




Trade name:	BIO-DIFF 1 REAGENT				
Product code:	BD1-OT-X**	Date of compilation:	03.04.2023.	Version:	6

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1.	Product identifier	
	Trade name:	BIO-DIFF 1 REAGENT
	Chemical name:	-
	Catalogue number:	BD1-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Fixative agent, component of Bio-Diff 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, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.
1.3.	Details of the supplier of the safety data sheet	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Telefax:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	
1.4.	Emergency telephone numbers	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2. Hazards identification		
2.1.	Classification of the substance or mixture	
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statement*:
	Flam. Liq. 2	H225
	Acute Tox. 3	H301
	Acute Tox. 3	H311
	Acute Tox. 3	H331
	STOT SE 1	H370
2.1.2.	Additional information	
	-	
* For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2.	Label elements	

Trade name:	BIO-DIFF 1 REAGENT				
Product code:	BD1-OT-X**	Date of compilation:	03.04.2023.	Version:	6

Product identification:	BIO-DIFF 1 REAGENT
Identification number:	-
Authorisation number:	-
Hazard pictograms:	 <p>GHS02</p>  <p>GHS06</p>  <p>GHS08</p>
Signal word:	Danger
Hazard statements:	<p>H225 Highly flammable liquid and vapor.</p> <p>H301+H311+H331 Toxic if swallowed, in contact with skin or if inhaled.</p> <p>H370 Causes damage to organs (eyes).</p>
Precautionary statements:	<p>P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.</p> <p>P233 Keep container tightly closed.</p> <p>P280 Wear protective gloves, protective clothing, eye protection, face protection.</p> <p>P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.</p> <p>P302+P352 IF ON SKIN: Wash with plenty of soap and water.</p> <p>P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.</p> <p>P308+P311 IF exposed or concerned: Call a POISON CENTER or doctor.</p>
Supplemental hazard information (EU):	-

2.3. Other hazards

Endocrine Disrupting Properties:
 No known endocrine disrupting properties

Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.

Trade name:	BIO-DIFF 1 REAGENT				
Product code:	BD1-OT-X**	Date of compilation:	03.04.2023.	Version:	6

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)
67-56-1/ 200-659-6/ 603-001-00-X	01-2119433307- 44-xxxx	99 %	methanol	Flam. Liq. 2, H225 Acute Tox. 3, H301 Acute Tox. 3, H311 Acute Tox. 3, H331 STOT SE 1, H370

