




Trading name:	OSTEOFAST 1				
Product code:	OF1-OT-X**	Revision date:	10 July 2024	Version:	8

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, 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 Corr. 1B	H314
	Skin Irr. 2	H315
	Skin Sens. 1	H317
	Eye Irr. 2	H319
	STOT SE 3	H335
	Muta. 2	H341
	Carc. 1B	H350
	STOT SE 1	H370
2.1.2.	Additional information	
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*For full text of Hazard- and EU Hazard-statements: see Section 16.

2.2. Label elements	
Product identification:	OSTEOFAST 1
Identification number:	-
Authorization number:	-
Hazard pictograms:	 GHS05  GHS07  GHS08
Signal word:	Danger
Hazard statement:	H314 Causes severe skin burns and eye damage. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye damage. H335 May cause respiratory irritation. H341 Suspected of causing genetic defects. H350 May cause cancer. H370 Cause damage to organs (eyes).

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Precautionary statement:	<p>P280 Wear protective gloves/protective clothing/eye/protection/face protection.</p> <p>P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.</p> <p>P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.</p> <p>P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P308+P311 IF exposed or concerned: Call a POISON CENTER or doctor.</p> <p>P501 Dispose of contents/container to an approved waste disposal plant.</p>
Supplemental hazard information (EU):	-

2.3.	Other hazards
<p>Endocrine Disrupting Properties: No known endocrine disrupting properties</p> <p>Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.</p>	

SECTION 3. Composition/information on ingredients
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CAS/ EC/ Index no.	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
7647-01-0/ 231-595-7/ 017-002-01-X	01-2119484862- 27-xxxx	23 -25 %	hydrochloric acid, 37%	Skin Corr. 1B; H314 STOT SE 3; H335
50-00-0/ 200-001-8/ 605-001-00-5	01-2119488953- 20-xxxx	10 %	formaldehyde, 37%	Acute Tox. 3, H301 Acute Tox. 3, H311 Acute Tox. 3, H331 Skin Corr. 1B; H314 Skin. Sens. 1; H317 Muta. 2; H341 Carc. 1B; H350
67-56-1/ 200-659-6/ 603-001-00-X	01-21194333307- 44-xxxx	2 – 3 %	methanol	Flam. Liq. 2; H225 Acute Tox. 3; H301 Acute Tox. 3; H311 Acute Tox. 3; H331 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.

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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 ingestion:	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 edema.
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.
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 ingestion:	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

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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

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	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.	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.	Advice for non-emergency personnel:	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	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.
	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.	Bundling, 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	

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<p>See Section 7 for information about secure handling. See Section 8 for information about personal protective equipment. See Section 13 for information about containment.</p>
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SECTION 7. Handling and storage

7.1.	Precautions for safe handling		
7.1.1.	Protection measures		
	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from sources of heat and ignition. Carry out measures for preventing static electricity.	
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.	
	Measures to protect the environment:	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		
	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.	
	Packaging 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.	
	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 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 No	Occupational exposure limit values/short term values	Biological limit values

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		ppm	mg/m ³	
Hydrogen chloride	7647-01-0	5/10	8/15	-
Formaldehyde	50-00-0	0.3/0.6	0.37/0.74	-
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:	-			
EC No:	-	CAS No:	-	

DNEL

Industrial				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	0.75 mg/m ³ (formaldehyde) 130 mg/m ³ (methanol)	- 130 mg/m ³ (methanol)	0,375 mg/m ³ (formaldehyde) 130 mg/m ³ (methanol)	9 mg/m ³ (formaldehyde) 130 mg/m ³ (methanol)
Dermal	-	20 mg/kg t/day (methanol)	0.037 mg/cm ² (formaldehyde)	240 mg/kg t/day (methanol) 20 mg/kg t/day (methanol)

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	4 mg/kg t/day (methanol)	-	4.1 mg/kg t/day (methanol) 4 mg/kg t/day (methanol)
Inhalation	- 26 mg/m ³ (methanol)	- 26 mg/m ³ (methanol)	0.1 mg/m ³ (formaldehyde) 26 mg/m ³ (methanol)	3.2 mg/m ³ (formaldehyde) 26 mg/m ³ (methanol)
Dermal	-	4 mg/kg t/day (methanol)	0.012 mg/cm ² (formaldehyde)	102 mg/kg t/day (formaldehyde) 4 mg/kg t/day (methanol)

PNEC

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Environmental protection target	PNEC
Fresh water	0.44 mg/l (formaldehyde) 20.8 mg/l (methanol)
Freshwater sediments	2.3 mg/kg (formaldehyde) 77 mg/kg (methanol)
Marine water	0.44 mg/l (formaldehyde) 2.08 mg/l (methanol)
Marine sediments	2.3 mg/kg (formaldehyde) 7.7 mg/kg (methanol)
Food chain	No information available
Microorganisms in sewage treatment	0.19 mg/l (formaldehyde) 100 mg/l (methanol)
Soil (agricultural)	0.2 mg/kg (formaldehyde) 100 mg/kg (methanol)
Air	No information available

8.2.	Exposure controls	
8.2.1.	Appropriate engineering controls	
	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:	Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face (EN 136) in case of higher levels of concentration in air.
8.2.2.2.	Skin protection	

