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Reg No: 2015/060029/07 Vat No: 4610268676

Identification

GHS Product Identifier

SODIUM HYDROXIDE 2 - 50%

Other means of identification

CAS:	1310-73-2 (Sodium Hydroxide)
EINECS:	215-185-5
RTECS:	WB4900000
ICSC:	0360
NSC:	135799
UN:	1824
Chemical Family:	Hydroxide
Synonyms:	50 % Caustic soda
	caustic lye
	CAUSTIC SODA
	Caustic soda liquor
	Caustic soda lye
	Caustic Soda NaOH
	Caustic Soda Solution
	caustic soda, liquid
	lye solution
	NaOH
	Soda lye
	Soda, caustic
	Sodium Hydroxide 50% Solution
	Sodium hydroxide in aqueous solution
Proper Shipping Name:	SODIUM HYDROXIDE SOLUTION
Chemical Formula:	NaOH

Recommended use of the chemical and restriction on use

Industrial Water Treatment.

Supplier's details

AQUATRADE WATER TREATMENT CHEMICALS (PTY) LTD

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<u>www.aquatradesa.co.za</u> Tel: +27 11 394 0752

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Emergency phone number

E le Sar: +27 82 921 0643 (Available Mon - Fri, GMT 5:00 to 20:00)

Spilltech: +27 861 000 366 (Available 24/7)

2 Hazard(s) identification

Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Corrosive to Metals (Category 1), H290

Skin corrosion/irritation (Category 1B), H314

Full text of H statements: see section 16

GHS label elements

Danger



May be corrosive to metals

Causes severe skin burns and eye damage

Keep only in original container.

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

Wash thoroughly after handling.

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

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

IF ON SKIN (or hair): Remove/Take off Immediately all contaminated clothing. Rinse SKIN with water/shower.

IF INHALED: Remove victim to fresh air and Keep at rest in a position comfortable for breathing.

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

Immediately call a POISON CENTER or doctor/physician.

Specific treatment (see P363 on this label).

Wash contaminated clothing before reuse.

Absorb spillage to prevent material damage.

Store locked up.

Store in corrosive resistant container with a resistant inner liner.

Dispose of contents and container in accordance with local, regional, national, international regulations.

Other hazards which do not result in classification

Sodium hydroxide is an inorganic substance. According to Annex XIII of the REACH Regulation the PBT and vPvB assessment only applies to organic substances, including organo-metals. Therefore the PBT and vPvB assessment does not apply to sodium hydroxide.

3 Composition/information on ingredients

Description	CAS Number	EINECS Number	%	Note
Sodium Hydroxide	1310-73-2	215-185-5	2 - 50	Acute Tox. 4 (Dermal), Skin Corr. 1A, Eye
				Dam. 1, Aquatic Acute 3

4 First-aid measures

Description of necessary first-aid measures

Call 112 or 10177 or your local emergency help number immediately, for emergency assistance. Call the Poison Control Center at +27 21 931 6129 – Tygerberg or +27 21 658 5308 – Red Cross, Email: poisonsinformation@uct.ac.za, Website: https://www.afritox.co.za for further instructions. Provide them with information such as the compound taken, quantity and time of ingestion, age, weight and general health status of affected individual. Carefully remove the individual from the exposure area.

Inhalation

- 1. Move to fresh air.
- 2. Oxygen or artificial respiration if needed.
- 3. Victim to lie down in the recovery position, cover and keep him warm.
- 4. Call a physician immediately.

Skin

- 1. Take off contaminated clothing and shoes immediately.
- 2. Wash off immediately with plenty of water.
- 3. Keep warm and in a quiet place.
- 4. Call a physician or poison control centre immediately.
- 5. Wash contaminated clothing before re-use.

Eye Contact

- 1. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
- 2. In the case of difficulty of opening the lids, administer an analgesic eye wash (oxybuprocaine).
- 3. Call a physician or poison control centre immediately.
- 4. Take victim immediately to hospital.

Ingestion

- 1. Call a physician or poison control centre immediately.
- 2. Take victim immediately to hospital.
- 3. In case of symptoms that indicate difficulty in swallowing including vomiting or decreased alertness, **DO NOT** give anything by way of mouth.
- 4. If swallowed, rinse mouth with water (only if the person is conscious).
- 5. Unless instructed by a healthcare professional, **DO NOT** induce vomiting in the affected individual. Following an ingestion of the substance, immediately give milk to drink
- 6. Artificial respiration and/or oxygen may be necessary.
- 7. Always try to take the compound bottle/container to the ER.

Most important symptoms/effects, acute and delayed

Sneezing

Breathing difficulties, if fumes of the solution or chemical powders are inhaled.

Speaking and swallowing difficulties due to swelling of tongue and throat.

Inflammation of the lung.

Severe burning and associated pain in the mouth, throat, and food-pipe (even the stomach may be burnt); drooling from the mouth.

Due to this, the eyes, nose, and ears may be affected.

Severe damage along the gastrointestinal tract including the stomach; severe stomach pain.

Severe skin irritation and burns (perforations on the skin may be observed).

Loss of vision.

Severe stomach pain.

Blood in stool and vomit.

Sudden decrease in blood pressure (hypotension).

Shock.

Collapse.

Severe changes in blood pH value affecting many parts of the body and organs.

Ingesting large quantities can result in long-term damage to the mouth, food-pipe, and stomach; the chemical has the potential to continue causing damage to the affected region, even after exposure is ceased.

Skin burns may be severe and if the eye is affected, it can also result in total loss of vision.

Indication of immediate medical attention and special treatment needed, if necessary

Immediate first aid

Remove patient from contact with the material. Ensure that adequate decontamination has been carried out. If patient is not breathing, start artificial respiration, preferably with a demand valve resuscitator, bag-valve-mask device, or pocket mask, as trained. Perform CPR if necessary. Immediately flush contaminated eyes with gently flowing water. **DO NOT** induce vomiting. If vomiting occurs, lean patient forward or place on the left side (head-down position, if possible) to maintain an open airway and prevent aspiration. Keep patient quiet and maintain normal body temperature. Obtain medical attention.

Basic treatment

Establish a patent airway (oropharyngeal or nasopharyngeal airway, if needed). Suction if necessary. Watch for signs of

respiratory insufficiency and assist ventilations if necessary. Administer oxygen by nonrebreather mask at 6 to 12 L/min. Monitor for pulmonary edema and treat if necessary. Monitor for shock and treat if necessary. For eye contamination, flush eyes immediately with water. Irrigate each eye continuously with 0.9% saline (NS) during transport. **DO NOT** use emetics. For ingestion, rinse mouth and administer 5 ml/kg up to 200 ml of water for dilution if the patent can swallow, has a strong gag reflex, and does not drool. **DO NOT** attempt to neutralize. Cover skin burns with dry sterile dressings after decontamination.

Advanced treatment

Consider orotracheal or nasotracheal intubation for airway control in the patient who is unconscious, has severe pulmonary edema, or is in severe respiratory distress. Early intubation, at the first signs of upper airway obstruction, may be necessary. Positive-pressure ventilation techniques with a bag valve mask device may be beneficial. Consider drug therapy for pulmonary edema. Monitor cardiac rhythm and treat arrhythmias as necessary. Start IV administration of D5W /SRP: "To keep open", minimal flow rate/. Use 0.9% saline (NS) or lactated Ringer's (LR) if signs of hypovolemia are present. For hypotension with signs of hypovolemia, administer fluid cautiously. Consider vasopressors if patient is hypotensive with a normal fluid volume. Watch for signs of fluid overload. Use proparacaine hydrochloride to assist eye irrigation.

Medical Surveillance

The skin, eyes, and respiratory tract should receive special attention in any placement or periodic examination. NIOSH recommends that workers subject to sodium hydroxide exposure have comprehensive preplacement medical examinations. Medical examinations shall be made available promptly to all workers with signs or symptoms of skin, eye, or upper respiratory tract irritation resulting from exposure to sodium hydoxide.

Fire-fighting measures

Suitable extinguishing media

Excerpt from ERG Guide 154 [Substances - Toxic and/or Corrosive (Non-Combustible)]

SMALL FIRE

Dry chemical, CO2 or water spray.

