pH: >13 (0.5%)
Kinematic viscosity: Not applicable/Not available due to the nature/properties of the product
Solubility: Not applicable/Not available due to the nature/properties of the product
Hydrosolubility: 1090 g/l (20 ºC)
Liposolubility: Not applicable/Not available due to the nature/properties of the product
Partition coefficient n-octanol/water (log value): Not applicable/Not available due to the nature/properties of the product
Vapour pressure: 1 mbar (739 ºC)
Absolute density: Not applicable/Not available due to the nature/properties of the product
Relative density: 2.13
Relative vapour density: Not applicable/Not available due to the nature/properties of the product
Particle characteristics: Not applicable/Not available due to the nature/properties of the product

9.2 Other information
Viscosity: 10.5 (30% - 20 º)
Explosive properties: Not applicable/Not available due to the nature/properties of the product
Oxidizing properties: Not applicable/Not available due to the nature/properties of the product
Dropping point: Not applicable/Not available due to the nature/properties of the product
Blink: Not applicable/Not available due to the nature/properties of the product

SECTION 10: STABILITY AND REACTIVITY.

10.1 Reactivity.
The product does not present hazards by their reactivity.

10.2 Chemical stability.
Unstable in contact with:
- Metals.

10.3 Possibility of hazardous reactions.
May be corrosive to metals.

10.4 Conditions to avoid.
Avoid any improper handling.

10.5 Incompatible materials.
Avoid the following materials:
- Explosives materials.
- Oxidizing materials.

10.6 Hazardous decomposition products.
Depending on conditions of use, can be generated the following products:
- Corrosive vapors or gases.

SECTION 11: TOXICOLOGICAL INFORMATION.

11.1 Information on hazard classes as defined in Regulation (EC) Nº 1272/2008.
Splatters in the eyes can cause irritation and reversible damage.

Toxicological information.

Name	Acute toxicity			
	Type	Test	Kind	Value
sodium hydroxide, caustic soda CAS No: 1310-73-2 EC No: 215-185-5	Oral	LD50	Rabbit	325 mg/kg bw [1]
		[1] Naunyn-Schmiedeberg's (1937), Archiv für experimentielle|Pathologie und Pharmakologie (Berlin, Germany), 184,|587-604		
	Dermal			
	Inhalation			

-Continued on next page.-

a) acute toxicity;
Not conclusive data for classification.

b) skin corrosion/irritation;
Product classified:
Skin Corrosive, Category 1A: Causes severe skin burns and eye damage.

c) serious eye damage/irritation;
Not conclusive data for classification.

d) respiratory or skin sensitisation;
Not conclusive data for classification.

e) germ cell mutagenicity;
Not conclusive data for classification.

f) carcinogenicity;
Not conclusive data for classification.

g) reproductive toxicity;
Not conclusive data for classification.

h) STOT-single exposure;
Not conclusive data for classification.

i) STOT-repeated exposure;
Not conclusive data for classification.

j) aspiration hazard;
Not conclusive data for classification.

11.2 Information on other hazards.
Endocrine disrupting properties
This product does not contain components with endocrine-disrupting properties with effects on human health.
Other information
There is no information available on other adverse health effects.

SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.

Name	Ecotoxicity			
	Type	Test	Kind	Value
sodium hydroxide, caustic soda CAS No: 1310-73-2 EC No: 215-185-5	Fish	Minimal Lethal Concentration	Notropis sp.	100 mg/L (120 h) [1]
		[1] Van Horn et al. (1949), Effects of Kraft Mill Wastes,|American Fisheries Society		
	Aquatic invertebrates	Lethal	Daphnia magna	156 mg/L ( ) [1]
		[1] Environment Canada (1984), EnviroTIPS, Sodium Hydroxide, |Environmental Protection Services, Ottawa, Ontario		
	Aquatic plants			

12.2 Persistence and degradability.
No information is available regarding the biodegradability

-Continued on next page.-

No information is available on the degradability
No information is available about persistence and degradability of the product.

12.3 Bioaccumulative potential.
No information is available regarding the bioaccumulation.

12.4 Mobility in soil.
No information is available about the mobility in soil.
The product must not be allowed to go into sewers or waterways.
Prevent penetration into the ground.

12.5 Results of PBT and vPvB assessment.
No information is available about the results of PBT and vPvB assessment of the product.

12.6 Endocrine disrupting properties.
This product doesn't contain components with environmental endocrine disrupting properties.

12.7 Other adverse effects.
No information is available about other adverse effects for the environment.

SECTION 13: DISPOSAL CONSIDERATIONS.

13.1 Waste treatment methods.
Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.
Follow the provisions of Directive 2008/98/EC regarding waste management.

SECTION 14: TRANSPORT INFORMATION.

Transport following ADR rules for road transport, RID rules for railway, ADN for inner waterways, IMDG for sea, and ICAO/IATA for air transport.
Land: Transport by road: ADR, Transport by rail: RID.
Transport documentation: Consignment note and written instructions
Sea: Transport by ship: IMDG.
Transport documentation: Bill of lading
Air: Transport by plane: ICAO/IATA.
Transport document: Airway bill.

14.1 UN number or ID number.
UN No: UN1823

14.2 UN proper shipping name.
Description:
ADR/RID: UN 1823, SODIUM HYDROXIDE, SOLID, 8, PG II, (E)
IMDG: UN 1823, SODIUM HYDROXIDE, SOLID, 8, PG II
ICAO/IATA: UN 1823, SODIUM HYDROXIDE, SOLID, 8, PG II

14.3 Transport hazard class(es).
Class(es): 8

14.4 Packing group.
Packing group: II

14.5 Environmental hazards.
Marine pollutant: No
Transport by ship, FEm – Emergency sheets (F – Fire, S - Spills): F-A,S-B

14.6 Special precautions for user.
Labels: 8

-Continued on next page.-

Hazard number: 80
ADR LQ: 1 kg
IMDG LQ: 1 kg
ICAO LQ: 5 kg

Provisions concerning carriage in bulk ADR: Not authorized carriage in bulk in accordance with ADR.
Proceed in accordance with point 6.
IMDG Code segregation group: 18 Alkalis

14.7 Maritime transport in bulk according to IMO instruments.
The product is not transported in bulk.

SECTION 15: REGULATORY INFORMATION.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture.
The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.

The product is not affected by Directive 2012/18/EU (SEVESO III).
The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.
The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

Kind of pollutant to water (Germany): WGK 1: Slightly hazardous to water. (Autoclassified according to the AwSV Regulations)

15.2 Chemical safety assessment.
No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.
Available Product Exposure Scenario.

SECTION 16: OTHER INFORMATION.

Classification codes:

Met. Corr. 1 : Corrosive to metals, Category 1
Skin Corr. 1A : Skin Corrosive, Category 1A

Changes regarding to the previous version:

- Modification in the values of the physical and chemical properties (SECTION 9).
- Modification of the classification ADR/IMDG/ICAO/IATA/RID (SECTION 14).
- Addition of abbreviations and acronyms (SECTION 16).

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Physical hazards	On basis of test data
Health hazards	Calculation method
Environmental hazards	Calculation method

-Continued on next page.-

It is advisable to carry out basic training with regard to health and safety at work in order to handle this product correctly.

Information on the TSCA Inventory (Toxic Substances Control Act) USA:

CAS No	Name	State
1310-73-2	sodium hydroxide, caustic soda	Registered

Available Product Exposure Scenario.

Abbreviations and acronyms used:

ADR/RID:	European Agreement concerning the International Carriage of Dangerous Goods by Road.
AwSV:	Facility Regulations for handling substances that are hazardous for the water.
CEN:	European Committee for Standardization.
DMEL:	Derived Minimal Effect Level, exposure level corresponding to a low risk, that risk should be considered a tolerable minimum.
DNEL:	Derived No Effect Level, level of exposure to the substance below which adverse effects are not anticipated.
EC50:	Half maximal effective concentration.
PPE:	Personal protection equipment.
IATA:	International Air Transport Association.
ICAO:	International Civil Aviation Organization.
IMDG:	International Maritime Code for Dangerous Goods.
LC50:	Lethal concentration, 50%.
LD50:	Lethal dose, 50%.
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail.
WGK:	Water hazard classes.

Key literature references and sources for data:
http://eur-lex.europa.eu/homepage.html
http://echa.europa.eu/
Regulation (EU) 2020/878.
Regulation (EC) No 1907/2006.
Regulation (EU) No 1272/2008.

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemical substances and mixtures (REACH).

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.

-End of safety data sheet.-

ANNEX TO THE EXTENDED SAFETY DATA SHEET (eSDS)

EXPOSURE SCENARIOS

PRODUCT NAME :	Caustic soda
CAS NUMBER:	1310-73-2
EC NUMBER :	215-185-5
Reach Reg. No. :	Not applicable

Number of exposure scenario	List of exposure scenario
ES 1	Manufacturing of liquid NaOH
ES 2	Manufacturing of solid NaOH
ES 3	Industrial and professional use of NaOH
ES 4	Consumer use of NaOH

Table of Contents

EXPOSURE ASSESSMENT

The exposure scenarios are organised in 4 main scenarios:

- Manufacturing of liquid NaOH
- Manufacturing of solid NaOH
- Industrial and professional use of NaOH
- Consumer use of NaOH

The overview of exposure scenarios and coverage of substance life cycle can be found in Table . The exposure assessment is primarily based on the exposure assessment of the EU RAR for NaOH (2007). The RAR (2007) and the information collected at that time was used as starting basis for this dossier. When available, new data and information was added to the dossier.

Table 1 Overview on exposure scenarios and coverage of substance life cycle

Number and title	Manu-facture	Prepa-ration making	Industrial and/or wide disperse use	Consumer use	Article service life	Waste stage
ES1: Manufacturing of liquid NaOH	X					
ES2: Manufacturing of solid NaOH	X					
ES3: Industrial and professional use of NaOH		X	X			
ES4: Consumer use of NaOH				X		

Note on accidental exposure

Since accidental exposure is normally excluded from an EU chemical safety assessment and accidental exposure is considered in the EU RAR (2007; section 4.1.1.3.2, pages 59-62), accidental exposure will not be further assessed in this dossier. However, the risk management measures for consumers, identified in the NaOH risk reduction strategy (EU RRS, 2008) are included in the dossier.

1. EXPOSURE SCENARIO 1: MANUFACTURING OF LIQUID NAOH

In the EU RAR (2007), the required information related with occupational exposure at the production sites was collected through a questionnaire, developed by Euro Chlor in cooperation with the Rapporteur Member State. In the questionnaire the following issues were addressed: type of products (solid/liquid), number of workers, estimation of exposure based on tasks, exposure measurements and accidental exposure. The questionnaires were sent by Euro Chlor to 97% of the European chlorine production sites (a total of 86). A total number of 36 production sites (42%) responded to the questionnaire and based on these data a detailed report has been prepared (Euro Chlor, 2004c).

1.1 Exposure scenario

1.1.1 Short title of the exposure scenario

SU 3, 8: Manufacture of bulk, large-scale substances

PROC 1, 2, 3, 4, 8, 9: use in (closed) continuous or batch process with no likelihood of exposure or where opportunity for exposure arises (industrial setting), including charging, discharging, sampling and maintenance

PC and AC not applicable for this ES

1.1.2 Operational conditions

The amount used per worker varies from activity to activity. In the EU RAR (2007), the amount of product sampled ranged between 0.1 and 15 litres. The responses with the highest quantities were “15”, “2.2”, “2”, “3x1” and “few litres per day”. The remaining respondents replied that an amount of less than 1 kg was sampled.

The duration considered for this exposure scenario is a full working shift (8h/day) and 200 days/year. For sampling the “task duration in minutes per day” ranged between 1 and 600 minutes and the average duration was 71 minutes.

From the questionnaire and the EU RAR (2007), it can be concluded that nearly all production sites manufacture liquid NaOH with a concentration of about 50%. For 36% of the sites also other liquid products (between 10 and 75%) are manufactured with concentrations which were in general lower than 50%.

1.1.3 Risk management measures

1) Risk management measures related to workers

The risk management measures related to workers are summarized in Table 2. A distinction is made between measures that are required or compulsory and measures that indicate good practice.

Because sodium hydroxide is corrosive, the risk management measures for human health should focus on the prevention of direct contact with the substance. For this reason automated and closed systems should preferably be used for industrial and professional uses of sodium hydroxide. Respiratory protection is needed when aerosols of sodium hydroxide can be formed. Due to the corrosive properties appropriate skin and eye protection is required.

Table 2 Risk management measures related to workers

Information type	Data field	Explanation
Containment plus good work practice required	Good practice: replacing, where appropriated, manual processes by automated and/or closed processes. This	Situation at the time of the EU RAR (2007): The confinement was in general “semi closed” (18 sites). In the remaining cases the confinement was

Information type	Data field	Explanation

	would avoid irritating mists and subsequent potential splashes (EU RRS, 2008): • Use closed systems or covering of open containers (e.g. screens) (good practice) • Transport over pipes, technical barrel filling/emptying of barrel with automatic systems (suction pumps etc.) (good practice) • Use of pliers, grip arms with long handles with manual use "to avoid direct contact and exposure by splashes (no working over one's head)" (good practice)	"open" (6 sites) or "totally closed" (9 sites).
Local exhaust ventilation required plus good work practise	Local exhaust ventilation is not required but good practice.	To improve air quality and avoid potential respiratory track irritation in working areas Situation at the time of the EU RAR (2007): Only five sites had "local exhaust ventilation".
General ventilation	General ventilation is good practice unless local exhaust ventilation is present	To improve air quality and avoid potential respiratory track irritation in working areas. Situation at the time of the EU RAR (2007): General ventilation was present for 26 sites, while 5 sites had no "general ventilation" during sampling. Four sites had neither "general ventilation" nor "local exhaust ventilation".

Personal protection equipment (PPE) required under regular working conditions	• Respiratory protection: In case of dust or aerosol formation: use respiratory protection with approved filter (P2) <u>(required)</u> • Hand protection: impervious chemical resistant protective gloves <u>(required)</u> o material: butyl-rubber, PVC, polychloroprene with natural latex liner, material thickness: 0.5 mm, breakthrough time: > 480 min o material: nitrile-rubber, fluorinated rubber, material thickness: 0.35-0.4 mm, breakthrough time: > 480 min • Eye protection: chemical resistant goggles must be worn. If splashes are likely to occur, wear tightly fitting safety goggles, face –shield <u>(required)</u> • Wear suitable protective clothing, aprons, shield and suits, if splashes are	Situation at the time of the EU RAR (2007): In nearly all cases no PPE was used to protect against inhalation, but in all cases the skin and eyes were protected (e.g. safety glasses, full face mask, gloves, special clothes).
Information type	Data field	Explanation
	likely to occur, wear: rubber or plastic boots, rubber or plastic boots <u>(required)</u>	
Other risk management measures related to workers. For example: Particular training systems, monitoring/reporting or auditing systems, specific control guidance.	2008): easures are <u>required</u> (from EU RRS, • workers in the risky process/areas identified should be trained a) to avoid to work without respiratory protection and b) to understand the corrosive properties and, especially, the respiratory inhalation effects of sodium hydroxide and c) to follow the safer procedures instructed by the • employer (EU RRS, 2008). the employer has also to ascertain that the required PPE is available and used according to instructions	

2) Risk management measures related to environment

Risk management measures related to the environment aim to avoid discharging NaOH solutions into municipal wastewater or to surface water, in case such discharges are expected to cause significant pH changes. Regular control of the pH value during introduction into open waters is required. In general discharges should be carried out such that pH changes in receiving surface waters are minimised. In general most aquatic organisms can tolerate pH values in the range of 6-9. This is also reflected in the description of standard OECD tests with aquatic organisms.

1.1.4 Waste related measures

Liquid NaOH waste should be reused or discharged to the industrial wastewater and further neutralized if needed (see risk management measures related to environment).

