

SAFETY DATA SHEET
According to Regulation (EC) No. 1907/2006

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Trading name:	OSTEOFAST 1				
Product code:	OF1-OT-X**	Revision date:	3 March 2017	Version:	3

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

1.1. Product identifier	
Trading name:	OSTEOFAST 1
Chemical name:	-
Catalogue number:	OF1-OT-X**
1.2. Relevant identified uses of the substance or mixture and uses advised against	
Identified uses:	Fixative and decalcifying solution for bone and hard tissue in histology.
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 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:	00-385-1-2404039
E-mail of competent person:	vladimir.ramljak@biognost.hr
National contact:	Vladimir Ramljak, professor of biology
1.4. Emergency telephone numbers	
National Protection and Rescue Directorate:	112
Medical information:	01-23-48-342
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*:
Acute toxicity 3	H331
Acute toxicity 3	H311
Acute toxicity 3	H301
Skin Corr. 1C	H314
STOT-SE 3	H335
Carcinogenic 2	H351
2.1.2. Additional information	
-	
*For full text of Hazard- and EU Hazard-statements: see Section 16.	
2.2. Label elements	
Product identification:	OSTEOFAST 1

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Identification number:	-
Authorization no.:	-
Hazard pictograms:	<p align="center">  GHS05 </p> <p align="center">  GHS06 </p> <p align="center">  GHS08 </p>
Signal word:	Danger
Warning statement:	H331 Toxic if inhaled. H311 Harmful in contact with skin. H301 Toxic if swallowed. H314 Causes severe skin burns and eye damage. H335 May cause respiratory irritation. H351 Suspected of causing cancer.
Precautionary statement:	P280 Wear protective gloves/protective clothing/eye/face protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312 Call a POISON CENTER/physician if you feel unwell. P403 Store in a well-ventilated place.
Supplemental hazard information (EU):	-
2.3. Other hazards	-

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS				
CAS/ EC/ Index no.	REACH registration number	Weight % content (or range)	Identification name	Classification according to (EC)1272/2008 (CLP)

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7647-01-0/ 231-595-7/ 017-002-01-X	-	≤ 30	Hydrochloric acid	Skin Corr. 1B; H314 STOT-SE 3; H335
50-00-0/ 200-001-8/ 605-001-00-5	-	9-11	Formaldehyde	Carcinogenic 2; H351 Acute toxicity 3; H331 Acute toxicity 3; H311 Acute toxicity 3; H301 Skin Corr. 1B; H314 Skin Sens.1, H317
67-56-1/ 200-659-6/ 603-001-00-X	-	< 3	Methanol	Flammable liquid 2, H225 Acute toxicity 3, H331 Acute toxicity 3, H311 Acute toxicity 3, H301 STOT-SE 1, H370

SECTION 4. FIRST AID MEASURES

4.1.	Description of first aid measures	
	General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen.
	Following skin contact:	Remove all contaminated clothes using sterile gauze. Immediately wash with plenty of water 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.
	Following swallowing:	Rinse the oral cavity, drink 1-2 glasses of water. Do not induce vomiting. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.
	Self-protection of the first aider	-
4.2.	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	Depending on concentration and exposure time, irritation of the mucous membrane of the nose/throat may occur (burning sensation, urge to sneeze, runny nose). High concentration levels may cause difficult breathing, coughing, chest tightness, headache, pneumonia and pulmonary oedema.
	Following skin contact:	Depending on concentration and exposure time, redness accompanied by sensation of stinging and pain may occur, defatting, skin cracking, rash, swelling, burns, blisters and delayed onset of inflammations.

