- inhalation exposure is assumed to be negligible; dermal exposure is assumed not to occur regularly due to the corrosive nature of the product handled.

4.1.2 Consumer exposure

Exposure to sodium hydroxide during general and accidental use of floor strippers, oven cleaners and drain openers can be summarised by the following table:

Table 4.2 Overview of consumer exposure

Scenario	Maximum content of NaOH	Potential dermal uptake after general use (mg/kg event)	Potential inhalatory uptake after general use (mg/kg event)	Accidental exposures in 2000-2003 in some European countries
I Floor strippers	10%	Negligible	Not relevant	About 37-277 cases (total per country)
II Hair straighteners	2%	23	Not relevant	
III Oven cleaners	5%	Negligible	Negligible	
IV Drain openers	30%	Negligible	Not relevant	

The systemic exposure in all scenarios can be considered to be negligible. It should be noted, that it is unlikely that sodium ions penetrate the skin to a considerable extent. In an extreme worst case assumption dermal absorption of these ions will be 1-10% following recommendations of the TGD. This would lead to a 1 to 2 orders of magnitude lower systemic dose than described above. This amount is negligible compared to the daily dietary intake of sodium ions.

In the risk characterisation the direct exposure expressed in percentages of sodium hydroxide will be discussed as well as the accidental exposure.

4.1.3 Humans exposed via the environment

Production and use of sodium hydroxide is normally not expected to increase the pH of the environment. Even after an accidental release the substance will be neutralised finally and therefore the human exposure to sodium hydroxide via the environment is expected to be negligible.

4.2 EFFECTS

NaOH has been used for a long time and has wide dispersive use and therefore there is information on human exposure and effects. For this reason the human health hazard assessment is not only based on animal toxicity data but also on human experience. The major human health hazard of NaOH is local irritation and/or corrosion.

Toxicokinetics, metabolism and distribution

Sodium is a normal constituent of the blood and an excess is excreted in the urine. A significant amount of sodium is taken up via the food because the normal uptake of sodium via food is 3.1-6.0 g per day. Exposure to NaOH could potentially increase the pH of the blood. However, the pH of the blood is regulated between narrow ranges to maintain homeostasis. Via urinary excretion of bicarbonate and via exhalation of carbon dioxide the pH of blood is maintained at the normal physiological pH of 7.4-7.5. Therefore, NaOH is not expected to be systemically available in the body under normal handling and use conditions.

Acute toxicity

No valid human and animal data are available on the acute systemic inhalation toxicity of NaOH. Limited animal data is available on acute systemic dermal toxicity. The hair of adult mice was clipped and a circular area 2 cm in diameter was painted by applicator with 50% NaOH. Afterwards the area was rinsed with water at various intervals. The mortality of mice was 20, 40, 80 and 71% when they were rinsed 30 minutes, 1 hour, 2 hours or not at all after the application. No mortality was observed when the mice were rinsed immediately after the application.

No acute oral toxicity study with animals has been carried out using (inter)national guidelines. Human case reports involving oral exposure were available in literature. The degree and type of injury after ingestion of NaOH depend on the physical form. Solid NaOH produces injury to the mouth and pharynx and is difficult to swallow. On the other hand liquid NaOH is easily swallowed, being tasteless and odourless, and is more likely to damage the oesophagus and stomach.

As NaOH is a corrosive substance, there is no need for further acute toxicity testing.

Irritation/corrosion

NaOH is a corrosive substance. A NaOH concentration of 2% is taken forward to the risk characterisation as concentration limit for corrosivity. Based on human data concentrations of 0.5–4% were irritating for the skin. No human data on local effects to the eyes was available. The available animal data on eye irritation revealed small differences in eye irritation levels. The non-irritant level was 0.2-1.0%, while the corrosive concentration was 1.2%. The concentration limits for irritation which are taken forward to the risk characterisation are 0.5-2% NaOH. Based

on a study among workers, concentrations up to 1.0 mg/m³ are not considered adverse with regard to respiratory tract irritation.

Sensitisation

Based on a negative human skin sensitisation study and the fact that no human cases of skin and respiratory sensitisation have been reported despite the long and widespread use of NaOH, the substance is not considered to be a skin and respiratory sensitiser.

Repeated dose toxicity

Although two inhalation studies showed local effects on the respiratory tract after repeated NaOH exposure, the data were not adequate to establish a N(L)OAEL because the exposure concentrations were not specified. Furthermore, no data with regard to repeated dermal toxicity was available. A limited oral drinking water study with rats revealed effects on growth. This effect can be explained by NaOH neutralising the acid environment in the stomach which decreases the digestion and the absorption of food.

