

Safety Data Sheet

According to Annex II to REACH - Regulation 2015/830

SECTION 1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name **STERYLFIX**

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

Intended use **Universal water based additive, resistant to mould and algae. Professional and Commercial Use**

Uses Advised Against

Uses other than those indicated

1.3. Details of the supplier of the safety data sheet

Name **OIKOS S.P.A. a socio unico**
Full address **Via Cherubini 2**
District and Country **47043 Gatteo Mare (FC)**
Italia
Tel. **0547 681412**
Fax **0547 681430**

e-mail address of the competent person responsible for the Safety Data Sheet **certificazioniprodotti@oikos-group.it**

1.4. Emergency telephone number

For urgent inquiries refer to **NHS National Health Service 111****OIKOS S.P.A. a socio unico Company emergency number: 0547 681412**
Technical support - Monday to Friday from 8.00-13.00; 13:30 to 16:30

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2015/830.

Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Substance or mixture corrosive to metals, category 1	H290	May be corrosive to metals.
Skin corrosion, category 1B	H314	Causes severe skin burns and eye damage.
Serious eye damage, category 1	H318	Causes serious eye damage.
Hazardous to the aquatic environment, acute toxicity, category 1	H400	Very toxic to aquatic life.
Hazardous to the aquatic environment, chronic toxicity, category 2	H411	Toxic to aquatic life with long lasting effects.

2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

Signal words: **Danger**

SECTION 2. Hazards identification ... / >>

Hazard statements:

H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.
EUH031	Contact with acids liberates toxic gas.
EUH206	Warning! Do not use together with other products. May release dangerous gases (chlorine).

Precautionary statements:

P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.
P273	Avoid release to the environment.
P280	Wear protective gloves/ protective clothing / eye protection / face protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
P405	Continue rinsing.
P501	Store locked up.
	Dispose of contents / container in accordance with local regulation.

Contains: Sodium hypochlorite, 5% active Cl solution
Sodium hydroxide

Ingredients compliant with Regulation (EC) No. 648/2004
Between 5% and 15% chlorine-based bleaching agents

2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification 1272I2008 (CLP)
Sodium hypochlorite		
20% - active chlorine		
CAS	7681-52-9 5 ≤ x < 7	Met. Corr. 1 H290, Skin Corr. 1B H314, Eye Dam. 1 H318, Aquatic Acute 1 H400 M=10, Aquatic Chronic 1 H410 M=1, EUH031, Classification note according to Annex VI to the CLP Regulation: B
EC	231-668-3	
INDEX	017-011-00-1	
Reg. no.	01-2119488154-34-0033	
Sodium hydroxide		
CAS	1310-73-2 1 ≤ x < 1,5	Met. Corr. 1 H290, Skin Corr. 1A H314, Eye Dam. 1 H318
EC	215-185-5	
INDEX	011-002-00-6	
Reg. no.	01-2119457892-27-xxxx	

The full wording of hazard (H) phrases is given in section 16 of the sheet.

SECTION 4. First aid measures

4.1. Description of first aid measures

EYES: Remove any contact lenses. Wash immediately and abundantly with water for at least 30/60 minutes, opening the eyelids well. See a doctor immediately.

SKIN: Take off contaminated clothes. Take a shower immediately. Do not use solvents. See a doctor immediately.

INGESTION: Give water to drink as much as possible. See a doctor immediately. Do not induce vomiting unless expressly authorized by the doctor.

INHALATION: Call a doctor immediately. Take the person outdoors, away from the accident site. If breathing stops, give artificial respiration. Take adequate precautions for the rescuer.

PROTECTION MEASURES FOR FIRST AIDERS: for PPE necessary for first aid, refer to section 8.2 of this safety data sheet.

SECTION 4. First aid measures ... / >>**4.2. Most important symptoms and effects, both acute and delayed**

Acute effects:

Skin: irritation, burn, necrosis and perforations.

Eyes: irritation, corneal damage.

Respiratory tract: severe irritation to the respiratory tract.

Ingestion: irritation of the digestive system with sometimes blood vomiting.

Chronic effects.

Skin: dermatosis

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

Treat symptomatologically.

In the event of an accident or if you feel unwell, seek medical advice immediately (if possible show the instructions for use or the safety data sheet).

SECTION 5. Firefighting measures**5.1. Extinguishing media**

SUITABLE EXTINGUISHING MEDIA

The extinguishing media are the traditional ones: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING MEDIA

Strong jets of water.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF A FIRE

Heating can release dangerous gases.

Reacts violently with acids and is corrosive to metals developing flammable hydrogen gas.

