

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: Potassium hydroxide (anhydrous)
Index number under Regulation (EC) No 1272/2008 on classification, labelling and packaging: 019-002-00-8
CAS number: 1310-58-3
REACH Registration number: 01-2119487136-33-0004

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

- Pharmaceutical industry,
- Potassium salts,
- Dyes and Colorants.

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:**

Acute toxicity: category 4, H302

Skin corrosive: category 1A, H314

| Metals corrosive; category 1, H290

H302: Harmful if swallowed.

H314: Causes severe skin burns and eye damage.

| H290: May be corrosive to metals.

Classification according to Directive 67/548/EEC:

Xn; R22: Harmful if swallowed.

C; R35: Causes severe burns.

2.2. Label elements**DANGER**

H302: Harmful if swallowed.

H314: Causes severe skin burns and eye damage.

| H290: May be corrosive to metals.

P260: Do not breathe dust/fume/gas/mist/vapours/spray.

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

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

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

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

2.3. Other hazards

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

Physicochemical hazards:

In contact with the metals aluminium, tin and zinc, it releases hydrogen (a flammable gas at between 4 and 75% by volume in air).

Dilution with water produces a very exothermic reaction.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS
3.1 Substances

Name: Potassium hydroxide

CAS number: 1310-58-3

EC number: 215-181-3

IUPAC name: Potassium hydroxide

Index number under Regulation (EC) No 1272/2008 on classification, labelling and packaging: 019-002-00-8

Composition:

| Index number R. 1272/2008 | EC number | CAS number | Name | Concentration | Classification Directive 67/548/EEC | Classification Regulation (EC) 1272/2008 | Specific concentration limits |
|------------------------------|-----------|------------|---------------------|---------------|----------------------------------------|-----------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 019-002-00-8 | 215-181-3 | 1310-58-3 | Potassium hydroxide | 89.5% min. | Xn; R22 C; R35 | Acute Tox. 4, H302 Skin Corr. 1A, H314 Met. Corr. 1, H290 | 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 % |
| 011-002-00-6 | 215-185-5 | 1310-73-2 | Sodium hydroxide | 1% max. | C; R35 | Skin Corr. 1A, H314 Met. Corr. 1, H290 | 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 patient to a well ventilated place and keep warm. Seek immediate medical attention

4.1.2. After skin contact:

Wash the area affected with plenty of water for at least 15 minutes, removing soiled clothing and shoes. Seek immediate medical attention.

4.1.3. After eye contact:

Wash eyes with plenty of water for at least 30 minutes. Seek immediate medical attention.

4.1.4. In case of ingestion:

Do not induce vomit.

If conscious, give water on demand and seek immediate medical attention.

4.1.5. Recommended personal protective equipment for first aid responders:

Use face-shield to prevent projections, as well as clothing, gloves and shoes suitable for the protection of 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:

Abundant pulverised water.

The heat generated in contact with water (heat of solution), may bring about the ignition of other combustible materials if the amount of water used is not abundant.

Unsuitable extinguishing media:

CO2 powder (powdered dry ice).

5.2. Special hazards arising from the substance or mixture

The product is not flammable or explosive.

5.3. Advice for firefighters

Use face-shield to prevent projections, as well as clothing, gloves and shoes suitable for the protection of the skin. Always seek emplacement with your back against the wind.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with the eyes and skin. Do not act without appropriate protective equipment (see section 8).

6.2. Environmental precautions

Keep the product away from drains and surface waters. If the product reaches a natural water course immediately inform Civil Protection authorities.

6.3. Methods and material for containment and cleaning up

Absorb the spill with sand, soil or clay.

Take the absorbent products to a controlled landfill or to a safe storage for treatment by an authorised waste manager.

6.4. Reference to other sections

See protection measures in section 8. Take into account the incompatibilities described in sections 7 and 10.

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, make sure that the containers, vessels and tanks to be used clean, dry and appropriate for the intended use.

Containers shall be properly closed and appropriately labelled.

Have special precaution to avoid remains of products such as aluminium, zinc, tin, acid or organic products.
Avoid dust formation during handling. Avoid contact with the skin, eyes and clothing.
Always use the recommended protective clothing.

7.2. Conditions for safe storage, including any incompatibilities

Recommended materials for containers: Approved double-layer polyethylene sacs or big-bags suitable for containing solids belonging to Packaging Group II.

Incompatible materials: Aluminium, tin, zinc and alloys (bronze), chromium and lead.

Storage conditions: Keep in a cool, well ventilated and dry place.

