

Safety Data Sheet
According to REACH Regulation (1907/2006/EC) and Regulation (EU) 453/2010

Date of issue: 01-12-2010

Revision: 01

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING**1.1. Product identifier**

Name: (Anhydrous) Sodium Hydroxide
Index number under Regulation (EC) No 1272/2008 on classification, labelling and packaging: 011-002-00-6
CAS number: 1310-73-2
REACH Registration number: 01-2119457892-27-0057

1.2. Relevant identified uses of the substance or mixture and uses advised against**Identified uses:**

- Manufacture of chemical products.
- Celluloses.
- Soap.
- Detergents.

Uses advised against:

There are no uses advised against providing that the instructions described in this Safety Data Sheet are observed.

1.3. Details of the supplier of the safety data sheet

Manufacturer, importer or distributor: Manufacturer.
Name: ERCROS S.A.
Group: ERCROS S.A.
Full address: Avda. Diagonal 595
08014 Barcelona - Spain
Telephone number: +34 934 393 009 Fax: +34 934 308 073

e-mail address for the competent person responsible for the safety data sheet: amunozl@ercros.es

1.4. Emergency telephone number

Manufacturing plant: Vilaseca: Tel: +34 977 370 354 Fax: +34 977 370 407
UK National Poisons Emergency number: 0870 600 6266

SECTION 2: HAZARDS IDENTIFICATION**2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008 on classification, labeling and packaging:**

Skin corrosive: Category 1A, H314

H314: Causes severe skin burns and eye damage.

H290: Corrosive to metals, category 1,

Classification according to Directive 67/548/EEC:

C; R35: Causes severe burns.

2.2. Label elements**DANGER**

H314: Causes severe skin burns and eye damage.

H290: May be corrosive to metals

P264: Wash hands and face thoroughly after handling.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P301 + P330 + P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

P303 + P361 + P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

P310: Immediately call a POISON CENTER or doctor/physician.

P304 + P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

2.3. Other hazards

The substance does not meet the criteria for PBT or vPvB (see section 12).

Physicochemical hazards:

Highly exothermic reaction with strong acids and water.

When coming into contact with aluminium, tin and zinc, it gives off hydrogen (a gas that is inflammable at between 4 and 75% in volume in the air).

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS
3.1 Substances

Name: Sodium hydroxide (min. 99 %).

CAS number: 1310-73-2

EC number: 215-185-5

IUPAC name: Sodium hydroxide

Index number under Regulation (EC) No 1272/2008 on classification, labelling and packaging: 011-002-00-6

Index number R. 1272/2008	EC number	CAS number	Name	Concentration	Classification Directive 67/548/EEC	Classification Regulation (EC) 1272/2008	Specific concentration limits
011-002-00-6	215-185-5	1310-73-2	Sodium hydroxide	min. 99 %	C; R35	Skin Corr. 1A, H314 <i>/Met. Corr. 1, H290</i>	Skin Corr. 1A; H314: C ≥ 5 % Skin Corr. 1B; H314: 2 % ≤ C < 5 % Skin Irrit. 2; H315: 0,5 % ≤ C < 2 % Eye Irrit. 2; H319: 0,5 % ≤ C < 2 %

SECTION 4: FIRST AID MEASURES
4.1. Description of first aid measures
4.1.1. In case of inhalation:

Move the affected party to a ventilated area and keep them warm. Seek urgent medical help.

4.1.2. After skin contact:

Wash the affected area with copious amounts of water for at least 15 minutes, and remove any contaminated clothing or footwear. Seek urgent medical help.

4.1.3. After eye contact:

Wash the eyes with copious amounts of water for at least 30 minutes. Seek urgent medical help.

4.1.4. In case of ingestion:

Do not provoke vomiting.

If conscious, give water to drink and seek urgent medical help.

4.1.5. Recommended personal protective equipment for first aid responders:

Use independent breathing apparatus to protect the respiratory system, along with the suitable clothing, gloves and footwear to protect the skin.

4.2 Most important symptoms and effects, both acute and delayed

Inhalation: Irritation of the respiratory system.

Skin contact: Intense burning and ulcers penetrating the skin.

Eye contact: Burns to the eyes. Can cause ulceration of the conjunctiva and cornea.