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	Hand protection:	<p>The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN374.</p> <p>Full contact:</p> <p style="padding-left: 40px;">Glove material: nitrile rubber Glove thickness: 0.40 mm Time until perforation: > 480 min</p> <p>Splash contact:</p> <p style="padding-left: 40px;">Gloves material: nitrile rubber Glove thickness: 0.11 mm Time until perforation: >240 min</p>
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN ISO 13688), and shoes (EN 13832) that cover the entire foot.
8.2.2.3.	Respiratory protection:	Suitable mask or half mask (EN 140) equipped with a combined "A-K" filter (EN 14387) and used when concentration levels exceed GVI.
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
Color:	light blue	No information available
Odour/odour threshold:	sharp/no information available	No information available
Melting point / freezing point:	No information available	No information available
Boiling point or initial boiling point and boiling range:	No information available	No information available
Flammability:	No information available	No information available
Lower and upper explosion limit:	No information available	No information available

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	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	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.
10.6.	Hazardous decomposition products:	Carbon monoxide and formaldehyde

SECTION 11. Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008					
Acute toxicity:					
Route of exposure:	Method	Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral:	No information available	No information available	LD ₅₀	No information available	100 mg/kg (formaldehyde) 100 mg/kg (methanol)

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Dermal:	No information available	No information available	LD ₅₀	No information available	300 mg/kg (formaldehyde) 300 mg/kg (methanol)
Inhalation:	No information available	rat	LC ₅₀	4 h	3 mg/l (formaldehyde) 3 mg/kg (methanol)

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: possible respiratory system irritation

Irritation and corrosion

	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation:	-	-	-	-	causes burns
Serious eye damage/irritation:	-	-	-	-	causes serious eye damage

Sensitization

Skin sensitization:	May cause an allergic skin reaction.
Respiratory sensitization:	Allergic persons may display irritation.

Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	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.
Dermal exposure:	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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Inhalation exposure:	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 exposure:	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 time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
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	-

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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:	May cause cancer.
Mutagenicity <i>in-vitro</i> :	No information available
Genotoxicity:	Probably causes genetic damage.
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.	Information on other hazards:
11.2.1.	Endocrine disrupting properties:
	Substance/mixture does not contain components considered to have endocrine disruption according to Article 57(f), regulation on registration, assessment, approval and restricting chemicals (REACH), or delegated Regulation (EU) 2017/2100 or (EU) 2018/605 at levels of 0.1% or above.
11.2.2.	Other informations:
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SECTION 12. Ecological information						
12.1.	Toxicity					
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note

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Fish	LC ₅₀	96 hours	<i>Pimephales promelas</i>	No information available	6.7 mg/l (formaldehyde) 15.400 mg/l (methanol)	-
Crustacea:	EC ₅₀	48 hours	water flea (<i>Daphnia magna</i>)	No information available	5.8 mg/l (formaldehyde)	-
Algae/aquatic plants	IC ₅₀	8 days	algae	No information available	4.89 mg/l (formaldehyde)	-
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	-
Other organisms	-	-	-	-	-	-

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	No information available	No information available	No information available

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12.3. Bioaccumulative potential						
Octanol-water partition coefficient (log Kow)						
Value	Concentration	pH	°C	Method	Evaluation	Note
No information available	No information available	-	-	No information available	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	-	
Chronic ecotoxicity						
Value	Dose	Exposure period	Organism	Method	Evaluation	Note
Chronic toxicity on fish	LC ₅₀	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea (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						

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Transport	A/D coefficient Henry's constant	log Pow	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

Substance(s) in the mixture do(es) not meet the criteria for PBT or vPvB

12.6. Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7. Other adverse effects

No adverse effects are expected.

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.

13.1.2. Waste codes/waste designations according to Law:

15 01 10*: packaging that contains residual hazardous substances or is contaminated with hazardous substances

13.1.3. Waste treatment – relevant information:

No information available

13.1.4. Sewage disposal – relevant information:

Waste must not be disposed of into the sewage system.

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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.
13.1.6.	Relevant Community provisions:
	-

SECTION 14. Transport information

Land transport (ADR)	
UN number:	3264
UN 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
UN 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:	-
Inland waterway transport (ADN)	
UN number:	3264
UN 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
UN proper shipping name:	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (HYDROCHLORIC ACID SOLUTION)
Transport hazard class(es):	8

Trading name:	OSTEOFAST 1				
Product code:	OF1-OT-X**	Revision date:	10 July 2024	Version:	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
UN 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:	-
Other EU regulations:	<p>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;</p> <p>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;</p> <p>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;</p> <p>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>

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	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)			
National regulation:	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:	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative
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
	-	-
16.5.	Relevant H statements (number and full text)	
	H225	Highly flammable liquid and vapor.
	H301+H311+H331	Toxic if swallowed, in contact with skin or if inhaled.
	H314	Causes severe skin burns and eye damage.
	H315	Causes skin irritation
H:	H317	May cause an allergic skin reaction.
	H319	Causes serious eye damage.
	H335	May cause respiratory irritation.
	H341	Suspected of casusing genetic defects.
	H350	May cause cancer.
	H370	Causes damage to organs.

Trading name:	OSTEOFAS 1				
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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
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