Special conditions: In contact with air it becomes carbonated with CO₂ (carbon dioxide).

Applicable regulations: COUNCIL DIRECTIVE 96/82/EC of 9 December 1996 on the control of major accident hazards involving dangerous substances.

7.3. Specific end use(s)

In the different applications of the product, direct contact with acids shall be avoided. **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 event of emission of potassium hydroxide powder, use mask with a dust filter (EN 143 P2 or

P3).

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

Eye protection: Use safety goggles (EN 166).

Skin protection: Anti-acid suit or plastic apron (EN 340).

8.2.3. Environmental exposure controls

Avoid the material from reaching drains and/or surface waters.

Measurement system: Acid-base titration.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

| | |
|-----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Appearance (physical state and colour): | Solid. White flakes. |
| Odour: | None. |
| Odour threshold: | No data available. |
| pH: | 14 |
| Melting point/freezing point: | 406 °C (CRC Handbook of Chemistry & Physics) |
| Initial boiling point and boiling range: | 1327 °C at 1013 hPa |
| 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. |
| 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 |

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| | 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: | 2,044 g/cm ³ at 20 °C |
| Solubility: | No data available. |
| Water solubility: | 121 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

The substance reacts exothermically with water and acids.

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

Highly exothermal reaction with water, acids and alcohols.

10.4. Conditions to avoid

Avoid storing outside for excessive periods of time to prevent degradation of the sac.

10.5. Incompatible materials

Aluminium, zinc, tin and acids.

10.6. Hazardous decomposition products

The product decomposes into toxic fumes of potassium oxide.

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%)

333-388 mg/kg body weight (male rat)
(Method equivalent to OECD 425) (Bruce RD, 1987)
Acute toxicity: category 4, Harmful if swallowed

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|---------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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. |
| 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. |
| 11.2.4. Skin corrosion /irritation | <p>Skin corrosive: Category 1A, H314: Causes severe skin burns and eye damage.</p> <p>Results from several <i>in vitro</i> and <i>in vivo</i> studies (rabbit, guinea pig)</p> |
| 11.2.5. Serious eye damage/irritation | <p>Corrosive: Category 1A, H314: Causes severe skin burns and eye damage.</p> <p><i>In vivo</i> study (rabbit) (Method equivalent to OECD 405) (Johnson GT et al., 1975)</p> |
| 11.2.6 Specific target organ toxicity – single exposure | No data available. |

11.3. Sensitisation:

Respiratory sensitisation: No data available.

Skin sensitisation: Not sensitising (male guinea pig) (Johnson GT et al., 1975)

11.4. Repeated dose toxicity:

Specific target organ toxicity – repeated exposure: Potassium hydroxide 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, since the substance rapidly dissociates and the OH⁻ ions are neutralised by the body mechanisms.

In vivo testing shall be avoided with corrosive substances at concentrations/dose levels causing corrosivity.

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

Carcinogenicity: The substance did not induce mutagenicity in *in vitro* and *in vivo* studies. 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:

Negative results observed in *in vitro* gene mutation studies in bacteria (Ames Test).

The *in vivo* studies carried out with the substance sodium hydroxide indicated no evidence of mutagenic activity.

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: No data available.

11.6. Aspiration hazard:

No data available.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

The hazard of KOH for the environment is caused by the hydroxyl ion (pH effect). For this reason the effect of KOH on the organisms depends on the buffer capacity of the aquatic or terrestrial.

Acute toxicity to fish

LC50 (lethal concentration, 50%):

Potassium hydroxide is a strong alkaline substance that dissociates completely in water to K⁺ and OH⁻. Therefore, the only possible effect would result from the pH effect. KOH added to any test medium will directly affect the pH and while at the same time the pH in tests needs to be controlled within a given range. Therefore, a “standard” test with KOH cannot be conducted.

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%):

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.

Chronic toxicity to crustaceans

POTASSIUM HYDROXIDE

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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%): | 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. |
| Toxicity data on soil micro- and macro-organisms and other environmentally relevant organisms, such as birds, bees and plants | |
| The presence of the substance in the soil will be negligible due to its high water solubility and its low octanol-water partitioning coefficient. Significant emissions to the terrestrial environment are not expected during normal handling and use of the substance. | |
| <u>12.2. Persistence and degradability</u> | |
| Readily biodegradable | Not applicable (inorganic substance). |
| Other relevant information | <p>Abiotic degradation:</p> <p>KOH is a strong alkaline substance that dissociates completely in water to K^+ and OH^-. High water solubility and low vapour pressure indicate that KOH 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.</p> |
| <u>12.3. Bioaccumulative potential</u> | |
| Bioconcentration factor (BCF): experimental data: | Considering its high water solubility, KOH is not expected to bioconcentrate in organisms. |
| Partition coefficient: n-octanol/water (log Pow): | Not applicable (inorganic substance). |
| <u>12.4. Mobility in soil</u> | |
| Not applicable. | |

