

Trading name:	<b>AURAMINE O, C.I. 41000</b>				
Product code:	AU-P-X**	Revision date:	21 Dec 2022	Version:	4

### SECTION 1. Identification of the substance/mixture and of the company/undertaking

1.1.	Product identifier	
	Substance name:	AURAMINE O, C.I. 41000
	EC No:	219-567-2
	Synonyms:	Basic Yellow 2
	Catalogue number:	AU-P-X**
	REACH registration number:	-
	CAS No:	2465-27-2
	Index no.:	-
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For staining acid-fast lung tissue bacteria acc. to Truant.
	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
	Fax no.:	+385 1 2404039
	e-mail of competent person:	<a href="mailto:msds@biognost.hr">msds@biognost.hr</a>
	National contact:	-
1.4.	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-



### SECTION 2. Hazards information

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*:
	Acute Tox. 4	H302
	Acute Tox. 3	H311
	Carc. 2	H351
2.1.2.	Additional information	

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\*For full text of Hazard- and EU Hazard-statements: see Section 16

<b>2.2. Label elements</b>	
Product identification:	AURAMINE O, C.I. 41000
Identification number:	-
Authorization no.:	-
Hazard pictograms:	  GHS06                      GHS08
Signal word:	Danger
Hazard statements:	H302 Harmful if swallowed. H311 Toxic in contact with skin. H351 Suspected of causing cancer.
Precautionary statements:	P280 Wear protective gloves/protective clothing/eye protection/face protection. P302+P352 IF ON SKIN: Wash with plenty of water and soap. P308 + P313 IF exposed or concerned: Get medical advice/attention.
Further information:	-
<b>2.3. Other hazards</b>	
<b>Endocrine Disrupting Properties:</b> No known endocrine disrupting properties <b>Results of PBT and vPvB assessment:</b> According to the results of its assessment, this substance is not a PBT or a vPvB.	

**SECTION 3. Composition/information on ingredients**

CAS No	EC No:	Index no.	Identification name	Weight % content (or range)
2465-27-2	219-567-2	-	4,4'-carbonimidoylbis(N,N-dimethylaniline) monohydrochloride	~ 80 %

**SECTION 4. First aid measures**

<b>4.1. Description of first aid measures</b>	
General notes:	-
Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. If breathing becomes erratic or it

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		stops, immediately apply artificial respiration (other than mouth-to-mouth) and contact a physician.
	Following skin contact:	Remove contaminated clothing. Immediately wash with copious amounts of water for at least 15 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 using clean fingers. If the symptoms remain, immediately call a physician.
	Following ingestion:	DO NOT induce vomiting. If the afflicted person is unconscious, do not provide them with anything orally. Seek medical attention in case of irritation or other symptoms.
	Self-protection of the first aider:	-
<b>4.2.</b>	<b>Most important symptoms and effects, both acute and delayed</b>	
	Following inhalation:	Harmful if swallowed.
	Following skin contact:	Harmful by inhalation and in contact with skin.
	Following eye contact:	Risk of serious damage to eyes.
	Following ingestion:	Harmful if swallowed.
<b>4.3.</b>	<b>Indication of any immediate medical attention and special treatment needed</b>	
	-	

**SECTION 5. Firefighting measures**

<b>5.1.</b>	<b>Extinguishing media</b>	
	Suitable extinguishing media:	In case of fire use water spray for cooling the jars. Use water spray, dry dust, CO <sub>2</sub> or suitable foam.
	Unsuitable extinguishing media:	-
<b>5.2.</b>	<b>Special hazards arising from the substance or mixture</b>	
	Hazardous combustion products:	-
<b>5.3.</b>	<b>Advice for firefighters</b>	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. Cool closed containers exposed to fire with water spray or vapor.	
<b>5.4.</b>	<b>Additional information</b>	
	-	

**SECTION 6. Accidental release measures**

<b>6.1.</b>	<b>Personal precautions, protective equipment and emergency procedures</b>	
<b>6.1.1.</b>	<b>For non-emergency personnel</b>	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	-
	Emergency procedures:	-

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6.1.2.	For emergency responders:				
	-				
6.2.	Environmental precautions:				
	-				
6.3.	Methods and material for containment and cleaning up				
6.3.1.	For creating barriers, covering and sealing:	-			
6.3.2.	Cleaning up:	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:	-			
6.4.	Reference to other sections				
	-				

