

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31, Annex II
according to Regulation (EU) No 2020/878

Printing date: 25.05.2021
Revision date: 25.05.2021
Version number: 4 (replaces version 3)

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Trade name: GIEMSA - ready

UFI: Not apply.

1.2 Relevant identified uses of the substance or mixture and uses advised against

No use descriptors (LCS, SU, PC, PROC, ERC, AC, TF categories) of the substance or mixture are available.

Application of the substance / the mixture: Preparation for in vitro diagnostic use.

Uses advised against: Any other than the above mentioned.

1.3 Details of the supplier of the safety data sheet**Supplier:**

TestLine Clinical Diagnostics s.r.o.

Production of diagnostic sets for human, veterinary, inorganic and organic laboratories.

Business Address: Křižíkova 68, 612 00 Brno, Czech Republic

Company Identification Number: 479 13 240

Phone/Fax: +420 541 243 390

E-mail: pospisiljar@testlinecd.com / Website: www.testlinecd.com

Further information obtainable from:

Ing. Karel Královec, Studio2K

Phone: +420 777 145 808, E-mail: bl@studio2k.cz, Website: www.bezpecnostni-listy.eu

1.4 Emergency telephone number

Phone: +420 224 919 293 or +420 224 915 402; E-mail: tis@vfn.cz

Toxicology Information Centre in Prague (TIS), Na Bojišti 1, 120 00 Prague 2, Czech Republic

Permanent medical information service for cases of acute poisoning of humans and animals.

National helpdesks contact details - <https://echa.europa.eu/support/helpdesks>.

Links to Poison Centers and Clinical Toxicologists all over the World: <https://www.eapcct.org/index.php?page=links>.

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture**

The product is an in vitro diagnostic medical device in accordance with Directive 98/79/EC of the European Parliament and of the Council, is in the finished state and intended for the final user.

It therefore does not apply to its Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) according to Article 1, par. 5d).

They need not be classified, labelled or packaged in accordance with this Regulation.

Classification according to Regulation (EC) No 1272/2008

The product is classified as dangerous in the terms of the Regulation (EC) No 1272/2008 (CLP).

Acute Tox. 4 H302 Harmful if swallowed.

STOT SE 2 H371 May cause damage to organs.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008: The product is classified and labelled according to the CLP regulation.

Hazard pictograms:

GHS07

GHS08

Signal word: Warning

Hazard-determining components of labelling:

methanol

Hazard statements:

H302 Harmful if swallowed.

H371 May cause damage to organs.

Precautionary statements:

P260 Do not breathe vapours.

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P330 Rinse mouth.

P308+P311 IF exposed or concerned: Call a POISON CENTER/doctor.

P405 Store locked up.

P501 Dispose of contents/container to hazardous or special waste collection point.

Additional information:

Restricted to professional users.

2.3 Other hazards Skin penetration occurs significantly upon exposure.

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Results of PBT and vPvB assessment

PBT:

The mixture does not contain substances classified at the date of preparation of the safety data sheet as PBT according to Regulation (EC) No 1907/2006 (REACH) in a concentration equal to or greater than 0.1 % by weight.

vPvB:

The mixture does not contain substances classified at the date of preparation of the safety data sheet as vPvB according to Regulation (EC) No 1907/2006 (REACH) in a concentration equal to or greater than 0.1 % by weight.

Determination of endocrine-disrupting properties

The mixture does not contain substances that have been identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1 % by weight.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:		
CAS: 67-56-1 EINECS: 200-659-6 Index number: 603-001-00-X Reg.-No: 01-2119433307-44-XXXX	methanol Flam. Liq. 2, H225 Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331 STOT SE 1, H370 Specific concentration limits: STOT SE 1; H370: C ≥ 10 % STOT SE 2; H371: 3 % ≤ C < 10 %	5.0%
Non dangerous components:		
CAS: 7732-18-5 EINECS: 231-791-2	water, distilled, conductivity or of similar purity	90.0%
CAS: 56-81-5 EINECS: 200-289-5 Reg.-No: 01-2119471987-18-XXXX	glycerol	5.0%

SVHC:

The product does not contain substances classified as of the date of preparation of the safety data sheet as PBT or vPvB and stated in the Candidate list of substances producing very high concerns for Appendix XIV of Regulation (EC) No 1907/2006 (REACH).