12.5. Results of PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) assessment**Persistence Assessment (P):**

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

Bioaccumulation Assessment (B):

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

Toxicity Assessment (T):

Although LC50 values for aquatic organisms could not be reliably measured, the lowest reported LC50 for freshwater and marine organisms suggests to be above the cut-off value of 0.1 mg/L. Therefore, KOH does not meet the T criterion in the PBT assessment.

The substance does not fulfill the criteria for persistence, bioaccumulation and toxicity. Therefore, KOH 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 the spill with sand, soil or clay. The absorbent products shall be treated by an authorised waste manager, the same as used containers and waste.

The product can be neutralised with very dilute hydrochloric acid, performing this operation very slowly and always by skilled personnel wearing appropriate protective clothing.

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 1813 | |
| 14.1.2 UN proper shipping name: | POTASSIUM 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 1813 | |
| 14.2.2 UN proper shipping name: | POTASSIUM 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 1813 | |
| 14.3.2 UN proper shipping name: | POTASSIUM 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 4^a 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).
- IUCLID DATA SET

Abbreviations:

N/A = not applicable

< SMALLER THAN > GREATER THAN

VLA-EC: Valor Limite 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: Potassium hydroxide.

| Section 1. Exposure Scenario Title | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| Exposure Scenario 1: Manufacturing of liquid KOH | | |
| <p>PROC 1, 2, 3, 4, 8a, 8b, 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> <p>PC and AC not applicable for this ES</p> | | |
| Description of activities and processes covered in the exposure scenario | | |
| <p>KOH is produced commercially by an electrolytic process. Brine, prepared from potassium chloride, is electrolyzed in either a mercury cell or membrane cell. The coproducts are chlorine and hydrogen. In the mercury cell process, a potassium-mercury amalgam is formed in the cell. The amalgam is sent to a decomposer where it is reacted with water to form liquid KOH, hydrogen and free mercury. The free mercury is returned to the electrolytic cell. The resulting KOH 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 KOH solution is stored in storage tanks prior to shipment. Solid KOH is obtained through further concentration of 50% KOH.</p> | | |
| Section 2. Operational conditions and risk management measures | | |
| Operational conditions | | |
| <p>The amount used per worker varies from activity to activity. The maximum duration considered for this exposure scenario is a full working shift (8h/day) and 200 days/year. Production sites usually manufacture liquid KOH with a concentration of about 50%. Some sites have also other liquid products (between 10 and 75%).</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 potassium 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 manufacturing of potassium hydroxide. Respiratory protection is needed when aerosols of potassium 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>Good practice: replacing, where appropriate, manual processes by automated and/or closed processes. This would avoid irritating mists, sprayings and subsequent potential splashes:</p> <ul style="list-style-type: none"> • 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) | Partly based on the EU RRS (2008) for NaOH |
| 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 |
| General ventilation | General ventilation is good practice unless local exhaust ventilation is present | To improve air quality and avoid potential respiratory track irritation in |

| | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| 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"> 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 (required) • Wear suitable protective clothing, aprons, shield, protective helmet and suits, if splashes are likely to occur, wear: rubber or plastic boots, rubber or plastic boots (required) | working areas. |
| Other risk management measures related to workers. For example: Particular training systems, monitoring/reporting or auditing systems, specific control guidance. | Next measures are required (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 protection and b) to understand the corrosive properties and, especially, the respiratory inhalation effects of potassium hydroxide and c) to follow the safer procedures instructed by the employer • the employer has also to ascertain that the required PPE is available and used according to instructions | Partly based on the EU RRS (2008) for NaOH |

Risk management measures related to environment

Risk management measures related to the environment aim to avoid discharging KOH solutions into municipal wastewater or to surface water, in case such discharges are expected to cause significant and undesired pH changes. Adequate 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. 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 KOH waste should be reused or discharged to the industrial wastewater and further neutralized if needed (cfr. RMM related to environment).

Section 3. Exposure Estimation

3.1. Health (workers exposure)

KOH 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 >2% KOH formulations is not quantitatively assessed. Ocular exposure is possible due to hand-eye contact but this is not quantified.