1.2 Exposure estimation

1.2.1 Workers exposure

NaOH is a corrosive substance. For the handling of corrosive substances and formulations, immediate dermal contacts occur only occasionally and it is assumed that repeated daily dermal exposure can be neglected. Therefore according to the NaOH EU RAR (2007), dermal exposure to pure NaOH will not be assessed. Repeated dermal exposure cannot be neglected for these substances and formulations. Ocular exposure is possible due to hand-eye contact but this is not quantified.

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

Due to the low vapour pressure of NaOH, the atmospheric concentration of NaOH based on vaporisation from the liquid will be very low. Although the exposure to a vapour of NaOH is estimated to be very low, the task related data can not be used to predict the exposure to aerosols (mists). An overview of the estimated and measured exposure concentrations can be found in Table 3.

Table 3 Exposure concentrations for workers

Routes of exposure	Estimated Exposure Concentrations		Measured exposure concentrations		Explanation / source of measured data
	Value	unit	Value	unit	
Dermal exposure	Not available		Not available		
Inhalation exposure			AM: 0.14	mg/m^3	From EU RAR (2007) Range: 0.02 – 0.5 mg/m^3 Truck loading of liquid STAT measurement, N=17, 2002; 2003
			AM: 0.33	mg/m^3	From EU RAR (2007) Range: 0.29 – 0.37 mg/m^3 Liquid, other task Spot measurement, N=5, 2003
			AM: <0.26	mg/m^3	From EU RAR (2007) Liquid, other task STAT measurement, N=20, 2002
			AM: 0.01*	mg/m^3	From EU RAR (2007) Range: 0.05 – 0.18 mg/m^3 * Liquid, pearls, close to installation STAT measurement, N=109, 2002

	0.02 (typical) 0.04 (RWC)	mg/m^3			**From EU RAR (2007)** Drumming liquid NaOH Typical and reasonable worst case exposure level

STAT Stationary Air Sample
Spot Short term stationary sample
N Amount of measurements
AM Arithmetic mean * These values are considered not to be correct. A mean value can’t be lower than the range.

Measured data

In the EU RAR (2007), atmospheric exposure measurements are available for 6 production sites from 4 different countries (Czech Republic, Poland, Spain and United Kingdom). In all cases the concentrations were lower than 2 mg/m^3 (see Table 3). Most NaOH production sites replied that the OEL was 2 mg/m^3 in their country. The data of the production site in Spain are based on measurements of the sodium content, which were performed according to a norm of the National Institute for Worker Safety and Hygiene (NTP-63 of 1983). For this production site the sampling duration was 6-8 hours. Other sites reported that the measurements were based on a Polish standard method, a colorimetric method or on atomic absorption spectroscopy. The sampling duration was unknown for these sites. Modelled data

The ECHA guidance on information requirements proposes ECETOC TRA as the preferred Tier 1 tool. ECETOC TRA is based on a modified version of EASE. EASE was the preferred model under the New & Existing Substances Directive. EASE is known to overpredict exposures in many cases. The reason for this is considered to be the fact that EASE relies upon historical exposure data from enforcement activities in known problem areas, rather than the typical/normal operations that are required for more routine risk assessment. For this reason the values from the output from EASE were reviewed and modified accordingly in the ECETOC TRA. Both the EASE predictions (from EU RAR, 2007) and ECETOC TRA approaches were considered here.

Inhalation exposure to vapour due to drumming is estimated in the EU RAR (2007) with EASE 2.0. The exposure range is estimated 0 – 0.17 mg/m^3 (0 – 0.1 ppm, 20°C), assuming very low vapour pressure, no aerosol formation and non-dispersive use. Typical exposure is estimated as 0.085 mg/m^3 (middle value of range). The reasonable worst-case exposure is estimated as 0.17 mg/m^3 (upper value of range) assuming no aerosol formation and non-dispersive use with dilution ventilation. Following the questionnaire, it is assumed that in the present industry LEV is not generally available. Presence of LEV will not influence the exposure range in this estimation. Assuming a NaOH concentration of 50% the typical exposure is estimated to be 0.04 mg/m^3 and the reasonable worst case exposure is estimated to 0.085 mg/m^3. Frequency of exposure for drumming is estimated to be up to 200 days per year with a duration of up to 4 hours/day, while the number of workers involved is estimated to be up to 50 (expert judgment). Assuming 4 hours of handling and zero exposure during the remainder of the working day, 8-hour TWA typical exposure is estimated as 0.02 mg/m^3 and an 8-hour TWA reasonable worst case exposure is estimated as 0.04 mg/m^3.

Inhalation exposure to vapour or aerosols due to all PROCs is estimated in the ECETOC TRA and the inhalation exposure is 0.1 ppm (0.17 mg/m^3), assuming very low vapour pressure, exposure duration of more than 4 hours/day and no local exhaust ventilation or respiratory equipment.

Summary of the exposure values

Only one single value will be used for risk characterisation. A summary of exposure concentration for workers is given in table 4.

Table 4 Summary of exposure concentration for workers

Routes of exposure	Concentrations	Justification
Dermal exposure (in mg/cm^2)	Negligible	From EU RAR (2007): NaOH products with a concentration > 2% are corrosive, therefore effective control measures are in place to prevent dermal exposure. Furthermore protective clothing and gloves are considered to be used consistently when handling corrosive substances. Production companies report the use of protective gloves, suits and boots while handling pure NaOH. Repeated daily dermal exposure to commercial product is therefore considered negligible. Dilutions of NaOH containing < 2% are not produced at the production sites.
Inhalation exposure (in mg/m^3)	0.33	From EU RAR (2007): For drumming liquid NaOH the modelled data are underestimated by EASE in comparison with the measured data. Because there is a relatively large number of measured data, these will be used for risk characterisation. The value 0.33 mg/m^3 is taken as reasonable worst case level and 0.14 mg/m^3 is taken as typical exposure level.

1.2.2 Indirect exposure of humans via the environment (oral)

Indirect exposure to humans, for example through the uptake of drinking water, is not relevant for NaOH. Any potential for exposure to NaOH due to environmental releases will only have relrevance at the local scale. Any pH effect of local releases will be neutralised in the receiving water at the regional scale. Therefore indirect exposure of humans via the environment (oral) is not relevant in the case of NaOH (EU RAR, 2007).

1.2.3 Environmental exposure

As stated in the EU RAR on NaOH (2007), the risk assessment for the environment is only relevant for the aquatic environment, when applicable including STPs/WWTPs, as emissions of NaOH in the different life-cycle stages (production and use) mainly apply to (waste) water. The aquatic effect and 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 will be addressed, including sewage treatment plants (STPs) or waste water treatment plants (WWTPs) when applicable, both for production and industrial use. Any effects that might occur would be expected to take place on a local scale. Therefore it was decided not meaningful to include the regional and continental scale in this risk assessment. Furthermore, the high water solubility and very low vapour pressure indicate that NaOH will be found predominantly in water. Significant emissions or exposure to air are not expected due to the very low vapour pressure of NaOH. Significant emissions or exposure to the terrestrial environment are not expected either. The sludge application route is not relevant for the emission to agricultural soil, as sorption of NaOH to particulate matter will not occur in STPs/WWTPs.

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. 1) Environmental releases

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 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. The production capacity and the applied processes for all sites in the EU are presented in table 3 of CSR.

Since the exposure assessment focussed on possible pH changes in the local aquatic environment, industry collected actual data on pH values in effluent and receiving surface waters at NaOH production sites for the purpose of the EU RAR (2007), based on the results of a questionnaire that was sent to a broad cross section of

NaOH producers in the EU via Euro Chlor, representing 97% of NaOH production capacity in the enlarged Europe (Euro Chlor, 2004b). The results of this questionnaire (Euro Chlor, 2004c) provided effluent and receiving water data for 43 out of 84 production sites. The sites are anonymised by numbers which do not correspond to the numbers in table 3 of CSR. The 43 responding production sites are from 15 different EU countries with a wide geographical spread. The respondents include 34 sites in the old EU member states, 6 sites in the new EU member states, 2 in Norway and 1 in Switzerland (Euro Chlor, 2004c). The three major NaOH production processes, i.e. membrane, diaphragm and mercury process, were well represented among the respondents to the questionnaire. The production capacities of the sites that responded represented a very broad range from several tens of ktonne/year up to several hundreds of ktonne/year (Euro Chlor, 2004b).

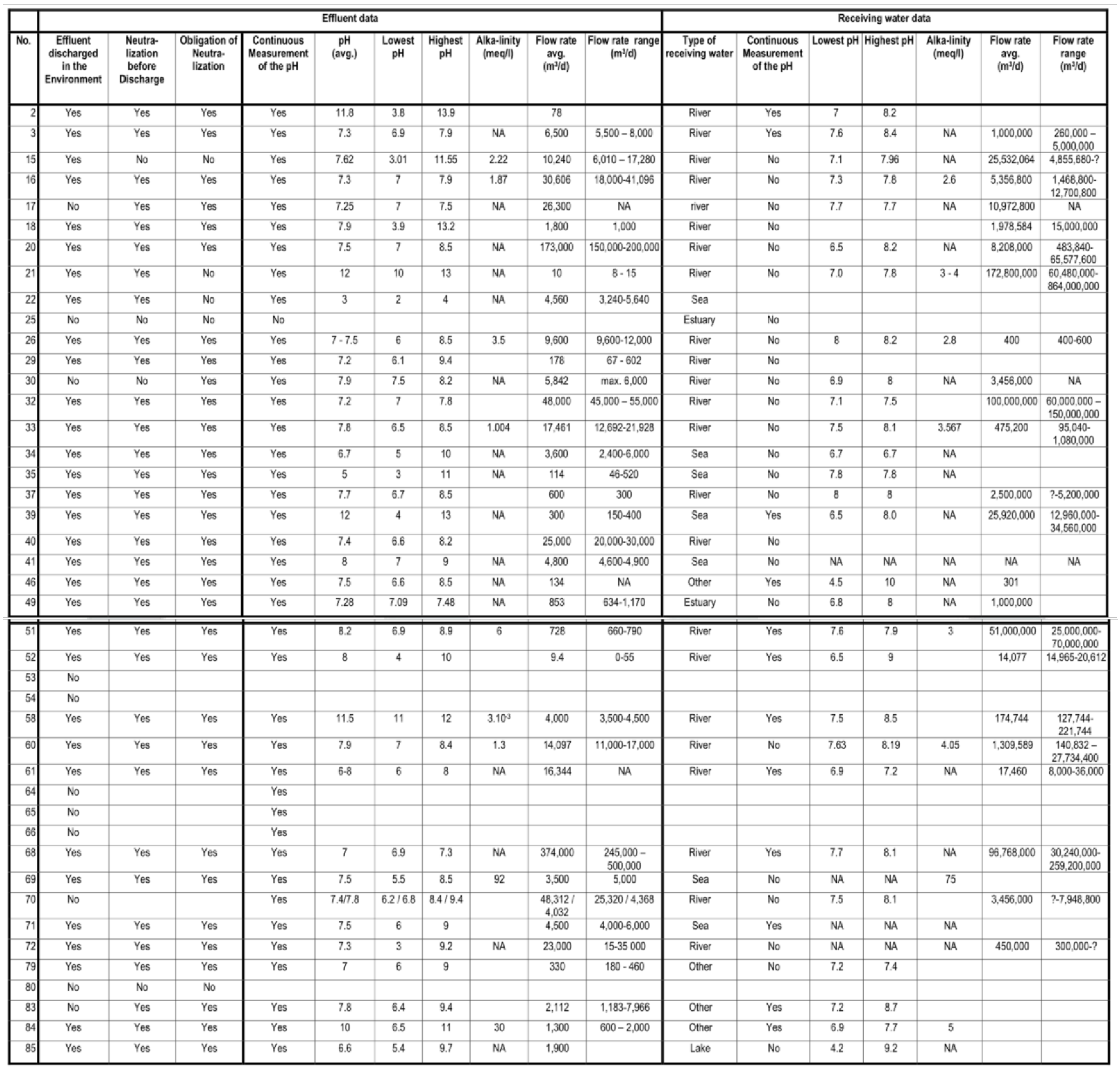
The questionnaire revealed that 11 sites do not have effluents which are discharged to the environment. On these specific sites the waste water can be completely recycled due to the specific on-site process conditions. The results also showed that out of 43 sites reporting, 31 sites neutralize their effluent before discharging into the receiving water. A total of 32 sites reported to be legally obliged to neutralize their effluent and 6 sites, which do not have effluents, did not respond to this question. However, 5 sites reported not to have such legal requirements, while 2 of these 5 sites reported actually to neutralize their effluents. One site (site 30) reports a legal obligation to neutralize but they do not adapt their pH, because the pH range of their effluent is already within a narrow range close to neutral.

According to Euro Chlor (2004c), many sites reported pH values for wastewater sub-streams instead of final effluents, even though they are included as ‘effluent data’ This was concluded from the fact that many sites reported broad ranges of pH values, but also indicated that final effluents were neutralised before discharging and from some subsequent checks with respondents. Substreams are normally combined with other wastewater sub-streams on the site before they are finally discharged into the receiving water. Therefore, the first two columns of

Table 5 on effluents are the most important with respect to the potential pH effect on receiving waters.

A total number of 36 production sites, including 2 sites (no. 17 and 30) that do not discharge their effluent into the environment, i.e. sewer or receiving water, reported measured pH values of the effluent. Of these 36 sites, 19 sites reported pH values within the range of 6-9 (range of lowest pH to highest pH), 7 sites reported pH values within the range of 5-10 and 10 sites reported pH values outside the range of 5-10. Most importantly, all but one of the sites that discharge effluent into the environment reported to neutralise their effluent before discharge. Only one site (no. 15) reporting a very wide effluent pH rang of 3.0-11.6 and stated not to neutralise its effluent before discharge. After contacting this site it became clear that the reported pH values for this site represented measurements in the wastewater sub-stream, immediately after leaving the production unit. Depending on the process conditions this can have the listed extreme values, which reportedly only last for 10-15 minutes because the wastewater sub-stream is then combined with other wastewater sub-streams at the site and the pH becomes circumneutral. Thereafter the final effluent (i.e. the combined wastewater sub-streams) enters a municipal sewage treatment plant before it is discharged into the receiving water. This site is not legally obliged to neutralise its effluent before discharge (Euro Chlor, 2004c). As all further sites that reported a high difference between the lowest and highest pH of the effluent also reported to neutralise their effluent, it can be assumed that for these sites the pH values are also for wastewater sub-streams (that are combined with other sub-streams before neutralisation of the final effluent) and not for the final effluents that are discharged into the environment. The results from the questionnaire, reported for 43 out of 84 production sites, demonstrate that the pH of waste water discharges is controlled and that generally proper regulations are in place.