SECTION 7. Handling an storage				
7.1.	Precautions for safe handling			
7.1.1.	Protection measures			
	Measures to prevent fire:	Heat sources.		
	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:	Wash hands thoroughly after handling. Use with appropriate ventilation. Minimize dust formation. Avoid inhaling vapor, dust, mist or gas. Avoid contact with skin, eyes and clothes. Keep in tightly closed container. Avoid swallowing and breathing.		
	Packaging materials:	Manufacturer's original packaging.		
	Requirements for storage rooms and vessels:	Keep container tightly closed. Keep in cool, dry and well-ventilated space, away from incompatible substances.		
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain		

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		that directly leads into sewage system. Secure proper ventilation.
	Further information on storage conditions:	No information available.
<b>7.3.</b>	<b>Specific end use(s)</b>	
	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 <sup>3</sup>	
-	-	-	-	-

Substance name:	-
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:

**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
Freshwater sediments	No information available
Marine water	No information available

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Marine 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 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:	Use with appropriate ventilation.

**8.2.2. Personal protection equipment**

8.2.2.1. Eye and face protection:	Safety glasses that stick to face (preventing splashing) or visor.
8.2.2.2. Skin protection	
Hand protection:	In case of coming into thorough contact, use butyl rubber gloves (0.4 mm thick). In case of contact with drops, use polychlorene gloves (0.1 mm thick).
Other skin protection:	During everyday work use cotton clothing and suitable footwear, such as rubber boots 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:	Required when dust are generated. Recommended filter type: Filter P 3 (acc. to DIN 3181) for solid and liquid particles of toxic and very toxic substances.
8.2.2.4. Thermal hazards:	-

**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.

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Technical measures to prevent exposure:	See Section 6
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### SECTION 9. Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

		Value	Method
	Physical state:	powder	No information available
	Color:	yellow	No information available
	Odour/odour threshold:	no odor/no information available	No information available
	Melting point / freezing point:	>250 °C	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
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	265 °C	No information available
	pH:	6 -7 (10g/l at 20°C)	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	soluble in alcohol and mildly soluble in water	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:	soluble in alcohol and mildly soluble in water	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available

#### 9.2. Other information

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### SECTION 10. Stability and reactivity

10.1.	Reactivity:	No information available
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

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10.4.	Conditions to avoid:	Incompatible materials.
10.5.	Incompatible materials:	Strongly oxidizing media.
10.6.	Hazardous decomposition products:	Reaction in contact with nitrates, nitric acid and nitrate gases may liberate carcinogenic nitrosamines.

**SECTION 11. Toxicological information**

11.1. Information on toxicological effects

Acute toxicity:

Route of exposure:	Method	Species	Dose LD <sub>50</sub> /LC <sub>50</sub>	Exposure time	Results
Oral exposure:	No information available	mouse	LD <sub>50</sub>	No information available	480 mg/kg
Dermal exposure:	No information available	mouse	LD <sub>50</sub>	No information available	300 mg/kg
Inhalation exposure:	No information available	No information available	No information available	No information available	-

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

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

Aspiration hazard: No information available

Irritation and corrosion

	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation:	No information available	No information available	-	No information available	No information available
Serious eye damage/irritation	No information available	No information available	-	No information available	No information available



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Sensitization						
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Dermal exposure:	No information available					
Inhalation exposure:	No information available					

Symptoms related to the physical, chemical and toxicological characteristics						
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Oral exposure:	Harmful if swallowed.					
Dermal exposure:	Harmful by inhalation and in contact with skin.					
Inhalation exposure:	Harmful if swallowed.					
Eye exposure:	Risk of serious damage to eyes.					