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

Furthermore KOH has a negligible vapour pressure and is rapidly neutralized in air by carbon dioxide and therefore dust and vapour exposure are not expected. For production and major uses of KOH, aerosols/mists do normally not occur. Different to NaOH, specific uses with a possibility of formation of aerosols are not known for KOH applications. In every case, it should be realised that aerosols of KOH are not stable. They are rapidly transformed due to an uptake of carbon dioxide from the atmosphere resulting in the formation of potassium bicarbonate and potassium carbonate. Cooper et al. (1979) reported that the transformation of respirable NaOH aerosols into carbonate aerosols could occur in seconds. Analytical measurements, to determine KOH concentrations in the air of working places during production and use, seem to be unavailable (OECD SIAR, 2002). There are no measured inhalation data available for KOH. However, measured data from the analogous NaOH can be used as a surrogate for KOH.

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

Measured data

In the EU RAR (2007) for NaOH, 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. 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.

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

Modelled data

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.

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 KOH. Any potential for exposure to KOH due to environmental releases will only have relevance at the local scale. Any pH effect of local releases will be neutralised by the buffer capacity of the receiving water and therefore no pH impacts at the regional scale related to KOH releases should be expected. Therefore *indirect* exposure of humans via the environment (oral) is not relevant in the case of KOH. This conclusion is similar to OECD SIAR (2002).

3.2. Environment

Similar to what is 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 only dealt 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. The same approach is valid for KOH. The main effect to organisms/ecosystems will be due to possible pH changes related to the OH⁻ discharges as the K⁺ ion is expected to be insignificant compared to the (potential) pH effect. Therefore, 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 safety assessment. Furthermore, the high water solubility and very low vapour pressure indicate that KOH will be found predominantly in water. Significant emissions or exposure to air are not expected due to the very low vapour pressure of KOH. 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 KOH to particulate matter will not occur in STPs/WWTPs.

In the EU RAR on NaOH (2007), a survey was conducted on environmental impact of NaOH at producer and downstream user level. The main outcome was that local procedures are usually in place to prevent discharges outside the pH range required by authorities, such as recycling, mixing with other streams for neutralisation or discharge to a WWTP when that is considered favourable. This outcome is also valid for KOH and will be used in this dossier.

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.

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 KOH

PROC 1, 2, 3, 4, 8a, 8b, 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 KOH include the processes and activities for liquid KOH. Solid KOH results when molten KOH, from which most of the water has been evaporated (commercial solid KOH typically contains ca.10 % of water), is allowed to cool and solidify. Flake KOH is made by passing molten KOH over cooled flaking rolls to form flakes of uniform thickness.

Flakes can be packed in bags (25 kg), bulk bags (500 or 1,000 kg) or in metallic drums (e.g. 400 kg). However, it should be realised that other packaging forms could exist. The shifts can be 8 hrs/day (40 hours/week).

Risk management measures related to workers

Relevant risk management measures related to workers are described in ES1.

Risk management measures related to environment

Relevant risk management measures related to environment are described in ES1.

Waste related measures

There is no solid waste of KOH. Liquid KOH 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)

KOH 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 is negligible. Therefore according to the NaOH EU RAR (2007), dermal exposure to >2% KOH will not be quantitatively assessed. KOH is not expected to be systemically available in the body under normal handling and use conditions and therefore systemic effects of KOH after dermal or inhalation exposure are not expected to occur.

Dust formation is unlikely because of the hygroscopic properties. Furthermore KOH has a negligible vapour pressure and is rapidly neutralized in air by carbon dioxide and therefore dust and vapour exposure are not expected. For production and major uses of KOH, aerosols/mists do normally not occur. Different to NaOH, specific uses with a possibility of formation of aerosols are not known for KOH applications. In every case, it should be realised that aerosols of KOH are not stable. They are rapidly transformed due to an uptake of carbon dioxide from the atmosphere resulting in the formation of potassium bicarbonate and potassium carbonate. Cooper et al. (1979) reported that the transformation of respirable NaOH aerosols into carbonate aerosols could occur in seconds. Analytical measurements, to determine KOH concentrations in the air of working places during production and use, seem to be unavailable (OECD SIAR, 2002).

Inhalation of KOH dust does normally not occur. Most of the production of KOH is in the liquid form (mostly 50% solution). Potential dust formation during drying, pellets production and packing occurs normally in closed systems, which is essential for the product quality, to avoid moisture and carbon dioxide absorption. Moreover, as KOH is a deliquescent solid, the potential for dust formation is low (OECD SIAR, 2002).