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	Following eye contact:	Depending on concentration and exposure time, mucosa stinging, lacrimation, redness and pain may occur, as well as bleeding, delayed onset of inflammations and permanent eyesight damage.
	Following swallowing:	Depending on concentration and exposure time, stinging and possible damage to the mucous membrane of the digestive tract is possible, as well as abdominal pain, nausea, vomiting (bloody vomit is possible), vertigo, headache, eyesight disorders and permanent blindness due to optical nerve damage, loss of consciousness.
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:	No information available
5.2.	Special hazards arising from the substance or mixture	
	Hazardous byproducts of fire:	Possible liberation of toxic carbon monoxide and formaldehyde gases due to thermal decomposition (increased temperature). Explosive mixtures of formaldehyde vapors and air also present danger.
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.	Further 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.	Advice for non-emergency personnel:	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention procedure:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Remove all sources of sparks and ignition. Do not smoke.
	Procedure in case of accident:	Mark the area using proper signs.
6.1.2.	Advice for emergency responders:	
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).	
6.2.	Environmental precautions:	

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	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.	Cleaning up:	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 sawdust, old cleaning rags, and tools that may cause sparks.
6.4.	Reference to other sections	
	-	

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.	Workspace hygiene measures	
	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	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms at temperatures ranging from 15 to 25 °C.
	Containers materials:	Manufacturer's original packaging.
	Requirements for storage and containers:	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.

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	Other 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 9).		
7.3.	Specific end use(s)			
	Recommendations:	-		
	Special decisions for industry sector:	-		

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control parameters

Substance	CAS number	Exposure limit values (GVI/KGVI)		Biological limit values
		ppm	mg/m ³	
Formaldehyde	50-00-0	2	2.5	-
Methanol	67-56-1	200	260	24.7 mmol/mol of creatinine* (7.0 mg/g of creatinine*), end-of-shift urinary excretion

* For all results pertaining creatinine levels, creatinine concentration < 0.5 g/l and > 3.0 g/l may not be taken into consideration

Substance name: -

EC number: - CAS number: -

DNEL

Industry

Exposure type:	Acute local effects	Acute systemic effects	Chronic local effects	Chronic systemic effects
By swallowing	-	-	-	-
By inhalation	-	-	-	-
By skin contact	-	-	-	-

Key physical parameters: solubility flammability, corrosion: -

User

Exposure type:	Acute local effects	Acute systemic effects	Chronic local effects	Chronic systemic effects
By swallowing	-	-	-	-
By inhalation	-	-	-	-
By skin contact	-	-	-	-

PNEC

Protected environmental element	PNEC
Fresh water	No information available
Fresh water sediments	No information available

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Salt water	No information available
Salt water sediments	No information available
Food chain	No information available
Microorganisms (during wastewater processing)	No information available
Soil (agricultural)	No information available
Air	No information available

8.2.	Exposure controls
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8.2.1.	Appropriate engineering controls
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	Measures for preventing exposure during recommended use:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures for preventing exposure:	No information available
	Organizational measures for preventing exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures for preventing exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.

8.2.2.	Personal protection equipment
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8.2.2.1.	Eye and face protection:	Safety glasses that stick to face or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.
8.2.2.2.	Skin protection	
	Hand protection:	Protective butyl or Viton rubber gloves.
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves, and shoes that cover the entire foot.
8.2.2.3.	Respiratory protection:	Suitable mask or half mask equipped with a combined "A-P" filter and used when concentration levels exceed GVI.
8.2.2.4.	Thermal hazards:	No information available

8.2.3.	Environmental exposure controls
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	Measures for preventing substance exposure:	See Section 6
	Structural measures for preventing exposure:	Use modern equipment.
	Organizational measures for preventing exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures for preventing exposure:	See Section 6

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES
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9.1.	Information on basic physical and chemical properties		
	Value	Method	
Form:	Liquid	No information available	
Color:	Blue	No information available	
Odor:	Sharp	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	
Evaporation rate:	No information available	No information available	
Flammability (solid, gas):	No information available	No information available	
Lower and upper explosion limits:	No information available	No information available	
Vapor pressure:	No information available	No information available	
Relative vapor density:	No information available	No information available	
Relative density:	1.01 g/cm ³ (20°C)	No information available	
Fill density:	No information available	No information available	
Solubility:	No information available	No information available	
Partition coefficient: n-octanol/water (log Pow):	No information available	No information available	
Self-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	
Oxidizing 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: Formaldehyde vapors and air can cause explosive mixtures.
10.4.	Conditions to avoid: Sources of heat, sparks, ignition, and low temperature.
10.5.	Incompatible materials: Alkali metals, oxidants, acids and alkalis, hydrogen peroxide, phenols, iodine, iron, copper and silver compounds.

