



Trade name:	IMMUNOFORM				
Product code:	IMF-X**	Date of compilation:	22 May 2019	Version:	2

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1.	Product identifier	
	Trade name:	IMMUNOFORM
	Chemical name:	-
	Catalogue number:	IMF-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Fixative for use in histology and immunohistochemistry.
	Uses advised against:	Only the identified uses are advised.
	Reasons 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*:
	Acute Tox. 4	H302
	Skin Irrit. 2	H315
	Skin Sens. 1	H317
	Resp. Sens. 1	H334
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see Section 16.		
2.2.	Label elements	
	Product identification:	IMMUNOFORM
	Identification number:	-

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Authorisation number:	-	
Hazard pictograms:	 	<p>GHS08 GHS07</p>
Signal word:	Danger	
Hazard statement:	<p>H302 Harmful if swallowed H315 Causes skin irritation H317 May cause an allergic skin reaction. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.</p>	
Precautionary statement:	<p>P280 Wear protective gloves/protective clothing/eye/protection/face protection. P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. P312 Call a POISON CENTER/physician if you feel unwell. P403 Store in a well-ventilated place.</p>	
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)
30525-89-4/ 608-494-5/ -	-	< 5%	paraformaldehyde	Acute Tox. 4; H302 Skin Irrit. 2; H315 Skin Sens. 1; H317 Eye Dam. 1; H318 Acute Tox. 4; H332 Resp. Sens. 1; H334

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.

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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

Hazardous by products 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.
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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.
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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).
	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.	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 incompatible materials (see Section 10).
6.4.	Reference to other sections
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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 formation: Secure proper ventilation.
	Measures to protect the environment: Prevent spilling into the sewage system and waterways.

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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.	
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.	
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 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	
-	-	-	-	-
Substance: -				
EC No:	-	CAS No.:	-	
DNEL				
Industrial				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-
Critical physical parameters: solubility, flammability, corrosivity:			-	

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Consumer				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

PNEC	
Environmental protection target	PNEC
Fresh water	No information available
Fresh water sediments	No information available
Salt water	No information available
Salt water sediments	No information available
Food chain	No information available
Microorganisms in sewage treatment	No information available
Soil (agricultural)	No information available
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 in case of higher levels of concentration in air.
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: Material: Nitrile rubber Minimum layer thickness: 0,11 mm Break through time: 480 min Splash contact: Material: Nitrile rubber Minimum layer thickness: 0,11 mm Break through time: 480 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:	Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type P3 (EN 143) respirator cartridges as a backup to engineering controls.
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:	colorless	No information available
	Odor	sharp	No information available
	Odor threshold:	No information available	No information available
	pH:	6.9-7.1	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:	Strong oxidizing agents.
10.6.	Hazardous decomposition products:	Carbon oxides.

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 (paraformaldehyde)	LD ₅₀	No information available	592 mg/kg

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Dermal	No information available	rabbit (paraformaldehyde)	LD ₅₀	No information available	10.000 mg/kg
Inhalation	No information available	rat (paraformaldehyde)	LC ₅₀	4 h	1.07 mg/l

Specific target organ toxicity - single exposure (STOT-SE):					
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	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:	No information available.
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Irritation and corrosion					
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	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation:	-	-	-	-	Causes skin irritation.
Serious eye damage/irritation:	-	-	-	-	no information available

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

Symptoms related to the physical, chemical and toxicological characteristics					
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Oral exposure:	Depending on concentration and exposure time, mucous membranes with retrosternal and abdominal pain, cramps, bloody vomiting, cyanosis, respiratory insufficiency, danger of perforation of the esophagus, stomach and small intestine; absorptive-toxic effects; delayed development of strictures possible.
Dermal exposure:	Depending on concentration and exposure time, superficial coagulation necrosis with hardening and tanning of the skin as well as anesthesia, allergic skin reactions (periorbital edema, urticaria, delayed development of eczema).
Inhalation exposure:	Depending on concentration and exposure time, irritation to the mucous membranes of the nose/throat (burning sensation, urge to sneeze, running nose), possibly even asthmoid reactions; for higher concentrations severe difficulty in breathing, fits of coughing, tightness in the chest, headache, reactions of the circulatory system, danger of glottic edema/cramp, bronchospasm, possible bronchiolitis, pneumonia, pulmonary edema

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Eye exposure:	Dependent on the intensity of exposure slight, reversible irritation through to permanent corneal lesion: seriousness probably only visible after a latency period of some hours.
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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	-
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 inhaling	No information available	No information available	-
Subchronic oral	No information available	No information available	-
Subchronic dermal	No information available	No information available	-

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

CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)	
Carcinogenicity:	No information available
Mutagenicity <i>In-vitro</i> :	No information available
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
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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	<i>Oncorhynchus mykiss (rainbow trout)</i>	No information available	46 – 78 mg/l (paraformaldehyde)	-
Crustacea:	EC ₅₀	48 hours	<i>Daphnia magna (water flea)</i>	No information available	42 mg/l (paraformaldehyde)	-
Algae/aquatic plants:	IC ₅₀	8 days	No information available	No information available	No information available	-
Other organisms:	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note

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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

12.3. Bioaccumulative potential

Octanol/water oartition coefficient (log Pow):

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	-

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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	-
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 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						
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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.	Product/packaging disposal:
	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.
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	
Transporting/shipment by road (ADR)	
UN number	Not regulated
UN proper shipping name:	-
Transport hazard classes:	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by rail (RID)	
UN number	Not regulated
UN proper shipping name:	-
Transport hazard classes:	-
Packing group:	-

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Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by inland waterways (ADN)	
UN number	Not regulated
UN proper shipping name:	-
Transport hazard classes:	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by sea (IMDG)	
UN number	Not regulated
UN proper shipping name:	-
Transport hazard classes:	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-
Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number	3334
UN Proper shipping name:	Aviation regulated liquid, n.o.s. (formaldehyde)
Transport hazard classes:	9
Packing group:	III
Environmentally hazardous:	no
Special precautions for user:	-
Further information: No information available	

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

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Other EU regulations:	<p>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</p>
Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline):	
National legislation:	<p>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, Transport of Hazardous Substances Act</p>
15.2. Chemical safety assessment	
	None

SECTION 16. Other information											
16.1. Indication of changes:	-										
16.2. Abbreviations and acronyms:	<table border="0"> <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> </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
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										
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)											

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H:	302	Harmful if swallowed
	315	Causes severe skin burns and eye damage
	317	Causes skin irritation
	318	Causes serious eye damage
	332	Harmful if inhaled
	334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
16.6.	Training advice:	-
16.7.	Further notice:	** "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	
-	