Regulation (EC) No 648/2004 on detergents / Labelling for contents: Not apply.

Additional information:

The substances named in this section are given with their actual, appropriate classification!

For substances that are listed in appendix VI, table 3 of the Regulation (EC) No 1272/2008 (CLP Regulation) this means that all notes that may be given here for the named classification have been taken into account.

For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

In case of doubt, appearance of symptoms or upon any problems, seek medical help and present this safety data sheet or the product label.

Never pour anything into the mouth of an unconscious person!

Personal protection for the First Aider.

Immediately remove any clothing soiled by the product.

After inhalation:

Remove person from danger area.

Lead the person to fresh air, put the person into a calm environment and immediately call a physician.

If the person is unconscious, place in a stable side position and consult a physician.

After skin contact:

Thoroughly wash the affected skin with copious amount of water for at least 15 minutes, immediately remove polluted and soaked clothing. Seek medical assistance immediately.

After eye contact:

Open the eyelids, possibly remove the contact lenses, and thoroughly rinse the affected eyes with clean flowing water for at least 20 minutes. Seek medical assistance immediately.

After swallowing:

Thoroughly rinse the mouth with water, have the affected person drink plenty of water and do not induce vomiting. Seek medical assistance immediately.

Information for doctor: Symptomatic treatment.

4.2 Most important symptoms and effects, both acute and delayed

Possible toxicological effects resulting from the classification are stated in Section 11.

Upon inhalation:

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Respiratory tract irritation.

Upon skin contact:

Skin irritation.

Upon eye contact:

Eye irritation.

In certain cases, the symptoms of poisoning may only appear after an extended period / after several hours.

Methanol can cause death or blindness upon ingestion. Ingestion may lead to consequences such as: nausea, headaches, vomiting, gastrointestinal disorders, vertigo, weakness, confusion, sleepiness, unconsciousness, may cause cramps.

The lethal dose of pure methanol for a human: upon ingestion - 30 ml; a dose of 7- 15 ml may cause blindness.

4.3 Indication of any immediate medical attention and special treatment needed

Upon any exposure, immediate medical assistance is necessary.

For special medical advice, contact the Toxicology Information Centre.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents:

Alcohol resistant foam, carbon dioxide (CO₂), water spray or water mist, extinguishing powder.

Use fire extinguishing methods suitable to surrounding conditions.

For safety reasons unsuitable extinguishing agents: Water with full jet.

5.2 Special hazards arising from the substance or mixture

Formation of irritating, toxic and harmful fumes of burning is possible in case of fire.

In case of fire, the following can be released:

Carbon monoxide (CO) a carbon dioxide (CO₂).

Vapours, which are heavier than air, may spread along the ground far from the point of creation and may ignite at a remote heat source.

Inhalation of hazardous decomposition products of burning may result in damaged health.

5.3 Advice for firefighters

Protective equipment:

Do not inhale explosion gases or combustion gases.

According to size of fire.

Corresponding protective insulation breathing apparatus and overpressure counter-chemical protective clothing.

Additional information:

Cool with water the products in enclosed packaging, which is near the fire. If possible, remove the products in un-damaged packaging from the danger area. Store the contaminated extinguishing water separately and do not let it into the sewerage. Remove the extinguishing water or used extinguishing materials together with the remnants of the fire according to the corresponding regulations.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel:

Ensure adequate ventilation.

Remove possible causes of ignition - do not smoke.

Use personal protective equipment.

Avoid contact with eyes and skin.

Avoid inhalation of vapors.

Prevent entry of unauthorized and unprotected persons.

For emergency responders: No relevant information available.

6.2 Environmental precautions

Prevent increasing of the leaked quantity. Do not let the product enter the sewerage, surface and ground water and soil. Upon a more extensive leak of the product into the environment, proceed according to local regulations and contact the respective departments of local authorities.

6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust) and place into suitable and marked vessels.

Possibly wipe the leaked product with a paper towel and place it into a waste vessel.

Thoroughly wash the affected spot and the tools used with a suitable detergent, it is possible to use a larger quantity of water.

