

	SAFETY DATA SHEET	SDS-M007
	<p style="text-align: center;">AMUCHINA SOLUZIONE DISINFETTANTE CONCENTRATA</p>	Edition: 1 Revision: 06 Revisione date: 21/12/2015 Date of replacement of the previous revision 30/10/2015

In accordance with Regulation (EC) n. 1907/2006 and subsequent amendments

SECTION 1 IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY /UNDERTAKING

1.1. Product identifier

Trade name:	AMUCHINA Soluzione Concentrata
Other names (if available):	Electrolytic chloroxidant - Sodium hypochlorite 1.15%
Product code:	419300 bottle PE 250 ml ; 419301 bottle PE 500 ml ; 419302 bottle PE 1 L; 419442 bottle PE 1 L; 419303 tank PE 5 L; 419600 bottle PE 250 ml; 419601 tank PE 500 ml

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

Relevant identified use:	Concentrated disinfectant solution to be used as diluted for the disinfection of fruit and vegetables, teats and baby bottles, infant objects.
Uses advised against:	There are no specific uses advised against.

1.3. Details of the supplier of the safety data sheet

Distributor:	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. Spa Address: Viale Amelia 70 – 00181 Roma -Italy Phone number : +39 06 780531 Fax number: +39 06 78053291
E-mail address of the competent person responsible for the safety data sheet: a.conto@chemsafe-consulting.com (Dr. Antonio Conto - Chemsafe Srl)	

1.4. Emergency telephone number

Phone number (office hours):	+39 071 809809
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SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the mixture

In accordance with the Regulation (EC) N. 1272/2008: the mixture does not satisfy the classification criteria

<i>Hazard class</i>	<i>Hazard class and category code</i>	<i>Hazard statements codes</i>	<i>Hazard statements</i>
-	-	-	-

Main adverse effects

Health effects:

Ingestion: if swallowed, the mixture might cause adverse effects.
 Skin contact: might cause irritation.
 Eye contact: might cause irritation.
 Inhalation: might cause irritation.
 Sensitization: no adverse effects are foreseeable.

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Environmental effects: Not significant. At the concentration contained in the mixture (1.15%) and in the presence of organic substances, sodium hypochlorite degrades rapidly in the environment.

See also sections 9, 11 and 12

2.2 Label elements

Labelling in accordance with Regulation (EC) N. 1272/2008:

Pictograms	None
Signal word	None
Hazard statements	None
Precautionary statements -Prevention -Response -Storage -Disposal	None
Supplemental information	EUH206: Warning! Do not use together with other products. May release dangerous gases (chlorine). EUH210: Safety data sheet available on request.

Safety precautions: Keep out of reach of children.
 Keep the container tightly closed, in a cool, dry and clean place, protected from direct sunlight and heat sources.
 Avoid the contact with eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention if irritation persists.
 If medical advice is needed, make available to the container or the label of the product.
 Do not pour the contents into another container.

2.3 Other hazards (which do not results in the classification)

The mixture satisfies the PBT criteria	YES	NO
- PBT		X
- vPvB		X

- Health hazards: No other hazards for humans are expected.
- Environmental hazards: No other hazards for environment are expected.
- Physic-chemical hazards: No other hazards related to physic-chemical characteristics are expected.
- Specific effects: No specific effects are expected.

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous ingredients

Name	EC Number	CAS Number	Conc.% (w/w)	Classification (1272/2008/EC)	Occupational Exposure Limits
Sodium hypochlorite Index n. 017-011-00-1 REACH Registration n. 01-2119488154-34-XXXX	231-668-3	7681-52-9	1.15	Skin Corr. 1B, H314 Aquatic Acute 1, H400 Note B Specific Limits EUH031: C ≥ 5 %	-

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Sodium Hydroxide Index n.011-002-00-6 REACH Registration n. 01-2119457892-27-XXXX	215-185-5	1310-73-2	0.035	Skin Corr. 1A, H314 <u>Specific Limits</u> Skin Corr. 1A; H314: $C \geq 5 \%$ Skin Corr. 1B; H314: $2 \% \leq C < 5 \%$ Skin Irrit. 2; H315: $0.5 \% \leq C < 2 \%$ Eye Irrit. 2; H319: $0.5 \% \leq C < 2 \%$	TLV-Ceiling: 2 mg/m ³ (ACGIH 2012)
Sodium tetraborate, decahydrate (Borax) Index n. 005-011-01-1 REACH Registration n. 01-2119490790-32-XXXX	215-540-4	1303-96-4	0.035	Repr. 1B, H360FD Eye Irrit. 2; H319 <u>Specific Limits</u> Repr. 1B; H360FD: $C \geq 8.5 \%$	TLV-TWA: Inorganic boron compounds 2 mg/m ³ TLV-STEL: Inorganic boron compounds 6 mg/m ³ (ACGIH 2012)

For Occupational exposure limits, see Section 8; for the full text of the Hazard statements, see Section 16.

SECTION 4 FIRST AID MEASURES

4.1 Description of the first aid measures

<i>Eye contact:</i>	Rinse eyes with water for at least 15 minutes, lifting the upper and lower eyelids. Seek medical advice, if the irritation persists.
<i>Skin contact:</i>	In case of skin irritation: wash the affected area with water. Seek medical advice, if the irritation persists.
<i>Ingestion:</i>	Drink plenty of water immediately. Do not induce vomiting, seek medical advice or poison control center immediately, showing the MSDS or the label of the product. Never give alcoholic beverages. Antidote: sodium thiosulfate. (see section 4.3)
<i>Inhalation:</i>	In case of inhalation, remove the person to fresh air. If breathing is difficult, seek medical advice.