If directly involved it can give rise to toxic fumes (chlorine). Avoid breathing combustion products.

5.3. Advice for firefighters

GENERAL INFORMATION

Cool containers with jets of water to avoid product decomposition and the development of substances potentially hazardous for health.

Always wear complete fire protection equipment. Collect extinguishing water that must not be discharged into the sewers. Dispose of the

contaminated water used for extinguishing and the residue of fire according to current regulations.

EQUIPMENT

Normal fire fighting clothing, such as an open circuit compressed air breathing apparatus (EN 137), flame retardant suit (EN469), flame retardant gloves (EN 659) and boots for the Fire Brigade (HO A29 or A30).

SECTION 6. Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

6.1.1 For those who do not intervene directly

Do not take any action involving any personal risk or without adequate training. Evacuate the surrounding areas. Do not touch or walk on spilled material.

Wear appropriate protective equipment (including personal protective equipment referred to in section 8 of this Safety Data Sheet) to prevent contamination of the skin, eyes and personal clothing. Wear appropriate respirator when ventilation is inadequate.

Do not inhale the mists / vapors / gas. Avoid dispersion of the product in the environment. Follow the appropriate internal procedures provided for personnel not authorized to intervene directly in case of accidental release.

6.1.2 For those who intervene directly

Stop the leak if there is no danger.

Evacuate unauthorized personnel. Wear suitable protective equipment. (see section 8 of this Safety Data Sheet). Follow the appropriate internal procedures for authorized personnel. Isolate the danger area and deny entry. Ventilate enclosed spaces before entering.

6.2. Environmental precautions

Prevent dispersal of spilled material, runoff and contact with soil, waterways, drains, sewers and groundwater. Immediately inform the competent authorities in case of pollution in order to limit environmental damage as much as possible.

Water spray can be used to dilute the vapors.

6.3. Methods and material for containment and cleaning up

Aspirate the liquid into a suitable container and absorb the rest with inert absorbent material (clay, sand or other non-combustible material).

SECTION 6. Accidental release measures ... / >>

Introduce the collected material in clean and labeled containers. Use neutralization means and keep the pH value under control. The equipment must be resistant to corrosion.

Provide sufficient ventilation of the place affected by the leak. The disposal of contaminated material must be carried out in accordance with the provisions of point 13.

In case of dispersion of a large quantity of product, inform the local authorities as soon as possible. After removing all the product, wash the contaminated area with plenty of water without using solvents and acid products, and retain the contaminated washing water to manage it as waste.

Do not use acid products to clean.

Cleaning products that are among the incompatible agents must not be used (ref. Section 10.5).

6.4. Reference to other sections

Any information regarding personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage**7.1. Precautions for safe handling**

Check the integrity of the packaging. Whenever possible, operate above wind.

Avoid contact with skin and eyes. Do not inhale the mists / vapors / gas. Do not eat, drink or smoke during use or handling. Wash hands after use. Avoid dispersal of the product in the environment. Handle in a suitable place with good general ventilation. Once emptied, the containers must be transferred without delay to the area identified for their collection pending disposal.

Keep away from heat, sparks and open flames, do not smoke or use matches or lighters. Avoid the accumulation of electrostatic charges.

7.2. Conditions for safe storage, including any incompatibilities

Handle the product after consulting all the other sections of this safety data sheet. Avoid dispersal of the product in the environment.

Remove contaminated clothing and protective equipment before entering areas where you eat.

Keep the packaging closed and labeled. The containers must also be protected from damage, accidental impacts and falls. Store in a well-ventilated, dry and cool place.

Protect from direct sunlight. Minimize all possible sources of loss through suitable procedural and plant engineering interventions. Keep away from food, feed or drinks. Keep only in the original container.

The arrangement of the storage area must be such as to prevent the percolation of accidental spills into the ground.

Keep containers away from any incompatible materials, checking section 10.

For the storage area, provide floors resistant to alkaline solutions.

Recommended storage temperature: <20 ° C.

7.3. Specific end use(s)

No use other than that indicated in section 1.2 of this safety data sheet.