Dispose contaminated material as waste according to item 13.

Cleaning and disposal by specialised employees only.

Ensure adequate ventilation.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

Before use, it is necessary to familiarize oneself with the contents of Sections 2, 6, 8, and 11 of the safety data sheet.

Use personal protective equipment.

Avoid inhalation of vapors.

Avoid contact with eyes and skin.

Ensure good ventilation/exhaustion at the workplace.

Use working methods according to operating instructions.

Open and handle receptacle with care.

General hygiene measures for the handling of chemicals are applicable.

Before a pause and after ending the work, wash the hands and take off the polluted working clothes. Keep these clothes separately.

Remove contaminated clothing and protective equipment before entering areas in which food is consumed.

Do not eat, drink, smoke, or snuff during use.

Information about fire - and explosion protection:

Keep ignition sources away - Do not smoke.

Possibly perform measures for protection against electrostatic discharge.

Respect general regulations on fire prevention.

7.2 Conditions for safe storage, including any incompatibilities

Storage

Requirements to be met by storerooms and receptacles:

Secure impermeable floors against the liquids.

Store only in unopened original receptacles.

Information about storage in one common storage facility:

Do not store with strong oxidizing agents.

Keep away from food, drink and animal feedingstuffs.

Further information about storage conditions:

Store in a dry and well ventilated place.

Keep containers tightly sealed.

Store under lock and key and with access restricted to technical experts or their assistants only.

Maximum storage temperature: Do not store at temperatures over +25 °C.

7.3 Specific end use(s)

The product is intended only for professional use.

Specific use is stated in the manual for use on the product packaging label or in the product documentation.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

67-56-1 methanol

IOELV	Long-term value: 260 mg/m ³ , 200 ppm
	Skin

Regulatory information:

IOELV: COMMISSION DIRECTIVE (EU) 2019/1831

Legend: IOELV = indicative occupational exposure limit values pursuant to Council Directive 98/24/EC and amending Commission Directive 2000/39/EC.

DNELs:

56-81-5 glycerol

Inhalative	DNEL - Long term exposure, local effects	56 mg/m ³ (workers)
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PNECs:

56-81-5 glycerol

PNEC - Freshwater	0.885 mg/l
PNEC - Marine water	0.0885 mg/l
PNEC - Sewage treatment plant	1,000 mg/l
PNEC - Sediment, freshwater	3.3 mg/kg
PNEC - Sediment, marine water	0.33 mg/kg
PNEC - Soil	0.141 mg/kg
PNEC - Water (sporadic release)	8.85 mg/l

Ingredients with biological limit values:

The product does not contain any relevant quantities of materials with biological limit values.

Additional information: The lists valid during the making were used as basis.

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8.2 Exposure controls

Appropriate engineering controls:

Ensure good ventilation. This can be achieved by local suction or general air extraction. If this is insufficient to maintain the concentration under WEL or IOEL values, suitable breathing protection should be worn. Applies only if maximum permissible exposure values are listed here.

Individual protection measures, such as personal protective equipment

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Keep away from foodstuffs, beverages and feed.

Do not eat, drink, smoke or sniff while working.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Store protective clothing separately.

Avoid contact with the eyes and skin.

Do not inhale gases/fumes/aerosols.

Eye/face protection:



Tightly sealed goggles (EN 166).

Body protection:



As needed, use the working protective clothes with long sleeves, possibly overalls, and protective working footwear.

Hand protection



Protective gloves (EN ISO 374-1).

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

Preventive skin protection by use of skin-protecting agents is recommended.

Material of gloves:

Glove material for long-term contact (> 480 minutes):

Butyl rubber, BR (EN ISO 374-1).

Recommended thickness of the material: ≥ 0.7 mm.

Glove material for short-term contact / against drops (> 10 minutes, < 480 minutes):

Fluorocarbon rubber, Viton (EN ISO 374-1).

Recommended thickness of the material: ≥ 0.7 mm.

Use for example:

For example protective surgical gloves.

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Penetration time of glove material:

Not determined.

No tests have been performed, glove resistance must be tested before use.

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Respiratory protection:

Unnecessary during regular use.