LARGE FIRE

Dry chemical, CO2, alcohol-resistant foam or water spray. Move containers from fire area if you can do it without risk. Dike fire-control water for later disposal; do not scatter the material.

FIRE INVOLVING TANKS OR CAR/TRAILER LOADS

Fight fire from maximum distance or use unmanned hose holders or monitor nozzles. Do not get water inside containers. Cool containers with flooding quantities of water until well after fire is out. Withdraw immediately in case of rising sound from venting safety devices or discoloration of tank. ALWAYS stay away from tanks engulfed in fire.

Specific hazards arising from the chemical

The product is not flammable. Not combustible. Reacts violently with water. Gives off hydrogen by reaction with metals.

Special protective actions for fire-fighters

In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. Wear chemical resistant oversuit. Cool containers / tanks with water spray.

6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

Isolation and Evacuation

Excerpt from ERG Guide 154 [Substances - Toxic and/or Corrosive (Non-Combustible)]

As an immediate precautionary measure, isolate spill or leak area in all directions for at least 50 meters (150 feet) for liquids and at least 25 meters (75 feet) for solids.

SPILL

Increase, in the downwind direction, as necessary, the isolation distance shown above.

FIRE

If tank, rail car or tank truck is involved in a fire, ISOLATE for 800 meters (1/2 mile) in all directions; also, consider initial evacuation for 800 meters (1/2 mile) in all directions.

Advice for non-emergency personnel

Prevent further leakage or spillage if safe to do so. Keep away from Incompatible products.

Advice for emergency responders

Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak. Ventilate the area. Wear suitable protective clothing.

Environmental precautions

Should not be released into the environment. **DO NOT** flush into surface water or sanitary sewer system. If the product contaminates rivers and lakes or drains inform respective authorities.

Methods and materials for containment and cleaning up

Soil, Liquid

Absorb small amounts of spill with sand, vermiculite or other inert absorbant material; Shovel into steel containers. May also remove material with vacuum equipment.

Environment considerations - Land spill

Dig a pit, pond, lagoon, or holding area to contain liquid or solid material. Dike surface flow using soil, sand bags, foamed polyurethane, or foamed concrete. Absorb bulk liquid with fly ash of cement powder.

Environmental considerations - Water spill

Use natural barriers or oil spill control booms to limit spill travel. Neutralize with dilute acid.

Perlite and Cellosive WP3H (hydroxyethyl cellulose) have been tested and recommended for vapor suppression and/or containment of 50% sodium hydroxide solutions.

Keep water away from release. Stop or control the leak, if this can be done without undue risk. Prompt cleanup and removal are necessary. Shovel into suitable dry container. Control runoff and isolate discharged material for proper disposal.

Disposal Methods

The most favorable course of action is to use an alternative chemical product with less inherent propensity for occupational harm/injury/toxicity or environmental contamination. Recycle any unused portion of the material for its approved use or return it to the manufacturer or supplier. Ultimate disposal of the chemical must consider: the material's impact on air quality; potential migration in soil or water; effects on animal and plant life; and conformance with environmental and public health regulations.

Following neutralization either at the spill site or at a waste management facility, the resultant sludge can be disposed of in a secure landfill.

Wastewater from contaminant suppression, cleaning of protective clothing/equipment, or contaminated sites should be contained and evaluated for subject chemical or decomposition product concentrations. Concentrations shall be lower than applicable environmental discharge or disposal criteria. Alternatively, pretreatment and/or discharge to a permitted wastewater treatment facility is acceptable only after review by the governing authority and assurance that "pass through" violations will not occur. Due consideration shall be given to remediation worker exposure (inhalation, dermal and ingestion) as well as fate during treatment, transfer and disposal.

Put into large vessel containing water. Neutralize with HCL. Discharge into the sewer with sufficient water. Recommendable methods: Neutralization & discharge to sewer. Peer review: Dilute greatly (< pH 9) before discharge.

7 Handling and storage

Precautions for safe handling

When diluting, always add the product to water. **Never** add water to the product. Use only equipment and materials which are compatible with the product. Keep away from Incompatible products. To avoid thermal decomposition, **DO NOT** overheat. Preferably transfer by pump or gravity.

Conditions for safe storage, including any incompatibilities

Storage

Store in original container. Keep in a well-ventilated place. Keep in a dry place. Keep in properly labelled containers. Keep container closed. Avoid dust formation. Keep away from incompatible products.

Packaging material

Suitable material

Stainless steel. Polyethylene

Unsuitable material

No data available

SANS 10263-0 Warehousing

- **8.4.3.2** Where flammable or **corrosive** substances are stored, the floor shall slope away from the storage area (primary collection area) to a secondary catch basin or sump of capacity at least 10 % of the total available storage volume of the fire section concerned. The secondary catch basin shall be within the fire section, and shall be such that it can be well ventilated. Care shall be taken in the design of such areas to prevent contamination of the soil or ground water.
- **9.7.2** Every type of storage area inside a warehouse shall be clearly demarcated, for example separate storage areas for poisons, flammables and **corrosives** shall display the relevant hazard class diamond (see table 1). The dimensions of the hazard class diamonds shall be at least 250 mm x 250 mm.
- 12.8.5 Storage of flammable liquids of class 3, toxic substances of division 6.1 and corrosives of class 8

Nitro-methane class 3, UN No. 1261, shall be separated from substances of class 6.1, and cyanides of division 6.1 shall be separated from acids of class 8. Concentrated acids and bases shall be segregated by at least 1 m. Packaged flammable liquids of class 3, toxic substances of division 6.1 and **corrosives** of class 8 that are of category 3 can be stored in the same area, provided that

- a) they are kept above floor level, and
- b) liquid dangerous goods of one class are not stored above dangerous goods of another class.
- **12.8.8.3** Toxic and infectious substances (see class 6 in SANS 10228) can contaminate firefighting water in the event of a fire, therefore:
- a) Toxic and infectious substances shall be separated from other flammable products and aerosols.
- b) Toxic and infectious substances shall be segregated from oxidizing substances, organic peroxides and corrosives.
- c) Flammable toxic and infectious substances shall be segregated from non-flammable toxic and infectious substances.
- **12.8.8.4 Corrosives** (see class 8 in SANS 10228) that leak or spill from their packaging can cause serious damage to other packages, with potentially hazardous consequences.

Corrosives shall be segregated from toxic substances, infectious substances, aerosols, flammables, oxidizing substances and organic peroxides.

The provisions of above apply to the storage of the following quantities of dangerous goods.

Corrosives (acids and bases) Class 8		
Category 1	> 50 kg	
Category 2	> 200 kg	
Category 3	> 1 000 kg	

8 Exposure controls/personal protection

Control parameters

Sodium H	Sodium Hydroxide, 50% w/w (1310-73-2)			
OSHA	OSHA PEL (TWA) (mg/m³)	2 mg/m³		
IDLH	US IDLH (mg/m³)	10 mg/m ³		
NIOSH	NIOSH REL (ceiling) (mg/m³)	2 mg/m		
Sodium H	Sodium Hydroxide, 50% w/w (1310-73-2)			
ACGIH	ACGIH Ceiling (mg/m³)	2 mg/m³ (Sodium hydroxide		
		USA; Momentary value TLV - Adopted Value)		
OSHA	OSHA PEL (TWA) (mg/m³)	2 mg/m³		
IDLH	US IDLH (mg/m³)	10 mg/m ³		

NIOSH	NIOSH REL (ceiling) (mg/m³)	2 mg/m

Appropriate engineering controls

Eyewash fountains should be provided in areas where there is any possibility that workers could be exposed to the substance; this is irrespective of the recommendation involving the wearing of eye protection.

Facilities for quickly drenching the body should be provided within the immediate work area for emergency use where there is a possibility of exposure. [Note: It is intended that these facilities provide a sufficient quantity or flow of water to quickly remove the substance from any body areas likely to be exposed. The actual determination of what constitutes an adequate quick drench facility depends on the specific circumstances. In certain instances, a deluge shower should be readily available, whereas in others, the availability of water from a sink or hose could be considered adequate.]

Ensure adequate ventilation. Apply technical measures to comply with the occupational exposure limits.

