

Trading name:	KOVAC INDOLE REAGENT			
Product code:	KOV-OT-X**	Revision date:	03 July 2019	Version: 3

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1	Product identifier	
	Trading name:	KOVAC INDOLE REAGENT
	Chemical name:	-
	Catalogue number:	KOV-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For identification of indole-positive and indole-negative microorganisms.
	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 number	
	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 statements*:
	Flam. Liq. 3	H226
	Acute Tox. 4	H302
	Skin Corr. 1B	H314
	STOT SE 3	H335
	STOT SE 3	H336
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2	Label elements	

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	Product identification:	KOVAC INDOLE REAGENT
	Identification number:	-
	Authorization number:	-
	Hazard pictograms:	 GHS02  GHS05  GHS07
	Signal word:	Danger
	Hazard statements:	H226 Flammable liquid and vapour. H302 Harmful if swallowed. H314 Causes severe skin burns and eye damage. H335 May cause respiratory irritation. H336 May cause drowsiness or dizziness.
	Precautionary statements:	P210 Keep away from heat/sparks/open flames/hot surfaces. Do not smoke. P280 Wear protective gloves/protective clothing/eye protection/face protection. P301+P330+P331 IF SWALLOWED: rinse mouth. DO NOT induce vomiting. P302+P352 IF ON SKIN: Wash with plenty of water and soap. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	Supplemental hazard information (EU):	-
2.3	Other hazards	
	-	

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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)
71-36-3/ 200-751-6/ 603-004-00-6	-	≥ 50% - < 80 %	<i>n</i> -butanol	Flam. Liq. 3; H226 Acute Tox. 4; H302 Skin Irr. 2; H315 Eye Dam. 1; H318 STOT SE 3; H335 STOT SE 3; H336
7647-01-0/ 231-595-7/ 017-002-01-X	01-2119484862- 27-xxxx	≤ 25%	hydrochloric acid, 37%	Skin Corr. 1B; H314 STOT SE 3; H335

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 contaminated clothing. 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:	Do not induce vomiting. Do not insert any object into the unconscious person's mouth. 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, it may lead to mucosa irritation, cough, and dyspnea.
	Following skin contact:	Defatting, dry skin.
	Following eye contact:	Depending on concentration and exposure time, it may lead to irritation, tearing, redness and pain.
	Following ingestion:	Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting.
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: water spray, dry powder, CO ₂ or alcohol resistant foam
	Unsuitable extinguishing media: water jet
5.2	Special hazards arising from the substance or mixture
	Hazardous combustion products: no information available
5.3	Advice for firefighters
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.
5.4	Additional information
	Collect contaminated fire fighting water separately. 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. Do not smoke. Keep away from ignition sources.
	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 material for containment and cleaning up
6.3.1.	Bunding, covering of drains; capping procedures: Sand protective barrier or barriers made of similar materials.
6.3.2.	Cleaning up: Where possible, the substance can be absorbed by using absorbing material. 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: Secure proper ventilation. Do not use incompatible materials (see Section 10).

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6.4	Reference to other sections
	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

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 ignition and heat. Do not use tools that cause sparks. Do not smoke.
	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:	Protect against electrostatic charges.
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 at temperatures ranging from +2 to +8 °C. Protect from heat and direct sunlight.
	Packaging materials:	Manufacturer's original packaging. Unsuitable material for receptacle: aluminium.
	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

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Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
n-butanol	71-36-3	-/50	-/154	-
Hydrogen chloride	7647-01-0	5/10	8/15	-

Substance name:	-			
EC No:	-	CAS No:	-	

DNEL

Industrial

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	3.125 mg/kg (n-butanol)
Inhalation	15 mg/m ³ (hydrochloric acid)	-	310 mg/m ³ (n-butanol) 8 mg/m ³ (hydrochloric acid)	-
Dermal	-	-	-	-

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	55 mg/m ³ (n-butanol)	-
Dermal	-	-	-	-

PNEC

Environmental protection target	PNEC
Fresh water	0.082 mg/l (n-butanol) 0.036 mg/l (hydrochloric acid)
Freshwater sediments	0.178 mg/kg (n-butanol)
Marine water	0.0082 mg/l (n-butanol) 0.036 mg/l (hydrochloric acid)
Marine sediments	0.0178 mg/kg (n-butanol)
Food chain	no information available
Microorganisms in sewage treatment	2476 mg/l (n-butanol) 0.036 mg/l (hydrochloric acid)
Soil (agricultural)	0.015 mg/kg (n-butanol)
Air	no information available

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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:	In accordance with Section 7.
	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. Secure stations for rinsing eyes and showering.
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	
	Hand protection:	The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN 374. Full contact: Glove material: butyl rubber Glove thickness: ≥ 0.50 mm Time until perforation: > 480 min Splash contact: Glove material: nitrile rubber Glove thickness: 0.40 mm Break through time: 35 min
	Other skin protection:	During everyday work use antistatic clothing (EN 13688) and suitable footwear, such as rubber boots (EN 20345) or shoes that cover the entire foot. In case of spilling hazard, use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material.
8.2.2.3.	Respiratory protection:	If the concentration level exceeds the GVI values (or because of inadequate ventilation), use a filter for organic vapors, type "A" (boiling point $> 65^{\circ}\text{C}$) according to EN 14387.
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

