

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

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Trading name:	GIEMSA SOLUTION			
Product code:	GM-OT-100; GM-OT-110; GM-OT-500; GM-OT-1L; GM-OT-2.5L	Revision date:	31 August 2015	Version: 4

SECTION 1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1. Product identifier	
Trading name:	GIEMSA SOLUTION
Chemical name:	-
Product code:	GM-OT-100; GM-OT-110; GM-OT-500; GM-OT-1L; GM-OT-2.5L
1.2. Relevant identified uses of the substance or mixture and uses advised against	
Identified uses:	Used for staining in hematology and staining sections of hematopoietic organs in histopathology.
Uses advised against:	Only the identified uses are advised.
Restrictions on use:	The product is intended for use only as an in vitro 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	
Company:	BioGnost Ltd.
Address:	Medjugorska 59, Zagreb
Tel. No.:	+385 1 2409997
Fax no.:	+385 1 2404039
Responsible person e-mail:	ivan.sovic@biognost.hr
National contact person:	Ivan Sovic
1.4. Emergency telephone numbers	
Emergency number:	112
Telephone number for medical information:	01-23-48-342
Other information:	-

SECTION 2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture	
2.1.1. Classification (REGULATION (EC) No. 1272/2008 (CLP))	
Hazard class and category code:	Warning statements*:
Flammable liquid 3	H226
Acute toxicity 3	H331
Acute toxicity 3	H311
Acute toxicity 3	H301
STOT-SE 1	H370
2.1.2. Additional information	

*For the full text of H and EUH phrases see Section 16.

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2.2. Classification according to EC Directive 1272/2008 CLP)	
Product identification:	GIEMSA SOLUTION
Index no.:	-
Authorization no.:	-
Pictograms	 GHS02  GHS06  GHS08
Signal word:	Danger
Warning statements:	H226 Flammable liquid and vapor. H301 + H311 + H331 Toxic if swallowed, in contact with skin or if inhaled. H370 Causes damage to organs by inhaling, by skin contact and by swallowing.
Precautionary statements:	P210 Keep away from heat/sparks/open flames/hot surfaces. - Do not smoke. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/protection/face protection. P309+P311 Call a POISON CENTER/physician in case of exposure or if you feel unwell.
Further information:	-
2.3. Other hazards	
-	

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

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CAS/ EC/ Index no.	REACH registration number	Mass % or range	Name	Classification according to (EC)1272/2008 (CLP)
67-56-1/ 200-659-6/ 603-001-00-X	-	> 20	methanol	Flammable liquid 2, H225 Acute toxicity 3, H331 Acute toxicity 3, H311 Acute toxicity 3, H301 STOT-SE 1, H370

SECTION 4. FIRST AID MEASURES

4.1.	Description of first aid measures	
	Note:	-
	After 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. Rush the afflicted person to the hospital while keeping them in lateral recumbent position in order to keep the airways clear.
	After 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.
	After 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.
	After swallowing:	Rinse with water and expectorate. Make the afflicted person drink 1 - 2 glasses of water (200 - 400 ml). The afflicted person should drink one glass (100 ml) of 40% ethanol (adult dose). Place the afflicted person in the half lying position and rush them to hospital while constantly calming them down. If the afflicted person is vomiting, there may be risk of pulmonary aspiration.
	Personal protection used by the person providing first aid measures:	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	
	After inhalation:	Airways irritation and possible lung damage due to high levels of vapor concentration. Absorption may cause toxic effects.
	After skin contact:	Minimum level of irritation, defatting; prolonged exposure may cause absorption and greater possibility of delayed systemic effects.
	After eye contact:	Mild to moderate irritation due to vapor, conjunctivitis, later chemosis, lesser possibility of cornea damage. Visual impairments may occur later, after the absorption.
	After swallowing:	Stomach and bowel irritation, feeling unwell, vomiting, strong abdominal pain. Absorption may cause toxic effects.

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4.3.	Indication of any immediate medical attention and special treatment needed
	Use ethanol as antidote. In case of severe poisoning, use hemodialysis with occasional ethanol intake.