Table 5 Effluent and receiving water data for NaOH producers in the EU (Euro Chlor, 2004c) (From EU RAR, 2007)



	Effluent data										Receiving water data						
No.	Effluent discharged in the Environment	Neutra-lization before Discharge	Obligation of Neutra-lization	Continuous Measurement of the pH	pH (avg.)	Lowest pH	Highest pH	Alka-linity (meq/l)	Flow rate avg. (m³/d)	Flow rate range (m³/d)	Type of receiving water	Continuous Measurement of the pH	Lowest pH	Highest pH	Alka-linity (meq/l)	Flow rate avg. (m³/d)	Flow rate range (m³/d)
2	Yes	Yes	Yes	Yes	11.8	3.8	13.9		78		River	Yes	7	8.2			
3	Yes	Yes	Yes	Yes	7.3	6.9	7.9	NA	6,500	5,500 – 8,000	River	Yes	7.6	8.4	NA	1,000,000	260,000 – 5,000,000
15	Yes	No	No	Yes	7.62	3.01	11.55	2.22	10,240	6,010 – 17,280	River	No	7.1	7.96	NA	25,532,064	4,855,680-?
16	Yes	Yes	Yes	Yes	7.3	7	7.9	1.87	30,606	18,000-41,096	River	No	7.3	7.8	2.6	5,356,800	1,468,800-12,700,800
17	No	Yes	Yes	Yes	7.25	7	7.5	NA	26,300	NA	river	No	7.7	7.7	NA	10,972,800	NA
18	Yes	Yes	Yes	Yes	7.9	3.9	13.2		1,800	1,000	River	No				1,978,584	15,000,000
20	Yes	Yes	Yes	Yes	7.5	7	8.5	NA	173,000	150,000-200,000	River	No	6.5	8.2	NA	8,208,000	483,840-65,577,600
21	Yes	Yes	No	Yes	12	10	13	NA	10	8 - 15	River	No	7.0	7.8	3 - 4	172,800,000	60,480,000-864,000,000
22	Yes	Yes	No	Yes	3	2	4	NA	4,560	3,240-5,640	Sea						
25	No	No	No	No							Estuary	No					
26	Yes	Yes	Yes	Yes	7 - 7.5	6	8.5	3.5	9,600	9,600-12,000	River	No	8	8.2	2.8	400	400-600
29	Yes	Yes	Yes	Yes	7.2	6.1	9.4		178	67 - 602	River	No					
30	No	No	Yes	Yes	7.9	7.5	8.2	NA	5,842	max. 6,000	River	No	6.9	8	NA	3,456,000	NA
32	Yes	Yes	Yes	Yes	7.2	7	7.8		48,000	45,000 – 55,000	River	No	7.1	7.5		100,000,000	60,000,000 – 150,000,000
33	Yes	Yes	Yes	Yes	7.8	6.5	8.5	1.004	17,461	12,692-21,928	River	No	7.5	8.1	3.567	475,200	95,040-1,080,000
34	Yes	Yes	Yes	Yes	6.7	5	10	NA	3,600	2,400-6,000	Sea	No	6.7	6.7	NA		
35	Yes	Yes	Yes	Yes	5	3	11	NA	114	46-520	Sea	No	7.8	7.8	NA		
37	Yes	Yes	Yes	Yes	7.7	6.7	8.5		600	300	River	No	8	8		2,500,000	?-5,200,000
39	Yes	Yes	Yes	Yes	12	4	13	NA	300	150-400	Sea	Yes	6.5	8.0	NA	25,920,000	12,960,000-34,560,000
40	Yes	Yes	Yes	Yes	7.4	6.6	8.2		25,000	20,000-30,000	River	No					
41	Yes	Yes	Yes	Yes	8	7	9	NA	4,800	4,600-4,900	Sea	No	NA	NA	NA	NA	NA
46	Yes	Yes	Yes	Yes	7.5	6.6	8.5	NA	134	NA	Other	Yes	4.5	10	NA	301	
49	Yes	Yes	Yes	Yes	7.28	7.09	7.48	NA	853	634-1,170	Estuary	No	6.8	8	NA	1,000,000	
51	Yes	Yes	Yes	Yes	8.2	6.9	8.9	6	728	660-790	River	Yes	7.6	7.9	3	51,000,000	25,000,000-70,000,000
52	Yes	Yes	Yes	Yes	8	4	10		9.4	0-55	River	Yes	6.5	9		14,077	14,965-20,612
53	No																
54	No																
58	Yes	Yes	Yes	Yes	11.5	11	12	3.10^{-3}	4,000	3,500-4,500	River	Yes	7.5	8.5		174,744	127,744-221,744
60	Yes	Yes	Yes	Yes	7.9	7	8.4	1.3	14,097	11,000-17,000	River	No	7.63	8.19	4.05	1,309,589	140,832 – 27,734,400
61	Yes	Yes	Yes	Yes	6-8	6	8	NA	16,344	NA	River	Yes	6.9	7.2	NA	17,460	8,000-36,000
64	No			Yes													
65	No			Yes													
66	No			Yes													
68	Yes	Yes	Yes	Yes	7	6.9	7.3	NA	374,000	245,000 – 500,000	River	Yes	7.7	8.1	NA	96,768,000	30,240,000-259,200,000
69	Yes	Yes	Yes	Yes	7.5	5.5	8.5	92	3,500	5,000	Sea	No	NA	NA	75		
70	No			Yes	7.4/7.8	6.2 / 6.8	8.4 / 9.4		48,312 / 4,032	25,320 / 4,368	River	No	7.5	8.1		3,456,000	?-7,948,800
71	Yes	Yes	Yes	Yes	7.5	6	9		4,500	4,000-6,000	Sea	Yes	NA	NA	NA		
72	Yes	Yes	Yes	Yes	7.3	3	9.2	NA	23,000	15-35 000	River	No	NA	NA	NA	450,000	300,000-?
79	Yes	Yes	Yes	Yes	7	6	9		330	180 - 460	Other	No	7.2	7.4			
80	No	No	No														
83	No	Yes	Yes	Yes	7.8	6.4	9.4		2,112	1,183-7,966	Other	Yes	7.2	8.7			
84	Yes	Yes	Yes	Yes	10	6.5	11	30	1,300	600 – 2,000	Other	Yes	6.9	7.7	5		
85	Yes	Yes	Yes	Yes	6.6	5.4	9.7	NA	1,900		Lake	No	4.2	9.2	NA		

2) Exposure concentration in waste water treatment plants (WWTP)

Waste water from NaOH production sites is coming from the salt electrolyses and is an inorganic wastewater stream. For this reason it is not feasible to treat it biologically. Therefore wastewater streams from NaOH production sites will normally not be treated in biological waste water treatment plants (WWTPs). NaOH may be used beneficially, however, for pH control of acid wastewater streams that are treated in biological WWTP's (EU RAR, 2007).

3) Exposure concentration in aquatic pelagic compartment

If emitted to surface water, sorption to particulate matter and sediment will be negligible. An addition of NaOH to surface water may increase the pH, depending on the buffer capacity of the water. The higher the buffer capacity of the water, the lower the effect on pH will be. In general the buffer capacity preventing shifts in acidity or alkalinity in natural waters is regulated by the equilibrium between carbon dioxide (CO_2), the bicarbonate ion (HCO_3^-) and the carbonate ion (CO_3^{2-}):

$$CO_2 + H_2O <-> HCO_3^- + H^+ \qquad (pKa1 = 6.35)$$

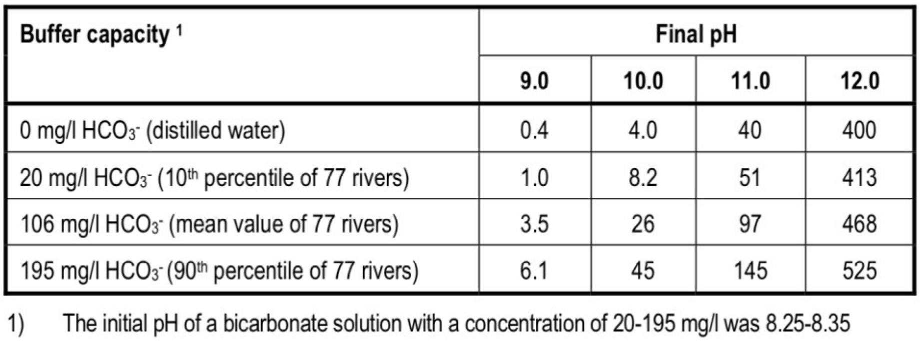
$HCO_3^- \leftrightarrow CO_3^{2-} + H^+$ (pKa2 = 10.33)

If the pH is < 6, un-ionised CO_2 is the predominant species and the first equilibrium reaction is most important for the buffer capacity. At pH values of 6-10 the bicarbonate ion (HCO_3^-) is the predominant species and at pH values > 10 the carbonate ion (CO_3^{2-}) is the predominant species. In the majority of natural waters the pH values are between 6 and 10, thus the bicarbonate concentration and the second equilibrium reaction are most important for the buffer capacity (Rand, 1995; De Groot et al., 2002; OECD, 2002). 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 concentrations were 20, 106 and 195 mg/l, respectively (OECD, 2002). To underline the importance of the bicarbonate concentration for the buffer capacity in natural waters, Table 6 summarises the concentration of NaOH needed to increase the pH from an initial pH of 8.258.35 to a value of 9.0, 10.0, 11.0 and 12.0 at different bicarbonate concentrations. The data of Table are based on calculations but were confirmed by experimental titrations of bicarbonate (HCO_3^-) concentrations of 20, 106 and 195 mg/l, respectively, in purified water. The difference between the calculated and measured NaOH concentration needed to obtain a certain pH value was always < 30% (De Groot et al., 2002; OECD, 2002). The data in Table 6 for distilled water are from OECD (2002).

The alkalinity, defined as the acid-neutralising (i.e. proton accepting) capacity of the water, thus the quality and quantity of constituents in water that result in a shift in the pH toward the alkaline site of neutrality, is determined for > 99% by the concentrations of bicarbonate (HCO_3^-), carbonate (CO_3^{2-}) and hydroxide (OH^-) (Rand, 1995), with bicarbonate being the predominant species at pH values in the range of 6-10 (see also above). Hydroxide is only relevant in alkaline waters. Thus, the data in Table 6 are useful to estimate pH increases in natural waters (most of them having a pH value of 7-8), if data on NaOH additions and bicarbonate concentrations are available. The alkalinity is determined from acid/base titration or can be calculated from the calcium concentration, as follows (De Schampelaere et al., 2003; Heijerick et al., 2003):

$$\text{Log (alkalinity in eq/l)} = -0.2877 + 0.8038 \text{ Log (Ca in eq/l)}$$

Table 6 Concentration of NaOH (mg/l) needed to increase the pH to values of 9.0, 10.0, 11.0 and 12.0 (De Groot et al., 2002; OECD, 2002)



Buffer capacity [1]	Final pH			
	9.0	10.0	11.0	12.0
0 mg/l HCO_3^- (distilled water)	0.4	4.0	40	400
20 mg/l HCO_3^- (10th percentile of 77 rivers)	1.0	8.2	51	413
106 mg/l HCO_3^- (mean value of 77 rivers)	3.5	26	97	468
195 mg/l HCO_3^- (90th percentile of 77 rivers)	6.1	45	145	525

1) The initial pH of a bicarbonate solution with a concentration of 20-195 mg/l was 8.25-8.35

Based on the neutralized environmental releases and the fate in the aquatic compartment described above, there is no environmental impact on the receiving surface water. 4) Exposure concentration in sediments

The sediment compartment is not included in this CSA, because it is not considered relevant for NaOH. If emitted to the aquatic compartment, sorption to sediment particles will be negligible (EU RAR, 2007). 5) Exposure concentrations in soil and groundwater

The terrestrial compartment is not included in this CSA, because it is not considered relevant for NaOH. With respect to the fate of NaOH in soil the following information is available. 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 (EU RAR, 2007).

6) Atmospheric compartment

The air compartment is not included in this CSA because it is considered not relevant for NaOH. With respect to the fate of NaOH in air the following information is available from EU RAR (2007). If emitted to air as an aerosol in water, NaOH will be rapidly neutralised as a result of its reaction with CO_2 (or other acids), as follows:

$NaOH + CO_2 \rightarrow HCO_3^- + Na^+$

Subsequently, the salts (e.g. sodium (bi)carbonate) will be washed out from the air (US EPA, 1989; OECD, 2002). Thus, atmospheric emissions of neutralised NaOH will largely end up in soil and water. Based on a NaOH concentration of 50% in the aerosol droplets, the atmospheric half-life of NaOH was estimated at 13 seconds. Based on model calculations, this degradation rate results in only 0.4% of the NaOH emitted to air remaining in the air at a point 200 metres from the emission point (U.S. EPA, 1988; 1989). 7) Exposure concentration relevant for the food chain (Secondary poisoning)

Bioaccumulation in organisms is not relevant for NaOH. Therefore, there is no need to perform a risk assessment for secondary poisoning (EU RAR, 2007).

2. EXPOSURE SCENARIO 2: MANUFACTURING OF SOLID NAOH

2.1 Exposure scenario

2.1.1. Short title of the exposure scenario

SU 3, 8: Manufacture of bulk, large scale substances

PROC 1, 2, 3, 4, 8, 9: use in (closed) continuous or batch process with no likelihood of exposure or where opportunity for exposure arises (industrial setting), including charging, discharging, sampling and maintenance

PC and AC not applicable for this ES

2.1.2 Operational conditions

Flakes can be packed in bags (25 or 50 kg). Micro pearls are packed in bags, bulk bags (500 or 1,000 kg) but it is also delivered in bulk (by road). Cast is delivered in metallic drums (e.g. 400 kg). However, it should be realised that other packaging forms could exist.

Solid NaOH (flakes, pearls or cast) is produced at 23% of the production sites. The shifts can be 12 hrs/day (40 hours/week).

2.1.3 Risk management measures

Risk management measures related to workers

Relevant risk management measures related to workers are described in section 1.1.3.

Risk management measures related to environment

Relevant risk management measures related to environment are described in section 1.1.3.

2.1.4 Waste related measures

There is no solid waste of NaOH. Liquid NaOH waste should be reused or discharged to the industrial wastewater and further neutralized if needed (see risk management measures related to environment).

2.2 Exposure estimation

2.2.1 Workers exposure

NaOH is a corrosive substance. For the handling of corrosive substances and formulations, immediate dermal contacts occur only occasionally and it is assumed that repeated daily dermal exposure can be neglected. Therefore according to the NaOH EU RAR (2007), dermal exposure to pure NaOH will not be assessed. Repeated dermal exposure cannot be neglected for these substances and formulations.

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

An overview of the estimated and measured exposure concentrations for inhalation can be found in Table .

Table 7 Exposure concentrations to workers

	Estimated Exposure Concentrations		Measured exposure concentrations		Explanation / source of measured data
Routes of exposure	Value	unit	Value	unit	
Inhalation exposure			AM: 0.84	mg/m^3	**From EU RAR (2007):** Range: 0.1 – 1.8 mg/m^3 Drumming/Bagging of liquid, cast, pellets PAS measurement, N=10, 2003
			AM: 0.09	mg/m^3	**From EU RAR (2007):** Range: 0.01 – 0.27 mg/m^3 Drumming/Bagging of liquid, cast, pearls PAS measurement, N=12, 2003
			AM: 0.05	mg/m^3	**From EU RAR (2007):** Range: 0.01 – 0.1 mg/m^3 Drumming of liquid, cast, pearls STAT measurement, N=20, 2003
			AM: 0.11 90P: 0.269	mg/m^3	**New industry data:** Pelletization belt: Range: 0.03 – 0.51 mg/m^3 Filling: Range: 0.11 – 0.38 mg/m^3 PAS, More details, see text
	2.5	mg/m^3			Maximum EASE and ECETOC TRA simulations

PAS	Personal Air Sample
STAT	Stationary Air Sample
N	Amount of measurements
AM	Arithmetic mean
*	These values are considered not to be correct. A mean value can't be lower than the range.

Measured data

In the EU RAR (2007), atmospheric exposure measurements are available for 6 production sites from 4 different countries (Czech Republic, Poland, Spain and United Kingdom). In all cases the concentrations were lower than 2 mg/m^3 (see Table 14). Most NaOH production sites replied that the OEL was 2 mg/m^3 in their country. One operation with the possibility of exposure is sampling. It is assumed that all the measurement at drumming/bagging was done with solid NaOH. The data of the production site in Spain are based on measurements of the sodium content, which were performed according to a norm of the National Institute for Worker Safety and Hygiene (NTP-63 of 1983). For this production site the sampling duration was 6-8 hours. Other sites reported that the measurements were based on a Polish standard method, a colorimetric method or on atomic absorption spectroscopy. The sampling duration was unknown for these sites. In one company, significant higher exposures were observed.