SECTION 4. First aid measures													
4.1.	Description of first aid measures												
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">General notes:</td> <td>First aider needs to protect himself.</td> </tr> <tr> <td>Following inhalation:</td> <td>Carry the afflicted person out for fresh air, place them in half lying position and calm them down. If breathing stops, immediately apply artificial respiration, if necessary also oxygen. In case of irregular breathing or respiratory arrest provide artificial respiration.</td> </tr> <tr> <td>Following skin contact:</td> <td>Remove contaminated clothing. Wash with plenty of water and soap for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.</td> </tr> <tr> <td>Following eye contact:</td> <td>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.</td> </tr> <tr> <td>Following ingestion:</td> <td>Rinse with water and expectorate. Make the afflicted person drink one glass (100 ml) of 40% ethanol (adult dose). Call a doctor immediately (mention methanol ingestion). Only in exceptional cases, if no medical care is available within one hour, induce vomiting (only in fully conscious persons) and make victim drink ethanol again (approx. 0.3 ml of a 40% alcoholic beverage/kg body weight/hour). Do not attempt to neutralise.</td> </tr> <tr> <td>Self-protection of the first aider</td> <td>Avoid direct contact with the chemical; use appropriate protective equipment described in Section 8.</td> </tr> </table>	General notes:	First aider needs to protect himself.	Following inhalation:	Carry the afflicted person out for fresh air, place them in half lying position and calm them down. If breathing stops, immediately apply artificial respiration, if necessary also oxygen. In case of irregular breathing or respiratory arrest provide artificial respiration.	Following skin contact:	Remove contaminated clothing. Wash with plenty of water and soap 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 with water and expectorate. Make the afflicted person drink one glass (100 ml) of 40% ethanol (adult dose). Call a doctor immediately (mention methanol ingestion). Only in exceptional cases, if no medical care is available within one hour, induce vomiting (only in fully conscious persons) and make victim drink ethanol again (approx. 0.3 ml of a 40% alcoholic beverage/kg body weight/hour). Do not attempt to neutralise.	Self-protection of the first aider	Avoid direct contact with the chemical; use appropriate protective equipment described in Section 8.
General notes:	First aider needs to protect himself.												
Following inhalation:	Carry the afflicted person out for fresh air, place them in half lying position and calm them down. If breathing stops, immediately apply artificial respiration, if necessary also oxygen. In case of irregular breathing or respiratory arrest provide artificial respiration.												
Following skin contact:	Remove contaminated clothing. Wash with plenty of water and soap 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 with water and expectorate. Make the afflicted person drink one glass (100 ml) of 40% ethanol (adult dose). Call a doctor immediately (mention methanol ingestion). Only in exceptional cases, if no medical care is available within one hour, induce vomiting (only in fully conscious persons) and make victim drink ethanol again (approx. 0.3 ml of a 40% alcoholic beverage/kg body weight/hour). Do not attempt to neutralise.												
Self-protection of the first aider	Avoid direct contact with the chemical; use appropriate protective equipment described in Section 8.												
4.2.	Most important symptoms and effects, both acute and delayed												
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">Following inhalation:</td> <td>Irritation to the airways and possible damage to the lung probably only through very high vapor concentrations, then even absorptive-toxic effects.</td> </tr> <tr> <td>Following skin contact:</td> <td>Minor/no irritation, degreasing action, following massive contact watch for danger of skin absorption and possibly delayed onset of systemic effects.</td> </tr> <tr> <td>Following eye contact:</td> <td>Slight through to moderate irritation due to the liquid and concentrated vapors, conjunctivitis, later chemosis, apparently minor probability of cornea damage, later occurring visual disturbances are caused not primarily through local contact but are systemically related (following absorption).</td> </tr> <tr> <td>Following ingestion:</td> <td>Stomach and bowel irritation, feeling unwell, nausea, vomiting, strong abdominal pain. Absorption may cause toxic effects.</td> </tr> </table>	Following inhalation:	Irritation to the airways and possible damage to the lung probably only through very high vapor concentrations, then even absorptive-toxic effects.	Following skin contact:	Minor/no irritation, degreasing action, following massive contact watch for danger of skin absorption and possibly delayed onset of systemic effects.	Following eye contact:	Slight through to moderate irritation due to the liquid and concentrated vapors, conjunctivitis, later chemosis, apparently minor probability of cornea damage, later occurring visual disturbances are caused not primarily through local contact but are systemically related (following absorption).	Following ingestion:	Stomach and bowel irritation, feeling unwell, nausea, vomiting, strong abdominal pain. Absorption may cause toxic effects.				
Following inhalation:	Irritation to the airways and possible damage to the lung probably only through very high vapor concentrations, then even absorptive-toxic effects.												
Following skin contact:	Minor/no irritation, degreasing action, following massive contact watch for danger of skin absorption and possibly delayed onset of systemic effects.												
Following eye contact:	Slight through to moderate irritation due to the liquid and concentrated vapors, conjunctivitis, later chemosis, apparently minor probability of cornea damage, later occurring visual disturbances are caused not primarily through local contact but are systemically related (following absorption).												
Following ingestion:	Stomach and bowel irritation, feeling unwell, nausea, vomiting, strong abdominal pain. Absorption may cause toxic effects.												

Trade name:	BIO-DIFF 1 REAGENT				
Product code:	BD1-OT-X**	Date of compilation:	03.04.2023.	Version:	6

4.3.	Indication of any immediate medical attention and special treatment needed
	-

SECTION 5. Firefighting measures	
5.1.	Extinguishing media
	Suitable extinguishing media: water spray, foam, dry powder, CO ₂
	Unsuitable extinguishing media: No information available
5.2.	Special hazards arising from the substance or mixture
	Hazardous by products of fire: Combustible. Vapours are heavier than air and may spread along floors. Forms explosive mixtures with air at ambient temperatures. Development of hazardous combustion gases or vapours possible in the event of fire.
5.3.	Advice for firefighters
	Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.
5.4.	Additional information
	Remove container from danger zone and cool with water. Prevent fire extinguishing water from contaminating surface water or the ground water system.

