

**SAFETY DATA SHEET**  
**According to Regulation (EC) No. 1907/2006**

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Trade name:	<b>BIOSCHIFF REAGENT</b>				
Product code:	BS-OT-X**	Date of compilation:	20 Feb 2017	Version:	2

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1. Product identifier		
Trade name:	BIOSCHIFF REAGENT	
Chemical name:	-	
Catalogue number:	BS-OT-X**	
1.2. Relevant identified uses of the substance or mixture and uses advised against		
Uses:	Used in microscopy and electrophoresis.	
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:	vladimir.ramljak@biognost.hr	
National contact:	Vladimir Ramljak, professor of biology	
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:	Warning statements*:
	-	EUH031
2.1.2. Additional information		
	-	
* For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2. Label elements		
Product identification:	BIOSCHIFF REAGENT	
Identification number:	-	
Authorisation number:	-	
Hazard pictograms:	-	
Signal word:	-	
Warning statements:	EUH031 Contact with acids liberates toxic gas.	

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Precautionary statements:	P281 Use personal protective equipment as required.
Supplemental hazard information (EU):	-
<b>2.3. Other hazards</b>	
	-

**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)
7681-57-4/ 231-673-0/ 016-063-00-2	-	< 3	sodium metabisulfite	Acute tox. 4; H302 Eye Dam. 1; H318 EUH031
7647-01-0/ 231-595-7/ 017-002-01-X	-	< 3	hydrochloric acid, 36.5%	Skin Corr. 1B; H314 STOT-SE 3; H335
569-61-9/ 209-321-2/ 611-031-00-X	-	< 0.1	4,4'-(4-iminocyclohexa-2,5-dienylidene)methylene) dianiline hydrochloride; C.I. Basic Red 9	Carc. 1B; H350

**SECTION 4. First aid measures**

<b>4.1. Description of first aid measures</b>	
General notes:	-
Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen. If the symptoms remain, immediately call a physician.
Following skin contact:	Remove contaminated clothing. Thoroughly wash with water and soap.
Following eye contact:	Rinse the eyes using mild jet of clean water for at least 10 minutes with the eyelids held wide open. If the symptoms of irritation remain, immediately call a physician.
Following ingestion:	Provide the afflicted person with water. DO NOT induce vomiting. If the symptoms remain, immediately call a physician.
Self-protection of the first aider	-
<b>4.2. Most important symptoms and effects, both acute and delayed</b>	
Following inhalation:	May cause respiratory system irritation. At high levels of concentration, prolonged exposure and when used by sensitive persons bronchospasm may occur, as well as asthma attack and gastrointestinal irritation.

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	Following skin contact:	May cause skin irritation.
	Following eye contact:	May cause eye irritation.
	Following ingestion:	May cause gastrointestinal irritation accompanied by abdominal pains and cramps; higher levels of concentration may induce vomiting and diarrhea.
4.3.	Indication of any immediate medical attention and special treatment needed	
	-	

<b>SECTION 5. Firefighting measures</b>		
5.1.	Extinguishing media	
	Suitable extinguishing media:	Water spray, dry powder, CO <sub>2</sub>
	Unsuitable extinguishing media:	Water jet
5.2.	Special hazards arising from the substance or mixture	
	Hazardous byproducts of fire:	Sulfur oxides.
5.3.	Advice for firefighters	
	Evacuate the area. Stay in danger area only with self-contained open-circuit compressed air breathing apparatus and a set for protecting the body from heat dissipation (fireproof clothing).	
5.4.	Additional information	
	-	

<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:	When disposing of small quantities use protective clothing. When disposing of large quantities use self-contained open-circuit compressed air breathing apparatus or self-contained closed-circuit air breathing apparatus.
	Accident prevention methods:	Secure a safety zone, remove all ignition sources, and in case of an accident inform the Emergency service (112) and the manufacturer or sender. Position a prohibition sign with symbols of flame and devices that cause sparks.
	Emergency procedures:	Remove or neutralize all factors that may exacerbate the condition, use all allowed means of containing the situation and use recommended means of personal protection.
6.1.2.	For emergency responders:	
	Self-contained open-circuit compressed air breathing apparatus, a set for protecting the body from heat dissipation (fireproof clothing).	
6.2.	Environmental precautions:	