A new data set was gathered from an open system with local exhaust ventilation. Sampling was done with air pump, flow going thorough the filter. NaOH is dissolved in with water and excess of HCl. The rest of HCl is titrated with KOH. Indicator is methylred. This analytical method is compliant with NIOSH 7401. The exposure time was 340 or 505 minutes. These relate to a 8 and 12 hour shift respectively. The exposure was zero during the remaining time of the shift. Measurements were done during one shift. The number of workers is 3 per shift and the amount of substance handled: 7 ton per shift. The size of packing is 25-1000 kg. The process was an open system and had local ventilation installed (20 m^3/hour). No respiratory protection was used. The ECHA guidance on information requirements R.14 suggests to take the 75th percentile for large databases and the 90th percentile for smaller databases. Therefore, the 90th percentile of 0.269 mg/m^3 was selected as a reasonable worst-case estimate. Also note that no respiratory tract effects were observed among the workers.

Modelled data

Considering the particle size distribution (more than 90% larger than 100 µm) of the substance other assumptions than the default assumptions "production and processing of powders" were used in the EU RAR (2007) to estimate inhalation exposure to dust with EASE 2.0. Typical exposure is estimated to be 0-1 mg/m^3, assuming low dust technique in the presence of LEV. The reasonable worst case exposure is estimated to be 0-5 mg/m^3, assuming the absence of LEV. Frequency of exposure for drumming is estimated to be up to 200 days per year with a duration of up to 4 hours/day, while the number of workers involved is estimated to be up to 50 (expert judgement). Assuming 4 hours of handling and zero exposure during the remainder of the working day, 8-hour TWA typical exposure is estimated as 0 – 0.5 mg/m^3 and the 8-hour TWA reasonable worst case exposure is estimated as 0 – 2.5 mg/m^3.

Considering low dustiness, no LEV and no respiratory protection, ECETOC TRA predicts inhalative exposure of 0.01 mg/m^3 for PROC 1 and PROC 2, 0.1 mg/m^3 for PROC 3 and PROC 9, 0.5 mg/m^3 for PROC 4 and PROC 8a. Following the EU RAR (2007) by assuming 4 hours of handling and zero exposure during the remainder of the working day, 8-hour TWA typical exposure is estimated as 0 – 0.5 mg/m^3 and the 8-hour TWA reasonable worst case exposure is estimated as 0 – 2.5 mg/m^3.

Summary of the exposure values

The summary of exposure concentrations to workers, taken forward to risk characterization is given in Table 8.

Table 8 Summary of exposure concentration to workers

Routes of exposure	Concentrations	Justification
Dermal exposure (in mg/cm^2)	Negligible	From EU RAR (2007): NaOH products with a concentration > 2% are corrosive, therefore effective control measures are in place to prevent dermal exposure. Furthermore protective clothing and gloves are considered to be used consistently when handling corrosive substances. Production companies report the use of protective gloves, suits and boots while handling pure NaOH. Repeated daily dermal exposure to commercial product is therefore considered negligible. Dilutions of NaOH containing < 2% are not possible for solid NaOH.
Inhalation exposure (in mg/m^3)	0.269	Highest exposures are measured at the drumming/bagging place and therefore these values are taken to the risk characterisation.

2.2.2 Indirect exposure of humans via the environment (oral)

Indirect exposure to humans, for example through the uptake of drinking water, is not relevant for NaOH. Any potential for exposure to NaOH due to environmental releases will only have relrevance at the local scale. Any pH effect of local releases will be neutralised in the receiving water at the regional scale. Therefore indirect exposure of humans via the environment (oral) is not relevant in the case of NaOH (EU RAR, 2007).

2.2.3 Environmental exposure

Sodium hydroxide will rapidly dissolve and dissociate in water when released to water. The environmental exposure assessment for solid sodium hydroxide is consequently the same as for liquid sodium hydroxide. The reader is referred to section 1.2.3.

3. EXPOSURE SCENARIO 3: INDUSTRIAL AND PROFESSIONAL USE OF NAOH

To collect the required information related with occupational exposure when using NaOH for the purpose of the EU RAR (2007), a questionnaire has been developed by Euro Chlor in cooperation with the Rapporteur Member State Portugal. In September 2004 questionnaires have been sent by e-mail to:

- The Confederation of European Paper Industries (CEPI). They have forwarded the questionnaires to their members (paper producing companies which use NaOH).

- Five different contact persons from Euro Chlor member companies (NaOH producers). Afterwards each producer of NaOH has sent the questionnaire to 20 customers (in most cases end users of NaOH).

The responses were analysed and the results reported by Euro Chlor (2005).

A total number of 58 replies were received, originating from about 10 different EU member states. The majority (59%) originated from the pulp and paper industry and and therefore the data for this sector can be considered as highly representative for the situation in Europe. For the pulp and paper industry one questionnaire was received from Germany (National Federation), which represented the common practice in this country.

The response from other industry customers was less but still covered a broad range of applications of NaOH. A total of 17 questionnaires (29%) were received from the chemical industry (e.g. production of crop protection chemicals, organic pigments, epoxy resins). The remaining 7 questionnaires were received from steel industry, textile industry, rubber production, food industry, metal industry, aluminium industry and distribution. This shows that 23 end users of NaOH replied, while one distributor completed the questionnaire. In most cases the NaOH was used as a reactant during the manufacturing/production of chemicals. In a few other cases it was used for neutralisation (steel industry, rubber production), cleaning and water treatment (food industry) or for extraction (aluminium industry).

3.1 Exposure scenario

3.1.1 Short title of the exposure scenario

Sodium hydroxide could be used according to the following process categories (PROC):

PROC1	Use in closed process, no likelihood of exposure
PROC2	Use in closed, continuous process with occasional controlled exposure
PROC3	Use in closed batch process (synthesis or formulation)
PROC4	Use in batch and other process (synthesis) where opportunity for exposure arises
PROC5	Mixing or blending in batch processes (multistage and/or significant contact)
PROC8a/b	Transfer of chemicals from/to vessels/large containers at (non)dedicated facilities
PROC9	Transfer of chemicals into small containers (dedicated filling line)
PROC10	Roller application or brushing
PROC11	Non industrial spraying
PROC13	Treatment of articles by dipping and pouring
PROC15	Use of laboratory reagents in small scale laboratories

The process categories mentioned above are assumed to be the most important ones but other process categories could also be possible (PROC 1 – 27).

Sodium hydroxide can be used in many different chemical product categories (PC). It can be used for example as an adsorbent (PC2), metal surface treatment product (PC14), non-metal-surface treatment product (PC15), intermediate (PC19), pH regulator (PC20), laboratory chemical (PC21), cleaning product (PC35), water softener (PC36), water treatment chemical (PC37) or extraction agent. However, it could potentially also be used in other chemical product categories (PC 0 – 40).

Because sodium hydroxide has so many uses and is used so widely it can potentially be used in all sectors of use (SU) described by the use descriptor system (SU 1-24). 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 (30%) and inorganics (13%). Other uses are in the sectors pulp and paper industry (12%), aluminium and metal industry (7%), 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 (Euro Chlor, 2009). The sector of use 21 is considered in Exposure Scenario 4.

Although sodium hydroxide can be used during the manufacturing process of articles, the substance is not expected to be present in the article. The article categories (AC) do not seem applicable for sodium hydroxide.

To assess the environmental exposure of substances environmental release categories (ERC) have been developed for REACH. For sodium hydroxide the following environmental release categories could be applicable:

ERC1	Manufacture of substances
ERC2	Formulation of preparations
ERC4	Industrial use of processing aids in processes and products, not becoming part of articles
ERC6A	Industrial use resulting in manufacture of another substance (use of intermediates)
ERC6B	Industrial use of reactive processing aids
ERC7	Industrial use of substances in closed systems
ERC8A	Wide dispersive indoor use of processing aids in open systems
ERC8B	Wide dispersive indoor use of reactive substances in open systems
ERC8D	Wide dispersive outdoor use of processing aids in open systems
ERC9A	Wide dispersive indoor use of substances in closed systems

The environmental release categories mentioned above are assumed to be the most important ones but other industrial environmental release categories could also be possible (ERC 1 – 12). The wide-dispersive uses are considered in Exposure Scenario 4.

3.1.2 Description of activities, processes and operational conditions covered in the exposure scenario

Typcial uses for NaOH solids are: dilution in water, dilution in methanol (biodiesel industry) and solids as drain unblockers. Typical uses for liquid NaOH are given below. 1) Production of chemicals

NaOH is used for the production of organic and inorganic chemicals which end up in a broad variety of end products (Euro Chlor, 2009). At the production sites of organic and inorganic chemicals, NaOH is used as pH stabiliser or as reactant for synthesis of other chemicals. In all cases NaOH must be added to a reaction vessel and will react after which no NaOH is left. In some plants NaOH is recycled to the process. 2) Formulation of chemicals

Occupational exposure can occur during production of formulations. Especially during loading and mixing a higher exposure can be expected. High exposures can occur during the production process of the cleaning products, when loading concentrated NaOH, which typically involves pumping or pouring a fluid from a barrel or a drum into a process vessel. Inhalation exposure during loading may take place due to vapours or aerosols formed when the barrel or drum is opened and when adding the product to the process. NaOH will be diluted after loading into a tank.

3) Production and whitening of paper pulp

The major applications of NaOH in the paper and pulp industry are pH regulation, pulping, bleaching reactant, cleaning agent, water treatment for steam production and demineralisation (Euro Chlor, 2005). Paper and pulp mills produce acid effluents and NaOH is used in waste water treatment for neutralisation, for example of strongly acidic condensate from vaporation of spent liquor. No surplus NaOH is discharged to the WWTP and/or in the receiving water (Euro Chlor, 2005). Other examples of pulp and paper processes using NaOH are:

- Kraft pulping, which is full chemical pulping with NaOH and Na_2S, pH above 12, 800 kPa (120 psi). Modern kraft pulping is usually carried out in a continuous digester often lined with stainless steel and exposure to NaOH is then expected to be minimised. The temperature of the digester is raised slowly to approximately 170°C and held at that level for approximately 3 to 4 hours. The pulp is screened to remove uncooked wood, washed to remove the spent cooking mixture, and send either to the bleach plant or to the pulp machine. At the end of the process step, sodium hydroxide is reformed in the recausticizing plant

(EOHS, 2001).

- The so-called extended delignification, which are techniques to remove more lignin prior to bleaching. NaOH and heat act to break complex bonds in the lignin to make them soluble in water or volatile. NaOH and heat also break bonds in the cellulose reducing strength and yield. To do this, wood pulp and chemicals (NaOH, Na_2S) are cooked together in a pressure vessel (digester) which can be operated on a batch or continuous basis. In case of batch filling the digester is filled through a top opening. This can cause exposure to the used chemicals.

- The bleaching process in the so-called alkali extraction where the organic acids and alcohols react with the NaOH to form organic sodium compounds and water. These organic substances dissolve in water. Here NaOH is used to create a high pH to optimise the bleaching process. NaOH is not the bleaching agent. The purpose of the bleaching is to remove lignin without damaging the cellulose.

- Waste paper recycling: adding water, NaOH, and heat repulps recycled material. The pulp is then used to make a finished paper product on a paper machine in the same manner as in a virgin paper mill. 4) Production of aluminium and other metals

NaOH is used in the treatment of bauxite, from which alumina, the basis of aluminium, is extracted. Aluminium is produced from bauxite by the Bayer process. Mixed with steam and a (strong) NaOH solution, alumina in the bauxite forms a concentrated sodium aluminate solution leaving undissolved impurities. The conditions to extract the monohydrate alumina are about 250˚C and a pressure of about 3,500 kPa (Queensland Alumina Limited, 2004)). At the end of the process NaOH is returned to the start and used again. Relatively high inhalation exposure to NaOH is expected to be caused during the mixing of bauxite with NaOH and steam due to the high temperatures and high concentrations of NaOH. In the stage of surface treatment of aluminium finished products, NaOH is used for pickling (Euro Chlor, 2005). 5) Food industry

NaOH can be used for a large number of applications in the food industry. In the food production sector, NaOH is regularly used for (Euro Chlor, 2005):

- washing and cleaning of bottles, processes and equipment;
- chemical peeling/shelling of fruits and vegetables;
- modification of starch;
- preparation of carboxyl methyl cellulose;

- preparation of salts such as sodium citrate and sodium acetate. 6) Water treatment

NaOH is widely used in the treatment of water. In sewage treatment stations, NaOH allows the neutralisation of effluent and a reduction in the hardness of water. In industry, NaOH allows the regeneration of ion exchange resins. NaOH is currently used in water treatment with various objectives:

- control of the water hardness;
- regulation of the pH of water;
- neutralisation of effluent before the water is discharged;
- regeneration of ion exchange resins;
- elimination of heavy metal ions by precipitation.

NaOH is also used for the cleaning of combustion or incineration flues. Among the technologies used, the washing of gases in a scrubber using alkaline solutions is a process offered by a large number of engineering companies. The concentrations of NaOH solutions used vary according to the application, the level of performance to be achieved, financial situation, etc. The level of scrubbing performance of this technology allows reductions in acid components (HCl, SO_2, etc.) and in heavy metals (Hg, Cd, etc.) to comply with the requirements of international and national standards (Euro Chlor, 2004a, 2005). 7) Production of textiles

Besides natural materials such as wool, cotton or linen, synthetic fibres are extensively used by the textile industry. Cellulose textiles, obtained by the viscose process (rayon, spun rayon) have a significant market share. At present (2004) annual world production of cellulose textiles easily exceeds 3 million tonnes. Their manufacture consumes considerable tonnages of NaOH, were 600 kg of NaOH is needed to produce a tonne of cellulose fibres. The function of NaOH in the production of cellulose is unknown. NaOH is also used as general processing aid such as neutralisation.

In the viscose process, cellulose derived from wood pulp is steeped in a sodium hydroxide solution (20-25%), and the excess liquid is squeezed out by compression to form alkali cellulose. Impurities are removed and, after being torn into shreds similar to white crumbs that are allowed to age for several days at controlled temperature, the shredded alkali cellulose is transferred into another tank were it is treated with carbon disulphide to form cellulose xanthate. These are dissolved in diluted sodium hydroxide to form a viscous orange liquid called viscose. The acids and alkalis used in the process are fairly dilute, but there is always danger from the preparing of the proper dilutions and splashes into the eyes. The alkaline crumbs produced during the shredding may irritate workers' hand and eyes. The major part of the sodium hydroxide used in the textile industry is used in the mercerization, bleaching, scouring and washing of cotton. 8) Other industrial uses

NaOH is further applied in various other industrial sectors such as in production of surfactants, soaps, mineral oils, bleach, phosphates, cellulose and rubber (Euro Chlor, 2009). In most of these applications NaOH also serves as a process aid, such as neutralisation.

9) Professional end use of formulated products

NaOH is used during the production phase of various cleaning products although in most case the amounts in the end products are limited. The NaOH used will interact with other ingredients in acid-base reactions and thus practically no free NaOH is left in the final product. Product categorization for professional cleaning products with remaining free NaOH after formulation can be found in the table below.

Product type	'free NaOH' content	pH range	Remarks concerning RMM/OC

Floor strippers	<10%	>13	
Oven cleaners	5-20%	>13	
Floor degreasers	<5%	>12.5	
Drain openers	<30%	>13	
Dish washing products	5-30%	>13	(concentrated product)
Interior heavy duty cleaners	<5%	>12.5	

Professional oven cleaners

Oven cleaners are strong degreasers and they are suitable for removing dirt stuck on ovens, grills, etc. Oven cleaners contain strong alkaline ingredients. Strong alkali is necessary to remove burned-on soils. There are trigger sprays and spray cans. When using a spray can, foam is formed on the target area. After spraying, the oven door is closed and the foam has to soak 30 minutes. Then the oven is wiped clean with a wet cloth or sponge and one has to rinse frequently. The maximum content of sodium hydroxide in a spray can is 10%. The product is either a gel, which leads to large droplets upon spraying (100% >10 µm), or a liquid which is apllied as a foam with a special trigger also leading to less aerosol.

The frequency of application is 1 event per day and the duration is 10 minutes per event. Spraying into cold oven, with potential exposure to hands and arms. One can spray up to 1g product per second, by hand-held ready-to-use trigger spray or foam sprayer.