Individual protection measures

The selection of PPE is dependent on a detailed risk assessment. The risk assessment should consider the work situation, the physical form of the chemical, the handling methods, and environmental factors. Recommendations below is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.











Eye/face protection

Face shield and safety glasses or safety goggles. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU). Contact lenses should not be worn; they may contribute to severe eye injury.

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de, test method: EN374

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves.

Body Protection

Chemical spray smock and long sleeve suit composed of natural rubber, neoprene, nitrile, or styrene/butadiene (SBR)coated fabric is highly recommended, having break through times greater than one hour. Butyl rubber, neoprene and SBR, polyethylene, chlorinated polyurethane, or polyvinyl alcohol may be used but data suggests break through times of approximately an hour or more. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type P2 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hygiene measures

Eye wash bottles or eye wash stations in compliance with applicable standards. Take off contaminated clothing and shoes immediately. Handle in accordance with good industrial hygiene and safety practice.

9 Physical and chemical properties

Physical and chemical properties

Appearance (physical state, colour etc):	Colourless liquid
Odour:	Odourless
Odour threshold:	No test data available
pH:	> 14
Melting/Freezing Point:	-12°C/-10°C
Initial boiling point and boiling range:	143°C/105 - 140°C
Flash point:	Do not flash
Evaporation rate:	No test data available
Flammability (solid, gas):	Not flammable
Upper/lower flammability or explosive limits:	Not flammable or explosive
Vapour pressure:	1.2 hPa (20 °C)
Vapour density:	1,38 - (Air = 1.0)
Relative density:	1,515 g/mL at 25°C
Solubility(ies):	Completely miscible
Partition coefficient: n-octanol/water:	No test data available
Auto-ignition temperature:	No test data available
Decomposition temperature:	No test data available
Viscosity:	No test data available

Other information:

Minimum ignition energy:

Not applicable

VOC content:

Not applicable (inorganic)

Other properties:

Clear. Slightly volatile. Substance has basic reaction.

NOTE: The physical data presented above are typical values and should not be construed as a specification.

10 Stability and reactivity

Reactivity

Strongly basic. Reacts rapidly and exothermically with organic and inorganic acids, with organic and inorganic acid anhydrides, including oxides of nonmetals such as sulfur dioxide, sulfur trioxide, phosphorus trioxide, phosphorus pentaoxide, and with organic and inorganic acid chlorides. May react explosively with maleic anhydride [MCA Case History 622 1960]. Attacks aluminum and zinc with evolution of hydrogen, a flammable gas. May initiate polymerization in polymerizable organic materials: a violent polymerization results if acetaldehyde contacts alkaline materials such as sodium hydroxide; an extremely violent polymerization results from contact of acrolein with alkaline materials such as sodium hydroxide [Chem. Safety Data Sheet SD-85 1961]. A violent explosion resulted when a quantity of pentol was accidentally brought in contact with a caustic cleaning solution chemically similar to aqueous sodium hydroxide [MCA Case History 363 1964]. Aqueous solutions of reducing sugars other than sucrose, when heated (above 84°C.), evolve toxic levels of carbon monoxide in the presence of alkalis or alkaline salts, such as sodium phosphate (also potassium hydroxide, sodium hydroxide, calcium hydroxide, etc.) [Bretherick 5th ed. 1995]. Hot and/or concentrated NaOH can cause hydroquinone to decompose exothermically at elevated temperature.

Chemical stability

Stable under recommended storage, handling and transport conditions.

Possibility of hazardous reactions

Gives off hydrogen by reaction with metals. Exothermic reaction with strong acids. Risk of violent reaction. Risk of explosion. Reacts violently with water.

Conditions to avoid

Keep away from direct sunlight. To avoid thermal decomposition, **DO NOT** overheat. Exposure to moisture. Freezing.

Incompatible materials

Metals, Oxidizing agents, Water, Acids, Aluminium, other light metals and their alloys.

Hazardous decomposition products

Hydrogen.

11 Toxicological information

Toxicological (health) effects

Measurement	Date	System	Route/Organism	Dose	Effect
Skin and Eye					
Irritation	Jul-15		eye /monkey	1%/24H	severe
Skin and Eye					
Irritation	Jul-15		eye /rabbit	400 μg	mild
Skin and Eye					
Irritation	Jul-15		eye /rabbit	1%	severe
Skin and Eye					
Irritation	Jul-15		eye /rabbit	50 μg/24H	severe
Skin and Eye					
Irritation	Jul-15		eye /rabbit	1 mg/24H	severe
Skin and Eye					
Irritation	Jul-15		eye /rabbit	1 mg/30S rinse	severe
Skin and Eye					
Irritation	Jul-15		skin /human	2%/24H	mild
Skin and Eye					
Irritation	Jul-15		skin /rabbit	500 mg/24H	severe
		Cytogenetic			
Mutation Data	Jul-15	Analysis	parenteral/grasshopper	20 mg	
		Cytogenetic			
Mutation Data	Jul-15	Analysis	lung/hamster	10 mmol/L	
		Cytogenetic			
Mutation Data	Jul-15	Analysis	ovary/hamster	16 mmol/L	
				Inhibitor	
				Concentration	L. M T
A cuto Tovicity			In Vitro / Luman liver	(50 percent kill): 0.03	In Vitro Toxicity Studies: Cell
Acute Toxicity Data	Jul-15		In Vitro/Human, liver tumor	mmol/L/24H	
Data	Jui-13		tumor		protein synthesis In Vitro Toxicity
					Studies: Cell
					viability
					(mitochondrial
				Inhibitor	reductase
				Concentration	assays): MTT,
Acute Toxicity				Low: 0.6	XTT, MTS, WSTs
Data	Jul-15		In Vitro/Human, skin	mg/well/60M	assays etc.
				Inhibitor	

				Concentration	In Vitro Toxicity
Acute Toxicity				Low: 0.2	Studies: Other
Data	Jul-15		In Vitro/jda	pph/1M	assays
					In Vitro Toxicity
					Studies: Cell
					viability
				Inhibitor	(mitochondrial reductase
					assays): MTT,
Acute Toxicity				Low: 0.05	XTT, MTS, WSTs
Data	Jul-15		In Vitro/Rabbit, ocular		assays etc.
			in the symbol of the		
					In Vitro Toxicity
					Studies: Cell
A surba Taviaitu				(50 percent	Viability (cell
Acute Toxicity Data	Jul-15		In Vitro/Rabbit, ocular	kill): 0.002 gm/L/10M	death), unspecified assay
Data	Jui-13		iii vitio/ Nabbit, Ocuiai	lethal dose (50	unspecified assay
Acute Toxicity				percent kill): 40	
Data	Jul-15		intraperitoneal/mouse	mg/kg	
Data	Jul 13		intrapentoneal/mouse	lowest	
				published lethal	Behavioral:
Acute Toxicity				dose: 1.57	Anorexia
Data	Jul-15		oral/human	mg/kg	(human)
				lowest	,
				published lethal	
Acute Toxicity				dose: 500	
Data	Jul-15		oral/rabbit	mg/kg	
					Gastrointestinal:
				lowest	Ulceration or
Acute Toxicity				published toxic	_
Data	Jul-15		oral/rat	dose: 44 mg/kg	stomach
Skin and Eye			_		
Irritation	Jul-15		eye /monkey	1%/24H	severe
Skin and Eye			,		
Irritation	Jul-15		eye /rabbit	400 μg	mild
Skin and Eye			1.119	40/	
Irritation	Jul-15		eye /rabbit	1%	severe
Skin and Eye	11 4 5		ava /vahhit	FO = /2.411	
Irritation	Jul-15		eye /rabbit	50 μg/24H	severe
Skin and Eye				4 /2 411	
Irritation	Jul-15		eye /rabbit	1 mg/24H	severe
Skin and Eye	11 1 5		ovo /robbit	1 mg/200 rinso	2011010
Irritation	Jul-15		eye /rabbit	1 mg/30S rinse	severe
Skin and Eye Irritation	Jul-15		skin /human	2%/24H	mild
	101-T2		SKIII / HUHIIdH	2/0/ Z+II	IIIIu
Skin and Eye	lul 45		ckin /robb:+	E00 ma/2411	sovers
Irritation	Jul-15	Cutomore	skin /rabbit	500 mg/24H	severe
Mutation Data	Jul-15	Cytogenetic Analysis	parenteral/grasshopper	20 mg	
iviutation Data	101-T2	Cytogenetic	harenreral/Rrassnohher	LOTTING	
Mutation Data	Jul-15	Analysis	lung/hamster	10 mmol/L	
ividiation Data	Jul-13	Cytogenetic	iding/ Hamstel	TO HIHIOI/ L	
Mutation Data	Jul-15	Analysis	ovary/hamster	16 mmol/L	
ividiation Data	201-13	Alialysis	Ovary/ Hailister	Inhibitor	
				Concentration	
					In Vitro Toxicity
I .	!	I	I	Noo bereent	I VICIO TOXICILY