SECTION 8. Exposure controls/personal protection**8.1. Control parameters**

Regulatory References:

TLV-ACGIH

ACGIH 2019

Sodium hypochlorite**Threshold Limit Value**

Type	Country	TWA/8h mg/m3	ppm	STEL/15min mg/m3	ppm	Remarks / Observations
TLV-ACGIH		0,1		0,4		Espresso come Cloro

Predicted no-effect concentration - PNEC

Normal value in fresh water	0,00021	mg/l
Normal value in marine water	0,00004	mg/l
	2	
Normal value of STP microorganisms	4,69	mg/l

Health - Derived no-effect level - DNEL I DMEL

Route of exposure	Effects on consumers				Effects on workers			
	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation					3.1 mg/m3	3,1 mg/m3	1.55 mg/m3	1,55 mg/m3

SECTION 8. Exposure controls/personal protection ... / >>

Sodium hydroxide								
Threshold Limit Value								
Type	Country	TWA/8h		STEL/15min		Remarks / Observations		
		mg/m3	ppm	mg/m3	ppm			
TLV-ACGIH				2 (C)				
Health - Derived no-effect level - DNEL I DMEL								
	Effects on consumers				Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation			1 mg/m3	VND			1 mg/m3	VND

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.

8.2. Exposure controls

The general practice of hygiene at work involves certain measures (for example, showering and changing clothes at the end of the work shift) in order to avoid any type of third party contamination and appropriate cleaning practices (i.e. regular cleaning with suitable cleaning devices), do not eat and smoke in the workplace.

In general, inhalation and ingestion must be avoided. Unless stated otherwise, certified work shoes and clothing must be worn.

Contaminated work clothing should not be taken out of the workplace.

Ensure good general ventilation in the place of and effective local suction or other technical equipment in order to keep the levels in the air below the exposure limit values.

In the absence of adequate ventilation, indicator devices and automatic warning devices must be installed to signal the achievement of concentrations or dangerous conditions.

Where this is not possible, frequent checks and measurements should be performed.

For the choice of personal protective equipment, if necessary ask for advice from your PPE suppliers.

The individual protection devices must bear the CE marking which certifies their compliance with the standards in force.

Provide emergency shower with visocular tray.

Exposure levels should be kept as low as possible to avoid significant build-up in the body.

Manage personal protective equipment in such a way as to ensure maximum protection (e.g. reduction of replacement times).

Provide an emergency shower with face and eye wash station.

If the product may or must come into contact or react with acids, suitable technical and/or organisational measures should be taken to prevent the development of toxic and/or inflammable gases.

HAND PROTECTION

Protect your hands with work gloves, category III (ref. standard EN 374).

Main recommended materials: PVC, latex, nitrile rubber.

Protection class: 6 (breakthrough time greater than 480 minutes).

When identifying the relevant material and the relative thickness to be used, it is highly recommended to contact the PPE manufacturer directly to evaluate the effective protection with regard to the specific characteristics of the same on the basis of use and duration of use.

The following must be considered: compatibility, degradation, breaking time and permeation.

In the case of preparations, the resistance of work gloves to chemical agents must be checked before use as it cannot be foreseen. The gloves have a wear time that depends on the duration and mode of use.

Thermal hazards: Wear heat resistant gloves in case of thermal hazards.

PROTECTION OF THE SKIN

Wear category III professional long-sleeved overalls and safety footwear (ref. Directive 89/686 / EEC and standard EN ISO 20344). Wash with soap and water after removing protective clothing.

EYE PROTECTION

Wear hood visor or protective visor combined with airtight goggles (ref. Standard EN 166).

RESPIRATORY PROTECTION

Wear a mask with type B filter (inorganic gases and vapors) whose class (1, 2 or 3) must be chosen in relation to the limit concentration of use. (ref. EN 14387 standard). If gases or vapors of a different nature and / or gases or vapors with particles (aerosols, fumes, mists, etc.) are present, combined filters must be provided.

The use of respiratory protection means is necessary if the technical measures adopted are not sufficient to limit the worker exposure to the threshold values taken into consideration. The protection offered by the masks is however limited.

In case the substance considered is odorless or its olfactory threshold is higher than the relative TLV-TWA and in case of emergency, wear an open circuit compressed air breathing apparatus (ref. Standard EN 137) or a plug-in respirator outdoor air (ref. standard EN 138). For the correct choice of the respiratory protection device, refer to EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

Product residues must not be indiscriminately disposed of with waste water or by dumping in waterways.