Professional floor strippers

Floor strippers in the I&I (Industrial and Institutional) area are not used neat. The highly alkaline products are dosed 15-20% and per 10 m^2 1-2 L stripper solution is brought onto the floor with a single disc machine. Usually 10-15 min acting time are necessary between laying down and scrubbing the floor. Afterwards the stripper/polish mixture is removed by a fat vacuum cleaner.

Drain cleaners

Drain openers open slow running and obstructed drains by dissolving and by loosening grease and organic waste. There are different kinds of drain openers, products containing either sodium hydroxide or sulphuric acid. Liquid drain openers have a maximum NaOH content of 30%. The use of liquid drain openers is comparable with the dosing of liquid cleaners. The drain opener must be dosed slowly down the drain. Pellets, which can also be use for opening the drain, have contents up to 100%. The drain opener must be dosed slowly down the drain. One has to wait at least 15 minutes so that the drain opener can clear the blockage.

Professional hair straightening products

Several hair straightening products used by professional hairdressers contain a certain amount of NaOH. Hair straightening products, containing more than 2% of NaOH, are applied to the hair with a brush and after a period of interaction with the hair the product is rinsed out with water. For estimating worker exposure no relevant inhalation exposure is expected because of the low volatility and the lack of aerosol formation. Dermal exposure is only relevant when concentrations of NaOH are below 2%, which probably will occur when the product is rinsed out of the hair. Above 2% the product will be corrosive which means control measures are expected to prevent dermal exposure. The exposure is therefore expected to occur mainly when the hairdresser decided to do a final rinsing step after the first rinsing is done.

3.1.3 Risk management measures

1) Risk management measures related to industrial workers

The risk management measures related to industrial workers can be found in Table . This table applies to both liquid and solid NaOH containing products at concentration > 2%. Because sodium hydroxide is corrosive, the risk management measures for human health should focus on the prevention of direct contact with the substance. For this reason automated and closed systems should preferably be used for industrial uses of sodium hydroxide. Respiratory protection is needed when aerosols of sodium hydroxide can be formed. Due to the corrosive properties appropriate skin and eye protection is required.

Table 9 Risk management measures releated to workers

Information type	Data field	Explanation
Containment plus good work practice required	Good practice: replacing, where appropriated, manual processes by automated and/or closed processes. This would avoid irritating mists, sprayings and subsequent potential splashes (EU RRS, 2008): • Use closed systems or covering of open containers (e.g. screens) (good practice) • Transport over pipes, technical barrel filling/emptying of barrel with automatic systems (suction pumps etc.) (good practice) • Use of pliers, grip arms with long handles with manual use "to avoid direct contact and exposure by splashes (no working over one's head)" (good practice)	**Situation at the time of the EU RAR (2007) for pulp and paper industry:** Almost all plants (97%) indicated having an automated closed system. Still 50% indicated that handling with NaOH still occurs during (re)filling of tanks/containers, cleaning, maintenance, unloading lorries, adding reactant, emptying drums or bags and sampling (average of 4 workers per plant). **Situation at the time of the EU RAR (2007) for chemical industry:** Highest inhalation exposure is expected to occur by loading NaOH from tanker to process vessel. Most of the industries use a closed and/or automated process and liquid 50% NaOH. **Situation at the time of the EU RAR (2007) for textile industry**: Exposure to NaOH can occur when steeping woodpulp and during dissolving cellulose xanthate. Most of the industries use a closed and/or automated process. The NaOH will not be sprayed.
Local exhaust ventilation required plus good work practise	Local exhaust ventilation is not required but good practice.	To improve air quality and avoid potential respiratory track irritation in working areas. **Situation at the time of the EU RAR (2007):** a total of 8 of 22 customers (36%) replied that they used local exhaust ventilation when they handle NaOH on their site.

General ventilation	General ventilation is good practice unless local exhaust ventilation is present	To improve air quality and avoid potential respiratory track irritation in working areas.
Personal protection equipment (PPE) required under regular working conditions	• Respiratory protection: In case of dust or aerosol formation (e.g. spraying): use respiratory protection with approved filter (P2) (required) • Hand protection: impervious chemical resistant protective gloves (required) o material: butyl-rubber, PVC, polychloroprene with natural latex liner, material thickness: 0.5 mm, breakthrough time: > 480 min o material: nitrile-rubber, fluorinated rubber, material thickness: 0.35-0.4 mm, breakthrough time: > 480 min • If splashes are likely to occur, wear tightly fitting chemical resistant safety goggles, face–shield (required) • if splashes are likely to occur, wear suitable protective clothing, aprons, shield and suits, rubber or plastic boots, rubber or plastic boots (required)	**Situation at the time of the EU RAR (2007):** the questionnaire indicated that twentynine percent of the customers replied that inhalation exposure was possible, while 71% answered that skin exposure was possible and finally 75% replied that eye exposure was possible. In most cases no PPE was used to prevent inhalation. To prevent skin exposure, 46% of the respondents reported that gloves were used, while 25% reported that special clothes were used and finally 29% replied that no PPE was used. To prevent eye exposure 67% of the customers answered that safety glasses or a full facemask was used and the remaining customers replied in most cases that no PPE was used (Euro Chlor, 2005).
Other risk management measures related to workers. For example: Particular training systems, monitoring/reporting or auditing systems,	Next measures are required (from EU RRS, 2008): • workers in the risky process/areas identified should be trained a) to avoid to work without respiratory protection and b) to understand the corrosive properties and, especially, the respiratory inhalation effects of sodium hydroxide and c) to follow the safer	
Information type	**Data field**	**Explanation**
specific control guidance.	procedures instructed by the employer (EU RRS, 2008). • the employer has also to ascertain that the required PPE is available and used according to instructions	
Measures related to the design of product (other than concentration) related to workers	• High viscosity adjustment with aids (good practice) • Delivery only as barrel commodity and/or in the tank car (good practice)	to avoid splashes

2) Risk management measures related to professional workers

Because sodium hydroxide is corrosive, the risk management measures for human health should focus on the prevention of direct contact with the substance. For this reason automated and closed systems should preferably be used for professional uses of sodium hydroxide. Since automated, closed systems and local exhaust ventilation may be less feasible to implement, product related design measures that prevent direct eye/skin contact with NaOH and prevent formation of aerosols and splashes are more important next to the personal protective equipment measures.

Product related design measures are required. These include specific dispensers and pumps etc specifically designed to prevent splashes/spills/exposure to occur.

Table 10 gives an overview of the personal protective equipment recommendations. Based on the NaOH concentration in the preparation, a different degree of restriction is proposed.

Table 10 Personal protective equipment releated to professional workers

	NaOH concentration in product > 2%	NaOH concentration in product between 0.5% and 2%	NaOH concentration in product < 0.5%
Respiratory protection: In case of dust or aerosol formation (e.g. spraying): use respiratory protection with approved filter (P2)	compulsory	good practice	No
Hand protection: In case of potential dermal contact: use impervious chemical resistant protective gloves	compulsory	good practice	No
Protective clothing: If splashes are likely to occur, wear suitable protective clothing, aprons, shield and suits, rubber or plastic boots, rubber or plastic boots	compulsory	good practice	No
Eye protection: If splashes are likely to occur, wear tightly fitting chemical resistant safety goggles, face –shield	compulsory	good practice	No

3) Risk management measures related to environment

Relevant risk management measures related to environment are described in section 1.1.3.

3.1.4 Waste related measures

There is no solid waste of NaOH. Liquid NaOH waste should be reused or discharged to the industrial wastewater and further neutralized if needed (see risk management measures related to environment).

3.2 Exposure estimation

3.2.1 Workers exposure

NaOH is a corrosive substance. For the handling of corrosive substances and formulations, immediate dermal contacts occur only occasionally and it is assumed that repeated daily dermal exposure can be neglected. Therefore according to the EU RAR (2007), dermal exposure to pure NaOH will not be assessed. Repeated dermal exposure cannot be neglected for these substances and formulations.

Relevant populations potentially exposed to generally corrosive products are workers in the chemical industry, aluminium industry and paper industry. Also textile workers and cleaners may have more or less direct contact with (diluted) NaOH.

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

Measured exposure concentrations

The measured exposure concentrations to workers are summarized in Table 11.

Table 11 Long-term exposure concentrations to workers (measured exposure concentrations)

Routes of exposure	Measured exposure concentrations		Explanation / source of measured data
	Value	unit	
Inhalation exposure			From EU RAR (2007): end use of formulated products
	<0.11	mg/m^3	Personal + area sampling, sample time: 250-364 min, locations: mechanic, table outside cleaning room, sidewall on electrical box, centre on unused equipment, black wall on tool cart (Burton et al., 2000)
			From EU RAR (2007): industrial use in pulp and paper
	<0.5/16*	mg/m^3	Locations: woodplant, pulping, bleach/chem.preparation, machine room, recover and recaust, Number: 2-12, Duration: >8 hours, TWA (Kennedy et al., 1991)
	0.001-0.70	mg/m^3	Locations: pulping, refining, etc. of stock, paper/paperboard machine, de-inking of waste paper, TWA, total number: 5, number of detects: 1-5, Range: 0.001 – 1.2 mg/m^3) (Korhonen et al., 2004)
			From EU RAR (2007): aluminium industry
Routes of exposure	Measured exposure concentrations		Explanation / source of measured data
	Value	unit	
	0.033-1.1 2.40*** 5.80** 4.70***	mg/m^3 AM	Data from 1997-1999, Locations: during caustic wash, sand trap dump (at operator location, caustic wash recycle tank, screw conveyor new building, overflow tank old building, decanter, filter wach at hoist control, over caustic tank ground floor, drum filters/normal operating, drum filters/normal operating, on ground in front of filter, on workbench on filter, 1st floor at filter drain valve, 1st floor by conveyor belt, over Launder gate during caustic wash, over precipitation tank, caustic wash, operator location, descaling launder gates, caustic wash filling Primary B tank, sample on top of tank, adjacent to cyclones during normal processing

			Medium: impinger/filter, 22 sample points with 1-5 repititions, t= 5-117 min
			New literature: aluminium industry
	0.2	mg/m^3 GM	Refinery 2, Maintenance, N=19, Range: 0.02-4 mg/m^3, 4 hour TWA (Musk et al., 2000)
	0.17	mg/m^3 GM	Refinery 3, Maintenance, N=8, Range: 0.05-0.6 mg/m^3, 4 hour TWA (Musk et al., 2000)
	0.11	mg/m^3 GM	Refinery 3, Digestion, N=6, Range: 0.05-0.6 mg/m^3, 15 min sample (Musk et al., 2000)
	0.46	mg/m^3 GM	Refinery 2, Clarification, N=27, Range: 0.1-2.3 mg/m^3, 4 hour TWA (Musk et al., 2000)
	0.09	mg/m^3 GM	Refinery 3, Clarification, N=9, Range: 0.05-1.1 mg/m^3, 4 hour TWA (Musk et al., 2000)
	0.34	mg/m^3 GM	Refinery 1, Precipitation, N=19, Range: 0.1-0.8 mg/m^3, 4 hour TWA (Musk et al., 2000)
	0.19	mg/m^3 GM	Refinery 3, Calcination or shipping, N=18, Range: 0.05-0.9 mg/m^3, 15 min TWA (Musk et al., 2000)
	0.56	mg/m^3 GM	Refinery 2, Descale, N=11, Range: 0.1-1 mg/m^3, 4 hour TWA (Musk et al., 2000)
	0.4	mg/m^3 GM	Refinery 3, Descale, N=12, Range: 0.05-3.5 mg/m^3, 15 min TWA (Musk et al., 2000)
			New data from aluminium industry:
	0.006	mg/m^3 AM	year: 2001, location = digestion, N=18, duration= 8 hours, range TWA= 0.002 – 0.024 mg/m^3
	0.021	mg/m^3 AM	year: 2001, location = filtration, N=19, duration= 8 hours, range TWA= 0.005 – 0.081 mg/m^3
	0.017	mg/m^3 AM	year: 2001, location = precipitation, N=11, duration= 8 hours, range TWA= 0.003 – 0.072 mg/m^3
	0.014	mg/m^3 AM	year: 2001, total, N=48, duration= 8 hours, range TWA= 0.002 – 0.081 mg/m^3
			From EU RAR (2007): textile industry
	1.7-6.8	mg/m^3 AM	Mercerization, Bleaching , Washing , Mixing and concentration , 1-13, Storage , workers exposed, N=8-86

* A single high reading because of upset conditions at the slaker/causticizer

** Sample known to be contaminated as no steam/mist came in contact with sampler during sampling; samples was taken up-wind of steam source due to prevailing wind conditions

*** Samples were taken in very wet steam/ mist clouds; problems with pumps cutting out and pumps flooding were recorded

End use of formulated products

In April 1998, a health hazard evaluation concerning the cleaning, overhauling and repair of aircraft lavatory tanks and hardware was conducted at one company. The main purpose was to study the potential exposure to infectious micro-organisms but also some measurements of NaOH exposure were conducted (Burton et al., 2000). NaOH was a component in the soaps and cleaning agents used in the cleaning room. One personal breathing zone and four area samples (three inside and one outside the lavatory cleaning room) were collected. The samples were analysed for alkaline dust and mist by acid-base titration according to NIOSH Method 7401.

Following Burton et al. (2000) the results were expected to be low since little spraying of the soap was done on the day of the monitoring. Because the exact exposure level is unknown, these measurements are not taken to the risk characterization (EU RAR, 2007).

Pulp and paper industry

In 1988 measurements were conducted in a paper mill (Kennedy et al., 1991). A total of 28 area samples were taken at different locations with a minimum measurement time of 8 hours (see Table). It is unclear how measurements were collected. None of the measurements exceeded the detection level. All measured areas where exposed for over 8 hours to a NaOH concentration below 0.5 mg/m^3.

In an international epidemiological study of workers exposure to chemical agents in the pulp and paper industry a database with a total of 3873 measurements were analysed (Korhonen et al., 2004). Most of the measurements were from 1980 to 1994 and from a total 12 countries. A total of 15 measurements were conducted to NaOH (see Table 11). Two measurements during pulping stock and one measurement at the paperboard machine were exceeding the detection limit. When de-inking waste paper all measurements were exceeding the detection limit with an AM of 0.70 mg/m^3 (range 0.30 – 1.20 mg/m^3). The duration of the measurements was more than one hour, but the exact duration was unclear. It was not clear from the article which tasks were conducted during the measurements. These measurements reflect the old situation where the proper risk management measures were not sufficiently taken into account. Following Table , the following RMMs are recommended: 1) to use closed systems as much as possible, 2) to use LEV where appropriate and 3) to use RPE in case of splashes or aerosol formation.

Alumina industry

At company A static measurements were conducted in 1997 and 1999 to “caustic mist” during production of aluminum. In Table , a summary is given of these measurements. Measurements were conducted to caustic mist with a 37 mm, 0.8 µm, MCEF, membrane filter with a cellulose backup pad in a closed face 3 piece cassette or with a SKC midget impinger containing ultra pure water. All measurements performed (see Table) are worstcase area samples and many of the locations selected for sampling were ones where high concentrations were expected. The arithmetic mean of all measurements is 0.39 mg/m^3 with a range 0.033-1.1 mg/m^3 (excluding measurements in accidental situations with failing equipment). Mean measurement time is 57 min. Because operators are not routinely present at the measured locations it is assumed that total present time during a day is the same as the approximate mean measurement time (1 hour). Expecting an 8-hour working day with an exposure of 1.1 mg/m^3 for 1 hour and zero exposure during the rest of the day gives a full shift reasonable worst case exposure level of 0.14 mg/m^3. The short-term reasonable worst-case value is estimated as 1.1 mg/m^3. Expecting an 8-hour working day with an exposure of 0.39 mg/m^3 for 1 hour and zero exposure rest of the day gives a full shift typical exposure level of 0.05 mg/m^3. The short-term typical exposure value is estimated as 0.39 mg/m^3 (EU RAR, 2007).