Ingestion: Burns to the mouth, oesophagus, can cause intestinal perforation.

4.3. Indication of any immediate medical attention and special treatment needed

Need of immediate medical attention.

SECTION 5: FIREFIGHTING MEASURES**5.1. Extinguishing media****Suitable extinguishing media:**

Non-flammable product. Use water spray to cool containers exposed to fire.

Unsuitable extinguishing media:

CO2 powder (Carbon dioxide snow)

5.2. Special hazards arising from the substance or mixture

Control run-off water and prevent it from entering water courses or drainage systems.

The heat generated by contact with water (heat of dilution) may be sufficient to ignite other combustible materials.

5.3. Advice for firefighters

Use independent breathing apparatus to protect the respiratory system, along with the suitable clothing, gloves and footwear to protect the skin.

Ensure that you always have your back to the wind.

SECTION 6: ACCIDENTAL RELEASE MEASURES**6.1. Personal precautions, protective equipment and emergency procedures**

Avoid contact with the eyes, skin and respiratory system. Do not act without the proper protective equipment (see section 8).

6.2. Environmental precautions

Prevent the product from reaching the drainage system or ground waters. If the product reaches a natural water course, advise the Civil Protection authorities.

6.3. Methods and material for containment and cleaning up

Mechanically collect as much of the product as possible.

Absorb any spillage using sand, earth or clay.

Move these absorbent products to a controlled waste disposal or secure storage site so that they can be treated by an authorised waste manager.

6.4. Reference to other sections

See protection measures in section 8.

SECTION 7: HANDLING AND STORAGE**7.1. Precautions for safe handling**

Do not smoke, eat or drink when handling the product.
Before handling the product, ensure that the recipient to be used is clean, dry and suitable.
Recipients should be properly sealed and correctly labelled.
Take special precautions if there is any residue from products such as aluminium, zinc, tin, acid products or organic products.
Prevent any possibility of contact between the product and the skin or eyes. Avoid the formation of dust.
Always use the recommended protective clothing.

7.2. Conditions for safe storage, including any incompatibilities

Recommended materials for warehouse storage and containers: Carbon steel, carbon steel drums, polythene sacks or Big-Bags.

Incompatible materials for warehouse storage: Aluminium, tin, zinc and alloys (bronzes), chrome and lead.

Storage conditions: A cool, well ventilated location, protected from damp and kept apart from acids, halogenated hydrocarbons, nitroparaffins, etc. The floor must be waterproof and anti-slip. A water supply or source must be provided in the place of storage. Emergency showers and eye-washes must be available.

Temperature and humidity range/limits: Not applicable.

Special conditions: Prevent the product from becoming damp or aerated. Hygroscopic product. Becomes carbonated in contact with the air or moisture.

7.3. Specific end use(s)

When used in its various applications, the product must be prevented from coming into uncontrolled direct contact with other products such as acids and metals. Never neutralise the solid product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1. Control parameters**

VLA-EC: 2 mg/m³ (INSHT).
TLV-STEL: 2 mg/m³ (ACGIH).
WEL-Limit value - Short term: 2 mg/m³ (UK)

Human exposure:

Workers:

DNEL (local effects): 1 mg/m³ (inhalation; long-term toxicity)

General population:

DNEL (local effects): 1 mg/m³ (inhalation; long-term toxicity)

8.2. Exposure controls

8.2.1. Appropriate engineering controls

No data available.

8.2.2. Individual protection measures, such as personal protective equipment

Respiratory protection: In the case of sodium hydroxide powder emissions, use mask with dust filter (EN 143 P2 o P3).

Hand protection: Gloves for chemical hazards (EN 374).

Eye protection: Use safety goggles (EN 166).

Skin protection: Suit or plastic apron providing protection against acids (EN 340).

8.2.3. Environmental exposure controls

Do not allow leakage into the drainage system and/or groundwater.

Measuring system: Acid-base volumetry.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
9.1. Information on basic physical and chemical properties

Appearance (physical state and colour):	Solid white, translucent, taking the form of beads or blocks.
Odour:	Odourless
Odour threshold:	No data available.
pH:	14
Melting point/freezing point:	323°C at 101 325 Pa.
Initial boiling point and boiling range:	1388°C at 101 325 Pa
Flash point:	Not applicable (inorganic substance).
Flammability (solid, gas):	Inorganic oxides in which the inorganic element is in its highest possible oxidation state are incapable of further reaction with oxygen and can thus be designated as non-flammable.