4.2 Most important symptoms and effects, both acute and delayed

<i>Acute and delayed symptoms and effects:</i>	Contact with eyes might cause burning sensation and red eyes. Ingestion might cause heartburn, abdominal pain, or damage to the gastro-intestinal wall. Delayed symptoms and effects are not known.
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4.3 Indication of any immediate medical attention and special treatment needed

<i>Medical monitoring:</i>	Medical monitoring has to be performed in case of known delayed effects.
<i>Antidotes, if known:</i>	Sodium thiosulfate (5 cc of a Sodium thiosulfate solution 5% for every 10 cc of swallowed product).
<i>Contraindications:</i>	In case of ingestion, possible damage to the gastrointestinal wall may contraindicate gastric lavage.
<i>Immediate treatment at workplace:</i>	In case of contact with eyes, rinse with plenty of water immediately. If swallowed, drink a lot of water immediately. Do not give alcoholic beverages.

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Administer sodium thiosulfate solution 5% (see above “Antidotes”).

SECTION 5 FIREFIGHTING MEASURES

5.1 Extinguishing media

- *Suitable extinguishing media* Water spray, dry chemical, foam, CO₂.
- *Unsuitable extinguishing media* Not known.

5.2 Special hazards arising from the mixture

- Hazardous combustion products:* In case of contact with acids or reducing substances, or on heating, the product may produce toxic fumes containing chlorine, hydrochloric acid and CO₂.
- Other special hazards:* No other special hazards are foreseeable.

5.3 Advice for firefighters

- *Recommendations, protection techniques:* Do not try to extinguish the fire without the use of a self-contained breathing apparatus (SCBA) and suitable protective clothing.
- *Special protective equipment for fire fighters* Wear protective equipments for eyes and face, boots, gloves, complying with the relevant EN standards. Use the devices in maximum precautionary conditions based on the information reported in previous subsections.

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Ventilate the area; remove all possible sources of ignition and heat.
In case of fire and/or explosion avoid breathing fumes and vapors.
The vapors can be removed by spraying with water.
Use suitable protective equipments (see section 8).

For emergency responders

Use suitable protective equipments (see section 8) to minimize the exposure to the product.

6.2 Environmental precautions

In case of accidental release or spills, prevent entry of the mixture into drains, surface water and ground water.
If the product has reached into a water course, into the drainage system, or has contaminated the ground or vegetation, notify the competent authorities.

6.3 Methods and material for containment and cleaning up

- *Containment procedures:* Collect all the material scattered on the ground with appropriate protective equipments; put it in a clean, dry container.
- *Cleaning up procedures:* Absorb the spilled product with inert materials. Do not contaminate the spilled product with organic materials, ammonia, ammonium salts or urea.

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6.4 Reference to other sections

See also sections 8 and 13

SECTION 7 HANDLING AND STORAGE

7.1. Precautions for safe handling

<i>Recommendation for handling:</i>	Handle in a well ventilated place Avoid contact with incompatible materials/substances. Do not use in combination with other products, especially acids; may release hazardous gases (chlorine). Wear suitable Personal Protective Equipment (see section 8). Keep the mixture away from drains.
<i>Advice on general occupational hygiene:</i>	Do not eat, drink and smoke in the working areas. Remove contaminated clothing and personal protective equipments before entering eating areas.

7.2. Condition for safe storage including any incompatibilities

The risk management measures described in this section depend on the properties reported in the section 9.
The mixture is not classified as hazardous for any physical and chemical properties and no special risk management measure is foreseen.

<i>Recommendations for safe storage:</i>	Store in a dry, cool and well ventilated place, at temperature not exceeding 30°C. Do not expose to heat sources and direct sunlight. Protect from moisture. Store in the original containers, tightly closed.
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7.3. Specific end use(s)

Recommendation for the end use: avoid the contact with eyes and the inhalation of vapours.

SECTION 8 EXPOSURE CONTROLS/ PERSONAL PROTECTION

8.1. Control parameters

Community/National occupational exposure limits	<i>Sodium Hydroxide</i> ⁽¹⁾ ppm	TLV – 8 hours mg/m ³	ppm	TLV - short term* mg/m ³
		2 inhalable aerosol	-	4 inhalable aerosol
Austria	-	2	-	-
Belgium	-	2	-	2
Denmark	-	2	-	-
France	-	2	-	-
Germany (AGS)	-	-	-	-
Germany (DFG)	-	-	-	-
Italy	-	-	-	-
Poland	-	0.5	-	1
The Netherlands	-	-	-	-
United Kingdom	-	-	-	2

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Spain	-	2	-	-
Sweden	-	1	-	-
Switzerland	-	2 inhalable aerosol	-	2 inhalable aerosol
Hungary	-	2	-	2
<u>Sodium tetraborate decahydrate</u> ⁽¹⁾				
Austria	-	-	-	-
Belgium	-	2	-	6
Denmark	-	-	-	-
France	-	5	-	-
Germany (AGS)	-	-	-	-
Germany (DFG)	-	0.75 inhalable aerosol – (as boron)	-	0.75 inhalable aerosol
Italy	-	-	-	-
Poland	-	0.5	-	2
The Netherlands	-	-	-	-
United Kingdom	-	5	-	-
Spain	-	2	-	6
Sweden	-	2	-	5
Switzerland	-	5 inhalable aerosol	-	5 inhalable aerosol
Hungary	-	-	-	-