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

Measured data

A data set is gathered from an open system with local exhaust ventilation. The pelletization belt and filling are the most critical processes. Other steps in the process are more contained. Sampling was done with air pump, flow was going through the filter. KOH is dissolved with water and in excess of HCl. The remaining of HCl is titrated with KOH. The indicator used is methylred. This analytical method is compliant with NIOSH 7401. The exposure time was 340 or 505 minutes. These relate to an 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 0.20 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 low dustiness, no LEV and no respiratory protection, ECETOC TRA predicts inhalative exposure of 0.01 mg/m³ for PROC 1 and PROC 2, 0.1 mg/m³ for PROC 3 and PROC 9, 0.5 mg/m³ for PROC 4 and PROC 8a.

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 KOH. Any potential for exposure to KOH due to environmental releases will only have relevance at the local scale. Any pH effect of local releases will be neutralised by the buffer capacity of the receiving water and therefore no pH impacts at the regional scale related to KOH releases should be expected. Therefore *indirect* exposure of humans via the environment (oral) is not relevant in the case of KOH. This conclusion is similar to OECD SIAR (2002).

3.2. Environment

Potassium hydroxide will rapidly dissolve and dissociate in water when released to water. The environmental exposure assessment for solid potassium hydroxide is consequently the same as for liquid potassium hydroxide. (See ES1)

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.

Inhalation exposure is estimated with 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 solid and liquid KOH**

The OECD SIAR report (last update Feb 2002) gives an overview of the uses for KOH.

KOH has mainly industrial uses. On a global level the main uses are: production of potassium carbonate (26 %), chemical manufacturing (16 %), production of potassium chemicals (12 %), production of fertilizers (11 %), production of phosphates (9 %), production of detergents (8 %), production of agricultural chemicals (7 %), production of alkaline batteries (6 %), all other (5 %) (OECD SIAR, 2002).

So, more than 95% of the KOH production is for non dispersive use, and is consumed by the industry, mainly by large enterprises. KOH is used in these applications as an intermediate or as a reactive processing aid and does not leave the plant where it is used. In these applications, KOH is consumed in a reaction and is no more present in the product that goes to the market.

KOH is still present in the alkaline batteries, but here this substance is strictly confined in the battery screening and does not come in contact with the consumer.

Less than 5% of the KOH production is for wide dispersive use and enters in the composition of products for professional use or consumer products (eventually to be consumed in small enterprises like garages or farms): paint and varnish removers, drain cleaners (Howell, 1991; Leape et al., 1971), degreasing agents (Swanson et al., 1995) and dairy pipeline cleaners (Edmonson, 1987).

Potassium 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 (e.g. sampling)
- 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 for formulation of preparations and articles
- PROC7 Spraying in industrial settings and applications
- PROC8a/b Transfer of substance or preparation (charging/discharging) from/to vessels/large containers
- PROC9 Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
- PROC 10 Roller application or brushing of adhesive and other coating
- PROC11 Spraying outside industrial settings or applications
- PROC13 Treatment of articles by dipping and pouring
- PROC14 Production of preparations or articles by tableting, compression, extrusion, pelettisation
- PROC15 Use a laboratory reagent
- PROC19 Hand-mixing with intimate contact and only PPE available
- PROC23 Open processing and transfer operations (with minerals) at elevated temperature
- PROC24 High (mechanical) energy work-up of substances bound in materials and/or articles
- PROC26 Handling of solid inorganic substances at ambient temperature

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

Potassium hydroxide can be used in many different chemical product categories (PC): Coatings and Paints, Fillers, Putties, Thinners (PC 9), Fertilizers (PC12), Intermediate (PC19), Products such as pH-regulators, flocculants, precipitants, neutralization agents (PC20), Washing and Cleaning Products (PC35), Water treatment chemicals (PC37), Cosmetics (PC39), Extraction agents (PC40). However, it could potentially also be used in other chemical product categories (PC 0 - 40).

Because potassium 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 1-23).

The article categories (AC) are not applicable for potassium hydroxide in this exposure scenario.

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

ERC2 Formulation of preparations ERC4 Industrial use of processing aids

ERC5 Industrial use resulting in inclusion into or onto a matrix ERC6 Industrial use of intermediates and reactive processing aids ERC7 Industrial use of substances in closed systems

ERC8 Wide dispersive indoor and outdoor use of reactive substances, processing aids in open systems

The environmental release categories mentioned above are assumed to be the most important ones but other environmental release categories could also be possible (ERC 1 - 11b).