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10.6.	Hazardous decomposition products:	Carbon monoxide and formaldehyde
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SECTION 11. TOXICOLOGICAL INFORMATION					
11.1. Information on toxicological effects					
Acute toxicity:					
Consumption:	Method	Organism	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure period	Outcome
Swallowing:	formaldehyde	rat	LD ₅₀	No information available	100 mg/kg
Skin contact:	formaldehyde	rabbit	LD ₅₀	No information available	270 mg/kg
Inhaling:	formaldehyde	rat	LC ₅₀	4 h	0.578 mg/l
Specific target organ toxicity - single exposure (STOT-SE):					
	Specific effects	Target organ	Note		
Swallowing:	No information available	No information available	-		
Skin contact:	No information available	No information available	-		
Inhaling:	No information available	No information available	-		
Aspiration hazard:					
	No information available.				
Irritation and corrosion					
	Exposure period	Organism	Evaluation	Method	Note
Skin corrosion/irritation:	-	-	-	-	Causes skin irritation.
Serious eye damage/irritation:	-	-	-	-	Causes serious eye irritation.
Sensitization					
Skin contact:	May cause an allergic skin reaction.				
Inhaling:	Allergic persons may display irritation.				
Symptoms related to the physical, chemical and toxicological characteristics					
Swallowing:	Depending on concentration and exposure time, stinging and possible damage to the mucous membrane of the digestive tract is possible, as well as abdominal pain, nausea, vomiting (bloody vomit is possible), vertigo, headache, eyesight disorders and permanent blindness due to optical nerve damage, loss of consciousness.				

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Skin contact:	Depending on concentration and exposure time, redness accompanied by sensation of stinging and pain may occur, defatting, skin cracking, rash, swelling, burns, blisters and delayed onset of inflammations.
Inhaling:	Depending on concentration and exposure time, irritation of the mucous membrane of the nose/throat may occur (burning sensation, urge to sneeze, runny nose). High concentration levels may cause difficult breathing, coughing, chest tightness, headache, pneumonia and delayed pulmonary oedema (up until 48 hours).
Eye contact:	Depending on concentration and exposure time, mucosa stinging, lacrimation, redness and pain may occur, as well as bleeding, delayed onset of inflammations and permanent eyesight damage.

Repeated dose toxicity (subacute, subchronic, chronic)

	Dose	Exposure period	Organism	Method	Evaluation	Note
Subacute oral toxicity	No information available	-				
Subacute dermal toxicity	No information available	-				
Subacute inhaling toxicity	No information available	-				
Subchronic oral toxicity	No information available	-				
Subchronic dermal toxicity	No information available	-				
Subchronic inhaling toxicity	No information available	-				
Chronic oral toxicity	No information available	-				
Chronic dermal toxicity	No information available	-				
Chronic inhaling toxicity	No information available	-				

Specific target organ toxicity - repeated exposure (STOT-RE):

	Specific effects	Target organ	Note
Subacute oral toxicity	No information available	No information available	-

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Subacute dermal toxicity	No information available	No information available	-
Subacute inhaling toxicity	No information available	No information available	-
Subchronic oral toxicity	No information available	No information available	-
Subchronic dermal toxicity	No information available	No information available	-
Subchronic inhaling toxicity	No information available	No information available	-
Chronic oral toxicity	No information available	No information available	-
Chronic dermal toxicity	No information available	No information available	-
Chronic inhaling toxicity	No information available	No information available	-

CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)	
Carcinogenicity:	Suspected of causing cancer.
<i>In vitro</i> mutagenicity:	Due to rapid biotransformation, there is no genetic risk for humans when exposed to concentration levels up to 0.3 ppm.
Genotoxicity:	No information available
<i>In-vivo</i> mutagenicity:	No information available
Germ cell mutagenicity:	No information available
Reproductive organs toxicity:	No toxic effects on reproductive organs were noted during testing on animals.
Total evaluation of CMR properties:	No information available