* “Short- term” means a period of 15 minutes unless otherwise stated

Nom community
occupational exposure
limits :

	TLV – 8 hours		TLV – short-term*	
	ppm	mg/m ³	ppm	mg/m ³
<u>Sodium Hydroxide</u> ⁽¹⁾⁽²⁾⁽³⁾				
NIOSH IDLH: 10 mg/m ³				
ACGIH (1992):	-	-	-	2 (ceiling)
Canada /Ontario:	-	-	-	2 (ceiling)
Canada /Québec:	-	-	-	2 (ceiling)
USA – NIOSH:	-	-	-	2 (ceiling 15 min)
USA - OSHA	-	2	-	-

Sodium tetraborate decahydrate ^{(1) (2)}

ACGIH (2004): Inorganic boron compounds: TWA = 2 mg/m³ - inhalable fraction;
 STEL = 6 mg/m³ - inhalable fraction. A4 group: not classifiable as a human carcinogen.
 Canada /Ontario: 2 aerosol inhalable 6 aerosol inhalable

Canada /Québec: 5 -
 USA – NIOSH: 5 -

For **sodium hypochlorite**, the ACGIH exposure limits for Chlorine are considered:

TLV – TWA (Chlorine): 0,5 ppm (ACGIH 2012)

TLV – STEL (Chlorine): 1 ppm (ACGIH 2012)

¹ Reference period: 15 minutes

* Short- term” means a period of 15 minutes unless otherwise stated

Community/National Biological Exposure Indices: Not established.

Not community Biological Exposure Indices: Not established.

Procedures for environmental monitoring: The measurement of substances in the workplace must be carried out with standardized methods (e.g. EN 689:1997: Workplace atmospheres - Guide for assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy; EN 482:2006: atmospheres in the workplace - General requirements for the provision of procedures for the measurement of chemical agents) or, failing that, with

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appropriate methods.

DNEL Values (for components):

Component	Exposure route	Workers				Consumers			
		Acute effects		Chronic effects		Acute effects		Chronic effects	
		local	systemic	local	systemic	local	systemic	local	systemic
Sodium Hydroxide (15)	Oral (mg/kgbw/day) Dermal (mg/kgbw/day) Inhalation (mg/m3)				1			1	
Sodium Hypochlorite (6)	Oral (mg/kgbw/day) Dermal - % in mixture (weight basis) Inhalation (mg/m3)			0.5%				0.5%	0.26
		3.1	3.1	1.55	1.55	3.1	3.1	1.55	1.55
Sodium tetraborate decahydrate (22)	Oral (mg/kgbw/day) Dermal (mg/kgbw/day) Inhalation (mg/m3)				316.4 6.7		0.79		0.79 159.5 3.4
bw : body weight									

According to the Regulation (EEC) N. 793/93 on the Evaluation and control of the risks of existing substance, a risk Assessment for *Sodium hypochlorite* ⁽⁶⁾ was performed and the following values were defined:

AEL (Admissible Exposure Level): 0.5 mg/kg bw, derived from NOAL = 50 mg/kg bw, that was established in a study on rats, treated with sodium hypochlorite dissolved in their drinking water for 104 weeks (Hasegawa, 1986), and a safety factor of 100.

ADI (Admissible Daily Intake): 0.5 mg/kg bw, derived from NOAL = 50 mg/kg bw, that was established in a study on rats, treated with sodium hypochlorite dissolved in their drinking water for 104 weeks (Hasegawa, 1986) and a safety factor of 100.

PNEC Values (for components):

Sodium Hypochlorite

According to the Regulation (EEC) N. 793/93 on the Evaluation and control of the risks of existing substance, a risk Assessment for *Sodium hypochlorite* ⁽⁶⁾ was carried out and the following values were defined:

$PNEC_{aquatic} = 2.1 \mu\text{gFAC/L} : 50 = 0.042 \mu\text{gFAC/L}$

$PNEC_{sediments} = 0.033 \mu\text{gFAC/kg}$, derived from $PNEC_{aquatic}$ using the equilibrium partitioning method in accordance with the technical guideline.

$PNEC_{terrestrial} = 0.005 \mu\text{gFAC/kg}$ derived from $PNEC_{aquatic}$ using the equilibrium partitioning method in accordance with the technical guideline.

Sodium tetraborate decahydrate ⁽²²⁾

Freshwater: 2.9 mg/l

Marine water: 2.9 mg/l

Intermittent release: 13.7 mg/l

Soil: 5.7 mg/kg.

Sewage treatment plant: 10 mg/l

8.2. Exposure controls

Under the normal conditions of use, specific measures to control the exposure are not needed. Provide an adequate ventilation at the place of use.

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According to the Regulation (EEC) N. 793/93 on the Evaluation and control of the risks of existing substance, a risk Assessment for *Sodium hypochlorite* was carried out and no significant risks were identified in the scenarios of professional uses, described in accordance with the technical guideline for human exposure.⁽⁶⁾

Appropriate risk management measures, that must be adopted at the workplace, have to be selected and applied, following the risks assessment carried out by the employer, in connection with his working activity (in according with Directive 98/24/EEC). If the results of this evaluation show that the general and collective prevention measures are not sufficient to reduce the risk, and if you can not prevent exposure to the mixture by other means, adequate personal protective equipments must be adopted, complying with the relevant technical EN standards.