SECTION 5. FIRE FIGHTING MEASURES	
5.1.	Extinguishing media
	Suitable extinguishing media: Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol-resistant foam
	Unsuitable extinguishing media: water jet
5.2.	Special hazards arising from the substance or mixture
	Hazardous byproducts of fire: No information available
5.3.	Advice for firefighters
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. Cool closed containers exposed to fire with water spray, in order to prevent explosion.
5.4.	Further information
	Remove sources of heat and ignition. Do not contaminate the environment with extinguishing media.

SECTION 6. ACCIDENTAL RELEASE MEASURES	
6.1.	Personal precautions, protective equipment and emergency procedures
6.1.1.	Advice for non-emergency personnel:
	Protective equipment: Use personal protective equipment (see Section 8).
	Accident prevention procedure: Evacuate members of all non-essential personnel and those members without protective equipment. Do not breathe in vapor, ensure adequate ventilation and avoid contact with skin and eyes. Remove all sources of sparks and ignition. Do not smoke.
	Procedure in case of accident: Mark the area using proper signs.
6.1.2.	Advice for emergency responders:
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).
6.2.	Environmental precautions:
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.
6.3.	Methods and materials for containment and cleaning
6.3.1.	Methods for Containment Sand or clay barriers.

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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 sawdust, old cleaning rags, and tools that may cause sparks.
6.4.	Reference to other sections	
	-	

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. Carry out measures for preventing static electricity.
	Measures for preventing spray and dust formation:	Secure proper ventilation.
	Environmental precautions:	Prevent spilling into the sewage system and waterways.
	Other measures:	-
7.1.2.	Advice regarding general hygiene in workspace	
	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.
	Containers materials:	Manufacturer's original packaging.
	Requirements for storage and containers:	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.
	Other 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)	

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Recommendations:	-
Special decisions for industry sector:	-

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control parameters

Substance	CAS number	Exposure limit values (GVI/KGVI)		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 name:	-		
EC number:	-	CAS number:	-

DNEL

Industry

Exposure type:	Acute local effects	Acute systemic effects	Chronic local effects	Chronic systemic effects
By swallowing	-	-	-	-
By inhalation	-	-	-	-
By skin contact	-	-	-	-

Key physical parameters: solubility flammability, corrosion:

User

Exposure type:	Acute local effects	Acute systemic effects	Chronic local effects	Chronic systemic effects
By swallowing	-	-	-	-
By inhalation	-	-	-	-
By skin contact	-	-	-	-

PNEC

Protected environmental element	PNEC
Fresh water	No information available
Fresh water sediments	No information available
Salt water	No information available
Salt water sediments	No information available
Food chain	No information available

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Microorganisms (during wastewater processing)	No information available
Soil (agricultural)	No information available
Air	No information available

8.2.	Exposure controls	
8.2.1.	Corresponding control mechanisms	
	Measures for preventing exposure during recommended use:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures for preventing exposure:	No information available
	Organizational measures for preventing exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures for preventing exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.
8.2.2.	Personal protection measures, such as personal protective equipment	
8.2.2.1.	Eye/face protection:	Safety glasses that stick to face or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.
8.2.2.2.	Skin protection	
	Hand protection:	Protective butyl rubber gloves (0.7 mm thick).
	Other body parts 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 system protection:	Suitable mask or half mask equipped with a combined "A-X" filter and used when concentration levels exceed GVI.
8.2.2.4.	Thermal risks:	No information available
8.2.3.	Environmental exposure controls	
	Measures for preventing substance exposure:	See Section 6
	Structural measures for preventing exposure:	Use modern equipment.
	Organizational measures for preventing exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures for preventing exposure:	See Section 6

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES	
9.1.	Information on basic physical and chemical properties

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	Value	Method
Form:	Liquid	No information available
Color:	Blue - pink	No information available
Odor:	methanol	No information available
Odor threshold:	6.8 - 7.0 (20 °C)	No information available
Melting point/freezing point	No information available	No information available
Initial boiling point and boiling range:	~ 65 °C	No information available
Flash point:	24 °C	No information available
Evaporation rate:	No information available	No information available
Flammability (solid substance, gas):	No information available	No information available
Lower and upper flammability (explosion) limits:	No information available	No information available
Vapor pressure:	No information available	No information available
Relative vapor density:	No information available	No information available
Relative density:	0.99 (20 °C)	No information available
Fill density:	No information available	No information available
Solubility:	Soluble in water.	No information available
Partition coefficient: n-octanol/water (log Pow):	No information available	No information available
Self-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
Oxidizing properties:	No information available	No information available
9.2.	Other information	
	-	

SECTION 10. STABILITY AND REACTIVITY		
10.1.	Reactivity:	See subsections 10.3 through 10.5.
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using (room temperature).
10.3.	Possibility of hazardous reactions:	With halogen elements, oxidizing substances, reducing agents, acids.
10.4.	Conditions to avoid:	Sources of heat, sparks, and ignition.
10.5.	Incompatible materials:	Halogen elements, oxidizing substances, reducing agents, acids.
10.6.	Hazardous decomposition products:	Irritating vapors and gases.