Acute Toxicity		In Vitro/Human, liver	kill): 0.03	Studies: Cell
Data	Jul-15	tumor	mmol/L/24H	protein synthesis
				In Vitro Toxicity
				Studies: Cell
				viability
				(mitochondrial
			Inhibitor	reductase
			Concentration	assays): MTT,
Acute Toxicity			Low: 0.6	XTT, MTS, WSTs
Data	Jul-15	In Vitro/Human, skin	mg/well/60M	assays etc.
			Inhibitor	
			Concentration	In Vitro Toxicity
Acute Toxicity			Low: 0.2	Studies: Other
Data	Jul-15	In Vitro/jda	pph/1M	assays
				In Vitro Toxicity
				Studies: Cell
				viability
				(mitochondrial
			Inhibitor	reductase
			Concentration	assays): MTT,
Acute Toxicity			Low: 0.05	XTT, MTS, WSTs
Data	Jul-15	In Vitro/Rabbit, ocular	pph/5M	assays etc.
			Inhibitor	In Vitro Toxicity
				Studies: Cell
			(50 percent	Viability (cell
Acute Toxicity			kill): 0.002	death),
Data	Jul-15	In Vitro/Rabbit, ocular	gm/L/10M	unspecified assay
2 4 4 4	00.1 20		lethal dose (50	anopeemed desay
Acute Toxicity			percent kill): 40	
Data	Jul-15	intraperitoneal/mouse	mg/kg	
			lowest	
			published lethal	Behavioral:
Acute Toxicity			dose: 1.57	Anorexia
Data	Jul-15	oral/human	mg/kg	(human)
			lowest	(Community)
			published lethal	
Acute Toxicity			dose: 500	
Data	Jul-15	oral/rabbit	mg/kg	
	_	,	<i>J. J</i>	Gastrointestinal:
			lowest	Ulceration or
Acute Toxicity			published toxic	
Data	Jul-15	oral/rat	dose: 44 mg/kg	_
L	_	, · ·	5, 10	l .

Information on the likely routes of exposure

Workers - Hazard via inhalation route Systemic effects

Long term exposure
Hazard assessment conclusion:

no hazard identified

Acute/short term exposure

Hazard assessment conclusion: no hazard identified

DNEL related information

Local effects

Long term exposure

Hazard assessment conclusion: DNEL (Derived No Effect Level)

Value: 1 mg/m³

Most sensitive endpoint: irritation (respiratory tract)

DNEL related information

Overall assessment factor (AF):

Dose descriptor: NOAEC

Acute/short term exposure

Hazard assessment conclusion: no hazard identified

DNEL related information

Workers - Hazard via dermal route

Systemic effects

Long term exposure

Hazard assessment conclusion: no hazard identified

Acute/short term exposure

Hazard assessment conclusion: no hazard identified

DNEL related information

Local effects

Long term exposure

Hazard assessment conclusion: high hazard (no threshold derived)

Acute/short term exposure

Hazard assessment conclusion: high hazard (no threshold derived)

Workers - Hazard for the eyes

Local effects

Hazard assessment conclusion: high hazard (no threshold derived)

Additional information - workers

The focus is the occurence of local effects after acute and repeated exposure at those places where NaOH is produced and/or used. This is because NaOH is not expected to become systemically available in the body under normal handling and use conditions, i.e. neither the concentration of sodium in the blo The focus is the occurence of local effects after acute and repeated exposure at those places where NaOH is produced and/or used. This is because NaOH is not expected to become systemically available in the body under normal handling and use conditions, i.e. neither the concentration of sodium in the blood nor the pH of the blood will be increased (EU RAR of sodium hydroxide, 2007; section 4.1.3.1, page 73). Acute exposure Acute / short-term exposure and long-term exposure - systemic effects NaOH is not expected to become systemically available in the body under normal handling and use conditions, i.e. neither the concentration of sodium in the blood nor the pH of the blood will be increased (EU RAR of sodium hydroxide, 2007; section 4.1.3.1, page 73). Therefore, it is not useful to derive a DNEL for acute exposure, systemic effects.

Acute - short-term exposure - local effects (dermal) According to the CLP Regulation No 1272/2008 Annex VI Table 3.1, the concentration limit for corrosivity of NaOH is considered to be 2%.

Acute - short-term exposure - local effects (inhalation) According to chapter R8 of the ECHA "Guidance on information requirements and chemical safety assessment' a DNEL for acute toxicity should be derived if an acute toxicity hazard (leading to C&L) has been identified.

Sodium hydroxide is not classified regarding acute inhalation toxicity. In addition, a DNEL for acute toxicity should be derived if there is a potential for high peak exposures, for instance when sampling or connecting/disconnecting vessels. This is not the case for sodium hydroxide. High peak exposure do not occur during the manufacturing or use.

Long-term exposure Long-term exposure - local effects (dermal DNEL in mg/kg bw): No DNEL long-term exposure - local effects could be derived as no reliable dose descriptors were available for that route of exposure.

Long-term exposure - local effects (inhalation DNEL in mg/m3): The most relevant starting point from the available data is the study of Fritschi et al (2001), which is a cross-sectional survey of 2404 employees from three aluminium refineries. Of these subjects, 1045 had been exposed to sodium hydroxide mist, leaving 1553 unexposed subjects. Exposure to sodium hydroxide mist had been assessed on a semi-quantitative basis and the exposed subjects had been assigned to one of three exposure groups: low (<0.05 mg/m3), medium (0.05 - 1.0 mg/m3) or high (>1.0 mg/m3) based on an assessment of peak exposures over a 15 -minute period. The authors concluded that exposure to high levels of sodium hydroxide mist (>1.0 mg/m3) was associated with an increased prevalence of reporting work-related wheeze and rhinitis, but not

impairment of lung function. These symptomatic reports of respiratory tract irritation, in the lack of any measured functional change in lung performance, suggest that any effects were minimal. Such reporting is also subject to recall bias, which can lead to over-reporting of symptomatology. No increased prevalence of respiratory symptoms was reported for the subjects in the medium exposure group.

This data suggests that the NOEL for respiratory irritation due to exposure to sodium hydroxide mist in a large sample of subjects from three factories was 1.0 mg/m3. This value is likely to be a conservative estimate due to the study design. As the study was conducted in human subjects, no interspecies assessment factor is required. Similarly, assessment factors to take account of differences in exposure duration, dose-response or quality of the database are not required. It is noted that in excess of 40% of the study subjects were reported to be atopic. This distribution suggests that the study population were towards the more sensitive end of the overall population in terms of their response to respiratory irritants. This fact, coupled with the fact that a relatively large random sample of workers had been studied, suggest also that no assessment factor is required to account for intraspecies differences in the human population. In addition, it is noted that in many EU countries, the OEL (8-hour TWA) for sodium hydroxide is 2.0 mg/m3, with a few exceptions (Czech Republic - 1.0 mg/m3; Poland – 0.5 mg/m3) (see Table 1).

In the UK, a Workplace Exposure Limit (15-minute STEL) of 2.0 mg/m3 exists. This value is most probably based on the ACGIH TLV Ceiling Limit of 2.0 mg/m3, which itself is based on "noticeable, but not excessive, ocular and upper respiratory tract irritation" (ACGIH, 1997). This latter statement is attributed to Patty, 1947. These OEL values are broadly consistent with a NOEL in humans for respiratory irritation of 1.0 mg/m3. 1 mg/m3 is considered to be the NOEL for sodium hydroxide mist in humans for respiratory irritation For the reasons stated above, it is proposed that no assessment factors are required to derive the DNEL.