Section 2. Operational conditions and risk management measures

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

Potential human exposure to KOH is thus for less than 5% of its total production. Without taking into account recycling of the alkaline batteries (these represent 6 % of the total production), which is normally done in many countries, the potential exposure to the environment is less than 11% of the total production. Losses through production, through processes that use the compound and through disposal of the compound are minimized. The pH of effluents of production sites is controlled and these must be neutralized, this being normally regulated according to local requirements.

Use of KOH and formulations by industry

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

KOH is also used in alkaline batteries. KOH is still present in the alkaline batteries, but here this substance is strictly confined in the battery screening and does not come in contact with the worker/professional/consumer. Recovery of KOH from alkaline batteries includes emptying the electrolyte, collection and neutralization with sulphuric acid and carbon dioxide, optionally including sedimentation step to remove Ni and Cd ions

Use of KOH and formulations by professionals

KOH also has professional uses. This includes following processes/activities: transfer of KOH by professionals and wide dispersive indoor and outdoor use of KOH-containing formulations: detergents, fertilizers, drain cleaners, paint strippers, cosmetics/personal care, etc.

In fertilizers, KOH usually interacts with other ingredients in acid-base reactions and thus practically no free KOH is left in the final product. In some cases, up to 20% of free KOH can still be present in the fertilizer. In that case, the fertilizer also has an intended pH-correction function.

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

Table 2: Product categorization for professional cleaning products with remaining free KOH after formulation

| Product type | 'free KOH' 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 cleaning ovens, grills, etc. Oven cleaners contain strong alkaline ingredients. Strong alkali is effective in removing burned-on contamination. 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 potassium 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 should be done into cold oven. There is 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. Liquid drain openers have a maximum KOH 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 90%. 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 floor strippers

Floor strippers in I&I applications are not used. The highly alkaline products are dosed 15-20% and per 10 m² 12 L stripper solution is applied to the floor with a single disc machine. Usually 10-15 min acting time are necessary between applying and scrubbing the floor. Afterwards the stripper/polish mixture is removed by a vacuum cleaner.

Risk management measures related to workers

The risk management measures related to workers can be found in Table 3. This table applies to both liquid and solid KOH containing products at concentration >2%. Because potassium hydroxide is corrosive, the risk management measures for human health aim to avoid direct contact with the substance. For this reason automated and closed systems should preferably be used for industrial and professional uses of potassium hydroxide. Respiratory protection is needed when aerosols of potassium hydroxide can be formed. Due to the corrosive properties appropriate skin and eye protection is required.

Table 3: Risk management measures related to worker

| Information type | Data field | Explanation |
|------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| Containment plus good work practice required | <p><u>Good practice</u>: replacing, where appropriate, manual processes by automated and/or closed processes. This would avoid irritating mists, sprays and subsequent potential splashes:</p> <ul style="list-style-type: none"> • Use closed systems or cover open containers (e.g. screens) (<u>good practice</u>) • Transport through 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>) | Partly based on the EU RRS (2008) for NaOH |
| 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 |
| General ventilation | General ventilation is good practice unless local exhaust ventilation is present | To improve air quality and avoid potential respiratory track irritation in |

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| | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| 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"> 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 (required) • Wear suitable protective clothing, aprons, shield, protective helmet and suits, if splashes are likely to occur, wear: rubber or plastic boots, rubber or plastic boots (required) | working areas. |
| Other risk management measures related to workers. For example: Particular training systems, monitoring/reporting or auditing systems, specific control guidance. | Next measures are required (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 protection and b) to understand the corrosive properties and, especially, the respiratory inhalation effects of potassium hydroxide and c) to follow the safer procedures instructed by the employer • the employer has also to ascertain that the required PPE is available and used according to instructions | Partly based on the EU RRS (2008) for NaOH |
| 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 tank car (good practice) | to avoid splashes |

Risk management measures related to professionals

Because potassium 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 potassium hydroxide. When automated, closed systems and local exhaust ventilation is less feasible to implement, product related design measures preventing direct eye/skin contact with KOH and preventing formation of aerosols and splashes are more important in addition 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 KOH concentration in the preparation, a different degree of restriction is proposed.