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Upper/lower flammability or explosive limits:	No data available.
Explosive properties:	There are no chemical groups associated with explosive properties present in the molecule.
Oxidising properties:	There are no chemical groups associated with oxidizing properties present in the molecule.
Vapour pressure:	It is not required to determined this property since the melting point is above 300°C
Relative density:	2.13 g/cm ³ at 20°C
Water solubility:	100 g/100 g H ₂ O at 25°C
Partition coefficient: n-octanol/water:	Not applicable (inorganic substance).
Viscosity:	Not applicable (the substance is a solid).
Vapour density:	No data available.
Evaporation rate:	Not applicable.
Auto-ignition temperature:	The study does not need to be conducted since the substance is a solid and the preliminary results exclude self-heating of the substance up to 400°C.
Decomposition temperature:	No data available.

9.2. Other information

Organic peroxide: Not classified (based on structure).

Self-heating: The preliminary results exclude self-heating of the substance up to 400°C. In the molecule there are no chemical groups that would indicate explosive or self-reactive properties.

Pyrophoric liquid/solid: Not classified. The substance is known to be stable at room temperature for prolonged periods of time.

Corrosive to metals: No data available.

Substance which in contact with water emits flammable gases: Not classified (based on structure).

SECTION 10: STABILITY AND REACTIVITY**10.1. Reactivity**

See section 10.3.

10.2. Chemical stability

The substance is stable under normal environmental conditions and foreseeable conditions of temperature and pressure during the storage and handling.

10.3. Possibility of hazardous reactions

Reacts with aluminium, tin, zinc and their alloys, copper, lead, etc. giving off hydrogen.

Highly exothermic reaction with strong acids.

Reacts dangerously with acetic acid, allyl chloride, chlorine trifluoride, chloroform, methylic alcohol, chloronitrotoluene, chlorosulphonic acid, glyoxal, cyanohydrin, hydrochloric acid, hydrofluoric acid, hydroquinone, nitric acid, sulphuric acid and oleum, nitropropane, phosphorous, propiolactone, phosphorous pentoxide, tetrachlorobenzene, tetrahydrofuran, etc.

Caustic soda forms salts with nitromethane and nitroparaffins that explode on impact.

10.4. Conditions to avoid

Do not expose to the elements for excessive periods, to prevent degradation of the container.

10.5. Incompatible materials

Aluminium, tin, zinc and their alloys, copper, lead, etc.

Acetic acid, allyl chloride, chlorine trifluoride, chloroform, methylic alcohol, chloronitrotoluene, chlorosulphonic acid, glyoxal, cyanohydrin, hydrochloric acid, hydrofluoric acid, hydroquinone, nitric acid, sulphuric acid and oleum, nitropropane, phosphorous, propiolactone, phosphorous pentoxide, tetrachlorobenzene, tetrahydrofuran, nitromethane and nitroparaffins.

10.6. Hazardous decomposition products

When the product decomposes, toxic sodium oxide gases are given off.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects:

11.2. acute effects (acute toxicity, irritation and corrosivity):

11.2.1. LD50 oral (lethal dose, 50%)	Acute toxicity testing does not need to be conducted since the substance is classified as corrosive to the skin. The substance is not expected to be systemically available and the effects are expected to be due to pH changes.
11.2.2. LD50 dermal (lethal dose, 50%)	Acute toxicity testing does not need to be conducted since the substance is classified as corrosive to the skin. The substance is not expected to be systemically available and the effects are expected to be due to pH changes.
11.2.3. LC50 inhalation (lethal dose, 50%)	Acute toxicity testing does not need to be conducted since the substance is classified as corrosive to the skin. The substance is not expected to be systemically available and the effects are expected to be due to pH changes.
11.2.4. Skin corrosion/irritation	Category 1A, H314: Causes severe skin burns and eye damage. Corrosive (<i>in vitro</i> study) (Method equivalent to OECD 435) (Stobbe et al., 2003)
11.2.5. Serious eye damage/irritation	Category 1A, H314: Causes severe skin burns and eye damage. Corrosive (rabbit) (Morgan et al., 1987; Reer et al., 1976; Wentworth et al., 1993).
11.2.6 Specific target organ toxicity – single exposure	No data available.