Eye and Face protection:	Special protections are not required during the normal conditions of use. In case of handling of large quantities and a prolonged contact, wear safety glasses.
Hand protection:	Special protections are not required during the normal conditions of use. In case of handling of large quantities and a prolonged contact, use protective latex or rubber gloves.
Respiratory protection:	Special protections are not required during the normal conditions of use; In case of handling of large quantities and events that may lead to the formation of vapors/aerosols, wear masks with appropriate filters.
Environmental exposure control:	Prevent entry of the mixture into drains, surface water and ground water. Dispose of contaminated waters in accordance with national and local laws.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance:	Clear liquid slightly straw
Odor:	Slight, of chlorine
pH	9.5-10.5
Freezing point:	from 0°C to -12°C
Boiling point and boiling range :	100°C -104°C
Flammability:	Not flammable (sodium hypochlorite) ⁽¹⁰⁾
Evaporation rate:	Data not available
Upper/ lower flammability or explosive limits	Not explosive
Vapour pressure:	Data not available
Vapour density	Data not available
Relative density:	1.120 at 20°C
Water solubility:	soluble
Partition coefficient octanol/water:	Sodium Hypochlorite: 0.87 at pH = 7 Sodium Hydroxide: virtually zero ⁽¹¹⁾ Sodium tetraborate decahydrate: -1.53 ± 0.05 (22 ± 1°C)
Autoignition temperature:	Data not available
Decomposition temperature:	Data not available
Viscosity:	Data not available
Explosive properties:	Not explosive (sodium hypochlorite) ⁽¹⁰⁾

9.2. Other information

Conductivity:	170 µs/cm
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SECTION 10 STABILITY AND REACTIVITY

10.1. Reactivity

Avoid contact with reducing agents and acids. Contact with acids liberates toxic gas (chlorine).

10.2. Chemical stability

The mixture is stable under the normal conditions of temperature and pressure and when stored in closed containers in a cool and ventilated place.

10.3. Possibility of hazardous reactions

No hazardous reactions occur under normal conditions of storage and use.

10.4. Condition to avoid

Do not exceed 55 °C for 24h. Do not expose to direct sunlight and heat sources. The exposure to direct sunlight for long periods or at high temperatures may cause swelling of the containers.
Do not mix with other products. Avoid contact with acids and reducing agents. The reaction with acids produces hazardous gases (chlorine gas).

10.5. Incompatible materials

Polyamide, low-alloy steel, iron and metals.

10.6. Hazardous decomposition products

If heated at high temperatures the product may decompose and release toxic fumes and gases containing chlorine (Cl₂), hydrochloric acid (HCl), CO₂.

SECTION 11 TOXICOLOGICAL INFORMATION

Toxicological information on components are reported below.

Exposure routes:

- Inhalation:
- Ingestion:
- Skin contact:
- Eye contact:

YES	NO
X	
X	
X	
X	

Symptoms and effects for each route of exposure :

- Inhalation: Might cause irritation.
- Ingestion: Might cause heartburn, abdominal pain, or damage to the gastro-intestinal wall.
- Skin contact: Might cause irritation.
- Eye contact: Might cause burning sensation and red eyes.

Toxico-kinetics information (ADME = Adsorption, Distribution, Metabolism, Excretion):

Sodium Hypochlorite: The substance is absorbed via oral, dermal and inhalation routes. Pick level in plasma is

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reached within 2 hours after oral administration to the young animal. The elimination half-life is 44 hours. A study in rats shows that the substance is metabolized to chloride ions, which are distributed in descending order within 96 hours after exposure in plasma, whole blood, bone marrow, testes, kidneys and lungs. Only 51.2% of the dose is excreted 96 hours after exposure, 36.4% in the urine and 14.8% in the feces. After 120 hours, the elimination is not yet completed.⁽⁴⁾

Sodium Hydroxide: In contact with the human skin, at not irritating concentrations, the passage of ions is small and the absorption is poor.⁽¹¹⁾ The major route of excretion of sodium hydroxide is via urine, small amounts were found in the feces, sweat, tears, nasal mucous, saliva, vaginal and urethral discharge.⁽¹²⁾

Sodium tetraborate decahydrate: More than 98% of all forms of boron ingested (boric acid, sodium tetraborate, or boron in plant and animal tissues) are absorbed as undissociated boric acid. The complete adsorption of borax dust via inhalation route is hypothesized. Boric acid is readily absorbed from gastrointestinal tract, serous cavities and inflamed skin. Studies on humans and rabbits showed that boric acid, borax, disodium tetrahydrate octaborate were poorly absorbed from the intact skin. Large amounts of boric acid are localized in brain, liver and kidneys. Accumulation of boron in bone has also been observed in humans and other animal species. There is no evidence that boric acid is metabolized in the animals or in the plants. Boric acid is predominantly eliminated unchanged by the kidney. Small amounts are also excreted into sweat, saliva, and feces. In humans, the reported excretion half-life is between 13 and 21 hr.⁽¹⁷⁾⁽¹⁸⁾

Toxicological information on components:

Acute toxicity:

<i>Oral:</i>	LD ₀ (rat) > 10.5 g/kg (3.6% solution, as active chlorine); LD ₅₀ (rat) > 5.8 g/kg (12.5% solution, as active chlorine); LD ₅₀ (rat) = 8.91 g/kg (commercialized solution of sodium hypochlorite at a not specified concentration). LD ₅₀ (rabbit) = 325 mg/kg LD ₅₀ (rat) > 3493 mg/kg	⁽⁶⁾ Sodium Hypochlorite
<i>Dermal:</i>	LD ₅₀ > 2000 mg/kg (5.25% solution, as active chlorine) LD ₅₀ (rabbit) = 1350 mg/kg LD ₅₀ (rat) > 2000 mg/kg	⁽¹¹⁾ NaOH ⁽¹⁸⁾ Borax ⁽⁶⁾ Sodium Hypochlorite
<i>Inhalation:</i>	LC ₀ > 10.5 mg/l/1 hour (commercialized solution of sodium hypochlorite at a not specified concentration). LC ₅₀ (rat) > 0.16 mg/l. Slight irritation to mucous membranes. No deaths were reported.	⁽¹¹⁾ NaOH ⁽¹⁸⁾ Borax ⁽⁶⁾ Sodium Hypochlorite
<i>Other information:</i>	The toxic effects on the humans depend on the solution concentration. The ingestion of small amounts of common solutions only cause light digestive problems. The concentrated solutions may cause irritation of the digesting tube with vomit, sometimes haemorrhagic. It may cause also necrosis, perforation and complications with shock and haemolysis. The inhalation may cause pulmonary edema. The lowest published toxic dose (oral, woman) = 1000 mg/kg	⁽¹⁸⁾ Boric acid ⁽⁴⁾ Sodium Hypochlorite
	Based on the existing data from studies on animals and humans, NaOH causes local effects and systemic effects are not expected. It may cause severe irritation and chemical burns to all mucous membranes and skin, irreversible damage to the eyes (danger of blindness). Serious poisoning cases due to oral intake of NaOH or formulations containing NaOH have been reported. Typical symptoms are: reddening, pain and edema of the mucous membranes in the mouth and the throat, serious pain behind the sternum and in the stomach, possible vomiting. Swallowing is extremely painful or	⁽⁵⁾ Sodium Hypochlorite ⁽¹³⁾ NaOH

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**Skin Corrosion/irritation
Skin:**

impossible.

Splashes to the skin of concentrated *Sodium Hypochlorite* may cause severe burns. ⁽⁴⁾
The overall evaluation of data on animal and human skin for concentrations < 5% which are typically marketed for consumer use leads to the conclusion that only mild irritating effects are caused at < 5% sodium hypochlorite. ⁽⁶⁾

Sodium Hydroxide: the substance causes chemical burns; severity of burns depends on the solution concentration, the importance of contamination and the contact duration. Depending on the damage depth, hot and painful erythema, blisters and necrosis are observed. The evolution may complicate with infection, aesthetic or functional sequelae. ⁽¹¹⁾

Sodium tetraborate decahydrate: in experiments on volunteers, skin contact with 5 % aqueous solution of Borax did not lead to irritation, even though it was left on the skin of the back for 24 hours. ⁽¹⁹⁾

**Serious eye damage/ eye
irritation**

Sodium Hypochlorite: the contact to eyes of concentrated solutions may cause severe burns with important sequelae. ⁽⁴⁾ The evaluation of all available data on eye irritation including human exposure leads to the conclusion that in the event of an accidental exposure to concentrations of < 5 % sodium hypochlorite, the risk for pronounced irritant effects is low. ⁽⁶⁾

Sodium Hydroxide: the substance causes chemical burns; severity of burns depends on the solution concentration, the importance of contamination and the contact duration. Immediate eye pain, tearing and conjunctival hyperaemia occur. Sequelae may occur, as scarring of the conjunctiva, corneal opacities, cataracts, glaucoma and even blindness. ⁽¹¹⁾

Sodium tetraborate decahydrate: is highly irritating to eyes (data on workers and rabbits). ⁽¹⁸⁾⁽¹⁹⁾

Sensitization:

Dermal:

Sodium Hypochlorite did not show any potential for sensitization in three separate guinea pig tests or in standard sensitization patch tests in healthy human volunteers. ⁽⁶⁾

Sodium Hydroxide: a study on volunteers showed that Sodium Hydroxide is not a skin sensitizer. Furthermore the substance is widely used and no case of sensitization has been reported. ⁽¹¹⁾

Sodium tetraborate decahydrate: Boric acid did not show any sensitization effects to skin in a guinea pig study (OECD 406, Buehler test). ⁽²⁰⁾

Respiratory:

Not available.

**Specific Target Organ
Toxicity (STOT) –
Single exposure:**

Sodium Hypochlorite: Sodium hypochlorite aerosols may be irritating to the respiratory tract. It is anticipated that exposure to domestic aerosols formulated with sodium hypochlorite solutions of less than 3.0% would not present a significant respiratory irritation hazard. ⁽⁶⁾

Sodium Hydroxide: The inhalation of vapors or aerosols causes: rhinorrhoea, sneezing, burning sensation in the nose and throat, coughing, dyspnea and chest pain. Complications are laryngeal edema or bronchospasm. After exposure symptoms may regress, but delayed pulmonary edema, within 48 hours, may occur. The substance is corrosive and ingestion of a concentrated solution of sodium hydroxide causes pain in the oral cavity, retrosternal and epigastric region, associated with drool, and frequent vomiting with traces of blood, or gastric and esophageal perforation. ⁽¹¹⁾

**Specific Target Organ
Toxicity (STOT) –
Repeated exposure:**

Sodium Hypochlorite: prolonged use of the substance may cause dermatosis. ⁽⁴⁾

In studies on animals treated with NaOCl via oral route, a decrease of body weight was observed, but no systemic effects to specific target organs were reported; NOAEL for rats: about 14 mg/kg bw/day (on the basis of chlorine content).