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	-

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Specific target organ toxicity – repeated exposure (STOT RE):			
	Specific effects	Target organ	Note
Subacute oral	No information available	No information available	-
Subacute dermal	No information available	No information available	-
Subacute inhalation	No information available	No information available	-
Subchronic oral	No information available	No information available	-
Subchronic dermal	No information available	No information available	-
Subchronic inhalation	No information available	No information available	-
Chronic oral	No information available	No information available	-
Chronic dermal	No information available	No information available	-
Chronic inhalation	No information available	No information available	-
CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)			
Carcinogenicity:		Suspected of causing cancer.	
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	
<b>11.2. Information on other hazards:</b>			
<b>11.2.1. Endocrine disrupting properties:</b>			
The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated			

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	regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
11.2.2.	Other information:
	-

<b>SECTION 12. Ecological information</b>						
<b>12.1. Toxicity</b>						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	No information available	No information available	No information available	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC <sub>50</sub>	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	No information available	No information available	No information available	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC <sub>50</sub>	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-
<b>12.2. Persistence and degradability</b>						
<b>Abiotic degradation</b>						
	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	-		
<b>Biodegradation</b>						
% Degradation	Time (days)	Method	Evaluation	Note		
No information available	No information available	No information available	No information available	-		

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**12.3. Bioaccumulative potential**

Partition coefficient: n-octanol/water (log Kow):

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

Chronic ecotoxicity

Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC <sub>50</sub>	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea (Daphnia)	EC <sub>50</sub>	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

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

12.5.	Results of PBT and vPvB assessment
	No information available
12.6.	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 information available

<b>SECTION 13. Disposal considerations</b>	
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:
	No information available
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. Do not dispose of in places where ignition may occur.

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13.1.6.	Relevant Community provisions:
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<b>SECTION 14. Transport information</b>
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Transporting/shipment by road (ADR)	
UN number:	2811
UN proper shipping name:	Toxic solid, organic, n.o.s. (4,4'-carbonimidoylbis (N, N-dimethylaniline) monohydrochloride)
Transport hazard class(es):	6.1
Packing group:	III
Environmental hazard(s):	-
Special precautions for user:	-
Transporting/shipment by rail (RID)	
UN number:	2811
UN proper shipping name:	Toxic solid, organic, n.o.s. (4,4'-carbonimidoylbis (N, N-dimethylaniline) monohydrochloride)
Transport hazard class(es):	6.1
Packing group:	III
Environmental hazard(s):	-
Special precautions for user:	-
Transporting/shipment by inland waterways (ADN)	
UN number:	2811
UN proper shipping name:	Toxic solid, organic, n.o.s. (4,4'-carbonimidoylbis (N, N-dimethylaniline) monohydrochloride)
Transport hazard class(es):	6.1
Packing group:	III
Environmental hazard(s):	-
Special precautions for user:	-
Transporting/shipment by sea (IMDG)	
UN number:	2811
UN proper shipping name:	Toxic solid, organic, n.o.s. (4,4'-carbonimidoylbis (N, N-dimethylaniline) monohydrochloride)
Transport hazard class(es):	6.1
Packing group:	III
Environmental hazard(s):	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-

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Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	2811
UN proper shipping name:	Toxic solid, organic, n.o.s. (4,4'-carbonimidoylbis (N, N-dimethylaniline) monohydrochloride)
Transport hazard class(es):	6.1
Packing group:	III
Environmental hazard(s):	-
Special precautions for user:	-
Further information:	-

<b>SECTION 15. Regulatory information</b>	
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>
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

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None
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**SECTION 16. Other information**

16.1.	Indication of changes:	-
16.2.	Abbreviations and acronyms:	<p>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p> <p>IATA: International Air Transport Association</p> <p>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</p> <p>EINECS: European Inventory of Existing Commercial Chemical Substances</p> <p>CAS: Chemical Abstracts Service (division of the American Chemical Society)</p> <p>DNEL: Derived No-Effect Level (UK REACH)</p> <p>LC50: Lethal concentration, 50 percent</p> <p>LD50: Lethal dose, 50 percent</p> <p>PBT: Persistent, Bioaccumulative and Toxic</p> <p>vPvB: very Persistent and very Bioaccumulative</p>
16.3.	Key literature references and source of data:	-
16.4.	Relevant H statements (number and full text)	
	302	Harmful if swallowed.
H:	311	Harmful in contact with skin.
	351	Suspected of causing cancer.
16.5.	Training advice:	-
16.6.	Further information:	<p>** "X" in the product code marks different volumes (different packagings 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>

<b>ANNEX:</b>
<b>EXPOSURE SCENARIO RESULTING TO CHEMICAL SAFETY ASSESSMENT</b>
-