In case of insufficient ventilation and exceeding of permitted exposure limits use a suitable breathing mask with a filter (EN 14387).

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Recommended filter device for short term use: Organic vapour filter (EN 14387+A1).

Thermal hazards: Not applicable.

Environmental exposure controls: Adhere to usual measures for environmental protection, see Section 6.

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Physical state:	Fluid.
Colour:	Violet.
Odour:	Alcohol-like.
Melting point/freezing point:	Not determined.
Boiling point or initial boiling point and boiling range:	Not determined.
Flammability:	Not applicable.
Lower and upper explosion limit	
Lower:	6.0 Vol % (*)
Upper:	36.0 Vol % (*)
Flash point:	Not applicable.
Auto-ignition temperature:	Not determined.
Decomposition temperature:	Not determined.
pH:	Not determined.
Viscosity	
Kinematic viscosity:	Not determined.
Dynamic viscosity at 20 °C:	0.52 mPas (*)
Solubility	
water:	Miscible.
Partition coefficient n-octanol/water (log value):	-0.77 log POW (*)
Vapour pressure at 20 °C:	128 hPa (*)
Density and/or relative density	
Density:	Not determined.
Vapour density:	Not determined.
Relative gas density:	Not determined.

9.2 Other information

Important information on protection of health and environment, and on safety.

Ignition temperature:	Not determined.
Explosive properties:	Not determined.
Solvent content	
VOC (2010/75/EC):	Not apply.
Oxidising properties:	No.
Evaporation rate:	Not determined.

Information with regard to physical hazard classes

Explosives:	Void.
Flammable gases:	Void.
Aerosols:	Void.
Oxidising gases:	Void.
Gases under pressure:	Void.
Flammable liquids:	Void.
Flammable solids:	Void.
Self-reactive substances and mixtures:	Void.
Pyrophoric liquids:	Void.
Pyrophoric solids:	Void.
Self-heating substances and mixtures:	Void.
Substances and mixtures, which emit flammable gases in contact with water:	Void.
Oxidising liquids:	Void.
Oxidising solids:	Void.
Organic peroxides:	Void.
Corrosive to metals:	Void.
Desensitised explosives:	Void.
Additional information:	(*) Value for methanol.

SECTION 10: Stability and reactivity

10.1 Reactivity Upon adhering to the determined regulations of storage and use, no reactivity is expected (see Section 7).

10.2 Chemical stability Upon adhering to the determined regulations of storage and use, the product is stable (see Section 7).

10.3 Possibility of hazardous reactions No dangerous reactions known.

10.4 Conditions to avoid

Prevent contact with incompatible materials.

Protect against heating, open flames, and ignition sources.

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10.5 Incompatible materials No further relevant information available.

10.6 Hazardous decomposition products

Carbon monoxide (CO) a carbon dioxide (CO₂).

At high temperatures, hazardous decomposition products may be created (see Subsection 5.2).

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity: Harmful if swallowed.

Relevant toxicological values for classification:

ATE (Acute Toxicity Estimates)

Oral	LD50	2,000 mg/kg
Dermal	ATE	6,000 mg/kg
Inhalative	ATE	60 mg/l/4h

56-81-5 glycerol

Oral	LD50	12,600 mg/kg (rat)
Dermal	LD50	> 10,000 mg/kg (rabbit)

67-56-1 methanol

Oral	LD50	100 mg/kg (ATE)
Dermal	ATE	300 mg/kg (ATE)
Inhalative	ATE	3 mg/l/4h (ATE)

Specific symptoms in biological assay:

Strong irritant effect - rabbit skin - 24 hours (methanol).

Strong irritant effect - rabbit eyes - 24 hours (methanol).

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/irritation: Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation: Based on available data, the classification criteria are not met.

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity: Based on available data, the classification criteria are not met.

STOT-single exposure: May cause damage to organs.

STOT-repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

Other information: No further information is available.

Experience with humans:

Methanol is toxic upon inhalation, causes coughing, headache, nausea, sight disorders.

Methanol is toxic upon skin contact via absorption. Causes irritation, cracking, and degreasing of the skin.

Methanol is toxic upon ingestion, causes inebriety, abdominal spasms, vertigo, nausea, vomiting, later vision disorders, damage to the kidneys, liver, and heart.