As a result, the DNEL for sodium hydroxide for long-term inhalation, workers = 1.0 mg/m³. Table 25. Occupational Exposure Limits (OELs) in the EU and Norway (ACGIH, 2006) EU Member State Unit TW ST Ceiling Referenceod nor the pH of the blood will be increased (EU RAR of sodium hydroxide, 2007; section 4.1.3.1, page 73).

Acute exposure

Acute / short-term exposure and long-term exposure - systemic effects NaOH is not expected to become systemically available in the body under normal handling and use conditions, i.e. neither the concentration of sodium in the blood nor the pH of the blood will be increased (EU RAR of sodium hydroxide, 2007; section 4.1.3.1, page 73). Therefore, it is not useful to derive a DNEL for acute exposure, systemic effects.

Acute - short-term exposure - local effects (dermal)

According to the CLP Regulation No 1272/2008 Annex VI Table 3.1, the concentration limit for corrosivity of NaOH is considered to be 2%.

Acute - short-term exposure - local effects (inhalation)

According to chapter R8 of the ECHA "Guidance on information requirements and chemical safety assessment' a DNEL for acute toxicity should be derived if an acute toxicity hazard (leading to C&L) has been identified. Sodium hydroxide is not classified regarding acute inhalation toxicity. In addition, a DNEL for acute toxicity should be derived if there is a potential for high peak exposures, for instance when sampling or connecting/disconnecting vessels. This is not the case for sodium hydroxide. High peak exposure do not occur during the manufacturing or use.

Long-term exposure

Long-term exposure - local effects (dermal DNEL in mg/kg bw):

No DNEL long-term exposure - local effects could be derived as no reliable dose descriptors were available for that route of exposure.

Long-term exposure - local effects (inhalation DNEL in mg/m3):

The most relevant starting point from the available data is the study of Fritschi et al (2001), which is a cross-sectional survey of 2404 employees from three aluminium refineries. Of these subjects, 1045 had been exposed to sodium hydroxide mist, leaving 1553 unexposed subjects.

Exposure to sodium hydroxide mist had been assessed on a semi-quantitative basis and the exposed subjects had been assigned to one of three exposure groups: low (<0.05 mg/m3), medium (0.05 - 1.0 mg/m3) or high (>1.0 mg/m3) based on an assessment of peak exposures over a 15 -minute period. The authors concluded that exposure to high levels of sodium hydroxide mist (>1.0 mg/m3) was associated with an increased prevalence of reporting work-related wheeze and rhinitis, but not impairment of lung function. These symptomatic reports of respiratory tract irritation, in the lack of any measured

functional change in lung performance, suggest that any effects were minimal. Such reporting is also subject to recall bias, which can lead to over-reporting of symptomatology. No increased prevalence of respiratory symptoms was reported for the subjects in the medium exposure group.

This data suggests that the NOEL for respiratory irritation due to exposure to sodium hydroxide mist in a large sample of subjects from three factories was 1.0 mg/m3. This value is likely to be a conservative estimate due to the study design.

As the study was conducted in human subjects, no interspecies assessment factor is required. Similarly, assessment factors to take account of differences in exposure duration, dose-response or quality of the database are not required. It is noted that in excess of 40% of the study subjects were reported to be atopic. This distribution suggests that the study population were towards the more sensitive end of the overall population in terms of their response to respiratory irritants. This fact, coupled with the fact that a relatively large random sample of workers had been studied, suggest also that no assessment factor is required to account for intraspecies differences in the human population.

In addition, it is noted that in many EU countries, the OEL (8-hour TWA) for sodium hydroxide is 2.0 mg/m3, with a few exceptions (Czech Republic - 1.0 mg/m3; Poland – 0.5 mg/m3) (see Table 1). In the UK, a Workplace Exposure Limit (15-minute STEL) of 2.0 mg/m3 exists. This value is most probably based on the ACGIH TLV Ceiling Limit of 2.0 mg/m3, which itself is based on "noticeable, but not excessive, ocular and upper respiratory tract irritation" (ACGIH, 1997). This latter statement is attributed to Patty, 1947. These OEL values are broadly consistent with a NOEL in humans for respiratory irritation of 1.0 mg/m3.

1 mg/m3 is considered to be the NOEL for sodium hydroxide mist in humans for respiratory irritation For the reasons stated above, it is proposed that no assessment factors are required to derive the DNEL.

As a result, the DNEL for sodium hydroxide for long-term inhalation, workers = 1.0 mg/m^3 .

General Population - Hazard via inhalation route

Systemic effects

Long term exposure

Hazard assessment conclusion: no hazard identified

Acute/short term exposure

Hazard assessment conclusion: no hazard identified

DNEL (Derived No Effect Level)

Value: 1 mg/m³

Most sensitive endpoint: irritation (respiratory tract)

DNEL related information

Overall assessment factor (AF): 1

Dose descriptor: NOAEC

Acute/short term exposure

Hazard assessment conclusion: no hazard identified

DNEL related information

General Population - Hazard via dermal route

Systemic effects Long term exposure

Hazard assessment conclusion: no hazard identified

Acute/short term exposure

Hazard assessment conclusion: no hazard identified

DNEL related information

Local effects

Long term exposure

Hazard assessment conclusion: high hazard (no threshold derived)

Acute/short term exposure

Hazard assessment conclusion: high hazard (no threshold derived)

General Population - Hazard via oral route

Systemic effects

Long term exposure

Hazard assessment conclusion: high hazard (no threshold derived)

Acute/short term exposure

Hazard assessment conclusion: high hazard (no threshold derived)

DNEL related information

General Population - Hazard for the eyes

Local effects

Hazard assessment conclusion: high hazard (no threshold derived)

Additional information - General Population

As sodium hydroxide is not expected to become systemically available in the body under normal handling and use conditions, the focus is on possible risks from acute exposure (local effects) (EU RAR of Sodium Hydroxide, 2007; section 4.1.3.2.4.1; page 77).

Acute exposure

Acute / short-term exposure and long-term exposure - systemic effects

As sodium hydroxide is not expected to become systemically available in the body under normal handling and use conditions, the focus is on possible risks from acute exposure (local effects) (EU RAR of Sodium Hydroxide, 2007; section 4.1.3.2.4.1; page 77).

Therefore, it is not useful to derive a DNEL for acute exposure, systemic effects.

Acute - short-term exposure - local effects - dermal

According to the CLP Regulation No 1272/2008 Annex VI Table 3.1, the concentration limit for corrosivity of NaOH is considered to be 2%.

Acute - short-term exposure - local effects - inhalation

According to chapter R8 of the ECHA "Guidance on information requirements and chemical safety assessment' a DNEL for acute toxicity should be derived if an acute toxicity hazard (leading to C&L) has been identified. Sodium hydroxide is not classified regarding acute dermal toxicity.

Long-term exposure

DNEL - long term exposure - local effects - dermal:

No DNEL long-term exposure - local effects could be derived as no reliable dose descriptors were available for that route of exposure.

DNEL - long term exposure - local effects - inhalation

The same point of departure is relevant for deriving a DNEL for the general population, i.e. the study by Fritschi et al (2001). The following comments apply in the assessment of the need for further Assessment Factors in deriving a local DNEL for the general population. The assessment of exposure to sodium hydroxide conducted by Fritschi et al was based on peak exposures over a 15-minute period. The same assessment of duration of exposure would be relevant for both the working population and the general population, given that the effect being assessed to dereive the NOAEL is local irritation of the respiratory tract. No further modification is therefore required to the NOAEL to take account of potential differences in the duration of exposure of the general population. In the population studied by Fritschi et al, in excess of 40% of the subjects were reported to be atopic. This distribution suggests that the study population were towards the more sensitive end of the overall population in terms of their response to respiratory irritants and, as such, could be regarded as an adequate representation of the general population in terms of their response to sodium hydroxide. It is concluded, therefore, that no additional assessment factor is required to take account of further intraspecies differences in the general human population. As a result, the DNEL for sodium hydroxide for long-term inhalation, general population = 1.0 mg/m³.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms

irritation eyes, skin, mucous membrane; pneumonitis; eye, skin burns; temporary loss of hair.

