

Trade name:	<b>SUDAN BLACK B, SOLUTION</b>		
Product code:	SBO-OT-X**	Date of compilation:	14 November 2022
		Version:	4

<b>SECTION 1. Identification of the substance/mixture and of the company/undertaking</b>	
1.1.	Product identifier
	Trade name: SUDAN BLACK B, SOLUTION
	Chemical name: -
	Catalogue number: SBO-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against
	Uses: For staining lipids, used with Sudan Black B lipid kit.
	Uses advised against: Only the identified uses are advised.
	Reason why uses advised against: The product is intended for use only as an <i>in vitro</i> diagnostic medical device and there is no reason to use it for other purposes.
1.3.	Details of the supplier of the safety data sheet
	Supplier: BioGnost Ltd.
	Address: Medjugorska 59, Zagreb
	Telephone number: +385 1 2409997
	Telefax: +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: -

<b>SECTION 2. Hazards identification</b>	
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*:
	Not identified as hazardous substance. -
2.1.2.	Additional information
	-
* For full text of Hazard- and EU Hazard-statements: see SECTION 16	
2.2.	Label elements
	Product identification: SUDAN BLACK B, SOLUTION
	Identification number: -
	Authorisation number: -
	Hazard pictograms: -

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Signal word:	-
Hazard statement:	-
Precautionary statements:	-
Supplemental hazard information (EU)	-

2.3.	Other hazards
<b>Endocrine Disrupting Properties:</b>	
No known endocrine disrupting properties.	

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)
-	-	-	Contains no hazardous substances	-

SECTION 4. First aid measures	
4.1.	Description of first aid measures
General notes:	-
Following inhalation:	Remove person to fresh air. If breathing stops, immediately apply artificial respiration. If breathing difficulties occur, use emergency breathing apparatus. If the symptoms persist, immediately consult a physician.
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:	No information available
Following skin contact:	No information available
Following eye contact:	No information available
Following ingestion:	No information available
4.3.	Indication of any immediate medical attention and special treatment needed

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	No information available
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<b>SECTION 5. Firefighting measures</b>	
5.1.	Extinguishing media
	Suitable extinguishing media: Water, CO <sub>2</sub> , foam, dry powder
	Unsuitable extinguishing media: No information available
5.2.	Special hazards arising from the substance or mixture
	Hazardous combustion products: No information available.
5.3.	Advice for firefighters
	Firefighters must always use fireproof suit and self-sustaining breathing apparatus with open circle that contains pressurized air in case of fire in closed space.
5.4.	Additional information
	Prevent spills and water used for putting out fire from contaminating waterways by enclosing and covering drains.

<b>SECTION 6. Accidental release measures</b>	
6.1.	Personal precautions, protective equipment and emergency procedures
6.1.1.	For non-emergency personnel
	Protective equipment: Use protective equipment in accordance with Section 8. Do not get in eyes or on skin. Do not inhale vapor/aerosols. Remove the persons not directly involved in rescuing procedure from the scene of event.
	Accident prevention methods: Keep away from heat, flames and sparks. Secure proper ventilation. Prevent electrostatic charge buildup. Use only grounded devices and equipment. Do not release in drains - explosion hazard.
	Emergency procedures: In case of accident secure the location and evacuate the personnel not involved in recovery.
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

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6.3.1.	Bunding, covering of drains; capping procedures:	Sand bags.
6.3.2.	Cleaning up:	Where possible, soak up the product using inert matter, such as sand, silica gel, saw dust). 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:	Recovery of contaminated area should only be conducted by qualified person that uses stipulated protective equipment. Prevent the waste water from entering waterways.
6.4.	Reference to other sections	
	See Section 7 for information about secure handling. See Section 8 for information about personal protective equipment. See Section 13 for information about containment.	

<b>SECTION 7. Handling and storage</b>		
7.1.	Precautions for safe handling	
7.1.1.	Protective measures	
	Measures to prevent fire:	Keep away from heat, flames and sparks. Secure proper ventilation.
	Measures to prevent aerosol and dust generation:	Adequate ventilation of the rooms where the product is kept and handled. Containers must be firmly closed.
	Measures to protect the environment:	Keep the containers firmly closed in vertical position when the product is not used. Prevent the product from entering waterways, sewerage and drainage systems by using barrage and semi-barrage made of sand, as well as covering the drainage by using plastic foil.
	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:	In dry, cold and well-ventilated space. Containers must be firmly closed. Maintain adequate ventilation of the rooms where the product is kept and handled.
	Packaging materials:	Manufacturer's original packaging.