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SECTION 11. TOXICOLOGICAL INFORMATION					
11.1. Information on toxicological effects					
Acute toxicity:					
Consumption:	Method	Organism	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure period	Outcome
Swallowing:	No information available	rat	LD ₅₀ (methanol)	-	5628 mg/kg
Skin contact:	No information available	rat	LD ₅₀ (methanol)	-	≥ 45000 mg/kg
Inhaling:	No information available	rat	LC ₅₀ (methanol)	6 hours	67.8 mg/l
Specific target organ toxicity - single exposure (STOT-SE):					
	Specific effects		Target organ		Note
Swallowing:	No information available		No information available		-
Skin contact:	No information available		No information available		-
Inhaling:	No information available		No information available		-
Aspiration hazard: Irritating to respiratory system.					
Irritation and corrosion					
	Exposure period	Organism	Evaluation	Method	Note
Skin corrosion/irritation:	24 h	rabbit	-	-	Dose: 20 mg (methanol)
Serious damage/irritation to eyes:	-	rabbit	-	-	Dose: 40 mg (methanol)
Sensitization					
Skin contact:	Does not cause sensitization.				
Inhaling:	No information available				
Symptoms related to physical, chemical, and toxicological properties					
Swallowing:	Stomach and bowel irritation, feeling unwell, vomiting, strong abdominal pain. Absorption may cause toxic effects.				
Skin contact:	Minimum level of irritation, defatting; prolonged exposure may cause absorption and greater possibility of delayed systemic effects.				

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Inhaling:	Airways irritation and possible lung damage due to high levels of vapor concentration. Absorption may cause toxic effects.
Eye contact:	Mild to moderate irritation due to vapor, conjunctivitis, later chemosis, lesser possibility of cornea damage. Visual impairments may occur later, after the absorption.

Repeated dose toxicity (subacute, subchronic, chronic)

	Dose	Exposure period	Organism	Method	Evaluation	Note
Subacute oral toxicity	No information available	-				
Subacute dermal toxicity	No information available	-				
Subacute inhaling toxicity	No information available	-				
Subchronic oral toxicity	No information available	-				
Subchronic dermal toxicity	No information available	-				
Subchronic inhaling toxicity	No information available	-				
Chronic oral toxicity	No information available	-				
Chronic dermal toxicity	No information available	-				
Chronic inhaling toxicity	No information available	-				

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

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

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Subchronic oral toxicity	No information available	No information available	-
Subchronic dermal toxicity	No information available	No information available	-
Subchronic inhaling toxicity	No information available	No information available	-
Chronic oral toxicity	No information available	No information available	-
Chronic dermal toxicity	No information available	No information available	-
Chronic inhaling toxicity	No information available	No information available	-

CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)

Carcinogenicity:	Current studies on mice and rats did not indicate carcinogenic effects.
<i>In vitro</i> mutagenicity:	Current <i>in vitro</i> tests did not indicate mutagenic effects.
Genotoxicity:	No information available
<i>In-vivo</i> mutagenicity:	Current <i>in vivo</i> tests did not indicate mutagenic effects.
Germ cell mutagenicity:	No information available
Reproductive organs toxicity:	No toxicity on reproductive organs was determined in low concentrations.
Total evaluation of CMR properties:	Current studies indicate that low methanol concentrations do not cause CMR effects. Further detailed tests are required.

11.2. Practical experiences:

Remarks relevant for classification:	No information available
Other remarks:	No information available

11.3. Note:

-

SECTION 12. ECOLOGICAL INFORMATION

12.1. Toxicity

Acute toxicity	Dose	Exposure period	Organism	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	15400 mg/l	for methanol
Crabs	EC ₅₀	48 hours	No information available	No information available	No information available	-

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Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-
Chronic toxicity	Dose	Exposure period	Organism	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crabs (Daphnia)	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				
	Half-life	Method	Evaluation	Note
Salt 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 %	Period (days)	Method	Evaluation	Note
No information available	No information available	No information available	No information available	Extremely biodegradable.