SECTION 9. Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Properties	Value	Information
Appearance	liquid	
Colour	transparent	
Odour	chlorine	
Odour threshold	3.2 ppm	Remark:v / v (referred to chlorine Cl2)
pH	12,9	
Melting point / freezing point	Not available	
Initial boiling point	> 100 °C	
Boiling range	Not available	
Flash point	Not available	
Evaporation Rate	Not available	
Flammability of solids and gases	not applicable based on physical state	
Lower inflammability limit	Not available	
Upper inflammability limit	Not available	
Lower explosive limit	Not available	
Upper explosive limit	Not available	
Vapour pressure	20 hPa	
Vapour density	Not available	
Relative density	Not available	
Solubility	soluble in water	
Partition coefficient: n-octanol/water	log Pow: -3.42 (dato riferito all'ipoclorito di sodio)	
Auto-ignition temperature	Not available	Remark:The substances contained are not subject to self-ignition
Decomposition temperature	> 35 °C	Remark:At temperatures> 35 ° C, sodium hypochlorite begins to releaseChlorine
Viscosity	Not available	
Explosive properties	Not explosive. None of the substances contained have functional groups associated with explosive properties	
Oxidising properties	Non oxidizing. None of the substances contained have functional groups associated with oxidizing properties	

Not applicable it means that is not useful for the determination of hazard.

9.2. Other information

Information not available

SECTION 10. Stability and reactivity**10.1. Reactivity**

Contact with metals develops flammable hydrogen gas. Contact with strong acids can cause violent reactions and explosions. Potential danger for exothermic reactions. Corrosive power towards metals.

10.2. Chemical stability

Stable under normal conditions of use and storage (at room temperature).

10.3. Possibility of hazardous reactions

Contact with strong acids releases chlorine and chlorine dioxide gas. It releases hydrogen in reaction with metals. Sodium hypochlorite decomposes on heating, in contact with acids and if exposed to light producing toxic and corrosive gases containing chlorine.

10.4. Conditions to avoid

Protect from light.
Avoid exposing the product to high temperatures. Avoid moisture.

Sodium hydroxide
Avoid exposure to: air,moisture,sources of heat.

SECTION 10. Stability and reactivity ... / >>**10.5. Incompatible materials**

Keep separate from flammable and reducing substances, acids, strong acids, metals, food and feedstuffs.

Sodium hydroxide

Incompatible with: strong acids, ammonia, zinc, lead, aluminium, water, flammable liquids.

10.6. Hazardous decomposition products

Decomposes on heating, developing toxic fumes containing sodium oxide, Chlorine. Sodium chlorate. Hypochlorous acid. Oxygen.

SECTION 11. Toxicological information**11.1. Information on toxicological effects**

Metabolism, toxicokinetics, mechanism of action and other information

Sodium hypochlorite is absorbed orally, skin and inhalation.

Information on likely routes of exposure

SODIUM HYPOCHLORITE

The main potential routes of exposure are inhalation, skin contact and ingestion.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

SODIUM HYPOCHLORITE

Toxic effects in humans depend on the concentration of the solution. High concentrations are dangerous while the dilutions usually used do not involve risks.

The main manifestations are related to the corrosive nature of concentrated forms.

The ingestion of modest quantities of dilutions normally used determines only mild digestive disorders.

On the contrary, concentrated solutions cause severe irritation of the digestive system with vomiting, sometimes blood. Necrosis and perforation can occur. These effects can be accompanied by shock and hemolysis. There is an important hyponatremia, sometimes the cause of death.

Prolonged use of the substance can cause dermatosis.

SODIUM HYDROXIDE

The ingestion of concentrated solutions is followed by buccal, retrosternal and epigastric pain associated with hypersalivation and bloody vomiting. Metabolic acidosis, hyperleukocytosis, hemolysis and hyponatremia occur. Complications are: esophageal or gastric perforation, digestive hemorrhage, fistulas, difficulty breathing, shock, intravascular coagulation.

Skin or eye contamination locally leads to chemical burns the severity of which depends on the concentration of the solution, the importance of contamination and the duration of contact.

At the skin level, depending on the depth of the damage, hot and painful erythema and necrosis are observed.

At the ocular level there is immediate pain, tearing and conjunctival hyperemia. Sequelae can occur such as: conjunctival adhesions, corneal opacities, cataracts, glaucoma and also blindness. (INRS, 2012; IPCS, 2010; Patty's Toxicology, 2001).

Interactive effects

SODIUM HYPOCHLORITE

Important are the dangers in case of mixtures with acid products. In these cases there is release of chlorine which can cause severe bronchial irritation and acute pulmonary edema, sometimes delayed.

Likewise mixtures with ammonia, which cause the formation of chloramine, are irritating to the respiratory tract (INRS, 2006).