Inhalation Symptoms

Cough. Sore throat. Burning sensation. Shortness of breath.

Skin Symptoms

Redness. Pain. Serious skin burns. Blisters.

Eye Symptoms

Redness. Pain. Blurred vision. Severe burns.

Ingestion Symptoms

Abdominal pain. Burns in mouth and throat. Burning sensation in the throat and chest. Nausea. Vomiting. Shock or collapse.

Target Organs

Eyes, skin, respiratory system.

Delayed and immediate effects and also chronic effects from short and long term exposure

Toxicokinetics, metabolism and distribution

Sodium is a normal constituent of the blood and an excess is excreted in the urine. A significant amount of sodium is taken up via the food because the normal uptake of sodium via food is 3.1-6.0 g per day according to Fodor et al. (1999). Exposure to NaOH could potentially increase the pH of the blood. However, the pH of the blood is regulated between narrow ranges to maintain homeostasis. Via urinary excretion of bicarbonate and via exhalation of carbon dioxide, the pH is maintained at the normal pH of 7.4-7.5 (EU RAR, 2007, section 4.1.2.1, page 63).

Mean daily sodium intakes of populations in Europe range from about 3-5 g (about 8 -11 g sodium hydroxide) and are well in excess of dietary needs (about 1.5 g sodium/day in adults) (EFSA, 2006). The main source of sodium in the diet is from processed foods (about 70 -75% of the total intake), with about 10 -15% from naturally occuring sodium in unprocessed foods and about 10 -15% from discretionary sodium added during cooking and at the table. The major effect of increased sodium intake is elevated blood pressure. The effect of sodium on blood pressure is linked to that of chloride. This is a continuous relationship which embraces the levels of sodium habitually consumed and it is not possible to determine a threshold level of habitual sodium consumption below which there is unlikely to be any adverse effect on blood pressure. Evidence that high sodium intake may have a direct adverse effect on heart function, independent of any secondary effect due to changes in blood pressure, is not conclusive. The Panel (EFSA, 2006) concludes that the available data are not sufficient to establish an upper level (UL) for sodium from dietary sources.

Basic Toxicokinetics

Twenty-nine studies of normotensive subjects and 30 studies of hypertensive subjects were identified and reviewed. Studies of normotensive subjects tended to be shortterm studies with less than 1 month of intervention. Only 3 long-term studies of normotensive subjects (lasting more than 1 year) were identified. The subjects in the studies of normotensive people were generally younger (mean age 26 years) than those in the studies of hypertensive people (mean age 47 years). Trials with hypertensive subjects had longer intervention periods, and 5 long-term studies were identified. Apart from the meta-analysis, 19 additional studies were evaluated.

- -Restriction of salt intake for normotensive people is not recommended at present because of insufficient evidence of hypertension (grade B recommendation)
- -To avoid excessive intake of salt people should be counselled to choose foods low in salt (e.g., pre-prepared foods), to refrain from adding salt at the table and minimize the amount of salt used in cooking, and to increase their awareness of the salt content of food choices in restaurants (grade D recommendations)
- -It is recommended that the salt consumption of hypertensive patients be determined by interview (grade D recommendation)

Acute toxicity

No classification is needed since no reliable studies are available and studies do not need to be generated. Furthermore, the substance is not expected to be systemically available and the effects are expected to be due to pH changes.

Skin irritation / corrosion

Endpoint conclusion: adverse effect observed (corrosive)

Eve irritation

Endpoint conclusion: adverse effect observed (irritating)

Additional information

Skin

Four reports were available on skin irritation studies with rabbits. BASF (1978a) reported that a concentration of 0.95%

was mildly irritating, while Kynoch et al. (1977a) reported that 1% was slightly irritating. According to BASF (1978b) a concentration of 4.9% was moderately irritating, while Kynoch et al. (1977b) reported that a concentration of 5% was irritating for 5 of 6 animals but corrosive for 1 of 6 animals. The corrosivity potential of NaOH was confirmed by an in vitro study (Stobbe et al., 2003).

Studies with human volunteers revealed that concentrations of 0.5 and 1 % were irritating (York et al., 1996; Dykes et al., 1995; York et al., 1996). A study with Caucasian volunteers showed that 2% NaOH was highly irritating (Fluhr et al., 2004).

Eye

Reliable eye irriation studies have been reported using rabbits as test species.

Several authors reported that low concentrations of NaOH did not result in eye irritation. According to Morgan et al. (1987) concentrations of 0.004; 0.04 and 0.2% NaOH are not irritating to the eye of rabbits. Murphy et al. (1982) found neither conjunctivitis nor iritis at concentrations of 0.1 and 0.2%. Jacobs (1992) observed no irritation at 1%.

Irritation of the eyes of rabbits was reported at NaOH concentrations of 0.4; 0.5; 0.95; 1; 2 and 3% (Jabobs, 1992; Morgan et al., 1987; Murphy et al., 1982; Reer et al., 1976). Corrosive effects were found at 1.2; 8 and 10% NaOH (Morgan et al., 1987; Reer et al., 1976; Wentworth et al., 1993).

Effects on skin irritation/corrosion: corrosive

Effects on eye irritation: irritating

- According to the CLP Regulation No 1272/2008 Annex VI Table 3.1, the concentration limit for corrosivity to the skin of NaOH is considered to be 2%
- According to the CLP Regulation No 1272/2008 Annex VI Table 3.1, NaOH is a skin corrosive category 1A at a concentration $\geq 5\%$
- According to the CLP Regulation No 1272/2008 Annex VI Table 3.1, the concentration range for eye/skin irritation is 0.5 % ≤ C < 2 %

Sensitisation

Existing data do not demonstrate that NaOH is a skin sensitizer.

Repeated Dose Toxicity

The introductory sections to Annexes VII-X point at a specific adaptation to the standard information requirements as in vivo testing shall be avoided with corrosive substances at concentration/dose levels causing corrosivity. However, NaOH is not expected to be systemically available in the body under normal handling and use conditions and therefore systemic effects of NaOH after repeated exposure are not expected to occur (EU RAR of sodium hydroxide (2007); section 4.1.3.1.4, page 76).

Genetic Toxicity

Negative mutagenicity tests support no classification.

Carcinogenicity

Lack of positive in vitro and in vivo mutagenicity data support no classification for carcinogenicity and support no additional animal testing to assess carcinogenicity.

Toxicity to reproduction

Classification for reproductive or developmental toxicity is not necessary since NaOH is not expected to be systemically available in the body under normal handling and use conditions and the substance will not reach the foetus nor reach male and female reproductive organs (EU RAR of sodium hydroxide (2007), section 4.1.2.8, page 73).

Numerical measures of toxicity (such as acute toxicity estimates)

Refer "Toxicological (health) effects".

Interactive effects

An experimental study was conducted to investigate the effects of erythropoietin on the acute phase of esophageal burn damage induced by sodium hydroxide. A standard esophageal alkaline burn was produced by the application of 10% sodium hydroxide to the distal esophagus in an in vivo rat model. Fifty-six female rats were allocated into three groups: Group BC (baseline control, n = 8) rats were uninjured and untreated, Group PC (positive control, n = 24) rats were injured but untreated and Group EPO (erythropoietin-treated, n = 24) rats were injured and given subcutaneous erythropoietin

(1,000 IU/kg per day), 15 min, 24, and 48 hr after administration of the NaOH solution. Six animals from Group PC and six from Group EPO were killed at 4, 24, 48, and 72 hr after application of NaOH to the esophagus. All of animals in Group BC were killed 4 hr after exposure to 0.9% NaCl. Oxidative damage was assessed by measuring levels of malondialdehyde (MDA) and nitric oxide (NO), and activities of superoxide dismutase (SOD) and catalase (CAT) in homogenized samples of esophageal tissue. Histologic damage to esophageal tissue was scored by a single pathologist blind to groups. MDA levels in the BC and EPO groups were significantly lower than those in the PC group (p < 0.05). CAT and SOD activities, and NO levels in the BC and EPO groups were significantly higher than in the PC group (p < 0.05). Esophageal tissue damage measured at 4, 24, 48, and 72 hr after NaOH application was significantly less in the EPO group than in the PC group (p < 0.05). When administered early after an esophageal burn induced by 10% sodium hydroxide in this rat model, erythropoietin significantly attenuated oxidative damage, as measured by biochemical markers and histologic scoring.