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No systemic effects were seen following dermal exposure to 10000 mg/l sodium hypochlorite; a NOEL = 1% was chosen for dermal exposure.

For the evaluation of the effects of repeated inhalation exposure to hypochlorite aerosols, it is proposed to use data from chlorine. The NOAEL for repeated exposure to chlorine gas is 0.5 ppm, as confirmed by studies in rhesus monkeys and human volunteers.⁽⁶⁾⁽⁷⁾

Sodium Hydroxide: a case study of obstructive disease of the airways with coughing, dyspnea and tachypnea on one worker, who was exposed via inhalation route to NaOH for 20 years, is reported. Long term dermal exposure may cause dermatitis.⁽¹¹⁾⁽¹³⁾

Sodium tetraborate decahydrate: exposure of workers to borax dust at concentration at or above 4.5 mg/m³ caused temporary irritation of the airways, with dryness of the mouth, throat and nose, sore throat, dyspnea, coughing, nosebleeds, but no chronic effect. Eye and skin irritation may also occur. Dust concentrations below 10 mg/m³ do not result in a serious health risk. In subacute and subchronic studies on rats, dosages at the level of around 100 mg/kg bw/d led mainly to damage to the testes (up to atrophy).⁽¹⁸⁾⁽¹⁹⁾

CMR Effects:

Mutagenicity:

Sodium Hypochlorite: In *in vitro* tests the substance showed mutagenic activity. An increase of chromosome aberration was observed in Chinese hamster cells, but not in human lymphocytes or fibroblasts. Negative results in *in vivo* studies in mouse bone marrow have been reported.⁽⁴⁾⁽⁶⁾

Sodium Hydroxide: in *in vitro* and *in vivo* studies suggest that Sodium Hydroxide is not genotoxic.⁽¹¹⁾⁽¹⁴⁾

Sodium tetraborate decahydrate and boric acid: not genotoxic in *in vivo* and *in vitro* studies.⁽¹⁸⁾⁽¹⁹⁾

Carcinogenicity:

Sodium Hypochlorite: In long term carcinogenicity studies, sodium hypochlorite administered in the drinking water to mice and rats did not show an increase of the tumors incidence. Sodium hypochlorite applied to the skin did not produce skin tumors in mice. In a multigenerational study (6 generations) in rats, sodium hypochlorite administered in the drinking water did not increase the incidence of tumours.⁽⁶⁾

The International Agency for Research on Cancer (IARC) has placed the substance in Group 3 (not classifiable as carcinogenic to humans), based on lacking of data in humans and insufficient evidences in animals.⁽⁴⁾

Sodium Hydroxide: A dated study (1976) on workers exposed to sodium hydroxide did not show any correlation between neoplasia, duration and intensity of exposure.⁽¹¹⁾

Sodium tetraborate decahydrate and boric acid: not carcinogenic in 2-years studies in rats and mice.⁽¹⁸⁾⁽¹⁹⁾

Toxicity for the reproduction:

Sodium Hypochlorite: based on limited data from studies on animals, treated with Sodium Hypochlorite in drinking water or from epidemiologic studies on humans, consuming chlorinated drinking water, the substance does not cause effects on fertility or development.⁽⁶⁾

Sodium Hydroxide: the substance has no systemic toxicity and the effects on reproduction do not seem plausible under normal conditions of use.⁽¹¹⁾⁽¹⁴⁾

Sodium tetraborate decahydrate and boric acid: caused toxic effects for the reproduction in short-term and long-term studies. In rats and mice, the daily administration of 163 and 1003 mg/kg of Boric acid, respectively, during pregnancy, lead to an increase of fetal malformations and maternal toxicity. In female rats, treated with Boric acid (up to 400 mg/kg of boron) before mating, an increase of pups mortality was observed. Male rats and dogs, fed with Boric acid with doses higher than 500 mg/kg/day, showed testicular atrophy and infertility. There are reports suggesting similar effects on humans.⁽¹⁸⁾⁽¹⁹⁾⁽²¹⁾

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Aspiration hazards: The aspiration hazard is not expected, taking into account the use of the mixture.

Reasons for no classification:

When the mixture is not classified for a particular hazard class, this is due to lack of data, inconclusive data or data which are conclusive although insufficient for the classification based on the criteria defined by the legislation, mentioned in this Safety Data Sheet.

SECTION 12 ECOLOGICAL INFORMATION

12.1. Toxicity

Ecological information on components are reported below.

Toxicity for aquatic organisms (short-term and long-term effects):

Toxicity for fish:	Depending on the weight of evidence, in acute ecotoxicity test with sodium hypochlorite, invertebrates show similar sensitivity or greater than fish.	(8) Sodium Hypochlorite
	CL ₅₀ (Gambusia affinis): 125 mg/l/96 hours.	(14) NaOH
	Prolonged exposure to 25-100 mg/l concentrations caused significant biological effects in fishes.	
	LC ₅₀ (Lepomis macrochirus) = 41 mg borax/l/24 h (4.6 mg boron/L)	(18) Borax
Toxicity for Daphnia Magna:	EC ₅₀ Daphnia > 1mg/l tested on a mixture containing sodium hypochlorite (immobilization test of Daphnia, in accordance with OECD 202)	(8) Sodium Hypochlorite (5% solution)
	EC ₅₀ = 40 mg/l/48 hours	(14) NaOH
	EC ₅₀ = 133 - 226 mg/l/48 hours	(18) Boric acid and borates
Toxicity for algae:	Standard tests for acute toxicity of sodium hypochlorite for algae are not considered technically feasible.	(8) Sodium Hypochlorite
	EC ₅₀ Photobacterium phosphoreum = 22 mg/l/15 minutes	(14) NaOH