ACUTE TOXICITY

LC50 (Inhalation) of the mixture:

Not classified (no significant component)

LD50 (Oral) of the mixture:

Not classified (no significant component)

LD50 (Dermal) of the mixture:

Not classified (no significant component)

Sodium hydroxide

LD50 (Oral)

325 mg/kg Coniglio

Sodium hypochlorite

LD50 (Oral)

1100 mg/kg Ratto (Wistar, maschio)

LD50 (Dermal)

> 2000 mg/kg Coniglio (Albino; maschio/femmina)

SECTION 11. Toxicological information ... / >>

LC50 (Inhalation)

> 10,5 mg/l/1h Ratto (Albino, maschio)

LC50 (Inhalation) of the mixture:> 20 mg / l
LD50 (Oral) of the mixture:> 2000 mg / kg
LD50 (Dermal) of the mixture:> 2000 mg / kg

SODIUM HYPOCHLORITE

Method: equivalent or similar to OECD 401
Reliability (Klimisch score): 2
Species: Rat (Wistar; male)
Routes of exposure: oral
Results: LD50 = 1100 mg / kg (12.5% Cl solution)

Method: equivalent or similar to OECD 403
Reliability (Klimisch score): 2
Species: Rat (Albino; male)
Routes of exposure: inhalation (vapors)
Results: LD50> 10.5 mg / L / 1h

Method: equivalent or similar to OECD 402
Reliability (Klimisch score): 2
Species: Rabbit (Albino; male / female)
Routes of exposure: cutaneous
Results: LD50> 2000 mg / kg

SODIUM HYDROXIDE

LD50 (Oral) 325 mg / kg Rabbit, 1 - 10% NaOH (Naunyn - Schiedeberg, 1937)

There are no reliable studies and no new studies have been generated in accordance with the REACH Regulation as the substance is classified as corrosive. In addition, the substance should not be available systemically and the effects are expected to cause changes in pH.

SKIN CORROSION / IRRITATION

Corrosive for the skin

SODIUM HYPOCHLORITE

In contact with the skin, concentrated solutions can cause severe burns.
Sodium hypochlorite is corrosive to rabbit skin (3.5% solution 15-30 min.); at a concentration of 20% the severity of the irritation is a function of the applied dose (INRS, 2006).
Causes severe skin burns (Harmonized classification, Annex VI, CLP Regulation).

SODIUM HYDROXIDE

Parameter: Effects of corrosion / dermal irritation
Result: Irritating to 61% of the volunteers
Species: Man
Test: Test conditions: 0.2 ml of 0.5% NaOH solution, for exposure up to 1 hour (15-60 minutes)

Parameter: Effects of corrosion / dermal irritation
Result: Slightly irritating
Species: White New Zealand rabbit
Test: OECD 404 method. Test conditions: aqueous solution of 1% w / w sodium hydroxide

Parameter: Effects of corrosion / dermal irritation
Result: Corrosive
Species: In vitro test (tested fabric: leather, Membrane Barrier)
Test: OECD 435 method

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye damage

SODIUM HYPOCHLORITE

In contact with the eye, concentrated solutions can cause severe burns with important sequelae.
In rabbits, eye corrosivity depends on the dose applied. A 0.5% solution causes a reversible irritation in 24 hours; a 5% solution causes immediate pain; if the eye is washed within 30 seconds, the lesion (slight transient opacification of the cornea and edema of the conjunctiva) is reversible within 24 hours, on the contrary, without washing, reversibility occurs after more than a week; an identical dose applied to a monkey's eye causes a more rapidly reversible injury (INRS, 2006).

SECTION 11. Toxicological information ... / >>

Causes serious eye damage (Harmonized classification, Annex VI, Reg. CLP).

SODIUM HYDROXIDE

irritant (2% sodium hydroxide solution) in vivo rabbit test (OECD method TG 405).

At the ocular level there is immediate pain, tearing and conjunctival hyperemia. Sequelae can occur such as: conjunctival adhesions, corneal opacities, cataracts, glaucoma and also blindness. (Harmonized classification, CLP Reg., Annex VI).

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

SODIUM HYPOCHLORITE

Method: equivalent or similar to OECD 406

Reliability (Klimisch score): 2

Species: guinea pig (Dunkin-Hartley; male / female)

Routes of exposure: cutaneous

Results: non sensitizing for the skin (aqueous solution at 40% v / v).

SODIUM HYDROXIDE

Inhalation of the substance can cause Brooks syndrome (irritant induced asthma).

SODIUM HYDROXIDE

Reliability (Klimisch score): 2

Species: man

Results: non sensitizing

Bibliographic reference: Journal of Dermatological Science, 10, 159-165, 1995.

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

SODIUM HYPOCHLORITE

Method: OECD 471 - In vitro test

Reliability (Klimisch score): 1

Species: bacteria (Salmonella typhimurium: TA98, TA100, TA102)

Results: Negative test

SODIUM HYDROXIDE

Both in vitro and in vivo genetic toxicity tests did not indicate any evidence of mutagenic activity. Furthermore, sodium hydroxide should not be available systemically in the body under normal conditions of use and handling, for this reason further tests are superficial.