Mutagenicity

Both the *in vitro* and the *in vivo* genotoxicity studies indicated no evidence for a mutagenic activity. Furthermore NaOH is not expected to be systemically available in the body under normal handling and use conditions and for this reason additional testing is considered unnecessary.

Carcinogenicity

NaOH did not induce mutagenicity in *in vitro* and *in vivo* studies. Systemic carcinogenicity is not expected to occur because NaOH is not expected to be systemically available in the body under normal handling and use conditions. Finally, no suitable studies are available to assess the risk on local carcinogenic effects.

Toxicity for reproduction

No valid studies were identified regarding effects on fertility or developmental toxicity in animals after oral, dermal or inhalation exposure to NaOH. NaOH is not expected to be systemically available in the body under normal handling and use conditions and for this reason it can be stated that the substance will not reach the foetus nor reach male and female reproductive organs. Therefore, a specific study to determine the reproduction toxicity is not necessary.

4.3 RISK CHARACTERISATION

4.3.1 Workplace

Assuming that oral exposure is prevented by personal hygienic measures, the risk characterisation for workers is limited to the dermal and inhalation routes of exposure. The focus is the occurrence of local effects after acute and repeated exposure at those places where NaOH is produced and/or used. This because NaOH is not expected to become systemically available in

the body under normal handling and use conditions, i.e. neither the concentration of sodium in blood nor the pH of blood will increase after exposure.

In the scope of the assessment of existing substances, dermal exposure to corrosive concentrations is not assessed (see section on occupational exposure). However, dermal exposure to non-corrosive dilutions of NaOH (concentrations < 2%) also occurs. Dermal exposure to such non-corrosive dilutions of NaOH will be taken into account. Furthermore, acute and repeated inhalation exposure to NaOH cannot be neglected. Eye protection is obligatory for activities where direct handling of NaOH occurs.

Acute toxicity

NaOH is not expected to be systemically available in the body under normal handling and use conditions and therefore acute systemic effects of NaOH after acute dermal or inhalation exposure are not expected to occur

Conclusion (ii).

Irritation and corrosivity

Skin

NaOH is considered to be a severe corrosive agent (concentrations $\geq 2\%$). However, dermal exposure to NaOH is considered to occur only accidentally if the required protection is strictly adhered to by workers. Therefore, conclusion (ii) is justifiable.

Dermal exposure to irritating, but non-corrosive, dilutions of NaOH (concentrations < 2%) also occurs. When existing controls based on classification and labelling with R38 are applied conclusion (ii) is applicable.

Eye

Theoretically, NaOH is of concern for workers with regard to eye effects because of the corrosive properties of NaOH (concentration of 1.2%) to the eye in an animal study. However, eye protection is obligatory for activities where direct handling of corrosive NaOH occurs. If the required protection is strictly adhered to, exposure will occur only incidentally, so conclusion (ii) is justifiable.

Exposure to irritating, but non-corrosive, dilutions of NaOH also occurs (concentrations < 2%). When existing controls based on classification and labelling with R36 are applied conclusion (ii) is applicable.

Respiratory tract

Exposure concentrations up to 1 mg/m^3 were not considered adverse with regard to local effects to the respiratory tract. As in the key study a relative large random sample of workers (1,045 exposed and 1,553 unexposed workers) was investigated, it is proposed to use a factor of 3 for intraspecies differences instead of the default factor of 5.

For inhalation exposure to NaOH, it cannot be excluded that respiratory tract irritation may occur in the scenarios 'Production – Bagging NaOH' (full shift exposure level: 1.8 mg/m^3 ; MOS value: 0.6), 'Uses – aluminium' (short-term exposure level: 1.1 mg/m^3 ; MOS value: 0.9), 'Uses – De-inking of waste paper' (full shift exposure level: 1.2 mg/m^3 ; MOS value: 0.83) and 'Uses -

Textile' (full shift exposure level: 3.4 mg/m³; MOS value: 0.3) (Conclusion (iii)). This conclusion is even more justified by the fact that the exposure values for the scenarios 'Production – Bagging NaOH', 'Uses – De-inking of waste paper' and 'Uses - Textile' represent 8h-TWA values instead of short-term peak values.

Sensitisation

Skin

A study with human volunteers did not indicate skin sensitisation potential of NaOH, which is supported by extensive human experience

Conclusion (ii).

Respiratory tract

No studies are available on respiratory sensitisation of NaOH. However, there are no reports on respiratory sensitisation, despite the long and widespread use of NaOH. Therefore, it is concluded that there is no concern for this endpoint.

Conclusion (ii).

Repeated dose toxicity

Inhalation

NaOH is not expected to be systemically available in the body under normal handling and use conditions and therefore systemic effects of NaOH after repeated inhalation exposure are not expected to occur.

Conclusion (ii).

