

Trading name:	BIOWAX BLUE		
Product code:	BWB-X**	Date of compilation:	14 November 2022
		Version:	5

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1.	Product identifier	
	Trading name:	BIOWAX BLUE
	Chemical name:	-
	Catalogue number:	BWB-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Blend of blue paraffin waxes with low melting point at 56/58°C and added plastic polymers for optimal infiltration.
	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:	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*:
	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:	BIOWAX BLUE
	Identification number:	-

Trading name:	BIOWAX BLUE				
Product code:	BWB-X**	Date of compilation:	14 November 2022	Version:	5

Authorization no.:	-
Hazard pictograms:	-
Signal word:	-
Hazard statements:	-
Precautionary statements:	-
Supplemental hazard information (EU):	-

2.3. Other hazards

Endocrine Disrupting Properties:
 No known endocrine disrupting properties.
 PBT: This product is not identified as a PBT/vPvB Substance according to REACH Annex XIII.

SECTION 3. Composition/information on ingredients

CAS/EC/ Index no.	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
8002-74-2/ 232-315-6/ -	01- 02119488076- 30	90-100 %	paraffin wax	-
9003-27-4/ 618-360-8/ -	-	< 1	polymer	-
14233-37-5/ 238-101-9/ -	-	< 1	Solvent Blue 36	

SECTION 4. First aid measures

4.1.	Description of first aid measures	
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 stops, immediately apply artificial respiration (other than mouth-to-mouth) and contact a physician.	
Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water and soap. 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.	

Trading name:	BIOWAX BLUE				
Product code:	BWB-X**	Date of compilation:	14 November 2022	Version:	5

	Following ingestion:	Do not induce vomiting. Make the afflicted person drink a glass of water. If spontaneous vomiting occurs, wash the mouth with water, then make the person drink 100-200 ml of water and seek medical attention.
	Self-protection of the first aider:	Treat symptomatically.
4.2.	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	High concentration of vapours may induce: Headache, nausea, dizziness. Irritant effect to the respiratory tract.
	Following skin contact:	May cause slight irritation to the skin. Heated product may cause burns.
	Following eye contact:	May cause slight irritation to eyes.
	Following ingestion:	May cause nausea.
4.3.	Indication of any immediate medical attention and special treatment needed	
	In contact with or splashed by melted product, quickly cool area with water.	

SECTION 5. Firefighting measures

5.1.	Extinguishing media	
	Suitable extinguishing media:	Foam, dry chemical powder, CO ₂
	Unsuitable extinguishing media:	water
5.2.	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Slight flammability hazard when exposed to heat or flame. During a fire, toxic gases (carbon monoxide, nitrous gases) may be generated by thermal decomposition or combustion.
5.3.	Advice for firefighters	
	Only suitably trained personnel should attempt to tackle fires. Breathing apparatus and protective clothing should be worn. Do not remain in the immediate vicinity without respiratory protective equipment and protective clothing.	
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).

Trading name:	BIOWAX BLUE				
Product code:	BWB-X**	Date of compilation:	14 November 2022	Version:	5

	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Remove all sources of sparks and ignition. Do not smoke.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
		Wear suitable protective clothing and breathing apparatus. See section 8. Stop leak if safe to do so. Remove sources of ignition
6.2.	Environmental precautions:	
		Water may be used to flush spills away from sources of ignition. Prevent spreading by damming. Do not allow the product to enter public drainage system or open water course. Avoid release to the environment.
6.3.	Methods and material for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Stop leak if safe to do so. Use damming system to prevent spreading.
6.3.2.	Cleaning up:	Use sand or active clay to absorb spilled substance and remove to containers for disposal. When in liquid state, cool and allow to solidify.
6.3.3.	Other information:	-
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.

SECTION 7. Handling and storage		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Keep away from sources of heat and ignition. 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:	-
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, and away from sources of heat, sunlight, and other incompatible substances.

Trading name:	BIOWAX BLUE				
Product code:	BWB-X**	Date of compilation:	14 November 2022	Version:	5

Packaging materials:	Manufacturer's original packaging.
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 9).
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	
Paraffin wax, smoke	8002-74-2	-/-	2/6	No information available

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

Trading name:	BIOWAX BLUE				
Product code:	BWB-X**	Date of compilation:	14 November 2022	Version:	5

Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

PNEC

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

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 (preventing splashing) (EN 166) or visor.
8.2.2.2. Skin protection	
Hand protection:	Protective gloves must be according to the EU Directive 2016/425/EEC and standard EN 374. Glove material: nitrile rubber Glove thickness: ≥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).