Table 4: Personal protective equipment related to professional use

| | KOH concentration in product > 2% | KOH concentration in product between 0.5% and 2% | KOH concentration in product < 0.5% |
|--|-----------------------------------|--------------------------------------------------|-------------------------------------|
| | | | |

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| | | | |
|--------------------------------------------------------------------------------------------------------------------------------------------|------------|---------------|------------|
| Respiratory protection: In case of dust or aerosol formation (e.g. spraying): use respiratory protection with approved filter (P2) | compulsory | good practice | Not needed |
| Hand protection: In case of potential dermal contact: use impervious chemical resistant protective gloves | compulsory | good practice | Not needed |
| Protective clothing: If splashes are likely to occur, wear suitable protective clothing, aprons, shield and suits, rubber or plastic boots | compulsory | good practice | Not needed |
| Eye protection: If splashes are likely to occur, wear tightly fitting chemical resistant safety goggles, face -shield | compulsory | good practice | Not needed |

Risk management measures related to environment

Relevant risk management measures related to environment are described in Section 9.1.1.4.2. There are additionally some specific environmental risk management measures related to fertilizers containing up to 20% of KOH in the end product. Direct releases to adjacent surface waters should be avoided. Drift should be minimized. And in line with the requirements for good agricultural practice, agricultural soil should be analyzed

Waste related measures

Liquid KOH waste should be reused or discharged to industrial wastewater and further neutralized if needed (cfr. RMM related to environment).

Section 3. Exposure Estimation

3.1. Health (workers exposure)

KOH is a corrosive substance at concentrations >2%. For the handling of corrosive substances and formulations, immediate dermal contacts occur only occasionally and it is assumed that repeated daily dermal exposure is negligible. Therefore according to the NaOH EU RAR (2007), dermal exposure to >2% KOH will not be quantitatively assessed. Repeated dermal exposure is negligible for <2% formulations.

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

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

Measured exposure concentrations

One measured exposure concentration of KOH was available from the textile industry. Even though the use of closed systems for KOH is wide-spread in the majority of the textile industry, an open use measurement for KOH (during cleaning of the machinery) showed less than 0.06 mg/m³.

The amount of alkali dust was measured in three sampling locations of a downstream user. The three sampling locations are packaging (filter placed where belt from container and elevator belt meet), personal sampler by operator and placed close to the filling operations. These are the most critical steps for occupational exposure to KOH. The exposure time was respectively 260, 270 and 263 minutes. The inhalable dust fraction was respectively 0.8, 1 and 0.3 mg/m³. These measurements are an overestimation because all dust is assumed to originate from alkali. These measurements are therefore not suitable for risk characterization of KOH.

Estimated exposure concentrations

The ECETOC TRA was used to estimate the concentrations. 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. Professional use was specified where relevant as a worst-case assumption. For the solid, the low dustiness class was selected because KOH is very hygroscopic. 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 is not applicable.

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 KOH. Any potential for exposure to KOH due to environmental releases will only have relevance at the local scale. Any pH effect of local releases will be neutralised by the buffer capacity of the receiving water and therefore no pH impacts at the regional scale related to KOH releases should be expected. Therefore indirect exposure of humans via the environment (oral) is not relevant in the case of KOH. This conclusion is similar to OECD SIAR (2002).

3.2. Environment

Analogously as argued 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 KOH 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 KO 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 KOH will be found predominantly in water. Significant emissions to air are not expected due to the very low vapour pressure of KOH. 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 KOH 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.

Inhalation exposure concentrations were estimated with 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 4: Consumer use of solid and liquid KOH (excl. batteries)

SU21: private households

PROC not applicable for this ES

PC 9 Coatings and Paints, Fillers, Putties, Thinners PC12 Fertilizers

PC20 Products such as pH-regulators, flocculants, precipitants, neutralization agents, other

PC28 Perfumes, fragrances

PC35 Washing and Cleaning Products (including solvent based products)

PC39 Cosmetics

However, it could potentially also be used in other chemical 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

Less than 5% of the KOH production is applied in wide dispersive uses and enters in consumer products paint and varnish removers, drain cleaners (Howell, 1991; Leape et al., 1971), degreasing agents (Swanson et al., 1995) and dairy pipeline cleaners (Edmonson, 1987).

The amounts used will interact with other ingredients in acid-base reactions and thus practically no KOH is left in the final consumer product. However, some cleaning products may contain 0.25-0.45% of KOH in the final formulation. Some toilet cleaners may contain up to 1.1% and certain soaps contain up to 0.5% of KOH in the final formulation.