12.2. Persistence and degradability

Information related to Sodium Hypochlorite ⁽⁹⁾

The **persistence in atmospheric compartment** is considered as negligible. At environmental pH (6.5 -8.5), sodium hypochlorite is dissociated into hypochlorous acid and hypochlorite anion (50:50). Only the fraction of hypochlorous acid is volatile. The Henry's Law constant, measured for hypochlorous acid, is 0.0097 Pa m³ mol⁻¹; this suggests that the concentration in air is very low. Therefore the atmospheric compartment is not considered as a significant exposure route.

The **persistence in soil** is considered as very low (Koc, calculated by QSAR = 0.57).

The **persistence in aquatic compartment** is evaluated as poor, in view of the rapid degradation of the substance. Hypochlorite degrades very rapidly (about 300 seconds) in the presence of organic matrixes. ⁽⁹⁾

Photo-oxidation, photolysis: Sodium hypochlorite is sensitive to light; sunlight decreases the half-life of a solution containing 10-15% of free chlorine by 3-4 times.

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Degradability: ready degradability in fresh water and sea water: not applicable; sodium hypochlorite is an inorganic substance. Degradability of metabolites: not significant; sodium hypochlorite is degraded into chlorine.

Sodium Hydroxide: the high water solubility and the low vapour pressure suggest that Sodium Hydroxide is mainly in the aquatic compartment. In the environment the substance is present as sodium and oxydrile ions; as a result, Sodium Hydroxide does not adsorb on particulate or on surfaces and does not accumulate in living tissues. Atmospheric emissions of Sodium Hydroxide are quickly neutralized by carbonium dioxide or other acids and salts (e.g. Sodium carbonate)⁽¹¹⁾

Boric acid and borates salts: are soluble in water. They are removed from soil by leaching and adsorption of the plant and they may reach the ground water due to their high water solubility and their variable adsorption to soil.

There are no data showing that borates or boric acid are transformed or degraded in atmosphere by photolysis, oxidation or hydrolysis.⁽¹⁸⁾

12.3. Bioaccumulative potential

Bioaccumulation capacity is not expected. The partition coefficient Kow of sodium hypochlorite is 0.87 at pH 7. Bioaccumulative potential of NaOH is not significant.

12.4. Mobility in soil

The mixture is soluble in water: it may be mobile in soil. Avoid release into the environment.

12.5. Results of PBT e vPvB assessment

On the basis of the information available in the literature about Sodium Hypochlorite, the substance does not fulfil PBT and vPvB criteria. It is not persistent and not bioaccumulative.⁽¹⁰⁾

12.6. Other adverse effects

Other adverse effects are not expected.

SECTION 13 DISPOSAL CONSIDERATION

13.1. Waste treatment methods

- Mixture wastes:
- Contaminated packaging:

Incineration	Recycling	Landfilling
X		
X		

Disposal in the wastewaters is advised against.

Refer to Community/ National/ Local requirements concerning the waste disposal.

SECTION 14 TRANSPORT INFORMATION

The mixture is outside the scope of the legislation transport.

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SECTION 15 REGULATORY INFORMATION

In this section, all other information on regulation are reported if not provided in other sections/subsection of the Safety Data Sheet.

15.1 Safety, Health and Environmental regulation/legislation specific for the mixture

- Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work and subsequent amendments and additions.
- Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment and subsequent amendments and additions.
- Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) and subsequent amendments and additions.

Restriction of use (for components): None.

Mixture which contains a substance under authorization: *The mixture contains Sodium tetraborate decahydrate. Sodium tetraborate decahydrate anhydrous and his two hydrated forms (sodium tetraborate pentahydrate and sodium tetraborate decahydrate) are identified as substances of very high concern (SVHC) according to the criteria of Article 57 (c) of Regulation (EC) No.1907/2006 (REACH), due to their classification as toxic for reproduction.*

15.2. Chemical Safety Assessment

Not carried out.

According to the Regulation (EEC) N. 793/93 on the Evaluation and control of the risks of existing substance, a risk Assessment for *Sodium hypochlorite* was carried out and no significant risks were identified in the scenarios of professional uses, described in accordance with the technical guideline for human exposure.⁽⁶⁾

SECTION 16 OTHER INFORMATION

Revisions:

REV	Reasons	Data
00	First edition in accordance with Annex II of Regulation 453/2010/EU	30/11/2010
01	Revision	30/07/2012
02	Sections modified 2-16 for adapting to Annex II of Regulation 453/2010/EU	30/07/2014
03	Sections modified 2, 3, 8, 16	01/06/2015
04	Re-emission of the previous revision for formal adaptation to Regulation (EU) N. 2015/830	31/07/2015
05	Section modified 1 for including new product codes	21/09/2015
06	Section modified 3 for including REACH Registration number of Sodium Tetraborate decahydrate	21/12/2015

Literature references and sources for data:

- (1) GESTIS International Limit Values, available on http://limitvalue.ifa.dguv.de/WebForm_ueliste.aspx
- (2) ACGIH 2012, TLVs and BEIs based on the Documentation of the Threshold Limit Values for Chemical Substances and Physical Agents & Biological exposure Indices
- (3) www.osha.gov, Safety and Health Topics: Sodium Hydroxide
- (4) <http://modellisds.iss.it/bitstream/123456789/1260/1/127.pdf>, Scheda di Dati di Sicurezza secondo l'Allegato II del Regolamento 1907/2006 (REACH), Ipoclorito di sodio, soluzione...%

