

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

Page 1 of 15

Trade name:	<b>DIFFERENTIATION REAGENT FOR GOMORI TRICHROME KIT</b>				
Product code:	RDG-OT-X**	Date of compilation:	17 Feb 2017	Version:	2

<b>SECTION 1: Identification of the substance/mixture and of the company/undertaking</b>		
1.1.	Product identifier	
	Trade name:	DIFFERENTIATION REAGENT FOR GOMORI TRICHROME KIT
	Chemical name:	-
	Catalogue number:	RDG-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use in Gomori Trichrome kit for staining cytoplasm red and collagen fibers green.
	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:	00-385-1-2404039
	e-mail of competent person:	<a href="mailto:vladimir.ramljak@biognost.hr">vladimir.ramljak@biognost.hr</a>
	National contact:	Vladimir Ramljak
1.4.	Emergency telephone numbers	
	National Protection and Rescue Directorate:	112
	Medical information:	01-23-48-342
	Other information:	-

<b>SECTION 2. Hazards identification</b>		
2.1.	Classification of the substance or mixture	
2.1.1.	Classification (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:	DIFFERENTIATION REAGENT FOR GOMORI TRICHROME KIT
	Identification number:	-
	Authorisation number:	-
	Hazard pictograms:	-
	Signal word:	-

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

Page 2 of 15

Trade name:	<b>DIFFERENTIATION REAGENT FOR GOMORI TRICHROME KIT</b>			
Product code:	RDG-OT-X**	Date of compilation:	17 Feb 2017	Version: 2

Warning statements:	-
Precautionary statements:	-
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)
64-19-7/ 200-580-7/ 607-002-00-6	-	< 1%	Acetic acid, glacial	Flam. Liquid 3; H226 Skin Corr. 1A; H314

**SECTION 4. First aid measures**

<b>4.1. Description of first aid measures</b>	
General notes:	-
Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. If breathing becomes erratic or it 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.
Following ingestion:	If the afflicted person is unconscious, do not provide them with anything orally.
Self-protection of the first aider	No information available
<b>4.2. Most important symptoms and effects, both acute and delayed</b>	
Following inhalation:	Allergic persons may display irritation after prolonged or repeated exposure.
Following skin contact:	Allergic persons may display irritation.
Following eye contact:	May cause irritation.
Following ingestion:	Swallowing may cause discomfort in abdomen and abdominal pains.
<b>4.3. Indication of any immediate medical attention and special treatment needed</b>	
	-

**SECTION 5. Firefighting measures**

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

Page 3 of 15

Trade name:	<b>DIFFERENTIATION REAGENT FOR GOMORI TRICHROME KIT</b>				
Product code:	RDG-OT-X**	Date of compilation:	17 Feb 2017	Version:	2

<b>5.1. Extinguishing media</b>	
Suitable extinguishing media:	Use fire extinguishing methods that suit the surrounding circumstances and ambient.
Unsuitable extinguishing media:	-
<b>5.2. Special hazards arising from the substance or mixture</b>	
Hazardous byproducts of fire:	No information available
<b>5.3. Advice for firefighters</b>	
Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. Cool closed containers exposed to fire with water spray or vapor.	
<b>5.4. Additional information</b>	
Remove sources of heat and ignition. Do not contaminate the environment with extinguishing media.	

<b>SECTION 6. Accidental release measures</b>	
<b>6.1. Personal precautions, protective equipment and emergency procedures</b>	
<b>6.1.1. For non-emergency personnel</b>	
Protective equipment:	Use personal protective equipment (see Section 8).
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.
<b>6.1.2. For emergency responders:</b>	
Wear protective equipment (see Section 8).	
<b>6.2. Environmental precautions:</b>	
Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.	
<b>6.3. Methods and materials for containment and cleaning up</b>	
<b>6.3.1. Bunding, covering of drains; capping procedures:</b>	Sand or clay barriers.
<b>6.3.2. Cleaning up:</b>	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.
<b>6.3.3. Other information:</b>	Do not use tools that may cause sparks.
<b>6.4. Reference to other sections</b>	
-	