Additional toxicological information: No relevant information is available.

Acute effects: Acute oral toxicity, Hazard category 4.

Sensitisation: Based on available data, the classification criteria are not met.

CMR effects (carcinogenity, mutagenicity and toxicity for reproduction): No CMR effects are known.

11.2 Information on other hazards

Endocrine disrupting properties:

None of the ingredients is listed.

Other information: No further information is available.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

Based on available data, the classification criteria are not met.

56-81-5 glycerol

LC50/24 h	> 10,000 mg/l (fish) Carassius auratus
EC50/24 h	> 10,000 mg/l (daphnia) Daphnia magna

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67-56-1 methanol	
LC50/96 h	15,400 mg/l (fish) Lepomis macrochirus
EC50/48 h	> 10,000 mg/l (daphnia) Daphnia magna
IC50/48 h	22,000 mg/l (algae) Scenedesmus capricornutum

12.2 Persistence and degradability

56-81-5 glycerol

Biodegradability in water 63 %/14 d (OECD 301 C - Modified MITI Test (I))
the substance is readily biodegradable

67-56-1 methanol

Biodegradability in water 72 %/5 d
the substance is readily biodegradable

Behaviour in waste water treatment plants: No relevant information is available.

12.3 Bioaccumulative potential

56-81-5 glycerol

log Pow -1.76
bioaccumulation is not expected

67-56-1 methanol

log Pow -0.77
bioaccumulation is not expected

12.4 Mobility in soil No further relevant information available.

12.5 Results of PBT and vPvB assessment

The product does not contain substances classified as PBT or vPvB and included in the list of substances subject to authorization (Annex XIV of EP and R Regulation No 1907/2006, as amended).

PBT: No relevant information is available.

vPvB: No relevant information is available.

12.6 Endocrine disrupting properties The product does not contain substances with endocrine disrupting properties.

12.7 Other adverse effects

Additional ecological information

COD-value:

56-81-5 glycerol

COD 1.16 g O₂/g

BOD5-value:

56-81-5 glycerol

BOD₅ 0.87 g O₂/g

AOX-indication: No relevant information is available.

General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation:

Must not be disposed together with household waste. Do not allow product to reach sewage system.

Hand over to hazardous waste disposers.

E.g. put away at suitable waste dumps or remove in suitable waste incineration plants.

Waste disposal key:

The catalogue numbers with the asterisk (*) mark hazardous waste (N), numbers without the asterisk mark other waste (O).

The waste codes are recommendations based on the scheduled use of this product. Owing to the user's specific conditions for use and disposal, other waste codes may be allocated under certain circumstances. (2001/118/EC, 2001/119/EC, 2001/573/EC, 2014/955/EU).

European waste catalogue and hazardous properties of waste:

18 02 05*	chemicals consisting of or containing hazardous substances
15 01 10*	packaging containing residues of or contaminated by hazardous substances

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15 01 02	plastic packaging
HP5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity
HP6	Acute Toxicity

Uncleaned packaging

Recommendation:

Dispose of packaging according to regulations on the disposal of packagings.

Non contaminated packagings may be reused.

Non contaminated packagings may be recycled.

Dispose of packaging that cannot be cleaned in the same manner as the mixture.

Empty container completely. Dispose of hazardous waste pursuant to corresponding local directives in adequate equipment. Put other waste away according to the material type into collection vessels for sorted waste.

Regulations:

Commission Decision No 2014/955/EU of 18 December 2014 amending Decision 2000/532/EC on the list of waste pursuant to Directive 2008/98/EC of the European Parliament and of the Council.

Commission Regulation (EU) No 1357/2014, replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives.

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, as amended.

SECTION 14: Transport information

14.1 UN number or ID number ADR, ADN, IMDG, IATA	Void.
14.2 UN proper shipping name ADR, ADN, IMDG, IATA	Void.
14.3 Transport hazard class(es) ADR, ADN, IMDG, IATA Class:	Void.
14.4 Packing group ADR, IMDG, IATA	Void.
14.5 Environmental hazards Marine pollutant:	No.
14.6 Special precautions for user	Unless specified otherwise, general measures for safe transport must be followed.
14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
Transport/Additional information:	Non-dangerous material according to Transport Regulations.
UN "Model Regulation":	Void.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Named dangerous substances - ANNEX I: None of the ingredients is listed.