In the key study with regard to respiratory tract irritation, it is mentioned that the results were not changed when the analysis was restricted to people who had ever worked in a production job. Therefore, the same conclusions as specified for acute respiratory tract irritation can be drawn for local effects after repeated inhalation exposure. Thus, it cannot be excluded that respiratory tract irritation may occur in the scenarios 'Production – Bagging NaOH', 'Uses – aluminium', 'Uses – De-inking of waste paper' and 'Uses - Textile' (Conclusion (iii)) after repeated inhalation exposure.

Dermal

NaOH is not expected to be systemically available in the body under normal handling and use conditions and therefore systemic effects of NaOH after repeated dermal exposure are not expected to occur.

Conclusion (ii).

No repeated dermal dose data on local effects of NaOH is available. For the handling of corrosive substances and formulations, it is assumed that repeated daily dermal exposure can be neglected because workers are protected from repeated dermal exposure and only accidental exposure may occur.

Conclusion (ii).

Repeated dermal exposure to non-corrosive dilutions of NaOH also occurs. It is assumed that existing controls based on classification and labelling with R38 are applied for these exposure situations. Therefore, conclusion (ii) is applicable.

Mutagenicity

Given the results from the *in vitro* and *in vivo* mutagenic studies, it is concluded that NaOH is of no concern for workers with regard to mutagenicity.

Conclusion (ii).

Carcinogenicity

No suitable studies are available to assess the risk on carcinogenic effects. However, it is not expected that NaOH will induce tumours (conclusion (ii)). First of all, NaOH did not induce mutagenicity in *in vitro* and *in vivo* studies. Secondly, systemic carcinogenicity is not expected to occur because NaOH is not expected to be systemically available in the body under normal handling and use conditions. Finally, the anticipated level of protection for dermal and inhalation exposure is assumed to prevent possible carcinogenic responses that may be due to chronic local irritation.

Toxicity for reproduction

NaOH is not expected to be systemically available in the body under normal handling and use conditions and for this reason it can be stated that the substance will not reach the foetus nor reach male and female reproductive organs.

Conclusion (ii).

4.3.2 Consumers

As sodium hydroxide is not expected to become systemically available in the body under normal handling and use conditions, the risk characterisation for consumers will focus on possible risks from acute exposure (local effects).

Following the normal use of corrosive and irritating concentrations of sodium hydroxide it is concluded that the substance is of no risk for consumers if the required protection is used.

Conclusion (ii).

However, the number of accidents (foreseeable misuse) that occur with sodium hydroxide is still high, which points out that consumer protection against improper use of sodium hydroxide is insufficient (Conclusion (iii)). Because sodium hydroxide has local effects the conclusion (iii) is applicable for the endpoint “irritation and corrosivity” for all routes of exposure (oral, dermal, ocular, and inhalatory exposure). To prevent improper use of sodium hydroxide, instructions for use should contain a warning against dangerous mixtures. For reducing the number of accidents in which (young) children are involved, it is advisable to use these products in the absence of children. Information regarding safe disposal of empty containers could also be useful.

4.3.3 Humans exposed via the environment

Production and use of sodium hydroxide is normally not expected to increase the pH of the environment. Even after an accidental release the substance will be neutralised finally and therefore the human exposure to sodium hydroxide via the environment is expected to be negligible. Therefore, no direct or systemic exposure is expected from sodium hydroxide.

Conclusion (ii).

4.4 HUMAN HEALTH (PHYSICO-CHEMICAL PROPERTIES)

NaOH is neither explosive, flammable, nor oxidizing and therefore it is concluded that NaOH is of no concern with regard to physical-chemical hazards.

Conclusion (ii).

5 RESULTS

5.1 ENVIRONMENT

Conclusions to the risk assessment for the aquatic compartment:

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion ii applies to:

- **Production;** based on the results from a questionnaire among producers, it is concluded that discharges of NaOH from production to STPs/WWTPs and receiving waters are well controlled in all investigated cases. Taking into account the existing EU Directives for pH control for surface water and the data of many Member States on (additional) national regulations to control the pH of waste waters (STP influents) and surface waters it is concluded that STPs and surface waters are sufficiently protected with regard to pH changes.
- **Use;** the results from a questionnaire among users indicate that in most cases the final effluent did not contain NaOH anymore, so it is concluded that discharges of NaOH from the various downstream applications rarely occur. If discharges do occur they are well controlled in all investigated cases and are often covered by EU and/or national regulations.

Regarding conclusion (ii) for the aquatic compartment it is emphasized that it cannot be excluded that there are (some) sites with NaOH discharges to the aquatic environment, resulting in significant pH changes and effects on biological STPs/WWTPs or receiving surface waters. However, the available data clearly indicate that neutralisation of NaOH containing waste waters and effluents is common practice, either from a legal point of view (legislation for surface waters) or from a practical point of view (protection of the functioning of biological STPs/WWTPs). Regarding surface water, the enforcement of the (EU) legislation is an important issue for the validity of conclusion (ii).