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

Page 4 of 15

Trade name:	<b>DIFFERENTIATION REAGENT FOR GOMORI TRICHROME KIT</b>			
Product code:	RDG-OT-X**	Date of compilation:	17 Feb 2017	Version: 2

<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 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.
	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: -

<b>SECTION 8. Exposure controls/personal protection</b>				
8.1.	Control parameters			
	Substance	CAS No	Occupational exposure limit values/short term values	Biological limit values
			ppm	mg/m <sup>3</sup>
	-	-	-	-
	Substance: -			
	EC No:	-	CAS No:	-

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

Page 5 of 15

Trade name:	<b>DIFFERENTIATION REAGENT FOR GOMORI TRICHROME KIT</b>			
Product code:	RDG-OT-X**	Date of compilation:	17 Feb 2017	Version: 2

<b>DNEL</b>				
<b>Industrial</b>				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-
Critical physical parameters: solubility, flammability, corrosivity:			-	
<b>User</b>				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

<b>PNEC</b>	
Environmental protection target	<b>PNEC</b>
Fresh water	No information available
Freshwater sediments	No information available
Marine water	No information available
Marine sediments	No information available
Food chain	No information available
Microorganisms in sewage treatment	No information available
Soil (agricultural)	No information available
Air	No information available

<b>8.2.</b>	<b>Exposure controls</b>	
<b>8.2.1.</b>	<b>Appropriate engineering controls</b>	
	Substance/mixture related measures to prevent exposure during identified uses:	Use 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:	No information available
<b>8.2.2.</b>	<b>Personal protection equipment:</b>	
<b>8.2.2.1.</b>	Eye and face protection:	Safety glasses that stick to face (preventing splashing) or visor.

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

Page 6 of 15

Trade name:	<b>DIFFERENTIATION REAGENT FOR GOMORI TRICHROME KIT</b>				
Product code:	RDG-OT-X**	Date of compilation:	17 Feb 2017	Version:	2

8.2.2.2.	Skin protection	
	Hand protection:	Protective gloves for long-time work (over 8 h) made of following materials: - polychloroprene, 0.5 mm, - nitrile rubber, 0.35 mm, - butyl rubber, 0.5 mm, - polyvinyl chloride, 0.5 mm.
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves, and shoes that cover the entire foot.
8.2.2.3.	Respiratory protection:	Not necessary. During long-term exposure wear a protective mask or a half mask equipped with filter A.
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

<b>SECTION 9. Physical and chemical properties</b>			
9.1.	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	Liquid	No information available
	Colour:	Colorless	No information available
	Odour:	No information available	No information available
	Odour threshold;	No information available	No information available
	pH:	No information available	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
	Vapour pressure:	No information available	No information available

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

Page 7 of 15

Trade name:	<b>DIFFERENTIATION REAGENT FOR GOMORI TRICHROME KIT</b>				
Product code:	RDG-OT-X**	Date of compilation:	17 Feb 2017	Version:	2

Vapour density:	No information available	No information available
Relative density	No information available	No information available
Bulk density:	No information available	No information available
Solubility(ies):	No information available	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 oxidizing media.
10.6.	Hazardous decomposition products:	No information available

**SECTION 11. Toxicological information**

11.1.	Information on toxicological effects				
	Acute toxicity:				
Route of exposure:	Method	Species	Effective Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixture</sub>	Exposure time	Results
Oral:	No information available	-	No information available	-	-
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	-	

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

Page 8 of 15

Trade name:	<b>DIFFERENTIATION REAGENT FOR GOMORI TRICHROME KIT</b>				
Product code:	RDG-OT-X**	Date of compilation:	17 Feb 2017	Version:	2

Dermal:	No information available	No information available	-
Inhalation:	No information available	No information available	-

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

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

Symptoms related to the physical, chemical and toxicological characteristics	
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Oral exposure:	Swallowing may cause discomfort in abdomen and abdominal pains.
Dermal exposure:	Allergic persons may display irritation.
Inhalation exposure:	Allergic persons may display irritation after prolonged or repeated exposure.
Eye exposure:	May cause 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	-				

