

Trade name:	LUGOL'S SOLUTION, ACID				
Product code:	LUGK-OT-X**	Date of compilation:	11 June 2019	Version:	2

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1.	Product identifier	
	Trade name:	LUGOL'S SOLUTION, ACID
	Chemical name:	-
	Catalogue number:	LUGK-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Aqueous solution of iodine and potassium iodide with added acid.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.
1.3.	Details of the supplier of the safety data sheet	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Telefax:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	
1.4.	Emergency telephone numbers	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2. Hazards identification		
2.1.	Classification of the substance or mixture	
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statement*:
	Skin Irr. 2	H315
	Eye Irr. 2	H319
2.1.2.	Additional information	
	-	
* For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2.	Label elements	
	Product identification:	LUGOL'S SOLUTION, ACID
	Identification number:	-
	Authorisation number:	-

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Hazard pictograms:	
	GHS07
Signal word:	Warning
Hazard statements:	H315 Causes skin irritation. H319 Causes serious eye irritation.
Precautionary statements:	P280 Wear protective gloves/protective clothing/eye/protection/face protection. P302+P352 IF ON SKIN: Wash with plenty of water. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308+P311 IF exposed or concerned: Call a POISON CENTER or doctor.
Supplemental hazard information (EU):	-
2.3. Other hazards	
	-

SECTION 3. Composition/information on ingredients				
CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
64-19-7/ 200-580-7/ 607-002-00-6	-	≤ 10	acetic acid, 99%	Flam. Liq. 3; H226 Skin corr. 1A; H314

SECTION 4. First aid measures		
4.1.	Description of first aid measures	
	General notes:	-
	Following inhalation:	Carry the afflicted person out for fresh air, place them in half lying position and calm them down. If breathing stops, immediately apply artificial respiration. Rush the afflicted person to the hospital while keeping them in lateral recumbent position in order to keep the airways clear.
	Following skin contact:	Remove contaminated clothing. Wash with plenty of water and soap for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.

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	Following ingestion:	Rinse with water and expectorate. Make the afflicted person drink 1 - 2 glasses of water (200 - 400 ml). The afflicted person should drink one glass (100 ml) of 40% ethanol (adult dose). Place the afflicted person in the half lying position and rush them to hospital while constantly calming them down. If the afflicted person is vomiting, there may be risk of pulmonary aspiration.
	Self-protection of the first aider	Avoid direct contact with the chemical; use appropriate protective equipment described in Section 8.
4.2.	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	Airways irritation and possible lung damage due to high levels of vapor concentration. Absorption may cause toxic effects.
	Following skin contact:	Minimum level of irritation, defatting; prolonged exposure may cause absorption and greater possibility of delayed systemic effects.
	Following eye contact:	Mild to moderate irritation due to vapor, conjunctivitis, later chemosis, lesser possibility of cornea damage. Visual impairments may occur later, after the absorption.
	Following ingestion:	Stomach and bowel irritation, feeling unwell, vomiting, strong abdominal pain. Absorption may cause toxic effects.
4.3.	Indication of any immediate medical attention and special treatment needed	
	-	

SECTION 5. Firefighting measures		
5.1.	Extinguishing media	
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol-resistant foam
	Unsuitable extinguishing media:	water jet
5.2.	Special hazards arising from the substance or mixture	
	Hazardous byproducts of fire:	No information available
5.3.	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. Cool closed containers exposed to fire with water spray, in order to prevent explosion.	
5.4.	Additional information	
	Remove sources of heat and ignition. Do not contaminate the environment with extinguishing media.	

SECTION 6. Accidental release measures		
6.1.	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).

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	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Do not breathe in vapor, ensure adequate ventilation and avoid contact with skin and eyes. Remove all sources of sparks and ignition. Do not smoke.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).	
6.2.	Environmental precautions:	
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.	
6.3.	Methods and materials for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.
6.3.2.	For cleaning:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and involved materials with water.
6.3.3.	Other information:	Do not use tools that may cause sparks.
6.4.	Reference to other sections	
	See Section 7 for information about secure handling. See Section 8 for information about personal protective equipment. See Section 13 for information about containment.	