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

SODIUM HYPOCHLORITE

Based on the available data, the substance has no carcinogenic effects and is not classified under the relevant CLP hazard class.

The International Agency for Research on Cancer (IARC) allocates hypochlorite salts in group 3 (not classifiable as a human carcinogen), based on the absence of data in humans and evidence of inadequate carcinogenicity in laboratory animals (IARC, 1991).

Two-year studies with chlorinated drinking water were conducted in F344 / N rats and B6C3F1 male and female mice. There is "no evidence of carcinogenic activity" in male rats and "doubtful evidence of carcinogenic activity" in female rats based on the increased incidence of mononuclear cell leukemias. In conclusion, there is "no evidence of carcinogenic activity" in mice (NTP, 1992).

SODIUM HYDROXIDE

Data not available.

Carcinogenic effects are not expected from exposure to sodium hydroxide since NaOH did not induce mutagenic effects either in vitro tests or in vivo tests. Furthermore, this substance should not be available systemically in the body under normal conditions of use and handling.

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

Harmful effects on sexual function and fertility

SODIUM HYPOCHLORITE

SECTION 11. Toxicological information ... / >>

Method: Equivalent or similar to OECD Guideline 415 Reliability (Klimisch score): 1

Species: Long-Evans rat, male / female

Routes of exposure: Oral

Results: No adverse effects observed

NO (A) EL

Male Parent Š 5.0 mg / kg bw / day

Female parent Š 5.0 mg / kg bw / day

F1 male Š 5.0 mg / kg bw / day

F1 female Š 5.0 mg / kg bw / day

Harmful effects on the development of offspring

SODIUM HYPOCHLORITE

Method: Equivalent or similar to OECD Guideline 414

Reliability (Klimisch score): 1

Species: Sprague-Dawley maschio rat / female

Routes of exposure: oral

Results: NOAEL (teratogenesis): > = 5.7 mg / kg bw / day

SODIUM HYDROXIDE

Since sodium hydroxide should not be available systemically in the body under normal conditions of use and handling, it can be said that the substance cannot reach the fetus or the male and female reproductive organs. Specific studies to determine any toxic effects for development or reproduction are therefore considered unnecessary.

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

SODIUM HYPOCHLORITE

Sodium hypochlorite aerosols can be irritating to the respiratory tract (EU, 2007).

In humans, toxic effects depend on the concentration of the solution. High concentrations are dangerous while the dilutions usually used do not involve risks.

The main manifestations are related to the corrosive nature of concentrated forms.

SODIUM HYDROXIDE

Bibliographic reference: Fritschi et al. (2001)

Type of population tested: workers.

Reliability (Klimisch score): 2

Results: Measurable changes in lung function were not found in workers exposed to this agent.

In this study, exposure concentrations up to 1 mg / m³ were not considered negative with regards to local effects on the respiratory tract.

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

SODIUM HYPOCHLORITE

Prolonged use of the substance can cause dermatosis (INRS, 2006).

SODIUM HYDROXIDE

There are no reliable studies available for this endpoint.

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

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

No data are available on aspiration hazard.

SECTION 12. Ecological information

This product is dangerous for the environment and highly toxic for aquatic organisms.

This product is dangerous for the environment and is toxic for aquatic organisms. In the long term, it have negative effects on acquatic environment.

12.1. Toxicity

SODIUM HYDROXIDE

Acute toxicity Crustaceans: (Ceriodaphnia sp.) CE50-48 hours: 40 mg / l Immobilization head. (EU, 2007; OECD, 2002)

Bibliographic reference: Warne et al. (1999).

Acute toxicity (fish): data not available.

There are no reliable studies and no new studies have been generated as all the available tests have led to a rather small range of toxicity values (acute toxicity tests for fish: from 35 to 189 mg / l) and there are also sufficient data on the pH range tolerated by the main taxonomic groups.

Growth inhibition (algae): data not available.

Long-term effects: data not available.

Sodium hypochlorite

LC50 - for Fish

0,032 mg/l/96h Oncorhynchus kisutch, Thatcher (1978)

EC50 - for Crustacea

0,165 mg/l/48h Daphnia magna (OECD TG 2002)

Chronic NOEC for Fish

0,04 mg/l/28d Menidia peninsulæ (pubblicazione, nessuna linea guida seguita)

Chronic NOEC for Crustacea

0,007 mg/l/14d Specie differenti (Liden et al., 1980)

Chronic NOEC for Algae / Aquatic Plants

0,02 mg/l/96h Myriophyllum spicatum (Water Res. 18(8), 1037-1043)

12.2. Persistence and degradability

SODIUM HYDROXIDE

Hydrolysis: Study not necessary. In water (including soil or sediment pore water), NaOH is present as sodium ion (Na⁺) and hydroxyl ion (OH⁻), since solid NaOH dissolves quickly and subsequently dissociates in water.