11.3. Sensitisation:

Respiratory sensitisation: No data available.

Skin sensitisation: a standard skin sensitization study does not need to be conducted since the substance is a strong base (pH > 11,5). Based on data obtained in a study with human volunteers the substance has no skin sensitisation potential (Park et al., 1995).

11.4. Repeated dose toxicity:

Specific target organ toxicity – repeated exposure: Corrosive substance. In addition, the substance is not expected to be systemically available in the body under normal handling and use conditions and therefore systemic effects of the substance after repeated exposure are not expected to occur.

11.5 CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction):

Carcinogenicity: The substance did not induce mutagenicity in *in vitro* and *in vivo* studies (EU RAR, 2007). Systemic carcinogenicity is not expected to occur because the substance is not expected to be systemically available in the body under normal handling and use conditions.

Germ cell mutagenicity: Both the *in vitro* and the *in vivo* genetic toxicity tests indicated no evidence of mutagenic activity. Furthermore the substance is not expected to be systemically available in the body under normal handling and use conditions and for this reason additional testing is considered unnecessary (EU RAR, 2007).

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

Reproductive toxicity, effects on or via lactation: The substance is not expected to be systemically available in the body under normal handling and use conditions and for this reason additional testing is considered unnecessary.

11.6. Aspiration hazard:

No data available.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

The hazard of the substance for the environment is caused by the hydroxyl ion (pH effect). For this reason the effect of the substance on the organisms depends on the buffer capacity of the aquatic or terrestrial ecosystem. The high water solubility and low vapour pressure indicate that the substance will be found predominantly in water. Also the variation in acute toxicity for aquatic organisms can be explained for a significant extent by the variation in buffer capacity of the test medium. LC50 values ranged between 33 and 189 mg/l.

Acute toxicity to fish

LC50 (lethal concentration, 50%):

All available tests resulted in a range of toxicity values between 35 to 189 mg/l. However, in the majority of these test reports there were no data on pH variation.

Chronic toxicity to fish

NOEC (no observed effect concentration):

It is not required to conduct this study since the substance dissociates in water and the only possible effect would result from the pH effect. However, pH will remain within environmentally expected ranges.

Acute toxicity to crustaceans

EC50 (effect concentration, 50%):

Species: *Ceriodaphnia*.
40.4 mg/l (48 h; based on immobility).
(Warne et al., 1999)

Chronic toxicity to crustaceans

NOEC (no observed effect concentration):

It is not required to conduct this study since the substance dissociates in water and the only possible effect would result from the pH effect. However, pH will remain within environmentally expected ranges.

Acute toxicity to algae and other aquatic plants

EC50 (effect concentration, 50%):

No data available.

Toxicity data on soil micro- and macro-organisms and other environmentally relevant organisms, such as birds, bees and plants

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. There is no direct exposure of soil to NaOH based on the available uses. In addition, no indirect exposure via air is expected as it rapidly neutralizes in air.

12.2. Persistence and degradability

Readily biodegradable

Not applicable (inorganic substance).

Other relevant information

Abiotic degradation:
NaOH is a strong alkaline substance that dissociates completely in water to Na⁺ and OH⁻. High water solubility and low vapour pressure indicate that NaOH will be found predominantly in aquatic environment. This implies that it will not adsorb on particulate matter or surfaces. Atmospheric emissions as aerosols are rapidly neutralized by carbon dioxide and the salts will be washed out by rain.

12.3. Bioaccumulative potential

Bioconcentration factor (BCF): experimental data:

Considering its high water solubility, NaOH is not expected to bioconcentrate in organisms. In addition, sodium is a naturally-occurring element that is prevalent in the environment and to which organisms are exposed regularly, for which they have some capacity to regulate the concentration in the organism.

Partition coefficient: n-octanol/water (log Pow):

Not applicable (inorganic substance).

12.4. Mobility in soil

High water solubility and mobility.