SECTION 7. Handling and storage		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures for fire prevention:	Use in well ventilated storage rooms. Keep away from sources of heat and ignition. Carry out measures for preventing static electricity.
	Measures for preventing spray and dust formation:	Secure proper ventilation.
	Environmental precautions:	Prevent spilling into the sewage system and waterways.
	Other measures:	-
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2.	Conditions for safe storage, including any incompatibilities	

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Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from sources of heat, sunlight, and other incompatible substances.
Packaging materials:	Manufacturer's original packaging.
Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 10).
7.3.	Specific end use(s)
Recommendations:	-
Industrial sector specific solutions:	-

SECTION 8. Exposure controls/personal protection				
8.1.	Control parameters			
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
Acetic acid	64-19-7	10/20	25/50	-
Substance:	-			
EC No:	-	CAS No:	-	
DNEL				
Industrial				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	25 mg/m ³ (acetic acid)	-
Dermal	-	-	-	-
Critical physical parameters: solubility, flammability, corrosivity:			-	
Consumer				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic

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Oral	-	-	-	-
Inhalation	-	-	25 mg/m ³ (acetic acid)	-
Dermal	-	-	-	-

PNEC	
Environmental protection target	PNEC
Fresh water	3.058 mg/l (acetic acid)
Freshwater sediments	11.36 mg/kg (acetic acid)
Marine water	0.3058 mg/l (acetic acid)
Marine sediments	1.136 mg/kg (acetic acid)
Food chain	No information available
Microorganisms in sewage treatment	85 mg/l (acetic acid)
Soil (agricultural)	0.478 mg/kg (acetic acid)
Air	No information available

8.2.	Exposure controls	
8.2.1.	Appropriate engineering measures	
	Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	No information available
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as EN 166(EU).
8.2.2.2.	Skin protection:	

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	Hand protection:	The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN374. Full contact: Glove material: nitrile rubber Glove thickness: 0.40 mm Time until perforation: > 480 min Splash contact: Gloves material: polychloroprene Glove thickness: 0.65 mm Time until perforation: >240 min
	Other skin protection:	Complete suit protecting against chemicals (EN 340) The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace and shoes that cover the entire foot.
8.2.2.3.	Respiratory protection:	Use mask that covers the entire face (EN 136). Recommended filter type: ABEK (EN 143). Use respirators and components tested according to and approved by the standard (EU).
8.2.2.4.	Thermal hazards:	No information available
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

SECTION 9. Physical and chemical properties			
9.1.	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	liquid	No information available
	Colour:	dark brown	No information available
	Odour:	acetic acid like	No information available
	Odor threshold:	No information available	No information available
	pH:	No information available	No information available
	Melting point/freezing point:	No information available	No information available
	Initial boiling point and boiling range:	No information available	No information available
	Flash point:	No information available	No information available

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	Evaporation rate:	No information available	No information available
	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	No information available	No information available
	Vapour pressure:	No information available	No information available
	Vapour density:	No information available	No information available
	Relative density	No information available	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	No information available	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	Viscosity:	No information available	No information available
	Explosive properties:	No information available	No information available
	Oxidising properties:	No information available	No information available
9.2.	Other information		
	-		

SECTION 10.: Stability and reactivity		
10.1.	Reactivity:	See subsections 10.3 through 10.5.
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using (room temperature).
10.3.	Possibility of hazardous reactions:	No information available
10.4.	Conditions to avoid:	No information available
10.5.	Incompatible materials:	No information available
10.6.	Hazardous decomposition products:	No information available

SECTION 11. Toxicological information					
11.1.	Information on toxicological effects				
	Acute toxicity:				
Route of exposure:	Method	Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral:	No information available	rat	LD ₅₀	-	3.310 mg/kg (acetic acid)