5.2 HUMAN HEALTH

Workers

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

Conclusion (iii) is reached because it cannot be excluded that respiratory tract irritation may occur in the production when bagging NaOH, and when using NaOH in aluminium and textile industry and in the de-inking of waste paper in pulp and paper industry. Risk reducing measures should be taken for these occupational scenarios.

It might be possible that in some workplaces adequate worker protection measures are already being applied.

In relation to all other potential adverse effects and the worker population it is concluded that based on the available information at present there is no concern and no further information/testing on the substance is needed.

Consumers

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to the normal use of corrosive and irritating concentrations of sodium hydroxide if the required protection is used.

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

Conclusion (iii) applies to the high number of accidents (foreseeable misuse) that occur with sodium hydroxide, which points out that consumer protection against improper use of sodium hydroxide is insufficient (foreseeable misuse). Because sodium hydroxide has local effects the conclusion (iii) is applicable for the endpoint “irritation and corrosivity” for all routes of exposure (oral, dermal, ocular, and inhalatory exposure).

Humans exposed via the environment

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Production and use of sodium hydroxide is normally not expected to increase the pH of the environment. Even after an accidental release the substance will be neutralised finally and therefore the human exposure to sodium hydroxide via the environment is expected to be negligible. Therefore, no direct or systemic exposure via the environment is expected from sodium hydroxide.

Conclusion (ii).

Human health (physico-chemical properties)

Conclusion (ii) There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied.

This conclusion is reached because the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

European Commission
DG Joint Research Centre, Institute of Health and Consumer Protection
Toxicology and Chemical Substances (TCS)
European Chemicals Bureau

EUR 23040 EN/2 European Union Summary Risk Assessment Report
sodium hydroxide

Editors: K. Aschberger, O. Cosgrove, W. De Coen, B-O. Lund, S. Pakalin, A. Paya-Perez, S. Vegro.

Luxembourg: Office for Official Publications of the European Communities

2008 – VIII pp., 194 pp. – 17.0 x 24.0 cm

EUR – Scientific and Technical Research series; ISSN 1018-5593

The summary report provides the targeted risk assessment of the substance sodium hydroxide (NaOH) It has been prepared by Portugal in the frame of Council Regulation (EEC) No. 793/93 on the evaluation and control of the risks of existing substances, following the principles for assessment of the risks to man and the environment, laid down in Commission Regulation (EC) No. 1488/94. In this context ‘targeted’ means that not all endpoints, as defined in the Technical Guidance Documents (TGD), are addressed thoroughly in this risk assessment. In a targeted risk assessment one deviates therefore from the standard comprehensive risk assessment that covers all possible exposure routes of the chemical and all protection goals.

The evaluation considers the emissions and the resulting exposure to the environment and the human populations in all life cycle steps. However, considering the likely emission pathways, the environmental exposure assessment was targeted at the aquatic emissions, and consequently, the environmental risk characterisation was targeted at the aquatic compartment. For human health, the scenarios for occupational exposure, consumer exposure and humans exposed via the environment have been examined and the possible risks for local effects at the site of contact with sodium hydroxide (NaOH) have been identified.

Part I - Environment

The environmental risk assessment is targeted solely on the aquatic environment, as the emissions of NaOH mainly apply to waste water, and to effects on organisms/ecosystems due to possible local pH changes. Based on the results from a questionnaire among producers and users of sodium hydroxide, it is concluded that discharges of NaOH from production are well controlled, and that discharges from downstream applications rarely occur. Regarding surface water, the enforcement of the (EU) legislation is an important assumption for the conclusion of no concern for the aquatic environment.

Part II – Human Health

The human health risk assessment is targeted on the risks for local effects at the site of contact with NaOH, both for workers and consumers. For workers, there is concern that respiratory tract irritation may occur in the production when bagging NaOH, when using NaOH in aluminium and textile industry, and in the de-inking of waste paper in pulp and paper industry. For consumers, there is no concern for the normal use of NaOH, where it is assumed that the required protection is used. However, there are a high number of accidents (foreseeable misuse) that occur with NaOH, which points out that consumer protection against improper use of NaOH is insufficient. Because NaOH has local effects, there is concern for irritation and corrosivity for all routes of exposure (oral, dermal, ocular, and inhalatory exposure) after foreseeable misuse of NaOH by consumers. There is no concern for humans exposed via the environment or for the physico-chemical properties.

The conclusions of this report will lead to risk reduction measures to be proposed by the Commission's committee on risk reduction strategies set up in support of Council Regulation (EEC) N. 793/93.