12.5. Results of PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) assessment

Persistence Assessment (P):

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

Bioaccumulation Assessment (B):

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

Toxicity Assessment (T):

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

NaOH does not fulfil the criteria for persistency, bioaccumulation and toxicity. Therefore, NaOH is not considered a PBT or vPvB substance.

12.6. Other adverse effects

No data available.

SECTION 13 DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Absorb any residue using sand, earth or clay. Any contaminated absorbent products must be treated by an authorised waste manager, along with any used packaging and residue.

The product can be neutralised using highly diluted hydrochloric acid, which should be added very slowly by specialised personnel wearing the proper protection. **Never neutralise the solid product.**

The product will be disposed of in accordance with the regulation currently in force and specifically with:

- Directive 2008/98/EC, of 19 November 2008 on waste and the corresponding national regulations which transpose this Directive.
- Directive 94/62/EC, of 20 December 1994 on packaging and packaging waste and its modifications and corresponding national regulations which transpose this Directive.
- Commission Decision 2001/118/EC of 16 January 2001 amending Decision 2000/532/EC as regards the list of wastes and any other regulation currently in force in the European Community, National and Local with regard to the correct disposal of this material and its empty containers.

SECTION 14: TRANSPORT INFORMATION
14.1 ADR (road)/RID (rail)

14.1.1 UN number:	UN 1823	
14.1.2 UN proper shipping name:	Sodium hydroxide, solid	
14.1.3 Transport hazard class:	8,	Label: 8
14.1.4 Packing group:	II	
14.1.5. Environmental hazards:	No.	

14.2 IMDG (sea)

14.2.1 UN number:	UN 1823	
14.2.2 UN proper shipping name:	Sodium hydroxide, solid	
14.2.3 Transport hazard class:	8,	Label: 8
14.2.4 Packing group:	II	
14.2.5. Environmental hazards:	No.	

14.3 ICAO / IATA (air)

14.3.1 UN number:	UN 1823	
14.3.2 UN proper shipping name:	Sodium hydroxide, solid	
14.3.3 Transport hazard class:	8,	Label: 8

14.3.4 Packing group:	II
14.3.5. Environmental hazards:	No.

14.4. Special precautions for user

It is necessary to attend to the same information described in the previous epigraphs: ADR, RID, IMDG, ICAO / IATA.

14.5. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work.

15.2. Chemical safety assessment

The supplier has carried out a chemical safety assessment for the substance.

SECTION 16: OTHER INFORMATION

Information sources used in the elaboration of this Safety Data Sheet:

- HANDBOOK OF REACTIVE CHEMICALS HAZARDS. BREThERIC 4ª Ed. 1990
- DANGEROUS PROPERTIES INDUSTRIAL MATERIALS (TENTH EDITION) SAX
- HAZARDOUS CHEMICALS DATA BOOK (2nd EDITION) G.WEIS.
- IARC (International Agency for Research on Cancer).
- NIOSH (National Institute for Occupational Safety and Health).
- NTP (National Toxicology Program).
- ACGIH (American Conference of Governmental Industrial Hygienist).
- OSHA (Occupational Health and Safety Assessment)
- INSHT (Instituto Nacional de Seguridad e Higiene en el Trabajo).
- SYNDICAT DES HALOGÉNES ET DÉRIVÉS
- EUROCHLOR
- IUCLID DATA SET

Abbreviations:

N/A = not applicable

< SMALLER THAN > GREATER THAN

VLA-EC: Valor Límite Ambiental-Exposición de Corta Duración (Spain)

TLV-STEL: Threshold Limit Value - Short term exposure limit

WEL: workplace exposure limit (UK)

DNEL: derived no effect level

Any chemical product can be handled safely if its physical and chemical properties are known, and appropriate safety measures and clothing are employed.

The information contained in this brochure is a guide for the user and based on both reference texts and on our own experience. It is intended to reflect the current state of the art, but shall under no circumstances compromise our liability. This information cannot be used as a substitute for patented processes.

Users shall comply with the legal dispositions and regulations in force, particularly those relating to Health and Safety and the Storage and Transport of Dangerous Goods.

We recommend that our clients perform the corresponding tests before using the product in new, insufficiently tested fields.

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FIRAT KIMYA

APPENDIX I Exposure scenarios: Sodium hydroxide.