Musk et al. (2000) provides occupational exposure data of caustic mist for three alumina refineries in Western Australia. The sample duration is 15 minutes and 4 hour time weight averages. The activities covered are maintenance, digestion, clarification, precipitation, calcination or shipping and descale.

In another study (Fritschi et al., 2001) the results for exposure to caustic mist were qualitatively presented and therefore not suitable for the risk assessment.

These measurements above reflect the old situation where the proper risk management measures were not sufficiently taken into account. Following Table , the following RMMs are recommended: 1) to use closed systems as much as possible, 2) to use LEV where appropriate and 3) to use RPE in case of splashes or aerosol formation.

More recent data were collected from the aluminum industry covering various activities (digestion, filtration, precipitation). Multiple samples were collected during the full shift. The maximum observed concentration is 0.021 mg/m^3. This value will be further considered for risk characterization.

Textile industry

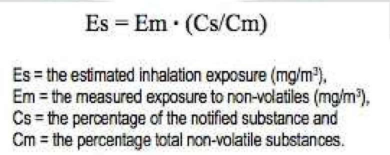
In 1981 measurements were conducted at different textile producing companies in Finland (Nousiainen et al., 1981). A total of 198 area samples were taken at different locations for a whole shift duration (see Table 11). During the measurements the fixed apparatus was positioned so that the best possible approximate values of the worker exposure would be obtained, without disturbing normal work routines. The distance from the outer edge of the mercerization, leaching or washing machine was 1 m and the sampling height from the floor or work platform was 1-5 m. The measurements were made at the front, middle and back part of each mercerization machine. The contents measured at the middle were often highest because the solution was hot there. For bleaching the measurements were likewise made at different points of the machine. Most measurements were conducted during mercerisation and bleaching and the number of workers possibly exposed is, in comparison with other locations, high. These measurements are out of date and they do not describe a worst case situation, they describe the textile industry 30 years ago. Following Table 9, the following RMMs are recommended: 1) to use closed systems as much as possible, 2) to use LEV where appropriate and 3) to use RPE in case of splashes or aerosol formation. So therefore, these RMMs should be used to avoid inhalation exposure. The use of NaOH in today's textile industry is mostly in closed system without exposure of the workers (see example pictures of Figure 2). In those cases where there is still open use, there is no relevant exposure because this would not be a spraying process but a dipping process without aerosol formation. An open use measurement for KOH which is very similar to NaOH (the cleaning of machinery which implies possible exposure) showed less than 0.06 mg/m^3 and this was the detection limit.

Figure 1: The use of NaOH in today's textile industry is in closed system without exposure of the workers (left: Distribution NaOH, middle; Storage of NaOH, right: Use of NaOH (dying))

Estimated exposure concentrations

The estimated exposure concentrations to workers reported in the EU RAR (2007) are summarized in table 12.

Table 12 Long-term exposure concentrations to workers (estimated exposure concentrations)

Routes of exposure	Estimated Exposure Concentrations		Explanation / source of measured data
	value	unit	
Dermal exposure	0.42-84	mg/d	Various dermal exposure estimates were calculated in the EU RAR (2007) using EASE for following scenarios: end use of liquid oven cleaner, end use of spray oven cleaner, end use of hair straightening products and use in textile industry.
Inhalation exposure	Typical: 0.04 RWC: 0.08	mg/m^3 mg/m^3	**From EU RAR (2007): formulation of NaOH containing products** Adding liquid NaOH (T = 20°C) to a process (vapour pressure very low, no aerosol formed, LEV present, use pattern non dispersive use), EASE predicts a typical inhalation exposure of 0-0.17 mg/m^3 (0 – 0.1 ppm). Assuming NaOH concentration of 50% a typical exposure value of 0.04 mg/m^3 (0.025 ppm) is estimated (half of range 0 – 0.05 ppm). Estimating the reasonable worst-case exposure gives a value of 0.08 mg/m^3 (0.05 ppm, upper value of the range).
	negligible		**From EU RAR (2007): end use of liquid oven cleaner** EASE estimates (assuming very low vapour pressure, no aerosol formed, direct handling, non-dispersive use) 0 - 0.17 mg/m^3 (0 – 0.1 ppm) for typical inhalation exposure. Assuming dilution of 1:50 (oven cleaner is not used purely) and NaOH concentration of 7.5% (mean concentration NaOH) typical inhalation value is estimated (by taken the mean value of the range) as 1.3 . 10-4 mg/m^3 (0.02 . 0.075 . 0.085). A reasonable worst case inhalation exposure is estimated by taking the upper range value which gives an estimation of 2.6 . 10-4 mg/m^3 (0.02 . 0.075 . 0.17). Both, typical and worst case estimates, can be considered to be negligible.
	0.13	mg/m^3	**From EU RAR (2007): end use of spray oven cleaner** NaOH is a non-volatile substance and therefore EASE is not suitable for estimating inhalation exposure occurred by spraying. The EU RAR (2007) refers to a model derived by De Pater et al. (1999) to estimate inhalation exposure to non-volatile substances during spraying. This model is based on measured exposure levels to polyisocyanates in spray coating and is also considered to be relevant for spray cleaning. Model:  $Es = Em \cdot (Cs/Cm)$ Es = the estimated inhalation exposure (mg/m^3), Em = the measured exposure to non-volatiles (mg/m^3), Cs = the percentage of the notified substance and Cm = the percentage total non-volatile substances. Assuming a NaOH concentration of 3% (mean concentration of NaOH in spray) Cs is 0.03. Because the measured exposure to non-volatiles and the percentage non-volatile substances are unknown, the estimates for spray painting are used as indicative values: Em = 10 mg/m^3 and Cm = 0.3. This results in an estimated inhalation exposure of 1 mg/m^3 (10 . 0.03/0.3). If spraying occurs 1 hour/day and rest of the day no exposure is assumed, a reasonable worst case of 0.13 mg/m^3 is estimated.

	Typical: 0.04 RWC: 0.08	mg/m^3 mg/m^3	**From EU RAR (2007): EASE simulation for chemical industry, industrial use in pulp and paper and for aluminium industry:** Adding liquid NaOH (T = 20°C) to a process (vapour pressure very low, no aerosol formed, use pattern non dispersive use) EASE predicts a typical inhalation exposure of 0 – 0.17 mg/m^3 (0 – 0.1 ppm). Assuming NaOH concentration of 50% a typical exposure value of 0.04 mg/m^3 (0.025 ppm) is estimated (half of range 0 – 0.05 ppm). For estimating the reasonable worst case exposure 0.08 mg/m^3 (0.05 ppm, upper value of the range) is taken.
	0 – 0.043	mg/m^3	**From EU RAR (2007): for textile industry** Steeping cellulose in sodium hydroxide solution can be compared with mixing. In this case cellulose will be added to sodium hydroxide. When assuming a closed system with vapour pressure very low, no aerosol formed and use pattern non-dispersive, EASE predicts a value of 0 – 0.17 mg/m^3 (0 – 0.1 ppm). If a concentration of 25% NaOH is used, the range will become 0 – 0.043 mg/m^3.

The estimated inhalation exposure concentrations to workers according to the ECETOC TRA tool are summarized in Table 24. It was assumed that there is no local exhaust ventilation and no respiratory protection unless specified otherwise. The duration of exposure was set at more than 4 hours per day as a worst-case assumption. And professional use was specified where relevant as a worst-case assumption. For the solid, the low dustiness class was selected because NaOH is very hydroscopic. Only the most relevant PROCs were considered in the assessment.

There is no need to quantitatively derive dermal exposure estimations because a DNEL for dermal exposure was not derived.

Table 13 Long-term inhalation exposure concentrations to workers (estimated exposure concentrations)

PROC	PROC description	Liquid (mg/m^3)	Solid (mg/m^3)
PROC 1	Use in closed process, no likelihood of exposure	0.17	0.01
PROC 2	Use in closed, continuous process with occasional controlled exposure (e.g. sampling)	0. 17	0.01
PROC 3	Use in closed batch process (synthesis or formulation)	0.17	0.1
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises	0.17	0.2 (with LEV)
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	0.17	0.2 (with LEV)
PROC 7	Spraying in industrial settings and applications	0.17	Not applicable
PROC 8a/b	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non dedicated or dedicated facilities	0.17	0.5
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	0.17	0.5
PROC10	Roller application or brushing of adhesiveand other coating	0.17	0.5
PROC11	Spraying outside industrial settings or applications	0.17	0.2 (with LEV)
PROC13	Treatment of articles by dipping and pouring	0.17	0.5

PROC14	Production of preparations or articles by tabletting, compression, extrusion, pelettisation	0.17	0.2 (with LEV)
PROC15	Use a laboratory reagent	0.17	0.1
PROC19	Hand-mixing with intimate contact and only PPE available.	0.17	0.5
PROC23	Open processing and transfer operations (with minerals) at elevated temperature	0.17	0.4 (with LEV and RPE(90%))
PROC24	High (mechanical) energy work-up of substances bound in materials and/or articles	0.17	0.5 (with LEV and RPE(90%))

PROC 26 was considered to mainly applicable to metals industry. Handling of inorganic substances is assumed to be included in the existing PROCs assessed.

Inhalation exposure during loading may take place due to vapours or aerosols formed when the barrel or drum is opened and when adding the product to the process. NaOH will be diluted after loading into a tank.

Summary of the exposure values

The summary of exposure concentrations to workers, taken forward to risk characterization, is given in Table .

Table 14 Summary of exposure concentration to workers

Routes of exposure	Concentrations	Justification
Dermal exposure (in mg/cm^2)	84 mg/d	From EU RAR (2007): NaOH products with a concentration > 2% are corrosive, therefore effective control measures are expected to be in place to prevent dermal exposure. Furthermore protective clothing and gloves are considered to be used consistently when handling corrosive substances. Production companies report the use of protective gloves, suits and boots while handling pure NaOH. Repeated daily dermal exposure to the pure substance is therefore considered negligible.
Routes of exposure	**Concentrations**	**Justification**
		Dilutions of NaOH containing less than 2% of the substance do not have corrosive properties. For this concentration a dermal exposure value is estimated. A reasonable worst case exposure of 84 mg/day will be taken to risk characterisation for handling concentrations < 2% NaOH.
Inhalation exposure (in mg/m^3)	< 1 mg/m^3	In the EU RAR (2007): following values were selected for risk charcterisation: 1 Pulp and paper industry: 0.08 mg/m^3 2 De-inking waste paper: 1.20 mg/m^3 3 Aluminium: 0.14 mg/m^3. Short-term value: 1.1 mg/m^3 4 Textile: 3.4 mg/m^3 5 Chemical industry: 0.08 mg/m^3 Most measurements reflect an outdated situation where the proper risk management measures were not sufficiently taken into account. Following Table 9, the following RMMs are recommended: 1) to use closed systems as much as possible, 2) to use LEV where appropriate and 3) to use RPE in case of splashes or

		aerosol formation. Applying an RMM efficiency rate of more than 90% would decrease the exposure concentrations up to a level below 1 mg/m^3.

3.2.2 Indirect exposure of humans via the environment (oral)

Indirect exposure to humans, for example through the uptake of drinking water, is not relevant for NaOH. Any potential for exposure to NaOH due to environmental releases will only have relrevance at the local scale. Any pH effect of local releases will be neutralised in the receiving water at the regional scale. Therefore indirect exposure of humans via the environment (oral) is not relevant in the case of NaOH (EU RAR, 2007).

3.2.3 Environmental exposure

As stated in the EU RAR on NaOH (2007), the risk assessment for the environment will focus solely on the aquatic environment, when applicable including STPs/WWTPs, as the emissions of NaOH in the different lifecycle stages (production and use) mainly apply to (waste) water. The aquatic effect and 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 will be addressed, including sewage treatment plants (STPs) or waste water treatment plants (WWTPs) when applicable, both for production and industrial use. Any effects that might occur would be expected to take place on a local scale and therefore it was decided as not meaningful to include the regional or continental scale in this risk assessment. Furthermore, the high water solubility and very low vapour pressure indicate that NaOH will be found predominantly in water. Significant emissions to air are not expected due to the very low vapour pressure of NaOH. Significant emissions to the terrestrial environment are not expected either. The sludge application route is not relevant for the emission to agricultural soil, as no sorption of NaOH to particulate matter will occur in STPs/WWTPs.

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. 1) Environmental releases

To estimate the environmental releases from the uses of NaOH a questionnaire was organised by Euro Chlor, in cooperation with the Portuguese and Dutch authorities, focussing on the major downstream uses (EU RAR, 2007). Because the exposure assessment focussed on possible pH changes in the local aquatic environment, data were requested on the pH control at user sites. Based on the experience with the results from the questionnaire to producers (see Section 9.1) it was envisaged that the pH of discharges would also be strictly controlled by the industry involved, often in response to local requirements. Therefore, the environmental part of the questionnaire was simplified in agreement with the rapporteur, asking the following two questions: ‘does your final waste water which is discharged to the receiving water still contain NaOH?’ and ‘if yes: what do you do to prevent an impact from NaOH discharge’? The results of the user questionnaire have been reported in detail in Euro Chlor (2005).

The paper and pulp industry was addressed via CEPI, the Confederation of the European Paper Industries and received 34 replies. For the paper and pulp industry one questionnaire was received from Germany (National Federation), which represented the common practice in this country.

Other industries were approached via five large producers of NaOH who each sent out a questionnaire to 20 of their customers, in nearly all cases end users of NaOH. A reply had been received from 24 customers, representing a response of 24%. From these 24 customers, 8 responses were received from Spain. The other customers were located in Belgium, France, Germany, The Netherlands and United Kingdom. The majority originated from the chemical industry (17 replies). One reply was received from the steel industry, textile industry, rubber production, distribution, food industry, metal industry and aluminium industry. In one case a distributor completed the questionnaire, which is not an end user of NaOH.

For the pulp and paper industry the average amount of NaOH used per day was 14 tonnes (range from 0.005 – 160 tonnes), while the remaining end users used an average amount of 24 tonnes/day (range from 1.5 – 110 tonnes). For the paper and pulp sector 32 respondents answered that the final wastewater did not contain NaOH, but in two cases it did. For these cases it was stated that the impact was controlled. For the 23 other end users questioned (excluding the distributor), 21 indicated to have no NaOH in the final effluent. For two sites, from the chemical industry, the final effluent contained NaOH. For these sites it is not specifically known if they neutralised their effluent. Normally, local procedures are in place to prevent discharges outside the range required by authorities, such as recycling, mixing with other streams for neutralisation or discharge to a WWTP when that is considered favourable.

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.

As stated above, 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.

2) Exposure concentration in waste water treatment plants (WWTP)

Referring to the RMMs related to the environment to avoid discharging NaOH solutions into municipal wastewater unless neutralization is carried out, the pH of the influent of a municipal wastewater treatment plant is neutral and therefore, there is no exposure to the biological activity. 3) Exposure concentration in aquatic pelagic compartment

The exposure concentration in aquatic pelagic compartment is similar to the assessment done in ES 1.

4) Exposure concentration in sediments

The exposure concentration in sediment compartment is similar to the assessment done in ES 1.

5) Exposure concentrations in soil and groundwater

The exposure concentration in soil and groundwater compartment is similar to the assessment done in ES 1.

6) Atmospheric compartment

The exposure concentration in atmospheric compartment is similar to the assessment done in ES 1.

7) Exposure concentration relevant for the food chain (Secondary poisoning)

The exposure concentration relevanty for the food chain is similar to the assessment done in ES 1.

4. EXPOSURE SCENARIO 4: CONSUMER USE OF NAOH

4.1 Exposure scenario

4.1.1 Short title of the exposure scenario

SU21: private households

PROC not applicable for this ES

PC 20, 35, 39 (neutralisation agents, cleaning products, cosmetics, personal care products). The other PCs are not explicitly considered in this exposure scenario. However, NaOH can also be used in other PCs in low concentrations e.g. PC3 (up to 0.01%), PC8 (up to 0.1%), PC28 and PC31 (up to 0.002%) but it can be used also in the remaining product categories (PC 0-40).