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	Use sand protective barrier to prevent further spillage of chemicals. Prevent environmental pollution by not allowing the chemicals to enter the sewage system, surface water or groundwater.	
6.3.	Methods and materials for containment and cleaning	
6.3.1.	Bunding, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials
6.3.2.	Cleaning up:	Sawdust, sand, mineral adsorbents
6.3.3.	Other information:	Secure proper ventilation. Contact the responsible person; in case of larger spills and possible environmental pollution contact National Protection and Rescue (112).
6.4.	Reference to other sections	
	Refer to Section 5 for firefighting measures. Refer to Section 4 for first aid measures. Refer to Section 8 for personal protection requirements.	

<b>SECTION 7. Handling and storage</b>		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Keep away from sources of ignition and heat. Do not use tools that cause sparks.
	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. Avoid skin contact.	
7.2.	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in a cool and well-ventilated place. Keep away from heat and direct solar radiation.
	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.
7.3.	Specific end use(s)	

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Recommendations:	No information available
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>	
sodium metabisulfite	7681-57-4	-/-	5/-	No information available
hydrochloric acid, 36.5 %	-	-/-	-/-	No information available
4,4'-(4-iminocyclohexa-2,5 -dienylidenemethylene) dianiline hydrochloride; C.I. Basic Red 9	569-61-9	-/-	-/-	No information available

Substance: -

EC No: -      CAS No: -

**DNEL**

**Industrial**

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

Critical physical parameters: solubility, flammability, corrosivity: -

**Consumer**

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

**PNEC**

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

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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>
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<b>8.2.1.</b>	<b>Appropriate engineering controls</b>
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	Substance/mixture related measures to prevent exposure during identified uses:	Do not eat, drink or smoke in the workspace. Use personal protective equipment. Wash hands after handling the product and before eating and/or drinking.
	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:	See Section 7.2

<b>8.2.2.</b>	<b>Personal protection equipment:</b>
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<b>8.2.2.1.</b>	Eye and face protection:	Safety glasses that stick to face or a visor.
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<b>8.2.2.2.</b>	<b>Skin protection</b>
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	Hand protection:	In case of full contact (substance permeability $\geq$ 8 h), use nitril rubber protective gloves 0.11 mm thick.
	Other skin protection:	Choose the type of personal protection according to the type of work and possible effects. Use equipment such as apron, protective boots, protective clothing for use against liquid chemicals

<b>8.2.2.3.</b>	Respiratory protection:	If the concentration level exceeds the GVI values (or because of inadequate ventilation), use full gas mask equipped with E-P2 or E-P3 combined protective filter.
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<b>8.2.2.4.</b>	Thermal hazards:	
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<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 for preventing exposure:	See Section 6

<b>SECTION 9. Physical and chemical properties</b>
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9.1.	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	Liquid	No information available
	Colour:	Colorless	No information available
	Odour:	Sharp	No information available
	Odour threshold;	No information available	No information available
	pH:	< 2	No information available
	Melting point / freezing point;	No information available	No information available
	Initial boiling point and boiling range:	No information available	No information available
	Flash point:	No information available	No information available
	Evaporation rate:	No information available	No information available
	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	No information available	No information available
	Vapor pressure:	No information available	No information available
	Vapour density:	No information available	No information available
	Relative density	1,01 (20 °C)	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	Soluble in water (20 °C)	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	Viscosity:	No information available	No information available
	Explosive properties:	No information available	No information available
	Oxidising properties:	No information available	No information available
9.2.	Other information		
	-		

SECTION 10.: Stability and reactivity		
10.1.	Reactivity:	No information available
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.
10.3.	Possibility of hazardous reactions:	No information available
10.4.	Conditions to avoid:	No information available
10.5.	Incompatible materials:	Strong oxidants (acids).

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10.6.	Hazardous decomposition products:	Sulfur dioxide, sodium oxide.
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**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	-	-
Dermal:	No information available	-	No information available	-	-
Inhalation:	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: No information available

Irritation and corrosion

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

Sensitization

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

Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	May cause gastrointestinal irritation accompanied by abdominal pains and cramps; higher levels of concentration may induce vomiting and diarrhea.
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Dermal exposure:	May cause skin irritation.
Inhalation exposure:	May cause respiratory system irritation. At high levels of concentration, prolonged exposure and when used by sensitive persons bronchospasm may occur, as well as asthma attack and gastrointestinal irritation.
Eye exposure:	May cause eye irritation.

