

Safety data sheet

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

Printing date: 26.05.2021
Revision date: 26.05.2021
Version number: 4 (replaces version 3)

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: Crystal violet solution

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).

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Eye Irrit. 2 H319 Causes serious eye irritation.

Carc. 2 H351 Suspected of causing cancer.

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

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:



GHS02

GHS07

GHS08

GHS09

Signal word: Danger

Hazard-determining components of labelling:

C.I. Basic Violet 3

Hazard statements:

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

H351 Suspected of causing cancer.

H411 Toxic to aquatic life with long lasting effects.

Precautionary statements:

P201 Obtain special instructions before use.

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P233 Keep container tightly closed.

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

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P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
Continue rinsing.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
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

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: 64-17-5 EINECS: 200-578-6 Index number: 603-002-00-5 Reg.-No: 01-2119457-610-43-XXXX	ethanol Flam. Liq. 2, H225 Eye Irrit. 2, H319 Specific concentration limit: Eye Irrit. 2; H319: C ≥ 50 %	97.5%
CAS: 548-62-9 EINECS: 208-953-6 Index number: 612-204-00-2	C.I. Basic Violet 3 Carc. 2, H351 Eye Dam. 1, H318 Aquatic Acute 1, H400; Aquatic Chronic 1, H410 Acute Tox. 4, H302	2.5%

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.

Take care of fresh air supply and seek medical assistance upon subsequent or lasting problems.

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

After skin contact:

Wash the affected skin with water and soap and rinse thoroughly. Upon skin irritation or other problems, consult further procedure with an expert physician.

After eye contact:

Open the eye lids, possibly remove contact lenses, and rinse the affected eyes thoroughly with clean flowing water for a period of several minutes. Seek medical assistance immediately.

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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 skin contact:

Skin irritation.

Upon eye contact:

Eye lachrymation and flush.

Upon ingestion:

There is a certain health risk upon ingestion.

4.3 Indication of any immediate medical attention and special treatment needed

In case of ingestion or affecting of eyes, seek medical help immediately.

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.

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 inhalation of vapors.

Avoid contact with eyes and skin.

Prevent entry of unauthorised persons.

For emergency responders: No relevant information available.

6.2 Environmental precautions

No special measures required.

The product is hazardous for the environment.

Do not allow to enter sewers/surface or ground water.

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.

Protect health against exposure of contained substances from the atmosphere, see the limit values of exposure, which are stated in Section 8.

Dispose contaminated material as waste according to item 13.

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.

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See Section 13 for disposal information.

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.

Prevent contact of the product with the skin and eyes, use personal protective means.

Avoid inhalation of vapors.

Ensure good ventilation.

Use working methods according to operating instructions.

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.

7.2 Conditions for safe storage, including any incompatibilities

Storage

Requirements to be met by storerooms and receptacles:

Store in a cool location.

Store only in unopened original receptacles.

Information about storage in one common storage facility:

Do not store together with strong oxidizing agents, acids and toxic metals.

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.

Protect from heat and direct sunlight.

Adhere to regulations and directives for flammable liquid storage.

Protect from frost.

Recommended storage temperature: Store at temperatures below +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:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

DNELs:		
64-17-5 ethanol		
Oral	DNEL - Long term exposure, systemic effects	87 mg/kg/d (consumers)
Dermal	DNEL - Long term exposure, systemic effects	206 mg/kg/d (consumers) 343 mg/kg/d (workers)
Inhalative	DNEL - Short term exposure, systemic effects	950 mg/cm ² (consumers)
	DNEL - Long term exposure, systemic effects	950 mg/m ³ (consumers)
	DNEL - Short term exposure, systemic effects	950 mg/m ³ (workers)
PNECs:		
64-17-5 ethanol		
PNEC - Freshwater	0.96 mg/l	
PNEC - Marine water	0.79 mg/l	
PNEC - Sewage treatment plant	580 mg/l	
PNEC - Sediment, freshwater	3.6 mg/kg	
PNEC - Sediment, marine water	2.9 mg/kg	
PNEC - Soil	0.63 mg/kg	
PNEC - Oral (animal feed)	0.72 mg/kg	
PNEC - Water (sporadic release)	2.75 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.

Avoid contact with the eyes and skin.

Do not inhale gases/fumes/aerosols.

Eye/face protection:



Tightly sealed goggles (EN 166).

It is recommended to provide an eye or safety shower near the workplace.

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:

Not determined.

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 permitted exposure limits, use a suitable half-mask (EN 149+A1) with a filter (EN 14387+A1), upon high concentrations, use an insulation breathing apparatus (EN 137, EN 138).

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.