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Dermal:	No information available	rabbit	LD ₅₀	-	1.060 mg/kg(acetic acid)
Inhalation:	No information available	-	LC ₅₀	-	-

Specific target organ toxicity - single exposure (STOT-SE):

	Specific effects	Target organ	Note
Oral:	No information available	No information available	-
Dermal:	No information available	No information available	-
Inhalation:	No information available	No information available	-

Aspiration hazard:	Irritating to respiratory system.
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Irritation and corrosion

	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation	-	-	-	-	-
Serious eye damage/irritation	-	-	-	-	-

Sensitization

Skin sensitization:	Does not cause sensitization.
Respiratory sensitization:	No information available

Symptoms related to the physical, chemical and toxicological characteristics:

Oral exposure:	Stomach and bowel irritation, feeling unwell, vomiting, strong abdominal pain. Absorption may cause toxic effects.
Dermal exposure:	Minimum level of irritation, defatting; prolonged exposure may cause absorption and greater possibility of delayed systemic effects.
Inhalation exposure:	Airways irritation and possible lung damage due to high levels of vapor concentration. Absorption may cause toxic effects.
Eye exposure:	Mild to moderate irritation due to vapor, conjunctivitis, later chemosis, lesser possibility of cornea damage. Visual impairments may occur later, after the absorption.

Repeated dose toxicity (subacute, subchronic, chronic)
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	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-

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Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-

Specific target organ toxicity - repeated exposure (STOT-RE):			
	Specific effects	Target organ	Note
Subacute oral	No information available	No information available	-
Subacute dermal	No information available	No information available	-
Subacute inhalation	No information available	No information available	-
Subchronic oral	No information available	No information available	-
Subchronic dermal	No information available	No information available	-
Subchronic inhalation	No information available	No information available	-
Chronic oral	No information available	No information available	-
Chronic dermal	No information available	No information available	-
Chronic inhalation	No information available	No information available	-

CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)	
Carcinogenicity:	No information available
Mutagenicity <i>in-vitro</i> :	No information available

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	Genotoxicity:	No information available
	Mutagenicity <i>in-vivo</i> :	No information available
	Germ cell mutagenicity :	No information available
	Reproductive toxicity:	No information available
	Summary of evaluation of the CMR properties; :	No information available
11.2.	Practical experiences:	
	Classification observations:	No information available
	Other observations:	No information available
11.3.	General notes:	
	-	

SECTION 12. Ecological information						
12.1.	Toxicity					
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	fish	No information available	No information available	300.82 mg/l (acetic acid)
Crustacea:	EC ₅₀	48 hours	Daphnia magna	No information available	No information available	300.82 mg/l (acetic acid)
Algae/aquatic plants:	IC ₅₀	8 days	algae	No information available	No information available	300.82 mg/l (acetic acid)
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants:	IC ₅₀	72 hours	No information available	No information available	No information available	-

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Other organisms	-	-	-	-	-
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12.2. Persistence and degradability

Abiotic degradation

	Degradation half-lives	Method	Evaluation	Note
Marine water	No information available	No information available	No information available	-
Fresh water	No information available	No information available	No information available	-
Air	No information available	No information available	No information available	-
Soil	No information available	No information available	No information available	-

Biodegradation

% Degradation	Time (days)	Method	Evaluation	Note
-	-	No information available	No information available	-

12.3. Bioaccumulative potential

Octanol-water partition coefficient (log Kow)

Value	Concentration	pH	°C	Method	Evaluation	Note
-	No information available	-	-	-	No information available	-

Bioconcentration Factor (BCF)

Value	Species	Method	Evaluation	Note
No information available	No information available	No information available	No information available	No information available

Chronic ecotoxicity

Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC ₅₀	No information available	No information available	No information available	No information available	-