Risk management measures related to consumers

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 potassium 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 appropriate use instructions, and product information should always be provided to consumers. This clearly can reduce the risk of misuse. For reducing the number of accidents, it is advisable to use these products in the absence of children or other sensitive groups. To prevent improper use of potassium 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 deliver 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

| | KOH concentration in product > 2% | KOH concentration in product between 0.5% and 2% | KOH 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 | Not needed |
| Hand protection: In case of potential dermal contact: use impervious chemical resistant protective gloves | required | good practice | Not needed |
| Eye protection: If splashes are likely to occur, wear tightly fitting goggles, face -shield | required | good practice | Not needed |

Risk management measures related to environment

There are no specific risk management measures related to environment.

Waste related measures

Wasted material and its containers 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.

Section 3. Exposure Estimation

3.1. Health (consumer exposure)

For consumer exposure it is important to stress that potassium hydroxide exposure is an external exposure. Contact with tissue and water will give potassium and hydroxide ions which are abundantly present in the body.

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.

Potassium hydroxide is a food additive, listed as E525 in Annex 1 of Directive 95/2/EU. This means that KOH is a general food additive to be used following the "quantum satis" principle: as much as necessary according to GMP (European Union, 1995).

The concentration of potassium is limited under the EU Directive on Drinking Water Quality 80/778/EEC. The potassium guide level is 10 mg/l and the maximum allowable concentration is 12 mg/l (European Economic Community, 1980). The taste threshold of KOH in water is reported to be 1 to 50 mg/l (Mc Kee et al., 1963).

The normal daily dietary intake of potassium in humans is approximately 2 - 4 g (FASEB, 1979), typically 2-6 g in the US diet (Saxena, 1989). The daily dietary intake of K is recommended to be approximately 2.4 g or more because this is associated with a reduced risk of stroke-related mortality (Burgess et al., 1999). In line with the conclusion for NaOH (EU RAR, 2007), it was concluded that the potassium uptake due to the use of KOH containing products is negligible compared to the daily dietary intake of potassium ions. The effect of potassium intake is not further considered in this dossier.

Since accidental exposure is normally excluded from an EU chemical safety assessment and accidental exposure is considered in the OECD SIAR of KOH (2002, Section 2.2, page 5), accidental exposure will not be further assessed in this dossier.

Indirect exposure of humans via the environment (oral)

Indirect exposure to humans, for example through the uptake of drinking water, is not relevant for KOH. Any potential for exposure to KOH due to environmental releases will only have relevance at the local scale. Any pH effect of local releases will be neutralised by the buffer capacity of the receiving water and therefore no pH impacts at the regional scale related to KOH releases should be expected. Therefore indirect exposure of humans via the environment (oral) is not relevant in the case of KOH. This conclusion is similar to OECD SIAR (2002).

3.2. Environment

Consumer uses relate to already diluted products which will be quickly further neutralized in the sewer and therefore will not reach 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.

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 5: Consumer use, service life and waste stage of KOH in batteries

SU21: private households

PROC not applicable for this ES

PC not applicable for this ES

AC 3: Electrical batteries and accumulators

Section 2. Operational conditions and risk management measures

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

Aqueous potassium hydroxide is employed as electrolyte in alkaline batteries based on nickel-cadmium and manganese dioxide-zinc. Potassium hydroxide is preferred over sodium hydroxide because its solutions are more conductive. KOH is still present in alkaline batteries, but the substance is strictly confined in the battery containers and is not in direct contact with consumers.

The industrial and professional uses of KOH in batteries (incl. recycling operations) are covered under ES 3 (Section 9.3). This ES focuses on the consumer use, the service life and the end-of-life stage of KOH in batteries. Batteries are sealed articles and during normal use its contents, including KOH, will not be directly released and emission from KOH in these life-cycle stages should be minimal.

Risk management measures related to consumers

Measures 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

Due to the negligible exposure of KOH during normal battery use and disposal, there are no specific risk management measures related to environment.

Waste related measures

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

Section 3. Exposure Estimation

3.1. Health (consumer exposure)

Consumer exposure is negligible 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 KOH. Any potential for exposure to KOH due to environmental releases will only have relevance at the local scale. Any pH effect of local releases will be neutralised by the buffer capacity of the receiving water and therefore no pH impacts at the regional scale related to KOH releases should be expected. Therefore indirect exposure of humans via the environment (oral) is not relevant in the case of KOH. This conclusion is similar to OECD SIAR (2002).

3.2. Environment

The environmental release from the consumer use during service life is negligible because batteries are sealed articles with a long service life. After use, batteries normally are recycled and even in case it is disposed as municipal waste, KOH is not expected to cause a significant (pH) effect to the environment when incinerated or landfilled.

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.

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).

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