Section 1. Exposure Scenario Title		
Exposure Scenario 1: Manufacturing of liquid NaOH		
<p>SU 3, 8: Manufacture of bulk, large-scale substances</p> <p>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</p>		
Description of activities and processes covered in the exposure scenario		
<p>NaOH is produced commercially by an electrolytic process. Brine, prepared from sodium chloride, is electrolyzed in either a mercury cell, diaphragm cell or membrane cell. The coproducts are chlorine and hydrogen. In the mercury cell process, a sodium-mercury amalgam is formed in the cell. The amalgam is sent to a decomposer where it is reacted with water to form liquid NaOH, hydrogen and free mercury. The free mercury is returned to the electrolytic cell. The resulting NaOH solution is then stored in storage tanks as a 50% solution. The solution is shipped in tank trucks, tank cars or barges. In the membrane process, a solution of approximately 30% in strength is formed in the cell. The solution is then sent to evaporators, which concentrate it to a strength of 50% by removing the appropriate amount of water. The resulting NaOH solution is stored in storage tanks prior to shipment. The diaphragm process is very similar to the membrane process except that a solution of only 10-12% is formed in the cell. Therefore, additional evaporation is required to reach the commercialised concentration of 50%. The anhydrous forms of NaOH are obtained through further concentration of 50% NaOH.</p>		
Section 2. Operational conditions and risk management measures		
Operational conditions		
<p>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.</p> <p>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.</p> <p>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%.</p>		
Risk management measures related to workers		
<p>The risk management measures related to workers are summarized in Table 1. A distinction is made between measures that are required or compulsory and measures that indicate good practice.</p> <p>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.</p>		
Table 1 Risk management measures related to workers		
Information type	Data field	Explanation
Containment plus good work practice required	<p><u>Good practice</u>: replacing, where appropriated, manual processes by automated and/or closed processes. This would avoid irritating mists and subsequent potential splashes (EU RRS, 2008):</p> <ul style="list-style-type: none"> • Use closed systems or covering of open containers (e.g. screens) (<u>good practice</u>) 	<p>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 “open” (6 sites) or “totally closed” (9 sites).</p>

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	<ul style="list-style-type: none"> • Transport over pipes, technical barrel filling/emptying of barrel with automatic systems (suction pumps etc.) (<u>good practice</u>) • 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)” (<u>good practice</u>) 	
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	<ul style="list-style-type: none"> • 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>) <ul style="list-style-type: none"> ○ material: butyl-rubber, PVC, polychloroprene with natural latex liner, material thickness: 0.5 mm, breakthrough time: > 480 min ○ 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 likely to occur, wear: rubber or plastic boots, rubber or plastic boots (<u>required</u>) 	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).
Other risk management measures related to workers. For example: Particular training systems, monitoring/reporting or auditing systems, specific control guidance.	Next measures are <u>required</u> (from EU RRS, 2008): <ul style="list-style-type: none"> • workers in the risky process/areas identified should be trained a) to avoid to work without respiratory 	

	<p>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).</p> <ul style="list-style-type: none"> • the employer has also to ascertain that the required PPE is available and used according to instructions 	
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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.

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).

Section 3. Exposure Estimation

3.1. Health (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).

See: http://www.ercros.es/esp/internas.asp?arxiu=sl_1

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/m³ (see Table 14). Most NaOH production sites replied that the OEL was 2 mg/m³ 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/m³ (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/m³ (middle value of range). The reasonable worst-case exposure is estimated as 0.17 mg/m³ (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/m³ and the reasonable worst case exposure is estimated to 0.085 mg/m³. 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/m³ and an 8-hour TWA reasonable worst case exposure is estimated as 0.04 mg/m³.

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/m³), assuming very low vapour pressure, exposure duration of more than 4 hours/day and no local exhaust ventilation or respiratory equipment.

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 relevance 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. Environment

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.

See: http://www.ercros.es/esp/internas.asp?arxiu=sl_1

Section 4. Guidance to check compliance with the Exposure Scenario

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as ECETOC TRA or EASE 2.0

Inhalation exposure to vapour due to drumming is estimated in the EU RAR (2007) with EASE 2.0.

Inhalation exposure to vapour or aerosols due to all PROCs is estimated in the ECETOC TRA.