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Chronic toxicity on crustacea (Daphnia)	EC ₅₀	No information available	No information available	No information available	No information available	-
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12.4. Mobility in soil

Known or predicted distribution in environmental compartments:					
No information available					
Surface tension:					
	Value	°C	Concentration	Method	Note
	No information available	No information available	No information available	No information available	-

Adsorption / desorption

Transport	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-Water	No information available	No information available	No information available	No information available	-
Water-Air	No information available	No information available	No information available	No information available	-
Soil-Air	No information available	No information available	No information available	No information available	-

12.5. Results of PBT and vPvB assessment

No information available

12.6. Other adverse effects

No information available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

13.1.1. Product/Packaging disposal:

Waste material must be disposed of according to the national and local rules and regulations. Do not mix with other sorts of waste. Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
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13.1.2.	Waste codes/waste designations according to Law:
	No information available
13.1.3.	Waste codes/waste designations according to Low:
	15 01 10*: packaging that contains residual hazardous substances or is contaminated with hazardous substances
13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations:
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.
13.1.6.	Relevant Community provisions:
	Directive 2009/98/EC on waste and repealing certain directives.

SECTION 14. Transport information

	Transporting/shipment by road (ADR)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
	Transporting/shipment by rail (RID)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
	Transporting/shipment by inland waterways (ADN)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-

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Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by sea (IMDG)	
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL73/78 and the IBC code:	-
Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Further information:	
-	

SECTION 15. Regulatory information	
15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture
	EU regulations
	Authorisations and/or restrictions on use
	Authorisations:
	-
	Restrictions:
	-

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Other EU regulations:	EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council; The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH); EC Regulation No. 2037/2000 of the European Parliament and Council of 29 June 2000 on ozone-depleting substances; EC Regulation No. 689/2008 of the European Parliament and Council of 17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council of 29 April 2004 on persistent organic pollutants; Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives
Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
15.2.	Chemical safety assessment
	None

SECTION 16. Other information																	
16.1.	Indication of changes: -																
16.2.	Abbreviations and acronyms: <table> <tr> <td>PBT</td><td>Stable, bioaccumulative and toxic</td></tr> <tr> <td>vPvB</td><td>Strongly stable and strongly bioaccumulative.</td></tr> <tr> <td>LD₅₀</td><td>Lethal dose, 50%</td></tr> <tr> <td>LC₅₀</td><td>Lethal concentration, 50%</td></tr> <tr> <td>STOT-SE</td><td>Specific target organ toxicity – single exposure</td></tr> <tr> <td>IMDG</td><td>International Maritime Dangerous Goods</td></tr> <tr> <td>IATA</td><td>International Air Transport Association</td></tr> <tr> <td>GHS</td><td>Globally Harmonized System of Classification and Labelling of Chemicals</td></tr> </table>	PBT	Stable, bioaccumulative and toxic	vPvB	Strongly stable and strongly bioaccumulative.	LD ₅₀	Lethal dose, 50%	LC ₅₀	Lethal concentration, 50%	STOT-SE	Specific target organ toxicity – single exposure	IMDG	International Maritime Dangerous Goods	IATA	International Air Transport Association	GHS	Globally Harmonized System of Classification and Labelling of Chemicals
PBT	Stable, bioaccumulative and toxic																
vPvB	Strongly stable and strongly bioaccumulative.																
LD ₅₀	Lethal dose, 50%																
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GHS	Globally Harmonized System of Classification and Labelling of Chemicals																
16.3.	Key literature references and source of data: -																
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)																
Classification	Classification procedure																
-	-																

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16.5.	Relevant H statements (number and full text)	
	H: H314 H315 H319	Causes severe skin burns and eye damage. Causes skin irritation. Causes serious eye irritation.
16.6.	Training advice:	-
16.7.	Further information:	** "X" in the product code marks different volumes (different packaging of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.

ANNEX: Exposure scenario resulting to Chemical safety assessment
-