AC not applicable for this ES

4.1.2 Description of activities, processes and operational conditions covered in the exposure scenario

NaOH (up to 100%) is also used by consumers. It is used at home for drain and pipe cleaning, wood treatment and it also used to make soap at home (Keskin et al., 1991; Hansen et al., 1991; Kavin et al., 1996). NaOH is also used in batteries and in oven-cleaner pads (Vilogi et al., 1985). Following uses are briefly described:

Floor strip products

Floor strippers are used to remove old protective layers. The maximum content of sodium hydroxide in floor strippers is 10%. For stripping the floor of the living room, 550 g of the product is needed for an area of 22 m^2. This is done with the undiluted product. The product is sprinkled on a cloth and is manually rubbed on the floor.

Hair straighteners

The maximum content of sodium hydroxide in hair straighteners for use by the general public is 2% (EU Cosmetics Directive). Sodium hydroxide as a caustic type of chemical will actually soften hair fibres. It will also cause the hair to swell at the same time. As the sodium hydroxide solution is applied of the hair, it penetrates into the cortical layer and breaks the cross-bonds. The cortical layer is actually the middle of inner layer of the hair shaft that provides the strength, elasticity and shape of the curly hair.

Oven cleaners

Oven cleaners are strong degreasers and they are suitable for removing dirt stuck on ovens, grills, etc. Oven cleaners contain strong alkaline ingredients. Strong alkali is necessary to remove burned-on soils. There are trigger sprays and spray cans. When using a spray can, foam is formed on the target area. After spraying, the oven door is closed and the foam has to soak 30 minutes. Then the oven is wiped clean with a wet cloth or sponge and one has to rinse frequently. The maximum content of sodium hydroxide in a spray can is 5%. For the purpose of the exposure calculations, the product is assumed to contain 0.83% NaOH (which is 2.5% of a 33% aqueous NaOH solution). The product is a milky-white gelatinous liquid. Formulation as a gel leads to large droplets upon spraying (100% >10 um). The frequency of application is 1 event per day and the duration is 2 minutes per event. Spraying into cold oven, with potential exposure to hands and arms. One can spray up to 1 g product per second, by hand-held ready-to-use trigger spray.

Drain openers

Drain openers open slow running and obstructed drains by dissolving and by loosening grease and organic waste. There are different kinds of drain openers, products containing either sodium hydroxide or sulphuric acid. Liquid drain openers have a maximum NaOH content of 30%. The use of liquid drain openers is comparable with the dosing of liquid cleaners. The drain opener must be dosed slowly down the drain. Pellets, which can also be use for opening the drain, have contents up to 100%. The drain opener must be dosed slowly down the drain. One has to wait at least 15 minutes so that the drain opener can clear the blockage.

Other cleaning products

NaOH is used during the production phase of various cleaning products although in most case the amounts are low and NaOH additions are mainly for pH adjustment. The amounts used will interact with other ingredients in acid-base reactions and thus practically no NaOH is left in the final consumer product. However, hypochlorite products may contain 0.25-0.45% of NaOH in the final formulation. Some toilet cleaners may contain up to 1.1% and certain soaps contain up to 0.5% of NaOH in the final formulation.

Consumer use, service life and waste stage of NaOH in batteries

Aqueous sodium hydroxide is employed as the electrolyte in alkaline batteries based on nickel-cadmium and manganese dioxide-zinc. Even though potassium hydroxide is preferred over sodium hydroxide, NaOH can still be present in the alkaline batteries, but here this substance is strictly confined in the battery screening and doesn’t come in contact with the consumer.

The industrial and professional uses of NaOH in batteries (incl. recycling operations) are covered under Exposure Scenario 3. This ES focuses on the consumer use, the service life and the end-of-life stage of NaOH in batteries. Given that batteries are sealed articles and that NaOH involved in their maintenance is not intended for direct release exposure to and emission from NaOH in these life-cycle stages should be minimal.

4.1.3 Risk management measures

Risk management measures related to consumers (all except batteries)

The risk management measures related to consumers are mainly related to prevent accidents.

Measured related to the design of the product

- It is required to use resistant labelling-package to avoid its auto-damage and loss of the label integrity, under normal use and storage of the product. The lack of quality of the package provokes the physical loss of information on hazards and use instructions.

- It is required that household chemicals, containing sodium hydroxide for more than 2%, which may be accessible to children should be provided with a child-resistant fastening (currently applied) and a tactile warning of danger (Adaptation to Technical Progress of the Directive 1999/45/EC, annex IV, Part A and Article 15(2) of Directive 67/548 in the case of, respectively, dangerous preparations and substances intended for domestic use). This would prevent accidents by children and other sensitive groups of society.

- It is required that improved use instructions, and product information should always be provided to the consumers. This clearly can efficiently reduce the risk of misuse. For reducing the number of accidents in which (young) children or elderly people are involved, it should be advisable to use these products in the absence of children or other potential sensitive groups. To prevent improper use of sodium hydroxide, instructions for use should contain a warning against dangerous mixtures

- It is advisable to deliver only in very viscous preparations
- It is advisable to delivery only in small amounts Instructions addressed to consumers

- Keep out of reach of children.
- Do not apply product into ventilator openings or slots. PPE required under regular conditions of consumer use

	NaOH concentration in product > 2%	NaOH concentration in product between 0.5% and 2%	NaOH concentration in product < 0.5%
Respiratory protection: In case of dust or aerosol formation (e.g. spraying): use respiratory	required	good practice	no
protection with approved filter (P2)			
Hand protection: In case of potential dermal contact: use impervious chemical resistant protective gloves	required	good practice	no
Eye protection: If splashes are likely to occur, wear tightly fitting goggles, face –shield	required	good practice	no

Risk management measures related to consumers (batteries)

Measured related to the design of the product: It is required to use completely sealed articles with a long service life maintenance.

Risk management measures related to environment

There are no specific risk management measures related to environment.

4.1.4 Waste related measures

This material and its container must be disposed of in a safe way (e.g. by returning to a public recycling facility). If container is empty, trash as regular muncipal waste.

Batteries should be recycled as much as possible (e.g. by returning to a public recycling facility). Recovery of NaOH from alkaline batteries includes emptying the electrolyte, collection and neutralization with sulphuric acid and carbon dioxide. The occupational exposure related to these steps is considered in the exposure scenario on industrial and professional use of NaOH.

4.2 Exposure estimation

4.2.1 Consumer exposure

For consumer exposure it is important to stress, that sodium hydroxide exposure is an external exposure. Contact with tissue and water will give sodium and hydroxide ions. These ions are abundantly available in the body.

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/day according to Fodor et al. (1999). In the NaOH EU RAR (2007), external exposure concentrations in mg/kg were calculated and compared with the sodium intake via food to see whether this is a relevant exposure route. Several scenarios were assessed: floor strippers, hair straighteners, oven cleaners and drain openers. Overall, it was concluded that the sodium uptake due to the use NaOH containing products is neglibible compared to the daily dietary intake of sodium ions (EU RAR, 2007). The effect of sodium intake is not further considered in this sodium hydroxide dossier.

Since accidental exposure is normally excluded from an EU chemical safety assessment and accidental exposure is considered in the EU RAR (2007, Section 4.1.3.2, pages 59-62), accidental exposure will not be further assessed in this dossier. However, the risk management measures for consumers, identified in the NaOH risk reduction strategy (EU RRS, 2008) are included in the dossier.

Acute/Short term exposure

Acute/short term exposure was assessed only for the most critical use: use of NaOH in a spray oven cleaner

Inhalation exposure to NaOH in the oven cleaner was estimated using different modelling approaches:

1) ConsExpo software (version 4.1, http://www.consexpo.nl; Proud'homme de Lodder et al., 2006): default product: oven cleaner (application: spraying), default values apply to trigger spray

2) SprayExpo (Koch et al., 2004): release pattern: wall area (surrogate for the use assessed here)

Conditions of use and input parameters

The conditions of use were given by the manufacturer of the product as shown in the following table. This table only lists specific values and their rationale but does not include the default values used in the different models:

Parameter	Value
Package	375 ml trigger spray
Amount used	120 g [1]
Spray duration	120 sec [1]
Calculated mass generation rate	1 g/sec [1]
Distance nozzle to face	0.5 m
Distance nozzle to oven wall	0.3 m
Weight fraction compound	0.025 (2.5% ingredient (33% NaOH) assumed to be relevant for possible irritation)
Median of the particle size distribution	273 µm [1] (mean of three measurements for one package; lowest value from three different packages tested)
Coefficient of variation (fraction) of the median	1.15 [1] (see text)
Maximum particle size	670 µm (estimated from graphical droplet size distribution)
Room volume	15 m^3 [2]
Air exchange	2.5/h (ConsExpo default, also used for SprayExpo)

Inhalation cut-off diameter	670 µm (set to maximum value of the distribution since exposure at the nose is estimated)

[1] These data deviate from the default values of the models, see text for details. SprayExpo requires a minimum spray duration of 300 seconds. In order to retain the total amount used of 120 g, the mass generation rate in this model was reduced.

[2] This is the default value from ConsExpo for a kitchen. The room size in SprayExpo (lowest possible room height: 3 m) was adapted to result in an identical room value.

The product-specific data slightly differ from the ones used in ConsExpo 4.1 (Proud'homme de Lodder et al., 2006). These authors report a mass generation rate of 0.78 g/sec for general oven cleaners. The value taken here is somewhat higher but still lower than the value of 1.28 g/sec given by the same authors for an anti-grease cleaning trigger spray.

The particle size distribution was taken from product-specific measurements. Three different packages of the product were tested with three measurements for each package. In addition, measurements were performed with distances of 10 and 20 cm, respectively, between nozzle and laser beam. For the exposure assessment, the 10 cm distance trials were taken and the lowest value (mean of three measurements) was chosen.

The respective distribution is described by (rounded to 3 significant figures):

- a 10th percentile of 103 µm • a 50th percentile of 273 µm
- a 90th percentile of 314 µm

Under the assumption of a lognormal distribution (Proud'homme de Lodder et al., 2006), the software @risk (version 4.5.2, Pallisade Corporation, 2002) was used to define a "product-specific distribution" with the following values:

- Median = 273 µm
- 10th percentile: 104 µm
- µ = ln(GM) (corresponds to ln(median)) = ln(273) = 5.61 • δ = ln(GSD) = 0.75

leading to a standard deviation of 314 and a C.V. of (314/273 =) 1,15 (the latter is required for ConsExpo software). The @risk software also allows deriving the percentages representing defined size classes (which are required for SprayExpo modelling).

See Annex for detailed results of the modelling with both models. Please note: a concentration of 2.5% (of 33% NaOH in water) was used in the modelling exercises. Results therefore were divided by 3 to derive the results as shown in Table 15.

Other exposure estimates

The EU Risk Assessment Report (2007) on sodium hydroxide estimates occupational exposure to NaOH from the use of oven cleaners. The estimate is based on an assumed exposure concentration of 10 mg/m^3 for aerosols. This value is derived from experiences with spray painting. With a concentration of 3% NaOH and 30% nonvolatile substances in the oven cleaner a short-term inhalation exposure (during spraying) of 1 mg/m^3 was estimated.

Accordingly, with a NaOH concentration in the product of 0.83% (this product) an inhalation exposure concentration of 0.3 mg/m^3 would result.

Modelling results

Results for the different modelling approaches are shown in Table . An ingredient concentration of 2.5% (with the ingredient being 33% NaOH in water) was used in the modelling exercises. Therefore, modelling results as given in the Annex were divided by 3 to arrive at results for pure NaOH.

Table 15 Acute exposure concentrations to consumers

Routes of exposure	Estimated Exposure Concentrations		Measured exposure concentrations		Explanation / source of measured data
	value	unit	Value	Unit	
Inhalation exposure	0.012 (mean) * 0.33 (peak concentration)	mg/m^3			ConsExpo 4.1: Spraying for 2 minutes, 60 minutes exposure period
	1.6	mg/m^3			SprayExpo: mean for spraying period (5 minutes)
	0.3	mg/m^3			According to EU RAR, 2007

* 0.012 mg/m^3 represents the mean for a total exposure period of 60 minutes, as calculated by ConsExpo and includes 58 minutes without application. As here the mean concentration during application is sought, the peak concentration (0.33 mg/m^3) is used as a conservative estimate of the average concentration.

Summary of the short-term exposure values

Table 16 Summary of acute exposure concentrations to consumers

Routes of exposure	Concentrations	Justification
Oral exposure (in mg/kg bw/d)		Not applicable
Dermal local exposure		Not applicable
(in mg/cm^2)		
Dermal systemic exposure (in mg/kg bw/d)		Not applicable
Inhalation exposure (in mg/m^3)	0.3 to 1.6	See modelling results above

Long-term exposure

Exposure to oven cleaner spray is restricted to few minutes per event with up to 1 event per day (worst case assumption, in practice a lower frequency of approx. once per week is reasonable). Therefore, no long-term exposure has to be considered.

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

If the recommended RMMs are respected, local exposure through inhalation will not be higher compared to inhalation exposures in ES3. Therefore, the consumer exposure through inhalation is not further quantitatively assessed.

Consumer exposure to NaOH in batteries is zero because batteries are sealed articles with a long service life maintenance.

4.2.2 Indirect exposure of humans via the environment (oral)

Indirect exposure to humans, for example through the uptake of drinking water, is not relevant for NaOH. Any potential for exposure to NaOH due to environmental releases will only be relevant at the local scale. And any pH effect of local releases will be neutralised in the receiving water at the regional scale. Therefore indirect exposure of humans via the environment (oral) is not relevant in the case of NaOH (EU RAR, 2007).

4.2.3 Environmental exposure

Consumer uses relates to already diluted products which will further be neutralized quickly in the sewer, well before reaching a WWTP or surface water.

4.3 Regional exposure concentrations

Any effects that might occur would be expected to take place on a local scale and therefore it was decided as not meaningful to include the regional or continental scale in this risk assessment (EU RAR, 2007). Predicted environmental concentrations (PECs) can not be calculated. Only a summary of measured levels is provided (EU RAR, 2007).

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.

4.3.1 Freshwater (surface waters)

The concentration of hydroxyl ions (OH^-) in the environment has been determined very extensively via pH measurements. Geochemical, hydrological and/or biological processes mainly determine the pH of an aquatic ecosystem. The pH is an important parameter of aquatic ecosystems and it is a standard parameter of water quality monitoring programs. The most important freshwater aquatic ecosystems of the world revealed average annual pH values between 6.5 and 8.3 but lower and higher values have been measured in other aquatic ecosystems. In aquatic ecosystems with dissolved organic acids a pH of less than 4.0 has been measured, while in waters with a high chlorophyll content the bicarbonate assimilation can result in pH values of higher than 9.0 at midday (OECD, 2002, from UNEP 1995).