REGULATION (EC) No 1907/2006 ANNEX XVII: Conditions of restriction for the group No 3, 69.

DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II:

None of the ingredients is listed.

REGULATION (EU) 2019/1148:

Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

Legal regulations of the European Community:

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, as amended.

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, as amended.

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COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC, as amended.

COMMISSION REGULATION (EU) 2016/918 of 19 May 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

COMMISSION REGULATION (EU) 2019/521 of 27 March 2019 amending, for the purposes of its adaptation to technical and scientific progress Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

15.2 Chemical safety assessment A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Warning:

The safety data sheet contains data needed for securing safety and health protection during work and environmental protection. The stated data correspond to the current state of knowledge and experience and is in accordance with valid legal regulations. It cannot be deemed as a guarantee of the properties, suitability, and usefulness of the product for specific application and therefore no contractual legal relationships are hereby created.

The safety data sheet is the property of the physical or legal entity stated in Section 1 and is protected by copy-right. All copying, distribution or sales without the consent of the owner is forbidden.

Relevant phrases:

H225 Highly flammable liquid and vapour.

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H331 Toxic if inhaled.

H370 Causes damage to organs.

Training hints:

Pursuant to article No 35 of the European Parliament and Council Regulation (ES) No 1907/2006, the employer must allow employees or their representatives access to information from the safety data sheet of the substance or preparation, which the employees use or to the effects of which they may be exposed during their work.

Physical entities performed individual activities within the scope of handling of this hazardous product are trained and regularly, at least once a year, retrained.

Product information sources: safety data sheet, product or technical information, safety instructions, and other expert documents for the product, issued by the supplier.

Recommended restriction of use:

The product is to be used only for the purpose, for which it is designed. It is up to the user's responsibility to adhere to the product usage conditions and to respect the safety instructions for health and environmental protection.

The product is designed only for professional purposes. It must not be used in households. The product can only be handled by a person older than 18 years, who is sufficiently informed about the work procedures, hazardous properties of the product, and also about the necessary safety measures.

Further information: This product must be stored, sold, and used in accordance with valid hygienic regulations.

Classification according to Regulation (EC) No 1272/2008:

Acute toxicity - oral	Calculation method
Specific target organ toxicity (single exposure)	

Department issuing SDS:

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First issue of SDS: 23.03.2014

Date of previous version: 26.04.2018

Version number of previous version: 3

Reasons for alterations:

Revision of the safety data sheet due to adaptation to the requirements of Commission Regulation (EU) 2020/878 of 18 June 2020 with effect from 1 January 2021.

Revised sections: 1, 2, 3, 4, 6, 7, 8, 9, 11, 12, 13, 15, 16.

Internal code formula: 810.003

Documents used to prepare SDS:

The original documents provided by the supplier or manufacturer related to the product (mixture), eventually to individual substances contained.

Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31, Annex II
according to Regulation (EU) No 2020/878

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Trade name: **GIEMSA - ready**

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EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
VOC: Volatile Organic Compounds (USA, EU)
DNEL: Derived No-Effect Level (REACH)
PNEC: Predicted No-Effect Concentration (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
SVHC: Substances of Very High Concern
vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 2: Flammable liquids – Category 2
Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 4: Acute toxicity – Category 4
STOT SE 1: Specific target organ toxicity (single exposure) – Category 1
STOT SE 2: Specific target organ toxicity (single exposure) – Category 2

Sources:

The safety data sheet was prepared in accordance with the European Parliament and Council Regulation (EC) No 1272/2008 (CLP) and according to the requirements of the European Parliament and Council Regulation (EC) No 1907/2006 about the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency - head IV, article 31, appendix II (instructions for safety data sheet compiling), as amended by the Commission Regulation (EU) No 2020/878 of 18 June 2020.

The missing ecotoxicology and toxicology data was obtained from the ESIS (European chemical Substances Information System), specifically from the IUCLID (International Uniform Chemical Information Database). As needed, data from further available chemical databases was used.

*** Data compared to the previous version altered.**

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