Trading name:	BIOWAX BLUE		
Product code:	BWB-X**	Date of compilation:	14 November 2022
		Version:	5

8.2.2.3.	Respiratory protection:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) according to EN 14387) used when concentration levels exceed GVI.
8.2.2.4.	Thermal hazards:	No information available
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

SECTION 9. Physical and chemical properties

9.1.	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	solid (pellets)	No information available
	Color:	blue	No information available
	Odour/odour threshold:	no odor/no information available	No information available
	Melting point / freezing point:	56 – 58 °C	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	245 °C	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	204°C	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

Trading name:	BIOWAX BLUE				
Product code:	BWB-X**	Date of compilation:	14 November 2022	Version:	5

	Particle characteristics:	No information available	No information available
9.2.	Other information		
	-		

SECTION 10.: Stability and reactivity		
10.1.	Reactivity:	See subsections 10.3 through 10.5.
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.
10.3.	Possibility of hazardous reactions:	No information available.
10.4.	Conditions to avoid:	Extremes of temperature (preferably, store between 5 and 39°C). The product is combustible when heated >300°C.
10.5.	Incompatible materials:	May react with strong oxidants (e.g. chlorates, peroxides) and reducing agents.
10.6.	Hazardous decomposition products:	Thermal decomposition or incomplete combustion may produce carbon monoxide, nitrous gases and irritating fumes.

SECTION 11. Toxicological information					
11.1.	Information on hazard classes as defined in Regulation (EC) No 1272/2008				
	Acute toxicity:				
Route of exposure:	Method	Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral exposure:	No information available	-	LD ₅₀	-	-
Dermal exposure:	No information available	-	LD ₅₀	-	-
Inhalation exposure:	No information available	-	LC ₅₀	-	-
	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:				

Trading name:	BIOWAX BLUE				
Product code:	BWB-X**	Date of compilation:	14 November 2022	Version:	5

	Exposure time	Species	Evaluation	Method	Note
Skin irritation:	-	-	-	-	-
Eye irritation:	-	-	-	-	-

Sensitization

Dermal exposure: No information available

Inhalation exposure: No information available

Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure: Diarrhoea, gastrointestinal complaints

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	-

Trading name:	BIOWAX BLUE				
Product code:	BWB-X**	Date of compilation:	14 November 2022	Version:	5

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):					
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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	-

	CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)					
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Carcinogenicity:	Current studies on test animals did not indicate carcinogenic effects.					
Mutagenicity <i>in-vitro</i> :	Current <i>in vitro</i> tests did not indicate mutagenic effects.					
Genotoxicity:	No information available					
Mutagenicity <i>in-vivo</i> :	Current <i>in vivo</i> tests did not indicate mutagenic effects.					
Germ cell mutagenicity:	No information available					
Reproductive toxicity:	No toxicity on reproductive organs was determined in reproductive organs.					

	Summary of evaluation of the CMR properties: -					
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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 information:					
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Trading name:	BIOWAX BLUE				
Product code:	BWB-X**	Date of compilation:	14 November 2022	Version:	5

SECTION 12. Ecological information

12.1. Toxicity

Acute toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	-	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	-	-
Algae/aquatic plants	IC ₅₀	8 days	No information available	No information available	-	-
Microorganisms	LC ₅₀	72 hours	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

12.2. Persistence and degradability

Abiotic degradation

	Degradation half-lives	Method	Evaluation	Note
Marine water	No information available	No information available	No information available	-
Fresh water	No information available	No information available	No information available	-
Air	No information available	No information available	No information available	-
Soil	No information available	No information available	No information available	-

Trading name:	BIOWAX BLUE			
Product code:	BWB-X**	Date of compilation:	14 November 2022	Version: 5

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 Kow)						
Value	Concentration	pH	°C	Method	Evaluation	Note
-	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 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:	

Trading name:	BIOWAX BLUE				
Product code:	BWB-X**	Date of compilation:	14 November 2022	Version:	5

	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

Not identified as a PBT/ vPvB Substance according to REACH Annex XIII.

12.6. Endocrine disrupting properties

No known endocrine disrupting properties that affect the environment.

12.7. Other adverse effects

No adverse effects are expected.

SECTION 13. Disposal considerations

13.1. Waste treatment methods

13.1.1. Product/Packaging disposal:

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

Trading name:	BIOWAX BLUE				
Product code:	BWB-X**	Date of compilation:	14 November 2022	Version:	5

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.
13.1.6.	Relevant Community provisions:
	-

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:	-
Environmentally hazardous:	-
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:	-
Environmentally hazardous:	-
Special precautions for user:	-
	Inland waterway transport (ADN)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-

Trading name:	BIOWAX BLUE				
Product code:	BWB-X**	Date of compilation:	14 November 2022	Version:	5

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:	-
Environmentally hazardous:	-
Special precautions for user:	-
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:	-
Environmentally hazardous:	-
Special precautions for user:	-
Further information:	The product is not subject to classification.

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: -

Trading name:	BIOWAX BLUE				
Product code:	BWB-X**	Date of compilation:	14 November 2022	Version:	5

Other regulations:	EU	<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, Ordinance on writing Material safety data sheet, 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)											
	H:	-										

Trading name:	BIOWAX BLUE		
Product code:	BWB-X**	Date of compilation:	14 November 2022
		Version:	5

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>

ANNEX: Exposure scenario resulting to Chemical safety assessment	
-	