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- (5) NIOSH The Registry of Toxic Effects of Chemical Substances, RTECS:NH3486300, Hypochlorous acid, sodium salt
- (6) European Union Risk Assessment Report, SODIUM HYPOCHLORITE, Final report, November 2007
- (7) GESTIS Substance database, Sodium hypochlorite, solution ... percent Cl active, ZVG No: 1410
- (8) A.I.S.E, Environmental classification of sodium hypochlorite containing bleach products.
- (9) Evaluation Report on Sodium Hypochlorite (CAS 7681-52-9) for inclusion of the Active Substance in Annex I to Directive 98/8/EC – Bozza Marzo 2010
- (10) Eurochlor registration group, Sodium Hypochloride, Final Assessment 2007
- (11) <http://modellisds.iss.it/bitstream/123456789/1241/1/11.pdf>, Scheda di Dati di Sicurezza secondo l'Allegato II del Regolamento 1907/2006 (REACH), Idrossido di sodio, Data di emissione: 01/08/2014
- (12) IUCLID data set for Sodium hydroxide, 18-feb-2000.
- (13) Sodium hydroxide, IFA, GESTIS Substance database , ZVG n. 1270
- (14) Sodium hydroxide, SIDS Initial Assessment Report For SIAM 14 Paris, 26-28 March 2002
- (15) [http://apps.echa.europa.eu/registered/data/dossiers/DISS-9ea1ebb9-dbf1-0959-e044-00144f67d031/DISS-9ea1ebb9-dbf1-0959-e044-00144f67d031.html](http://apps.echa.europa.eu/registered/data/dossiers/DISS-9ea1ebb9-dbf1-0959-e044-00144f67d031/DISS-9ea1ebb9-dbf1-0959-e044-00144f67d031_DISS-9ea1ebb9-dbf1-0959-e044-00144f67d031.html), Dossier di registrazione, Sodium hyroxide
- (16) MEMBER STATE COMMITTEE DRAFT SUPPORT DOCUMENT FOR IDENTIFICATION OF DISODIUM TETRABORATE, ANHYDROUS AS A SUBSTANCE OF VERY HIGH CONCERN BECAUSE OF ITS CMR PROPERTIES, Adopted on 9 June 2010
- (17) HSDB Hazardous Substances Databank, Boric acid
- (18) <http://npic.orst.edu/factsheets/borictech.html>, National Pesticide Information Center, Boric Acid Technical Fact Sheet
- (19) GESTIS Substance database, Sodium tetraborate, ZVG No: 1820
- (20) IUCLID dataset for Boric acid, 18 feb. 2000
- (21) U. S. Pharmacopeia Material safety datasheet, Boric acid (Revision date September 29, 2009)
- (22) Sodium tetraborate, decahydrate, ECHA database

Acronyms

- ACGIH: American Conference of Governmental Industrial Hygienists
- ADI : Admissible Daily Intake
- ADME (Adsorption, Distribution, Metabolism, Excretion)
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- AEL : Admissible Exposure level
- BCF: Bioconcentration factor
- BEI : Biological Exposure Indices
- CAS: Chemical Abstract Service (division of the American Chemical Society)
- CLP: Classification, Labelling and Packaging
- CMR: Carcinogenic, Mutagenic or toxic to Reproduction (substances)
- LC₅₀: the concentration required to kill 50% of the members of a tested population in ecotoxicological tests
- LD₀: dose that does not cause any mortality of the tested population.
- LD₅₀: median lethal dose, required to kill 50% of the members of a tested population.
- DNEL: Derived Non Effect Level
- PPE: Personal protection equipment
- EINECS: European Inventory of Existing Commercial Chemical Substances
- EPA: US Environmental Protection Agency
- FAC : Free Available Chlorine
- GHS: Globally harmonized system of Classification and Labelling of Chemicals
- IARC: International Agency for Research on Cancer
- IATA: International air transport association
- IMDG: International maritime dangerous goods
- IUPAC: International Union of Pure and Applied Chemistry
- LOEL: Lowest Observed Effect Level
- N.A.: non available
- NOAEL: No Observed Adverse Effect Level
- NOAL: No Observed Adverse Level
- NTP: National Toxicology Program
- OEL: Occupational Exposure Limit
- OSHA: Occupational Safety and Health Administration

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- PBT: Persistent Bioaccumulative and Toxic
- PNEC: Predicted No Effective Concentration
- RID: European Agreements Concerning the International Carriage of Dangerous Goods by Rail
- STEL : Short Term Exposure Limit (15 minutes)
- TLV-TWA: Threshold Limit Value - time-weighted average
- vPvB: very Persistent and very Bioaccumulative

Information concerning health, safety and environment, in accordance with Regulation (EC) No. 1272/2008:

List of hazards statements:

H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H360FD	May damage fertility. May damage the unborn child.
H400	Very toxic to aquatic life.
EUH031	Contact with acids liberates toxic gas

Information on workers training

Comply with the provisions of Directive 98/24/EC

Classification and method used for classification of mixture according to Regulation (EC) N. 1272/2008 (CLP):

<i>Classification according to Regulation (EC) n. 1272/2008:</i>	<i>Method for classification:</i>
Not classified	

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