SRP4: Interacts with acid salts to form bases.

Esophageal burns were induced in male rats by the administration of 10% sodium hydroxide. Lipid peroxidation (LPO) products were then measured at the following times: 0, 1, 6, 24, 48 and 72 hr after treatment. Tissue hydroxyproline (HP) concentrations in the injured area were assessed at 14 days after the administration of sodium hydroxide. The groups received either systemic melatonin or normal saline. There were two, non-ischemic, sham control groups treated with or without melatonin. LPO products, malondialdehyde (MDA) and 4-hydroxyalkenal (4-HDA), increased immediately after the administration of sodium hydroxide; this indicates the participation of free radicals in the development of damage. Melatonin diminished the oxidative response and the amount of HP in the late phase of the lesion. Melatonin reduced oxidative damage in the early phase of the esophageal burns induced by sodium hydroxide.

The gastric damaging effects of necrotizing concentration of sodium hydroxide were strongly reduced by paracetamol. Paracetamol might be protective by stimulating the biosynthesis of prostaglandins in the stomach wall.

Protection against damage from locally applied sodium hydroxide has been shown to be possible under expected conditions in rabbit corneas by injection of animal's serum into cornea to increase its local buffering capacity.

Where specific chemical data are not available

No further information available.

Mixtures

No further information available.

Mixture versus ingredient information

No further information available.

Other information

None.

12 Ecological information

Toxicity

Hazard for aquatic organisms

Freshwater

Hazard assessment conclusion: no data available: testing technically not feasible

Marine water

Hazard assessment conclusion: no data available: testing technically not feasible

STP

Hazard assessment conclusion: no data available: testing technically not feasible

Sediment (freshwater)

Hazard assessment conclusion: no data available: testing technically not feasible

Sediment (marine water)

Hazard assessment conclusion: no data available: testing technically not feasible

Hazard for air

Air

Hazard assessment conclusion: no hazard identified

Hazard for terrestrial organisms

Soil

Hazard assessment conclusion: no data available: testing technically not feasible

Hazard for predators Secondary poisoning

Hazard assessment conclusion: no potential for bioaccumulation

Environmental Fate & Pathways Summary

The emissions of NaOH mainly apply to (waste)water. Furthermore, the high water solubility and very low vapour pressure indicate that NaOH will be found predominantly in water. In water (including soil or sediment pore water), NaOH is present as the sodium ion (Na+) and hydroxyl ion (OH-), as solid NaOH rapidly dissolves and subsequently dissociates in water (EU RAR 2007 of sodium hydroxide, section 3.1.3, page 24).

If emitted to the air as an aerosol in water, NaOH will be rapidly neutralised as a result of its reaction with CO2 (or other acids), as follows (EU RAR 2007, section 3.1.3.4, page 26): NaOH + CO2 -> HCO3- + Na+

Subsequently, the salts (e.g. sodium(bi)carbonate) will be washed out from the air (US EPA, 1989; OECD, 2002). Thus, atmospheric emissions of neutralised NaOH will largely end up in soil and water.

If emitted to soil, sorption to soil particles will be negligible (EU RAR 2007, section 3.1.3.3, page 26). Depending on the buffer capacity of the soil, OH- will be neutralised in the soil pore water or the pH may increase.

Stabilty Summary

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 (EU RAR 2007, section 3.1.1 page 19 and section 3.1.3.4, page 26).

Additional information

Based on the results of the ecotoxicity studies, its dissociation in the environment and lack of bioaccumulation NaOH is not classified for the environmental compartment.

Persistence and degradability

According to the REACH Regulation, the study does not need to be conducted if the substance is inorganic (Annex VII, Column 2 adaption).

Bioaccumulative potential

According to the REACH Regulation, the study does not need to be conducted if the substance has a low potential for bioaccumulation (Annex IX, column 2 adaptation).

Considering its high water solubility, NaOH is not expected to bioconcentrate in organisms. Log Pow is not applicable for an inorganic compound that dissociates (EU RAR 2007, section 3.1.1 page 19 and section 3.1.3.4, page 26). 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.

Mobility in soil

According to the REACH Regulation, an adsorption/desorption study does not need to be conducted if based on the physicochemical properties the substance can be expected to have a low potential for adsorption (Annex VIII, column 2 adaptation).

Considering its high water solubility, NaOH is not expected to bioconcentrate in organisms. High water solubility and low vapor pressure indicate that NaOH will be found predominately in the aquatic environment.

The 73% aqueous solution of NaOH at ambient temperatures is a highly viscous, gelatinous material and without additional

dilution (precipitation), it is not expected to infiltrate soil to any significant extent. The 50% aqueous solution of NaOH is liquid and is expected to infiltrate soil to a measurable degree. As the dilution of NaOH increases, its speed of movement through soil increases. During movement through soil, some ion exchange will occur. Also, some of the hydroxide may remain in the aqueous phase and will move downward through soil in the direction of groundwater flow (EU RAR 2007, section 3.1.3, page 24).

Other adverse effects

Water hazard class 1 (Self-assessment): slightly hazardous for water. **DO NOT** allow undiluted product or large quantities of it to reach ground water, water course or sewage system. Must not reach bodies of water or drainage ditch undiluted or unneutralized.

13 Disposal considerations

Disposal methods

Waste disposal recommendations

Dispose of waste and container in accordance with local and/or national regulations. Hazardous waste shall not be mixed together with other waste. Different types of hazardous waste shall not be mixed together if this may entail a risk of pollution or create problems for the further management of the waste. Hazardous waste shall be managed responsibly. All entities that store, transport or handle hazardous waste shall take the necessary measures to prevent risks of pollution or damage to people or animals. Recycle/reuse. Remove for physico-chemical/biological treatment. **DO NOT** discharge into drains or the environment.

Dilute with plenty of water. Solutions with high pH-value must be neutralized before discharge. Neutralise with acid. In accordance with local and national regulations.

Ecology - waste materials

DO NOT release to the environment.

Empty Container

Avoid reuse of empty container. Consider refilling. Rinse/Decontaminate thoroughly with water before disposal or return to supplier. Where possible recycling is preferred to disposal or incineration. Dispose of as unused product. In accordance with local and national regulations.

14 Transport information

UN Number

TRANSPORTATION CLASSIFICATION	ADR/RID	ADN(R)	IMDG	ICAO/IATA
Identification Number	1824	1824	1824	1824
Proper Shipping Name	SODIUM	SODIUM	SODIUM	SODIUM
	HYDROXIDE	HYDROXIDE	HYDROXIDE	HYDROXIDE
	SOLUTION	SOLUTION	SOLUTION	SOLUTION
Transport Hazard Class(es)	8	8	8	8
Packing Group	II	II	II	II
Environmental Hazards	DO NOT release to			
	the environment.	the environment.	the environment.	the environment.
Emergency Response	ERG: 154	N/A	EMS: F-A, S-B	N/A
Special provisions	Exempt Quantity			Quantity
	Road			Limitations
	50Kg F: 20			1L - Passenger
	Quantity	_	-	30 L - Cargo
	Limitations			
	1L - Passenger Rail			

UN Proper Shipping Name

Refer above section 14.1

Transport hazard class(es)

Refer above section 14.1

Packing group, if applicable

Refer above section 14.1

Environmental hazards

Refer above section 14.1

Special precautions for user

DO NOT load with Class 1.

Keep aluminium gas cylinders apart from caustic bases.

May be loaded with Class 8A if kept at least 1 metre apart.

Can be loaded with all other classes.

Goods of different classes **must** be segregated by an air space of at least 100mm or by an approved segregation device or non-dangerous goods.

P, B, L and O provisions as per SANS 10231:2006

None

GUIDE 154: SUBSTANCES - TOXIC AND/OR CORROSIVE (NON-COMBUSTIBLE) Public Safety

CALL Emergency Response Telephone Number 112 or 10177. As an immediate precautionary measure, isolate spill or leak area in all directions for at least 50 meters (150 feet) for liquids and at least 25 meters (75 feet) for solids. Keep unauthorized personnel away. Stay upwind. Keep out of low areas. Ventilate enclosed areas.