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: Do not breathe vapours, aerosols. Avoid substance contact. Ensure adequate ventilation. Keep away from heat and sources of ignition. Evacuate the danger area, observe emergency procedures, consult an expert.s
	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 let product enter drains. Risk of explosion.
6.3.	Methods and materials for containment and cleaning up
6.3.1.	Bunding, covering of drains; capping procedures: Cover drains. Collect, bind and pump off spills.

Trade name:	BIO-DIFF 1 REAGENT				
Product code:	BD1-OT-X**	Date of compilation:	03.04.2023.	Version:	6

6.3.2.	For cleaning:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and involved materials with water.
6.3.3.	Other information:	Do not use tools that may cause sparks.
6.4.	Reference to other sections	
	See Section 7 for information on safe handling. See Section 8 for information on personal protective equipment. See Section 13 for disposal information.	

SECTION 7. Handling and storage		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures for fire prevention:	Use in well ventilated storage rooms. Keep away from sources of heat and ignition and direct sunlight. Do not smoke. Take precautionary measures against static discharge.
	Measures for preventing spray and dust formation:	Secure proper ventilation. Prevent formation of aerosols.
	Environmental precautions:	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 in a well ventilated storage rooms, and away from sources of heat, sunlight, and other incompatible substances.
	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.

Trade name:	BIO-DIFF 1 REAGENT				
Product code:	BD1-OT-X**	Date of compilation:	03.04.2023.	Version:	6

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

Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
Methanol	67-56-1	200	260	24.7 mmol/mol of creatinine* (7.0 mg/g of creatinine*), end-of-shift urinary excretion

* For all results pertaining creatinine levels, creatinine concentration < 0.5 g/l and > 3.0 g/l may not be taken into consideration

Substance: -

EC No: - CAS No: -

DNEL

Industrial

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	260 mg/m ³ (methanol)	260 mg/m ³ (methanol)	260 mg/m ³ (methanol)	260 mg/m ³ (methanol)
Dermal	-	40 mg/kg (methanol)		40 mg/kg (methanol)

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	8 mg/kg (methanol)	-	8 mg/kg (methanol)
Inhalation	50 mg/m ³ (methanol)	50 mg/m ³ (methanol)	50 mg/m ³ (methanol)	50 mg/m ³ (methanol)
Dermal	-	8 mg/kg (methanol)		8 mg/kg (methanol)

PNEC

Trade name:	BIO-DIFF 1 REAGENT				
Product code:	BD1-OT-X**	Date of compilation:	03.04.2023.	Version:	6

Environmental protection target	PNEC
Fresh water	154 mg/l (methanol)
Freshwater sediments	570.4 mg/kg (methanol)
Marine water	15.4 mg/l (methanol)
Marine sediments	No information available
Food chain	No information available
Microorganisms in sewage treatment	100 mg/l (methanol)
Soil (agricultural)	23.5 mg/kg (methanol)
Air	No information available

8.2. Exposure controls

8.2.1. Appropriate engineering measures

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:	Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as EN 166(EU).
-----------------------------------	---

8.2.2.2. Skin protection:

Hand protection:	<p>The protective gloves to be used must comply with the specification of EC Directive 2016/425 and the related standard EN374.</p> <p>Full contact:</p> <ul style="list-style-type: none"> Glove material: butyl rubber Glove thickness: 0.70 mm Break through time: > 480 min <p>Splash contact:</p> <ul style="list-style-type: none"> Gloves material: viton (R) Glove thickness: 0.70 mm Break through time: > 120 min
------------------	---

Trade name:	BIO-DIFF 1 REAGENT				
Product code:	BD1-OT-X**	Date of compilation:	03.04.2023.	Version:	6

	Other skin protection:	Complete antistatic suit protecting against chemicals (EN 13688). The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace and shoes that cover the entire foot.
8.2.2.3.	Respiratory protection:	Required when vapours/aerosols are generated. Recommended filter type: gas filter AX, colour code brown (EN 371). The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer.
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. Do not let product enter drains. Risk of explosion.
	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:	colourless	No information available
	Odour/odour threshold:	methanol like/no information available	No information available
	Melting point / freezing point:	-98 °C	No information available
	Boiling point or initial boiling point and boiling range:	65 °C (at 1.013 hPa)	No information available
	Flammability:	No information available	No information available
	Lover and upper explosion limit:	lower: 6 % (V) methanol upper: 36.5 % (V) methanol	No information available
	Flash point:	12 °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