Important note: By demonstrating a safe use when comparing exposure estimates with the long-term DNEL, the acute DNEL is therefore also covered (according to R.14 guidance, acute exposure levels can be derived by multiplying long-term exposure estimates by a factor of 2).

Section 1. Exposure Scenario Title

Exposure Scenario 2: Manufacturing of solid NaOH

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

Section 2. Operational conditions and risk management measures

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

The processes and activities for solid NaOH include the processes and activities for liquid NaOH. Solid NaOH results when molten NaOH, from which all the water has been evaporated, is allowed to cool and solidify. Flake NaOH is made by passing molten NaOH over cooled flaking rolls to form flakes of uniform thickness. The flakes can be milled and screened into several crystalline products with controlled particle size. The manufacture of NaOH beads involves feeding molten liquor into a prilling tower under carefully controlled operating conditions, producing a spherical bead (OxyChem, 2000).

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).

Risk management measures related to workers

The risk management measures related to workers are summarized in Table 1. 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	<p><u>Good practice</u>: replacing, where appropriated, manual processes by automated and/or closed processes. This would avoid irritating mists and subsequent potential splashes (EU RRS, 2008):</p> <ul style="list-style-type: none"> • Use closed systems or covering of open containers (e.g. screens) (<u>good practice</u>) • Transport over pipes, technical barrel filling/emptying of barrel with automatic systems (suction pumps etc.) 	<p>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 “open” (6 sites) or “totally closed” (9 sites).</p>

SODIUM HYDROXIDE

	<p>(good practice)</p> <ul style="list-style-type: none"> 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) 	
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	<ul style="list-style-type: none"> Respiratory protection: In case of dust or aerosol formation: use respiratory protection with approved filter (P2) (required) Hand protection: impervious chemical resistant protective gloves (required) <ul style="list-style-type: none"> material: butyl-rubber, PVC, polychloroprene with natural latex liner, material thickness: 0.5 mm, breakthrough time: > 480 min 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 (required) Wear suitable protective clothing, aprons, shield and suits, if splashes are likely to occur, wear: rubber or plastic boots, rubber or plastic boots (required) 	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).
Other risk management measures related to workers. For example: Particular training systems, monitoring/reporting or auditing systems, specific control guidance.	<p>Next measures are <u>required</u> (from EU RRS, 2008):</p> <ul style="list-style-type: none"> 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).	
	<ul style="list-style-type: none"> • the employer has also to ascertain that the required PPE is available and used according to instructions 	

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.

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).

Section 3. Exposure Estimation

3.1. Health (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.

See: http://www.ercros.es/esp/internas.asp?arxiu=sl_1

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/m³ (see Table 14). Most NaOH production sites replied that the OEL was 2 mg/m³ 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 m³/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/m³ 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 .

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 relevance 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. Environment

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.

See: http://www.ercros.es/esp/internas.asp?arxiu=sl_1

Section 4. Guidance to check compliance with the Exposure Scenario

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as ECETOC TRA or EASE 2.0.

Inhalation exposure to dust is estimated in the EU RAR (2007) with EASE 2.0 and ECETOC TRA

Important note: By demonstrating a safe use when comparing exposure estimates with the long-term DNEL, the acute DNEL is therefore also covered (according to R.14 guidance, acute exposure levels can be derived by multiplying long-term exposure estimates by a factor of 2).

Section 1. Exposure Scenario Title**Exposure Scenario 3: Industrial and professional use of NaOH**

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.

Section 2. Operational conditions and risk management measures

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

Typical 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.

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.

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

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 Na₂S, 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, Na₂S) 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.

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).

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.

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, SO₂, etc.) and in heavy metals (Hg, Cd, etc.) to comply with the requirements of international and national standards (Euro Chlor, 2004a, 2005).

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 where 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.

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.

Professional end use of formulated products

NaOH is used during the production phase of various cleaning products although in most cases 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 applied 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.

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.