Repeated dose toxicity (subacute, subchronic, chronic)
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	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	-				
Subacute dermal	No information available	-				
Subacute inhalation	No information available	-				
Subchronic oral	No information available	-				
Subchronic dermal	No information available	-				
Subchronic inhalation	No information available	-				
Chronic oral	No information available	-				
Chronic dermal	No information available	-				
Chronic inhalation	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	-

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

CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)	
Carcinogenicity:	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
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**11.2. Practical experiences:**

Classification observations:	No information available
Other observations:	No information available

**11.3. General notes:**

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**SECTION 12. Ecological information**

**12.1. Toxicity**

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	Doza	Exposure time	Species	Method	Evaluation	Note

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Fish:	LC <sub>50</sub>	96 hours	No information available	No information available	No information available	No information available
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	No information available	No information available
Algae/aquatic plants:	IC <sub>50</sub>	72 hours	No information available	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	-	-	No information available	No information available	No information available

Bioconcentration factor (BCF)

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Value	Species	Method	Evaluation	Note
No information available	-	No information available	No information available	-

Chronic ecotoxicity

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

**12.4. Mobility in soil**

Known or predicted distribution in environmental compartments:

No information available

Surface tension:

Value	°C	Concentration	Method	Note
No information available	No information available	No information available	No information available	-

Adsorption / desorption

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

**12.5. Results of PBT and vPvB assessment**

No information available

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<b>12.6.</b>	<b>Other adverse effects</b>
	No information available

**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 Low:**

No information available

**13.1.3. Waste treatment – relevant information:**

Incinerating the product at high temperatures is recommended in order to avoid incomplete combustion products.

**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.

**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:	-
Environmental hazards:	-
Special precautions for user:	-

Transporting/shipment by rail (RID)

UN number:	Not subject to transport regulations.
UN proper shipping name:	-

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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:	-
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:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-

Further information:	Does not comply to transport regulations.
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<b>SECTION 15. Regulatory information</b>	
15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture
	EU regulations
	Authorisation and/or restrictions on use
	Authorisations: -
	Restrictions: -

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	Other EU regulations:	<p>EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council;</p> <p>The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH);</p> <p>EC Regulation No. 2037/2000 of the European Parliament and Council of 29 June 2000 on ozone-depleting substances;</p> <p>EC Regulation No. 689/2008 of the European Parliament and Council of 17 June 2008 concerning the export and import of dangerous chemicals;</p> <p>EC Regulation No. 850/2004 of the European Parliament and Council of 29 April 2004 on persistent organic pollutants;</p> <p>Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives</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	

<b>SECTION 16. Other information</b>												
16.1.	Indication of changes:	-										
16.2.	Abbreviations and acronyms:	<table style="width: 100%; border: none;"> <tr> <td style="width: 15%;">PBT</td> <td>Stable, bioaccumulative and toxic</td> </tr> <tr> <td>vPvB</td> <td>Strongly stable and strongly bioaccumulative.</td> </tr> <tr> <td>LD<sub>50</sub></td> <td>Lethal dose, 50%</td> </tr> <tr> <td>LC<sub>50</sub></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 <sub>50</sub>	Lethal dose, 50%	LC <sub>50</sub>	Lethal concentration, 50%	STOT-SE	Specific target organ toxicity – single exposure
PBT	Stable, bioaccumulative and toxic											
vPvB	Strongly stable and strongly bioaccumulative.											
LD <sub>50</sub>	Lethal dose, 50%											
LC <sub>50</sub>	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)											

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Trade name:	<b>BIOSCHIFF REAGENT</b>			
Product code:	BS-OT-X**	Date of compilation:	20 Feb 2017	Version: 2

		H302 H314 H: H318 H335 H350 (EUH031)	Harmful if swallowed. Causes severe skin burns and eye damage Causes serious eye damage. May cause respiratory irritation. May cause cancer. Contact with acids liberates toxic gas.
16.6.	Training advice:	-	
16.7.	Further information:	** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.	

<b>ANNEX: Exposure scenario resulting to Chemical safety assessment</b>	
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