Protective Clothing

Wear positive pressure self-contained breathing apparatus (SCBA). Wear chemical protective clothing that is specifically recommended by the manufacturer. It may provide little or no thermal protection. Structural firefighters' protective clothing provides limited protection in fire situations ONLY; it is not effective in spill situations where direct contact with the substance is possible.

Evacuation

Fire - If tank, rail car or tank truck is involved in a fire, ISOLATE for 800 meters (1/2 mile) in all directions; also, consider initial evacuation for 800 meters (1/2 mile) in all directions.

Fire

Small fires - Dry chemical, CO2 or water spray. Large fires: Dry chemical, CO2, alcohol-resistant foam or water spray. Move containers from fire area if you can do it without risk. Dike fire control water for later disposal; do not scatter the material. Fire involving tanks or car/trailer loads - Fight fire from maximum distance or use unmanned hose holders or monitor nozzles. DO NOT get water inside containers. Cool containers with flooding quantities of water until well after fire is out. Withdraw immediately in case of rising sound from venting safety devices or discoloration of tank. ALWAYS stay away from tanks engulfed in fire.

Spill or Leak

ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). **DO NOT** touch damaged containers or spilled material unless wearing appropriate protective clothing. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Absorb or cover with dry earth, sand or other noncombustible material and transfer to containers. **DO NOT** GET WATER INSIDE CONTAINERS.

First Aid

Move victim to fresh air. Call 911 or emergency medical service. Give artificial respiration if victim is not breathing. **DO NOT** use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Administer oxygen if breathing is difficult. Remove and isolate contaminated clothing and shoes. In case of contact with substance, immediately flush skin or eyes with running water for at least 20 minutes. For minor skin contact, avoid spreading material on unaffected skin. Keep

victim warm and quiet. Effects of exposure (inhalation, ingestion or skin contact) to substance may be delayed. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

5 Regulatory information

Safety, health and environmental regulations specific for the product in question

SA NATIONAL LEGISLATION

Hazardous Substances Act 15 of 1973 and Regulations.

Occupational Health and Safety Act 85 of 1993 and Regulations.

SA NATIONAL STANDARDS

SANS 10228: 2006: Identification and Classification of Dangerous Goods for Transport by Road and Rail.

SANS 10231 : 2018 : Transport of dangerous goods - Operational requirements for road vehicles. SANS 10234 : 2008 : Globally Harmonized System of classification and labelling of chemicals (GHS).

SANS 11014: 2010: Safety Data Sheets for chemical Products.

REACH Regulation (EC) No 1907/2006

This product contains only components that have been either pre-registered, registered, are exempt from registration, are regarded as registered or are not subject to registration according to Regulation (EC) No. 1907/2006 (REACH)., The aforementioned indications of the REACH registration status are provided in good faith and believed to be accurate as of the effective date shown above. However, no warranty, express or implied, is given. It is the buyer's/user's responsibility to ensure that his/her understanding of the regulatory status of this product is correct.

Seveso III: Directive 2012/18/EU

Listed in Regulation: Not applicable

Clean Water Act Requirements

Sodium hydroxide is designated as a hazardous substance under section 311(b)(2)(A) of the Federal Water Pollution Control Act and further regulated by the Clean Water Act Amendments of 1977 and 1978. These regulations apply to discharges of this substance. This designation includes any isomers and hydrates, as well as any solutions and mixtures containing this substance.

CERCLA Reportable Quantities

Persons in charge of vessels or facilities are required to notify the National Response Center (NRC) immediately, when there is a release of this designated hazardous substance, in an amount equal to or greater than its reportable quantity of 1000 lb or 454 kg. The toll free number of the NRC is (800) 424-8802. The rule for determining when notification is required is stated in 40 CFR 302.4 (section IV.D.3.b).

FIFRA Requirements

Residues of sodium hydroxide are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. Use: neutralizer. Limit: none.

Residues of sodium hydroxide are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to animals. Use: neutralizer. Limit: none.

The Agency has completed its review of all available information, and has determined that the data are sufficient to support reregistration of products containing sodium hydroxide. The Agency therefore finds that products containing sodium hydroxide as an active ingredient are eligible for reregistration. Although the Agency has found that certain products containing sodium hydroxide are eligible for registration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing sodium hydroxide, if new information comes to the Agency's attention or if the data requirements for reregistration (or the guidelines for generating such data) change.

As the federal pesticide law FIFRA directs, EPA is conducting a comprehensive review of older pesticides to consider their

health and environmental effects and make decisions about their continued use. Under this pesticide reregistration program, EPA examines newer health and safety data for pesticide active ingredients initially registered before November 1, 1984, and determines whether the use of the pesticide does not pose unreasonable risk in accordance to newer saftey standards, such as those described in the Food Quality Protection Act of 1996. Pesticides for which EPA had not issued Registration Standards prior to the effective date of FIFRA '88 were divided into three lists based upon their potential for human exposure and other factors, with List B containing pesticides of greater concern than those on List C, and with List C containing pesticides of greater concern than those on List D. Sodium hydroxide is found on List D. Case No: 4065; Pesticide type: fungicide, herbicide, antimicrobial; Case Status: RED Approved 09/92; OPP has made a decision that some/all uses of the pesticide are eligible for reregistration, as reflected in a Reregistration Eligibility Decision (RED) document .; Active ingredient (AI): sodium hydroxide; Data Call-in (DCI) Date(s): 09/30/92; AI Status: OPP has completed a Reregistration Eligibility Decision (RED) document for the case/AI.

United States Environmental Protection Agency/ Prevention, Pesticides and Toxic Substances; Status of Pesticides in Registration,

FDA Requirements

Substance added directly to human food affirmed as generally recognized as safe (GRAS).

Sodium hydroxide used as a general purpose food additive in animal drugs, feeds, and related products is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Chemical safety assessment

Performed for substance: Yes

6 Other information

Other information

Full text of H-Statements referred to under section 2

Hazard statements

H290 May be corrosive to metals.

H314 Causes severe skin burns and eye damage.

Precautionary statements

P234 Keep only in original container.

H260 Do not breathe dust/fume/gas/mist/vapours/spray.

P264 Wash 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.

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.

P310 Immediately call a POISON CENTER or doctor/physician.

P321 Specific treatment (see P363 on this label).
P363 Wash contaminated clothing before reuse.
P390 Absorb spillage to prevent material damage.

P405 Store locked up.

P406 Store in corrosive resistant container with a resistant inner liner.

P501 Dispose of contents and container in accordance with local, regional, national, international

regulations.

Labelling REGULATION (EC) No 1272/2008

Signal Word

Danger

Pictograms Hazard to Human

GHS05 Corrosive Hazard

Pictogram Hazard during Transport

Class 8 Corrosive substance

Acronyms:

ACGIH American Conference of Governmental Industrial Hygienists

ATE Acute Toxicity Estimate

CAS Chemical Abstract Service

DOT Department of Transport (USA)

EINECS European Inventory of Existing Commercial Chemical Substances

ICSC International Chemical Safety Cards
IDLH Immediately dangerous to life or health

LC₅₀ Median Lethal Concentration

RTECS Registry of Toxic Effects of Chemical Substances

NFPA National Fire Protection Agency (USA)

NIOSH National Institute for Occupational Safety and Health (USA)
OSHA Occupational Safety and Health Administration (USA)

PEL Permissible Exposure Limit
REL Recommended Exposure Limit
TWA Time-Weighted Average

Training advice

Provide adequate information, instruction and training for operators.

Information sources

 European Chemicals Agency https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15566/1

2. National Center for Biotechnology Information. PubChem Database. Sodium hydroxide, CID=14798, https://pubchem.ncbi.nlm.nih.gov/compound/14798 (accessed on Apr. 23, 2019)

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MANUFACTURER/SUPPLIER DISCLAIMER:

IMPORTANT: This information is given without a warranty or guarantee. No suggestions for use are intended or shall be construed as a recommendation to infringe any existing patents or violate any national or local laws. Safe handling and use is the responsibility of the customer. Read the label before using this product. This information is true and accurate to the best of our knowledge.

Revision History

Revision	Date	Change
1.0	2019/04/24	Preparation of the safety data sheet according to SANS 11014:2010