Risk management measures related to industrial workers

The risk management measures related to industrial workers can be found in Table 3. 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 3 Risk management measures related to workers

Information type	Data field	Explanation
Containment plus good work practice required	<p><u>Good practice:</u> replacing, where appropriated, manual processes by automated and/or closed processes. This would avoid irritating mists, sprayings and subsequent potential splashes (EU RRS, 2008):</p> <ul style="list-style-type: none"> • Use closed systems or covering of open containers (e.g. screens) (<u>good practice</u>) • Transport over pipes, technical barrel filling/emptying of barrel with automatic systems (suction pumps etc.) (<u>good practice</u>) • 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)” (<u>good practice</u>) 	<p>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).</p> <p>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.</p> <p>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.</p>
Local exhaust ventilation required plus good work practise	Local exhaust ventilation is not required but good practice.	<p>To improve air quality and avoid potential respiratory track irritation in working areas.</p> <p>Situation at the time of the EU RAR</p>

		<p>(2007): a total of 8 of 22 customers (36%) replied that they used local exhaust ventilation when they handle NaOH on their site.</p>
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	<ul style="list-style-type: none"> • Respiratory protection: In case of dust or aerosol formation (e.g. spraying): use respiratory protection with approved filter (P2) (<u>required</u>) • Hand protection: impervious chemical resistant protective gloves (<u>required</u>) <ul style="list-style-type: none"> ○ material: butyl-rubber, PVC, polychloroprene with natural latex liner, material thickness: 0.5 mm, breakthrough time: > 480 min ○ 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 (<u>required</u>) • if splashes are likely to occur, wear suitable protective clothing, aprons, shield and suits, rubber or plastic boots, rubber or plastic boots (<u>required</u>) 	<p>Situation at the time of the EU RAR (2007): the questionnaire indicated that twenty-nine 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).</p>
Other risk management measures related to workers. For example: Particular training systems, monitoring/reporting or auditing systems, specific control guidance.	<p>Next measures are <u>required</u> (from EU RRS, 2008):</p> <ul style="list-style-type: none"> • 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 	
Measures related to the design of product (other than concentration) related to workers	<ul style="list-style-type: none"> • High viscosity adjustment with aids (good practice) • Delivery only as barrel commodity and/or in the tank car (good practice) 	to avoid splashes

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 4 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 4 Personal protective equipment related 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

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.

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).

Section 3. Exposure Estimation

3.1. Health (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

See: http://www.ercros.es/esp/internas.asp?arxiu=sl_1

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 relevance 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. Environment

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 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 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.

See: http://www.ercros.es/esp/internas.asp?arxiu=sl_1

Section 4. Guidance to check compliance with the Exposure Scenario

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as ECETOC TRA.

Estimated inhalation exposure concentrations to workers according to the ECETOC TRA tool.

Important note: By demonstrating a safe use when comparing exposure estimates with the long-term DNEL, the acute DNEL is therefore also covered (according to R.14 guidance, acute exposure levels can be derived by multiplying long-term exposure estimates by a factor of 2).

Section 1. Exposure Scenario Title

Exposure Scenario 4: Consumer use of NaOH

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

Section 2. Operational conditions and risk management measures

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 m².

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 to 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 µm). 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 used 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 cases 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.

Risk management measures related to consumers (all except batteries)

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

Measures 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 protection with approved filter (P2)	required	good practice	no
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.			
Waste related measures			
<p>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 municipal waste.</p> <p>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.</p>			
Section 3. Exposure Estimation			
3.1. Health (consumer exposure)			
<p>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.</p> <p>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 negligible 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.</p> <p>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.</p>			
Acute/Short term exposure			
<p>Acute/short term exposure was assessed only for the most critical use: use of NaOH in a spray oven cleaner</p> <p>Inhalation exposure to NaOH in the oven cleaner was estimated using different modelling approaches:</p> <ol style="list-style-type: none"> 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) <p>See: http://www.ercros.es/esp/internas.asp?arxiu=sl_1</p>			
Long-term exposure			
<p>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.</p> <p>NaOH is not expected to be systemically available in the body under normal handling and use conditions and therefore systemic</p>			

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.

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).

3.2. 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.

Section 4. Guidance to check compliance with the Exposure Scenario

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as ConsExpo software.

Inhalation exposure to NaOH in the oven cleaner was estimated using ConsExpo software.

Important note: By demonstrating a safe use when comparing exposure estimates with the long-term DNEL, the acute DNEL is therefore also covered (according to R.14 guidance, acute exposure levels can be derived by multiplying long-term exposure estimates by a factor of 2).