Degradability: the study is not applicable as the substance is inorganic.

SODIUM HYPOCHLORITE

No dispersion is expected in the atmosphere since the hypochlorite solutions are not volatile. However, when hypochlorite is accidentally mixed with acids it can release chlorine. No data are available on the effects of hypochlorite in atmospheric pity (EU, 2009).

Degradability: the study is not applicable as the substance is inorganic.

12.3. Bioaccumulative potential

Sodium hypochlorite

Partition coefficient: n-octanol/water

-3,42 a 20°C (KOWWIN v1.67.)

12.4. Mobility in soil

SODIUM HYDROXIDE

Given the high mobility in the soil and the high solubility, it can melt following rains and infiltrate the soil.

12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects

Information not available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Reuse if possible. Product residues are to be considered special hazardous waste. The hazardous nature of the waste which partially contains this product must be assessed on the basis of the laws in force. (Ref. Annex D - Part IV of Legislative Decree no. 152/2006 and

SECTION 13. Disposal considerations ... / >>

subsequent amendments and adjustments). Disposal must be entrusted to a company authorized to manage waste, in compliance with national and possibly local regulations.

The legal responsibility for disposal lies with the producer / holder of the waste.

CER (European Waste Code) codes may be applied to this product according to the specific circumstances that generated the waste, any alterations and contaminations.

The product as it is, out of specification in the original packaging, or transferred to a suitable container for disposal as waste, or the product in specific but no longer usable (for example following an accidental spill), is to be classified with a code CER compatible with the description of use indicated in section 1.2.

The appropriate final destination of the waste will be assessed by the manufacturer according to the chemical-physical characteristics of the waste itself compatible with the authorized plant to which it will be conferred for recovery, treatment or final disposal in the manner prescribed by current regulations.

Disposal through wastewater discharge is not permitted.

CONTAMINATED PACKAGING

Contaminated packaging must be sent, properly labeled, for recovery or disposal in compliance with national waste management regulations and is to be classified with the following EWC code: 15 01 10 *: packaging containing residues of dangerous substances or contaminated by these substances.

SECTION 14. Transport information**14.1. UN number**

ADR / RID, IMDG, IATA: 3266

14.2. UN proper shipping name

ADR / RID: CORROSIVE LIQUID, BASIC, INORGANIC, N.O.S. (Sodium hypochlorite, Sodium, hydroxide)
IMDG: CORROSIVE LIQUID, BASIC, INORGANIC, N.O.S. (Sodium hypochlorite, Sodium, hydroxide)
IATA: CORROSIVE LIQUID, BASIC, INORGANIC, N.O.S. (Sodium hypochlorite, Sodium, hydroxide)

14.3. Transport hazard class(es)

ADR / RID: Class: 8 Label: 8



IMDG: Class: 8 Label: 8



IATA: Class: 8 Label: 8

**14.4. Packing group**

ADR / RID, IMDG, IATA: II

14.5. Environmental hazards

ADR / RID: Environmentally Hazardous



IMDG: Marine Pollutant



IATA: NO

For Air transport, environmentally hazardous mark is only mandatory for UN 3077 and UN 3082.