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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:	greenish yellow	No information available
	Odour:	characteristic	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:	36°C	No information available
	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		
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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:	Risk of explosion with alkali metals, conc. sulfuric acid.
10.4	Conditions to avoid:	Avoid heat, sparks, direct sunlight, open flames and other ignition sources.
10.5	Incompatible materials:	Various metals , rubber, various plastics.
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	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results
Oral:	-	rat (n-butanol)	LD ₅₀	-	790 mg/kg (n-butanol)
Dermal:	-	rabbit (n-butanol)	LD ₅₀	-	3.400 mg/kg (n-butanol)
Inhalation:	-	rat	LC ₅₀	4h (n-butanol) 1h (hydrochloric acid)	18 mg/l (n-butanol) 4.74 mg/l (hydrochloric acid)
	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		may cause drowsiness or dizziness
	Aspiration hazard:		No information available.		
	Irritation and corrosion				
Exposure time		Species	Evaluation	Method	Note
Skin corrosion/irritation:	No information available	rabbit	-	-	irritations

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Serious eye damage/irritation	No information available	rabbit	-	-	irreversible effects on the eye
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Sensitization

Skin sensitization:	No information available.
Respiratory sensitization:	No information available.

Symptoms related to the physical, chemical and toxicological characteristics
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Oral exposure:	If swallowing occurs, aspiration of the vomit may also occur and cause chemical pneumonitis or pulmonary oedema.
Dermal exposure:	Prolonged and/or repeated exposure to low viscosity content may cause irritation and dermatitis, skin drying or cracking.
Inhalation exposure:	Respiratory system irritation, headache, vertigo, nausea and faint may occur during exposure to vapor concentrations above recommended level. It may also act as an anesthetic and affect central nervous system.
Eye exposure:	Eye irritation may occur during exposure to vapor concentrations above recommended level.

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	-

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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	-

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

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	CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)
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	Carcinogenicity:	Based on available data, the classification criteria are not met.
	Mutagenicity <i>in vitro</i> :	Based on available data, the classification criteria are not met.
	Genotoxicity:	Based on available data, the classification criteria are not met.
	Mutagenicity <i>in vivo</i> :	Based on available data, the classification criteria are not met.
	Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
	Reproductive toxicity:	Based on available data, the classification criteria are not met.

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	Summary of evaluation of the CMR properties:	Based on available data, the classification criteria are not met.
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11.2	Practical experiences:
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	Classification observations:	No information available
	Other observations:	No information available

11.3	General notes:
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% Degradation	Time (days)	Method	Evaluation	Note
0%	28 days	OECD TEST 301F	No information available	Not readily biodegradable

12.3 Bioaccumulative potential

Octanol-water partition coefficient (log Kow)

Value	Concentration	pH	°C	Method	Evaluation	Note
1.28	-	-	23 °C	OECD 107	-	bioaccumulation is not expected

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 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 (<i>Daphnia</i>)	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
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	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 Kow	Evaporation rate	Method	Note
Soil-water	No available	information	No information available	No information available	No information available	-
Water-air	No available	information	No information available	No information available	No information available	-
Soil-air	No available	information	No information available	No information available	No information available	-

12.5	Results of PBT and vPvB assessment				
	Not applicable.				

12.6	Other adverse effects				
	No further relevant information available.				

SECTION 13. Disposal considerations

13.1	Waste treatment methods				
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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:				
	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:
	Disposal must be made according to official regulations.

SECTION 14 TRANSPORT INFORMATION

	Transporting/shipment by road (ADR)
UN number:	2920
UN proper shipping name:	Corrosive liquid, flammable, n.o.s. (butanol, hydrochloric acid)
Transport hazard class(es):	8 (3)
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
	Transporting/shipment by rail (RID)
UN number:	2920
UN proper shipping name:	Corrosive liquid, flammable, n.o.s. (butanol, hydrochloric acid)
Transport hazard class(es):	8 (3)
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
	Inland waterway transport (ADN)
UN number:	2920
UN proper shipping name:	Corrosive liquid, flammable, n.o.s. (butanol, hydrochloric acid)
Transport hazard class(es):	8 (3)
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
	Transporting/shipment by sea (IMDG)
UN number:	2920
UN proper shipping name:	Corrosive liquid, flammable, n.o.s. (butanol, hydrochloric acid)
Transport hazard class(es):	8 (3)
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Transport in bulk according to Annex II	-

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of MARPOL 73/78 and the IBC code:	
	Transporting/shipment by air (ICAO-TI/IATA-DGR)
UN number:	2920
UN proper shipping name:	Corrosive liquid, flammable, n.o.s. (butanol, hydrochloric acid)
Transport hazard class(es):	8 (3)
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:	EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council; 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 from 29 June 2000 on substances that damage the ozone layer; EC Regulation No. 689/2008 of the European Parliament and Council from 17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about 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	

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SECTION 16. Other information			
16.1	Indication of changes:		-
16.2	Abbreviations and acronyms:		PBT Stable, bioaccumulative and toxic vPvB Strongly stable and strongly bioaccumulative. LD ₅₀ Lethal dose, 50% LC ₅₀ Lethal concentration, 50% TCOJ 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)		
	H:	H226 H302 H314 H315 H318 H335 H336	Flammable liquid and vapour. Harmful if swallowed. Causes severe skin burns and eye damage. Causes skin irritation. Causes serious eye damage. May cause respiratory irritation. May cause drowsiness or dizziness.
16.6.	Training advice:		-
16.7.	Further information:		** "X" in the product code marks different volumes (different packagings 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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