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

Page 9 of 15

Trade name:	<b>DIFFERENTIATION REAGENT FOR GOMORI TRICHROME KIT</b>				
Product code:	RDG-OT-X**	Date of compilation:	17 Feb 2017	Version:	2

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):

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

CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)

Carcinogenicity:	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; : -

<b>11.2.</b>	<b>Practical experiences:</b>	
	Classification observations:	No information available
	Other observations:	No information available

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

Page 10 of 15

Trade name:	<b>DIFFERENTIATION REAGENT FOR GOMORI TRICHROME KIT</b>				
Product code:	RDG-OT-X**	Date of compilation:	17 Feb 2017	Version:	2

11.3.	General notes:
	-

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

**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	-		

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

Trade name:	<b>DIFFERENTIATION REAGENT FOR GOMORI TRICHROME KIT</b>				
Product code:	RDG-OT-X**	Date of compilation:	17 Feb 2017	Version:	2

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

12.3. Bioaccumulative potential						
Octanol-water partition coefficient (log K <sub>ow</sub> )						
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)						
Value	Species	Method	Evaluation	Note		
No information available	No information available	No information available	No information available	No information available		

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

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

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

Page 12 of 15

Trade name:	<b>DIFFERENTIATION REAGENT FOR GOMORI TRICHROME KIT</b>				
Product code:	RDG-OT-X**	Date of compilation:	17 Feb 2017	Version:	2

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

<b>12.5.</b>	<b>Results of PBT and vPvB assessment</b>
	No information available

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

<b>SECTION 13. Disposal considerations</b>	
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<b>13.1.</b>	<b>Waste treatment methods</b>
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<b>13.1.1.</b>	<b>Product/Packaging disposal:</b>
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.

<b>13.1.2.</b>	<b>Waste codes/waste designations according to Low:</b>
	No information available

<b>13.1.3.</b>	<b>Waste treatment – relevant information:</b>
	No information available

<b>13.1.4.</b>	<b>Sewage disposal – relevant information:</b>
	Waste must not be disposed of into the sewage system.

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

Trade name:	<b>DIFFERENTIATION REAGENT FOR GOMORI TRICHROME KIT</b>			
Product code:	RDG-OT-X**	Date of compilation:	17 Feb 2017	Version: 2

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 regulated.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by rail (RID)	
UN number:	Not regulated.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by inland waterways (ADN)	
UN number:	Not regulated.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by sea (IMDG)	
UN number:	Not regulated.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Transport in bulk according to	-

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

Page 14 of 15

Trade name:	<b>DIFFERENTIATION REAGENT FOR GOMORI TRICHROME KIT</b>				
Product code:	RDG-OT-X**	Date of compilation:	17 Feb 2017	Version:	2

Annex II of MARPOL73/78 and the IBC code:	
	Transporting/shipment by air (ICAO-TI/IATA-DGR)
UN number:	Not regulated.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Further information:	The product is not subject to classification.

<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: -
	Other EU regulations: EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council; 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); EC Regulation No. 2037/2000 of the European Parliament and Council of 29 June 2000 on ozone-depleting substances; EC Regulation No. 689/2008 of the European Parliament and Council of 17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council of 29 April 2004 on persistent organic pollutants; Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)
	National legislation: 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
15.2.	Chemical safety assessment
	None

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

Page 15 of 15

Trade name:	<b>DIFFERENTIATION REAGENT FOR GOMORI TRICHROME KIT</b>			
Product code:	RDG-OT-X**	Date of compilation:	17 Feb 2017	Version: 2

<b>SECTION 16. Other information</b>														
16.1.	Indication of changes:	-												
16.2.	Abbreviations and acronyms:	<table style="width: 100%; border-collapse: collapse;"> <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> <tr> <td>STOT-RE</td> <td>Specific target organ toxicity - repeated 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	STOT-RE	Specific target organ toxicity - repeated 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													
STOT-RE	Specific target organ toxicity - repeated 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: 226 314	Flammable liquid and vapor. Causes severe skin burns and eye damage.												
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>												

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