12.3. Bioaccumulative potential

Partition coefficient: n-octanol/water (log Pow):						
Value	Concentration	pH	°C	Method	Evaluation	Note
- 0.74	No information available	-	-	No information available	No information available	No information available

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Bio-Concentration Factor (BCF)				
Value	Organism	Method	Evaluation	Note
10	Fish	No information available	No information available	for methanol

Chronic ecotoxicity						
Value	Dose	Exposure period	Organism	Method	Evaluation	Note
Chronic toxicity for fish	LC ₅₀	No information available	No information available	No information available	No information available	-
Chronic toxicity for crabs (Daphnia)	EC ₅₀	No information available	No information available	No information available	No information available	-

12.4. Mobility in soil					
Known or presumed distribution in environment:					
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 law	log Pow	Volatility	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	-

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12.5.	Results of PBT and vPvB assessment
	No information available
12.6.	Other adverse effects
	No information available
SECTION 13. WASTE DISPOSAL	
13.1.	Waste processing methods
13.1.1.	Disposing of the product/packaging:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
13.1.2.	Waste code
	No information available
13.1.3.	Waste processing method:
	No information available
13.1.4.	Possibility of spilling into the sewage system:
	Waste must not be disposed of into the sewage system.
13.1.5.	Other recommendations for disposal:
	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 regulations:
	-
SECTION 14. TRANSPORT INFORMATION	
	Land transport (ADR)
UN number:	1992
Proper shipping name:	Flammable liquid, toxic, n.o.s. (methanol)
Transport hazard class(es):	3 (6.1)
Packing group:	III

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Environmentally hazardous:	-
Special precautions for user:	-
Land transport by rail (RID)	
UN number:	1992
Proper shipping name:	Flammable liquid, toxic, n.o.s. (methanol)
Transport hazard class(es):	3 (6.1)
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Inland waterway transport (ADN)	
UN number:	1992
Proper shipping name:	Flammable liquid, toxic, n.o.s. (methanol)
Transport hazard class(es):	3 (6.1)
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Sea transport (IMDG)	
UN number:	1992
Proper shipping name:	Flammable liquid, toxic, n.o.s. (methanol)
Transport hazard class(es):	3 (6.1)
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Transport in bulk condition in accordance with Annex II. of MARPOL 73/78 and IBC Codex:	
Air transport (ICAO-TI/IATA-DGR)	
UN number:	1992
Proper shipping name:	Flammable liquid, toxic, n.o.s. (methanol)
Transport hazard class(es):	3 (6.1)
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Further information:	

SECTION 15. REGULATORY INFORMATION

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15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture	
EU regulations	
Authorization and/or restrictions of use	
Authorizations:	-
Restrictions:	-
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. 453/2010 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. 2037/200 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 (Regulation 1999/13/EC) on restricting emissions of volatile organic compounds ("VOC"):	
National regulation:	<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. Specifying changes:	-
16.2. Abbreviations:	<p>PBT Stable, bioaccumulative and toxic</p> <p>vPvB Strongly stable and strongly bioaccumulative</p> <p>LD₅₀ Lethal dose, 50%</p> <p>LC₅₀ Lethal concentration, 50%</p> <p>STOT - SE Specific target organ toxicity - single exposure</p>
16.3. Main literature and sources of information:	-
16.4. Classification and using blend classification procedures according to CLP	
Classification according to CLP	Classification

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Trading name:	GIEMSA SOLUTION			
Product code:	GM-OT-100; GM-OT-110; GM-OT-500; GM-OT-1L; GM-OT-2.5L	Revision date:	31 August 2015	Version: 4

16.5.	Full text of R and H phrases referred to under sections 2 and 3		
	H:	225 301 311 331 370	Highly flammable liquid and vapor. Toxic if swallowed. Harmful in contact with skin. Toxic if inhaled. Causes damage to organs if inhaled, if it comes into contact with skin, and if swallowed.
16.6.	Training advice:	-	
16.7.	Further notice:	** "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.	