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Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
Advices for storage equipment:	Keep away from heat, flames, sparks and sunlight.
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).
<b>7.3. Specific end use(s)</b>	
Recommendations:	Secure stations for rinsing eyes and showering in the vicinity of work area.
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**

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Environmental protection target	PNEC
Fresh water	No information available
Freshwater sediments	No information available
Marine water	No information available
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

<b>8.2.</b>	<b>Exposure controls</b>	
<b>8.2.1.</b>	<b>Appropriate engineering controls</b>	
	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.
<b>8.2.2.</b>	<b>Personal protection equipment</b>	
<b>8.2.2.1.</b>	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.
<b>8.2.2.2.</b>	<b>Skin protection</b>	
	Hand protection:	Protective gloves must be according to the EU Directive 2016/425/EEC and standard EN 374. Glove material: nitrile rubber Glove thickness: $\geq 0.50$ mm Break through time: >480 min
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 13034), and shoes that cover the entire foot (EN 10335).
<b>8.2.2.3.</b>	Respiratory protection:	Suitable mask or half mask equipped with a combined "A-P" filter and used when concentration levels exceed GVI.
<b>8.2.2.4.</b>	Thermal hazards:	No information available
<b>8.2.3.</b>	<b>Environmental exposure controls</b>	

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	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

<b>SECTION 9. Physical and chemical properties</b>			
9.1.	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	liquid	No information available
	Colour:	black	No information available
	Odour/odour threshold:	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
	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		
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<b>SECTION 10.: Stability and reactivity</b>
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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.
10.3.	Possibility of hazardous reactions:	No information available.
10.4.	Conditions to avoid:	No information available.
10.5.	Incompatible materials:	No information available.
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	Effective dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixture</sub>	Exposure time	Results
Oral:	No information available	-	No information available	No information available	-
Dermal:	No information available	-	No information available	No information available	-
Inhalation:	No information available	-	No information available	No information available	-

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:

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Irritation and corrosion

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



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Sensitization						
Dermal exposure:	No information available					
Inhalation exposure:	No information available					
Symptoms related to the physical, chemical and toxicological characteristics						
Oral exposure:	No information available					
Dermal exposure:	No information available					
Inhalation exposure:	No information available					
Eye exposure:	No information available					
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	-

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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:	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	

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Summary of evaluation of the CMR properties:	No information available					
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11.2.	Information on other hazards:					
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11.2.1.	Endocrine disrupting properties:					
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	No known endocrine disrupting properties that affect human health.					
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11.2.2.	Other informations:					
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<b>SECTION 12. General notes:</b>						
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12.1.	Toxicity					
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Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	No information available	-	No information available	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	-	No information available	-
Algae/aquatic plants	IC <sub>50</sub>	72 hours	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	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	-	No information available	-
Algae/aquatic plants	IC <sub>50</sub>	72 hours	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 partition coefficient (log K <sub>ow</sub> )					
Value	Concentration	pH	°C	Method	Evaluation	Note

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

<b>12.4. Mobility in soil</b>						
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	

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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
	No known endocrine disrupting properties that affect the environment.

12.7.	Other adverse effects
	No information available

<b>SECTION 13. Disposal considerations</b>
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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 Low:
	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:
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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.

13.1.6.	Relevant Community provisions:
	Sustainable Waste Management Act, Ordinance on Waste Management, Regulation on categories, types and classification of waste with waste catalog and list of hazardous waste

**SECTION 14. Transport information**

	Transporting/shipment by road (ADR)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
	Transporting/shipment by rail (RID)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
	Transporting/shipment by inland waterways (ADN)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
	Transporting/shipment by sea (IMDG)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	Not subject to transport regulations

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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:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
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	
Authorisations and/or restrictions of use	
Authorisations:	-
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)	

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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, Transport of Hazardous Substances Act
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15.2.	Chemical safety assessment
	None

**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.	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: -	-
16.6.	Training advice:	-
16.7.	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>
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