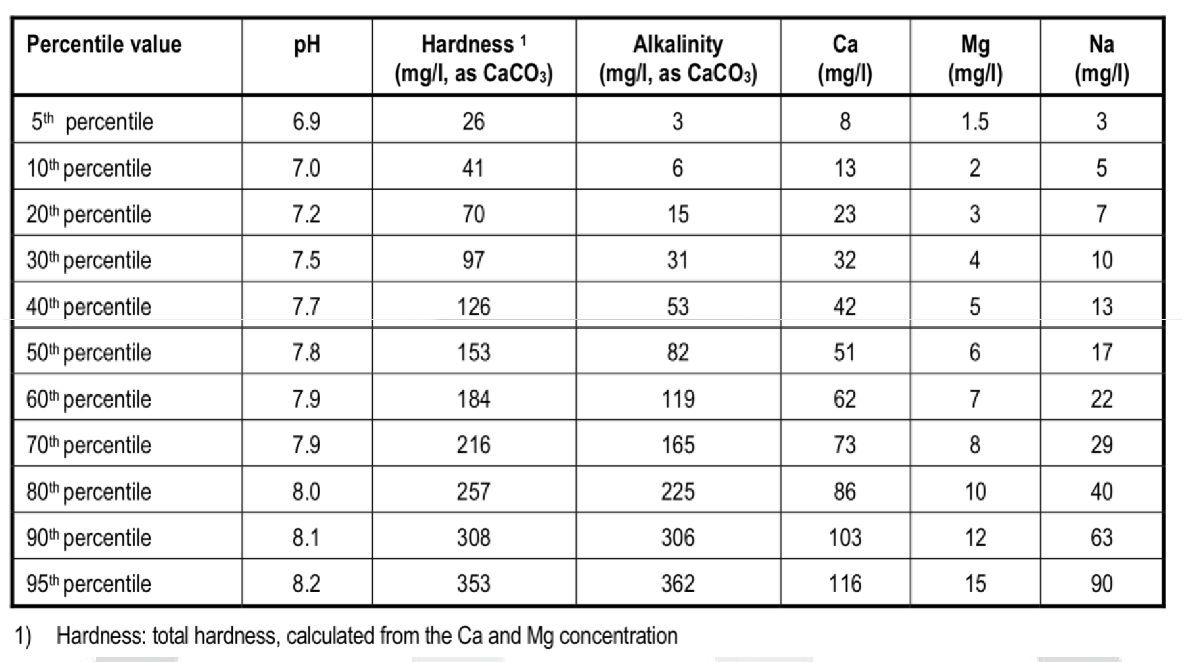
Also sodium (Na^+) has been measured extensively in freshwater aquatic ecosystems. For example, the 10thpercentile, mean and 90th-percentile concentrations for a total number of 75 rivers in North-America, SouthAmerica, Asia, Africa, Europe and Oceania were 1.5, 28 and 68 mg/l, respectively (OECD, 2002, from UNEP, 1995).

For European freshwaters, there are extensive databases on physico-chemical properties, including pH, hardness (calculated from the measured calcium and magnesium concentration), alkalinity (determined by acid/base titration or calculated from the calcium concentration, see further Section 3.1.3.2) and sodium concentration. In the framework of the EU Risk Asessment Report on Zn Metal (The Netherlands, 2004), data on physicochemical properties of freshwaters in individual European countries and the combined data for freshwaters in European countries were collected and reported by De Schampelaere et al. (2003) and Heijerick et al. (2003). The combined European data for the above physico-chemical properties, all relevant for pH changes, are summarised in **Błąd! Nie można odnaleźć źródła odwołania.**. The data in this table are based on 1991-1996 data for 411 European locations, extracted from the 'GEMS/Water database' (Global Environmental Monitoring System) that is mainly aimed on the large river systems. A correlation analysis on the data from all 411 locations indicate that all parameters listed in **Błąd! Nie można odnaleźć źródła odwołania.**17 are positively correlated, i.e. an increased pH is associated with increased concentrations of Ca, Mg and Na and increased hardness and alkalinity (De Schampelaere et al., 2003; Heijerick et al., 2003).

The variation in the above physico-chemical properties of the large river systems in different European countries is rather small, with exception of some areas in the Nordic countries (Denmark, Sweden, Norway and Finland) which are characterised by 'soft water' conditions, i.e. a hardness <24 mg $CaCO_3$/l and low pH. For example, in Sweden the 50th percentile value for hardness is 15 mg $CaCO_3$/l, which is 10-times lower than that for whole Europe. In Sweden the 50th percentile value for pH is just below 7, which is about 1 pH unit lower than that for whole Europe (De Schampelaere et al., 2003; Heijerick et al., 2003; The Netherlands, 2004).

Data on pH (and for some sites data on alkalinity) in surface waters, receiving effluent of NaOH producers, are given in **Błąd! Nie można odnaleźć źródła odwołania.**17. In all but 3 of the receiving waters for which pH values are available, the pH values are within the range of 6.5-8.5. These waters include freshwater (rivers) and seawater; each of these waters have a more narrow range of pH values, usually within one pH unit (most waters: pH range of 7.0 to 8.0). Thus, in most receiving waters the pH values are in the range that is expected in most EU waters (see **Błąd! Nie można odnaleźć źródła odwołania.**17). In one river the pH ranged from 6.5-9.0 and in two waters there was an even wider range of pH values, viz. 4.2-9.2 in a lake and 4.5-10.0 in another, unspecified water type. There is no data on sodium concentrations in the receiving waters at the NaOH production sites (a question on the sodium content was not included in the questionnaire).

Table 17 Physico-chemical properties of European freshwaters (De Schampelaere et al., 2003; Heijerick et al., 2003) (From EU RAR, 2007)



Percentile value	pH	Hardness [1] (mg/l, as $CaCO_3$)	Alkalinity (mg/l, as $CaCO_3$)	Ca (mg/l)	Mg (mg/l)	Na (mg/l)
5th percentile	6.9	26	3	8	1.5	3
10th percentile	7.0	41	6	13	2	5
20th percentile	7.2	70	15	23	3	7
30th percentile	7.5	97	31	32	4	10
40th percentile	7.7	126	53	42	5	13
50th percentile	7.8	153	82	51	6	17
60th percentile	7.9	184	119	62	7	22
70th percentile	7.9	216	165	73	8	29
80th percentile	8.0	257	225	86	10	40
90th percentile	8.1	308	306	103	12	63
95th percentile	8.2	353	362	116	15	90

1) Hardness: total hardness, calculated from the Ca and Mg concentration

4.3.2 Seawater

In over 97% of the seawater in the world, the salinity (the amount of dissolved inorganic constituents), is 35% (promille, in g/kg), but can be lower[1]. The major constituents of seawater at 35 0/00 are Cl^- (19.35 g/kg), Na^+ (10.77 g/kg), SO_4^{2-} (2.71 g/kg), Mg^{2+} (1.29 g/kg), Ca^{2+} (0.41 g/kg), K^+ (0.40 g/kg) and HCO_3^- (0.142 g/kg, being the carbonate alkalinity expressed as though it were all HCO_3^-, as this is the dominant species in seawater; the concentrations of CO_2 and CO_3^{2-} in seawater are very low compared to that of HCO_3^-) (Stumm et al., 1981).

The pH of seawater (ocean water) is normally 8.0-8.3, which is very similar to the 80th to 95th percentile values in European freshwaters (8.0-8.2, **Błąd! Nie można odnaleźć źródła odwołania.**). The total range of pH values reported for seawater is 7.5-9.5 (Caldeira et al., 1999) and data from several sources on the internet). The sodium (Na) concentration in seawater (10,770 mg/kg, equivalent to 10,450 mg/l) is 115-times higher than the 95th percentile value in European freshwaters (90 mg/l). The bicarbonate (HCO_3^-) concentration in seawater (142 mg/kg, equivalent to 137 mg/l) is between the mean HCO_3^- concentration (106 mg/l) and the 90th percentile HCO_3^- concentration (195 mg/l) in European freshwaters, indicating a relatively high buffer capacity in seawater. The total hardness of seawater (6,100 mg/l, as $CaCO_3$, calculated from the Ca and Mg concentration) is 17-times higher than the 95th percentile value in EU freshwaters, due to the much higher Ca and especially Mg concentration in seawater compared to freshwater.

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[1] Commonly use classification of watertypes based on salinity: seawater: salinity >20 $^{o}/_{oo}$, brackish water: salinity 5-20 $^{o}/_{oo}$, freshwater: salinity < 5 $^{o}/_{oo}$

5. RISK CHARACTERISATION

The potential for human health effects is the occurrence of local effects after acute and repeated exposure at those places where NaOH is produced and/or used. This is 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 the blood not the pH of the blood will be increased.

Dermal exposure to corrosive concentrations is not assessed following the EU RAR (2007). 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 direct dermal contacts occur only accidentally. Techniques and equipment (including PPE) are used that provide a high level of protection from direct dermal contact. Eye protection is obligatory for activities where direct handling of NaOH occurs. However, dermal exposure to noncorrosive 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.

5.1 Exposure Scenario 1: Manufacturing of liquid NaOH

5.1.1 Human health

Workers

Table 18 Risk characterisation for workers

Route		ES 1- exposure concentrations (EC)	Leading toxic end point / Critical effect	DNEL	Risk characterisation ratio
Dermal-local	Acute	Not relevant	Skin/eye irritation/ corrosion	**Qualitative**: NaOH is considered to be a severe corrosive agent (concentrations ≥ 2%). Workers can be exposed to corrosive concentrations. However, dermal exposure to NaOH is considered to occur only accidentally if the required protection is strictly adhered to. Therefore, a conclusion on adequately controlled risks is justifiable for scenarios in which corrosive concentrations of NaOH are handled. NaOH concentrations < 2% are not relevant for this ES.	
	Long term	Not relevant	Skin/eye irritation/ corrosion		
Inhalation-local	Acute/ Long term	0.33 mg/m^3	Respiratory tract irritation	1 mg/m^3	0.33

Since the risk characaterisation ratio is below one, it is demonstrated that the manufacturing of liquid NaOH is adequately under control for workers.

Indirect exposure of humans via the environment

Indirect exposure to humans, for example through the uptake of drinking water, is not relevant for NaOH. Any potential for exposure to NaOH due to environmental releases will only have relrevance at the local scale. Any pH effect of local releases will be neutralised in the receiving water at the regional scale. Therefore indirect exposure of humans via the environment (oral) is not relevant in the case of NaOH (EU RAR, 2007).

5.1.2 Environment

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 (EU RAR, 2007; section 3.3.1.1, page 34).

Therefore, the manufacturing of liquid NaOH is adequately under control for the environment.

5.2 Exposure Scenario 2: Manufacturing of solid NaOH

5.2.1 Human health

Workers

Table 19 Risk characterisation for workers

Route		ES 2- exposure concentrations (EC)	Leading toxic end point / Critical effect	DNEL	Risk characterisation ratio
Dermal-local	Acute	Not relevant	Skin/eye irritation/ corrosion	**Qualitative**: NaOH is considered to be a severe corrosive agent (concentrations ≥ 2%). Workers can be exposed to corrosive concentrations. However, dermal exposure to NaOH is considered to occur only accidentally if the required protection is strictly adhered to. Therefore, a conclusion on adequately controlled risks is justifiable for scenarios in which corrosive concentrations of NaOH are handled. NaOH concentrations < 2% are not relevant for this ES.	
	Long term	Not relevant	Skin/eye irritation/ corrosion		
Inhalation-local	Acute/ Long term	0.269 mg/m^3	Respiratory tract irritation	1 mg/m^3	0.269

Since the risk characaterisation ratio is below one, it is demonstrated that the manufacturing of solid NaOH is adequately under control for workers.

Indirect exposure of humans via the environment

Indirect exposure to humans, for example through the uptake of drinking water, is not relevant for NaOH. Any potential for exposure to NaOH due to environmental releases will only have relrevance at the local scale. Any pH effect of local releases will be neutralised in the receiving water at the regional scale. Therefore indirect exposure of humans via the environment (oral) is not relevant in the case of NaOH (EU RAR, 2007).

5.2.2 Environment

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 (EU RAR, 2007; section 3.3.1.1, page 34).

Therefore, the manufacturing of solid NaOH is adequately under control for the environment.

5.3 Exposure Scenario 3: Industrial and professional use of NaOH

5.3.1 Human health

Workers

Table 20 Risk characterisation for workers

Route		ES 3- exposure concentrations (EC)	Leading toxic end point / Critical effect	DNEL	Risk characterisation ratio
Dermal-local	Acute	Not relevant	Skin/eye irritation/ corrosion	**Qualitative (case NaOH concentrations ≥ 2%)**: Workers can be exposed to corrosive concentrations. However, dermal exposure to NaOH is considered to occur only accidentally if the required protection is strictly adhered to. Therefore, a conclusion on adequately controlled risks is justifiable for scenarios in which corrosive concentrations of NaOH are handled. **Qualitative (case NaOH concentrations < 2% and > 0.5%):** When existing controls and recommended RMMs are applied, safe use can be concluded. **Qualitative (case NaOH concentrations < 0.5%):** Safe use can be concluded because no health effects are observed.	
	Long term	Not relevant	Skin/eye irritation/ corrosion		
Inhalation-local	Acute/ Long term	< 1 mg/m^3	Respiratory tract irritation	1 mg/m^3	<1

Since the risk characaterisation ratios are below one, it is demonstrated that industrial and professional use of NaOH is adequately under control for workers.

Indirect exposure of humans via the environment

Indirect exposure to humans, for example through the uptake of drinking water, is not relevant for NaOH. Any potential for exposure to NaOH due to environmental releases will only have relrevance at the local scale. Any pH effect of local releases will be neutralised in the receiving water at the regional scale. Therefore indirect exposure of humans via the environment (oral) is not relevant in the case of NaOH (EU RAR, 2007).

5.3.2 Environment

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 (EU RAR, 2007; section 3.3.1.2, page 34).

It is noted 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) (EU RAR, 2007; section 3.3.1.2, page 34).

Therefore, industrial and professional use of NaOH is adequately under control for the environment.

5.4 Exposure Scenario 4: Consumer use of NaOH

5.4.1 Human health

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). For NaOH in products, the risk characterization can be found in 21. For NaOH in batteries, consumer exposure is zero because batteries are sealed articles with a long service life maintenance. Therefore, consumer use of NaOH in batteries is adequately under control.

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.

Table 21 Risk characterisation for consumers

Route		ES 4- exposure concentrations (EC)	Leading toxic end point / Critical effect	DNEL	Risk characterisation ratio
Dermal-local	Acute	Not relevant	Skin/eye irritation/ corrosion	**Qualitative (case NaOH concentrations ≥ 2%)**: Consumers can be exposed to corrosive concentrations. However, dermal exposure	

	Long term	Not relevant	Skin/eye irritation/ corrosion	to NaOH is considered to occur only accidentally if the required protection is strictly adhered to. Therefore, a conclusion on adequately controlled risks is justifiable for scenarios in which corrosive and irritating concentrations of NaOH are handled. **Qualitative (case NaOH concentrations < 2% and > 0.5%):** When existing controls and recommended RMMs are applied, safe use can be concluded. **Qualitative (case NaOH concentrations < 0.5%):** Safe use can be concluded because no health effects are observed.
Inhalation-local	Acute	1.6 mg/m^3	Respiratory tract irritation	**Qualitative**: The calculated short-term exposure of NaOH is slightly higher than the long term DNEL for inhalation of 1 mg/m^3 but smaller than the short term occupational exposure limit of 2 mg/m^3 (see table 10 in CSR). Furthermore, NaOH will be rapidly neutralised as a result of its reaction with CO_2 (or other acids),
	Long term	Not relevant	Respiratory tract irritation	**Qualitative**: Since the NaOH concentration and amount handled are smaller compared to professional use and since the DNEL and RMMs are similar, safe use can be concluded for consumer use.

Indirect exposure of humans via the environment

Indirect exposure to humans, for example through the uptake of drinking water, is not relevant for NaOH. Any potential for exposure to NaOH due to environmental releases will only have relrevance at the local scale. Any pH effect of local releases will be neutralised in the receiving water at the regional scale. Therefore indirect exposure of humans via the environment (oral) is not relevant in the case of NaOH (EU RAR, 2007).

5.4.2 Environment

Consumer uses relates to already diluted products which will further be neutralized quickly in the sewer, well before reaching a WWTP or surface water. Therefore, consumer use of NaOH is adequately under control for the environment.

Consumer uses related to NaOH in batteries, the environmental release from the consumer use and the service life are zero because the batteries are sealed articles with a long service life maintenance. After use, batteries should be recycled as much as possible but in case it is disposed as municipal waste, NaOH is not expected to cause a significant pH effect to the environment when incinerated or landfilled. Therefore, the use of NaOH in alkaline batteries is adequately under control for the environment.