<div>OIKOS</div>		<div>OIKOS S.P.A. a socio unico</div> <div>STERYLFIX</div>		<div>Revision nr.10</div> <div>Dated 06/05/2020</div> <div>Printed on 18/06/2020</div> <div>Page n. 13 / 15</div> <div>Replaced revision:9 (Dated 19/05/2017)</div>		EN	
<div>SECTION 14. Transport information ... / >></div>							
<div>14.6. Special precautions for user</div>							
ADR / RID:		HIN - Kemler: 80		Limited Quantities: 1 L		Tunnel restriction code: (E)	
IMDG:		Special Provision: -		Limited Quantities: 1 L			
IATA:		EMS: F-A, S-B		Maximum quantity: 30 L		Packaging instructions: 855	
		Cargo:		Maximum quantity: 1 L		Packaging instructions: 851	
		Pass.:		A3, A803			
		Special Instructions:					
<div>14.7. Transport in bulk according to Annex II of Marpol and the IBC Code</div>							
<div>Information not relevant</div>							
<div>SECTION 15. Regulatory information</div>							
<div>15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture</div>							
<div>Seveso Category - Directive 2012/18/EC:</div>				<div>41</div>			
<div>Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006</div>							
<div>Product</div>							
<div>Point</div>		<div>3</div>					
<div>Substances in Candidate List (Art. 59 REACH)</div>							
<div>On the basis of available data, the product does not contain any SVHC in percentage greater than 0,1%.</div>							
<div>Substances subject to authorisation (Annex XIV REACH)</div>							
<div>None</div>							
<div>Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:</div>							
<div>None</div>							
<div>Substances subject to the Rotterdam Convention:</div>							
<div>None</div>							
<div>Substances subject to the Stockholm Convention:</div>							
<div>None</div>							
<div>Healthcare controls</div>							
<div>Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.</div>							
<div>15.2. Chemical safety assessment</div>							
<div>A chemical safety assessment has been performed for the following contained substances</div>							
<div>Sodium hypochlorite</div>							
<div>Sodium hydroxide</div>							
<div>SECTION 16. Other information</div>							
<div>Training for workers:</div>							
<div>The training of workers must include contents, updates and duration according to the risk profiles assigned to the working sectors to which they belong, according to the procedures provided for by Legislative Decree 81/2008.</div>							
<div>Classification and procedure used to derive it according to Regulation (EC) 1272/2008 (CLP) in relation to mixtures:</div>							
<div>Classification according to Regulation (EC) n. 1272/2008 Classification procedure</div>							
<div>Corrosive substance or mixture for metals, category 1 H290 Expert judgment</div>							
<div>Skin corrosion, category 1B H314 Calculation method</div>							
<div>Serious eye damage, category 1 H318 Calculation method</div>							
<div>Hazardous to the aquatic environment, acute toxicity, category 1 H400 Calculation method</div>							
<div>Hazardous to the aquatic environment, chronic toxicity, category 2 H411 Calculation method</div>							
<div>Text of hazard (H) indications mentioned in section 2-3 of the sheet:</div>							
<div>Met. Corr. 1</div>		<div>Substance or mixture corrosive to metals, category 1</div>					
<div>Skin Corr. 1A</div>		<div>Skin corrosion, category 1A</div>					
<div>Skin Corr. 1B</div>		<div>Skin corrosion, category 1B</div>					

SECTION 16. Other information ... / >>

Eye Dam. 1	Serious eye damage, category 1
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
Aquatic Chronic 1	Hazardous to the aquatic environment, chronic toxicity, category 1
Aquatic Chronic 2	Hazardous to the aquatic environment, chronic toxicity, category 2
H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
EUH031	Contact with acids liberates toxic gas.
EUH206	Warning! Do not use together with other products. May release dangerous gases (chlorine).

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
 2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
 3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
 4. Regulation (EU) 2015/830 of the European Parliament
 5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
 6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
 7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
 9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
 10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
 11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
 12. Regulation (EU) 2016/1179 (IX Atp. CLP)
 13. Regulation (EU) 2017/776 (X Atp. CLP)
 14. Regulation (EU) 2018/669 (XI Atp. CLP)
 15. Regulation (EU) 2018/1480 (XIII Atp. CLP)
 16. Regulation (EU) 2019/521 (XII Atp. CLP)
- The Merck Index. - 10th Edition
 - Handling Chemical Safety
 - INRS - Fiche Toxicologique (toxicological sheet)
 - Patty - Industrial Hygiene and Toxicology
 - N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

SECTION 16. Other information ... / >>

- IFA GESTIS website- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) – Italy

Note for the recipient of the Safety Data Sheet (SDS):

It is the recipient of this SDS who must ensure that the information contained is read and understood by all the people who handle, store, use, or in any case come into contact in any way with the substance or mixture to which this sheet refers. In particular, the recipient must provide adequate training to personnel involved in the use of dangerous substances or mixtures.

The recipient must ensure the suitability and completeness of the information in relation to the specific use of the substance or mixture. However, the substance or mixture to which this SDS refers must not be used for uses other than those specified in section 1. No liability is assumed for improper use. Since the use of the product does not fall under the direct control of the Supplier, it is the user's obligation to observe the national and community hygiene and safety laws and provisions under his own responsibility.

The information contained in this SDS is provided in good faith and is based on the current state of scientific and technical knowledge, available at the indicated revision date, available from the Supplier indicated in section 1 of this sheet. SDS should not be interpreted as a guarantee of any specific property of the substance or mixture. The information refers only to the substance or mixture specifically designated in section 1 and may not be valid for the substance or mixture used in combination with other materials or in other processes not specifically indicated in the text.

This version of the SDS replaces all previous versions.