Trade name:	BIO-DIFF 1 REAGENT				
Product code:	BD1-OT-X**	Date of compilation:	03.04.2023.	Version:	6

Solubility:	No information available	No information available
Partition coefficient n-octanol/water (log value):	No information available	No information available
Vapour pressure:	128 hPa (20 °C)	No information available
Density and/or relative density	0.79 (20 °C)	No information available
Relative vapour density:	No information available	No information available
Particle characteristics:	No information available	No information available
9.2.	Other information	
	Ignition temperature: 455 °C	

SECTION 10.: Stability and reactivity		
10.1.	Reactivity:	Vapours may form explosive mixture with air.
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: Oxidizing agents, alkali metals, nitric acid, sulphuric acid, hydrogen peroxide, permanganic acid, sodium hypochlorite. The substance can react dangerously with: halogens, oxidizing agents, reducing agents, acids, acetyl bromide, alkylaluminium solutions, beryllium hydride, chloroform, chromium (VI)-oxide, cyanuric chloride, alkaline-earth metals, magnesium splinters, phosphorus trioxide, Raney-nickel/hydrogenation, acid anhydrides, acid halogenides, tetrachloromethane/light metals.
10.4.	Conditions to avoid:	Sources of heat, sparks, and ignition.
10.5.	Incompatible materials:	Various plastics, magnesium, zinc alloys, aluminium and galvanised iron.
10.6.	Hazardous decomposition products:	No information available.

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:	No information available	rat	LD ₅₀	-	125.13 mg/kg (methanol)
Dermal:	No information available	rabbit	LD ₅₀	-	375.13 mg/kg (methanol)

Trade name:	BIO-DIFF 1 REAGENT				
Product code:	BD1-OT-X**	Date of compilation:	03.04.2023.	Version:	6

Inhalation:	No information available	rat	LC ₅₀	4 h	3.88 mg/l (methanol)
-------------	--------------------------	-----	------------------	-----	-------------------------

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	Eyes	mixture causes damage to organs

Aspiration hazard:	No information available
--------------------	--------------------------

Irritation and corrosion					
--------------------------	--	--	--	--	--

	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation	-	-	-	-	drying-out effect resulting in rough and chapped skin
Serious eye damage/irritation	-	-	-	-	irritations of mucous membranes

Sensitization					
---------------	--	--	--	--	--

Skin sensitization:	Does not cause sensitization.
Respiratory sensitization:	No information available

Symptoms related to the physical, chemical and toxicological characteristics:					
---	--	--	--	--	--

Oral exposure:	Stomach and bowel irritation, acidosis, drop in blood pressure, feeling unwell, vomiting, strong abdominal pain. Absorption may cause toxic effects. Damage to liver, kidney, cardiac.
Dermal exposure:	Minimum level of irritation, defatting; prolonged exposure may cause absorption and greater possibility of delayed systemic effects.
Inhalation exposure:	Airways irritation and possible lung damage due to high levels of vapor concentration, dizziness, drowsiness, headache. Absorption may cause toxic effects.
Eye exposure:	Mild to moderate irritation due to vapor, conjunctivitis, later chemosis, lesser possibility of cornea damage, blindness, irreversible damage of the optical nerve. Visual impairments may occur later, after the absorption.

Repeated dose toxicity (subacute, subchronic, chronic)					
--	--	--	--	--	--

	Dose	Exposure time	Species	Method	Evaluation	Note
--	------	---------------	---------	--------	------------	------

Trade name:	BIO-DIFF 1 REAGENT				
Product code:	BD1-OT-X**	Date of compilation:	03.04.2023.	Version:	6

Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-

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

	Specific effects	Target organ	Note
Subacute oral	No information available	No information available	-
Subacute dermal	No information available	No information available	-
Subacute 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	-

Trade name:	BIO-DIFF 1 REAGENT				
Product code:	BD1-OT-X**	Date of compilation:	03.04.2023.	Version:	6

CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)	
Carcinogenicity:	No information available
Mutagenicity <i>in-vitro</i> :	No information available
Genotoxicity:	No information available
Mutagenicity <i>in-vivo</i> :	No information available
Germ cell mutagenicity:	No information available
Reproductive toxicity:	No information available
Summary of evaluation of the CMR properties:	No information available
11.2. Information on other hazards:	
11.2.1. Endocrine disrupting properties:	
No known endocrine disrupting properties that affect human health.	
11.2.2. Other informations:	
-	

SECTION 12. Ecological information						
12.1. Toxicity						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	<i>Lepomis macrochirus</i> (Bluegill sunfish)	No information available	No information available	15.400 mg/l (methanol)
Crustacea:	EC ₅₀	48 hours	<i>Daphnia magna</i>	No information available	No information available	> 18.260 mg/l (methanol)
Algae/aquatic plants:	IC ₅₀	8 days	<i>Pseudokirchneriella subcapitata</i> (green algae)	No information available	No information available	22.000 mg/l (methanol)
Other organisms	-	-	-	-	-	-
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	-

Trade name:	BIO-DIFF 1 REAGENT				
Product code:	BD1-OT-X**	Date of compilation:	03.04.2023.	Version:	6

Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants:	IC ₅₀	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

12.2. Persistence and degradability

Abiotic degradation

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

Biodegradation

% Degradation	Time (days)	Method	Evaluation	Note
-	-	-	No information available	-

12.3. Bioaccumulative potential

Octanol-water partition coefficient (log Kow)

Value	Concentration	pH	°C	Method	Evaluation	Note
-	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

Trade name:	BIO-DIFF 1 REAGENT				
Product code:	BD1-OT-X**	Date of compilation:	03.04.2023.	Version:	6

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

12.4. Mobility in soil						
Known or predicted distribution in environmental compartments:						
No information available						
Surface tension:						
Value	°C	Concentration	Method	Note		
No information available	No information available	No information available	No information available	-		

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

12.5. Results of PBT and vPvB assessment	
Substance(s) in the mixture do(es) not meet the criteria for PBT or vPvB	
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.	

Trade name:	BIO-DIFF 1 REAGENT				
Product code:	BD1-OT-X**	Date of compilation:	03.04.2023.	Version:	6

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:
	Waste material must be disposed of according to the national and local rules and regulations. Do not mix with other sorts of waste. 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 codes/waste designations according to Low:
	15 01 10*: packaging that contains residual hazardous substances or is contaminated with hazardous substances

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:
	Disposal must be made according to official regulations.

SECTION 14. Transport information

	Transporting/shipment by road (ADR)
UN number:	1230
UN proper shipping name:	Methanol
Transport hazard class(es):	3 (6.1)
Packing group:	II
Environmental hazards:	-
Special precautions for user:	-

Trade name:	BIO-DIFF 1 REAGENT			
Product code:	BD1-OT-X**	Date of compilation:	03.04.2023.	Version: 6

Transporting/shipment by rail (RID)	
UN number:	1230
UN proper shipping name:	Methanol
Transport hazard class(es):	3 (6.1)
Packing group:	II
Environmental hazards:	-
Special precautions for user:	-

Transporting/shipment by inland waterways (ADN)	
UN number:	1230
UN proper shipping name:	Methanol
Transport hazard class(es):	3 (6.1)
Packing group:	II
Environmental hazards:	-
Special precautions for user:	-

Transporting/shipment by sea (IMDG)	
UN number:	1230
UN proper shipping name:	Methanol
Transport hazard class(es):	3 (6.1)
Packing group:	II
Environmental hazards:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL73/78 and the IBC code:	-

Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	1230
UN proper shipping name:	Methanol
Transport hazard class(es):	3 (6.1)
Packing group:	II
Environmental hazards:	-
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

Trade name:	BIO-DIFF 1 REAGENT				
Product code:	BD1-OT-X**	Date of compilation:	03.04.2023.	Version:	6

Authorisations and/or restrictions on 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)	
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: -

Trade name:	BIO-DIFF 1 REAGENT				
Product code:	BD1-OT-X**	Date of compilation:	03.04.2023.	Version:	6

16.2.	Abbreviations and acronyms:	and	<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:	225 301+311+331 370	Highly flammable liquid and vapor. Toxic if swallowed, in contact with skin or if inhaled. Causes damage to organs (eyes).
16.6.	Training advice:		-
16.7.	Further information:		<p>** "X" in the product code marks different volumes (different packaging 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
-