11.2.	Practical experiences:
Remarks relevant for classification:	No information available
Other remarks:	No information available

11.3.	Note:
	-

SECTION 12. ECOLOGICAL INFORMATION

12.1.	Toxicity					
Acute toxicity	Dose	Exposure period	Organism	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	Fish	formaldehyde	24-41 mg/l	-
Crabs	EC ₅₀	48 hours	water flea (<i>Daphnia magna</i>)	formaldehyde	2 mg/l	-
Algae/aquatic plants	IC ₅₀	8 days	algae	formaldehyde	2.5 mg/l	-

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Chronic toxicity	Dose	Exposure period	Organism	Method	Evaluation	Note
Other organisms	-	-	-	-	-	-
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crabs (Daphnia)	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	-
Other organisms	-	-	-	-	-	-

12.2. Persistence and degradability
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Abiotic degradation				
	Half-life	Method	Evaluation	Note
Salt 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				
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Degradation %	Period (days)	Method	Evaluation	Note
No information available				

12.3. Bioaccumulative potential						
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Partition coefficient: n-octanol/water (log Pow):						
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Value	Concentration	pH	°C	Method	Evaluation	Note
No information available	No information available	-	-	No information available	No information available	No information available

Bio-Concentration Factor (BCF)						
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Value	Organism	Method	Evaluation	Note

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No information available	No information available	No information available	No information available	-

Chronic ecotoxicity						
Value	Dose	Exposure period	Organism	Method	Evaluation	Note
Chronic toxicity for fish	LC ₅₀	No information available	No information available	No information available	No information available	-
Chronic toxicity for crabs (Daphnia)	EC ₅₀	No information available	No information available	No information available	No information available	-

12.4. Mobility in soil

Known or presumed distribution in environment:						
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 law	log Pow	Volatility	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						
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12.6. Other adverse effects

No information available						
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SECTION 13. DISPOSAL CONSIDERATIONS	
13.1.	Waste treatment methods
13.1.1.	Disposing of the product/packaging: Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
13.1.2.	Waste code 15 01 10: packaging that contains residual hazardous substances or is contaminated with hazardous substances
13.1.3.	Waste processing method: No information available
13.1.4.	Possibility of spilling into the sewage system: Waste must not be disposed of into the sewage system.
13.1.5.	Other recommendations for disposal: 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.
13.1.6.	Relevant community provisions: -

SECTION 14. TRANSPORT INFORMATION	
Land transport (ADR)	
UN number:	3264
Proper shipping name:	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (HYDROCHLORIC ACID SOLUTION)
Transport hazard class(es):	8
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Land transport by rail (RID)	
UN number:	3264
Proper shipping name:	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (HYDROCHLORIC ACID SOLUTION)
Transport hazard class(es):	8
Packing group:	II
Environmentally hazardous:	-

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Special precautions for user:	-
Inland waterway transport (ADN)	
UN number:	3264
Proper shipping name:	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (HYDROCHLORIC ACID SOLUTION)
Transport hazard class(es):	8
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Sea transport (IMDG)	
UN number:	3264
Proper shipping name:	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (HYDROCHLORIC ACID SOLUTION)
Transport hazard class(es):	8
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-
Air transport (ICAO-TI/IATA-DGR)	
UN number:	3264
Proper shipping name:	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (HYDROCHLORIC ACID SOLUTION)
Transport hazard class(es):	8
Packing group:	II
Environmentally hazardous:	-
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
	Authorization and/or restrictions of use
	Authorizations: -
	Restrictions: -

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	H:	225 301 311 314 317 331 335 351 370	Highly flammable liquid and vapor Toxic if swallowed Harmful in contact with skin Causes severe skin burns and eye damage May cause an allergic skin reaction Toxic if inhaled May cause respiratory irritation. Suspected of causing cancer Causes damage to organs
16.6.	Training advice:	-	
16.7.	Further notice:	<p>** "X" in the product code marks different volumes (different packaging of the product)</p> <p>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.</p>	

ANNEX: Exposure scenario resulting to Chemical safety assessment
-