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:

78 °C

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Flammability:	The mixture is highly flammable.
Lower and upper explosion limit	
Lower:	3.9 Vol %
Upper:	20.5 Vol %
Flash point:	14 °C
Auto-ignition temperature:	Product is not selfigniting.
Decomposition temperature:	Not determined.
pH:	Not determined.
Viscosity	
Kinematic viscosity:	Not determined.
Dynamic viscosity:	Not determined.
Solubility	
water:	Soluble.
Partition coefficient n-octanol/water (log value):	Not determined.
Vapour pressure at 20 °C:	5.6 kPa
Density and/or relative density	
Density:	Not determined.
Relative 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:	Product does not present an explosion hazard. In use, may form flammable vapour-air mixture.
Solvent content	
VOC (2010/75/EC):	Not determined.
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:	Highly flammable liquid and vapour.
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:	No relevant information available.

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 The product does not polymerise.

10.4 Conditions to avoid

Prevent contact with incompatible materials.

Protect against heating, open flames, and ignition sources.

Protect against frost.

10.5 Incompatible materials Strong oxidizing agents.

10.6 Hazardous decomposition products

Carbon monoxide (CO).

Nitrogen oxides (NO_x).

Sulphur oxides (SO_x).

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Sodium compounds.

SECTION 11: Toxicological information

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

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

Relevant toxicological values for classification:

ATE (Acute Toxicity Estimates)

Oral	LD50	16,800 mg/kg (rat)
------	------	--------------------

64-17-5 ethanol

Oral	LD50	10,470 mg/kg (rat) (OECD 401 - Acute Oral Toxicity)
Dermal	LD50	> 2,000 mg/kg (rabbit) (OECD 402 - Acute Dermal Toxicity)
Inhalative	LC50/4 h	124.7 mg/l (rat) (OECD 403 - Acute Inhalation Toxicity)
	NOAEL	> 3,000 mg/kg (rat) (OECD 451 - Carcinogenicity Studies)
	NOAEL	1,730 mg/kg/d (rat) (OECD 408 - Repeated Dose 90-D Oral Toxicity Study)
		Specific target organ toxicity - Repeated exposure (STOT-RE) - Females

548-62-9 C.I. Basic Violet 3

Oral	LD50	420 mg/kg (rat)
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Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/irritation:

Causes serious eye irritation.

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:

Suspected of causing cancer.

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

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

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.

Additional toxicological information: No relevant information is available.

Acute effects: Serious eye irritation, Eye Irrit. category 2.

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

CMR effects (carcinogenity, mutagenicity and toxicity for reproduction):

The mixture containing the substance (C.I. Basic Violet 3), which raises suspicion human carcinogenicity.

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:

Hazardous to the aquatic environment - Aquatic Chronic 2.

64-17-5 ethanol

NOAL	> 20 mg/l (rat) (OECD 403 - Acute Inhalation Toxicity)
	Specific target organ toxicity - Repeated exposure (STOT-RE)
LC50/96 h	13,000 mg/l (fish) (OECD 203 - Fish, Acute Toxicity Test)
	Oncorhynchus mykiss
EC50/48 h	12,900 mg/l (algae) (OECD 201 - Alga, Growth Inhibition Test)
	Selenastrum capricornutum

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LC50/96 h	0.7 mg/l (fish)
	S. gairdnerii

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12.2 Persistence and degradability	
64-17-5 ethanol	
Biodegradability in water	97 %/28 d (OECD 301 B - CO2 Evolution Test) the substance is readily biodegradable

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

12.3 Bioaccumulative potential	
64-17-5 ethanol	
log Pow	-0.32 bioaccumulation is not expected
log Kow	-0.31
548-62-9 C.I. Basic Violet 3	
log Pow	0.51 bioaccumulation is not expected

Bioconcentration factor (BCF):	
64-17-5 ethanol	
BCF	0.66 - 3.2

12.4 Mobility in soil	
64-17-5 ethanol	
Koc	1
Henry's constant H	0.461 Pa*m ³ /mol
Surface tension σ	0.02339 N/m (25 °C)

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

Remark: Toxic for fish.

Additional ecological information

COD-value:	
64-17-5 ethanol	
COD	1.9 g O ₂ /g
BOD5-value:	
64-17-5 ethanol	
BOD5	1 g O ₂ /g

AOX-indication: No relevant information is available.

General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water.

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

Also poisonous for fish and plankton in water bodies.

Toxic for aquatic organisms.

* 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.

Remove product residues according to the corresponding local directives in the adequate equipment as hazardous waste.

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

Soaked polluted cloths, paper or other organic materials represent a fire hazard and should be controlled, collected and disposed of.

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).

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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
15 01 02	plastic packaging
HP3	Flammable
HP4	Irritant - skin irritation and eye damage
HP7	Carcinogenic
HP14	Ecotoxic

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, IMDG, IATA	UN1993
14.2 UN proper shipping name ADR	1993 FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHYL ALCOHOL)), ENVIRONMENTALLY HAZARDOUS, special provision 640D
IMDG	FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHYL ALCOHOL)), [4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride), MARINE POLLUTANT
IATA	FLAMMABLE LIQUID, N.O.S. (ETHANOL)
14.3 Transport hazard class(es) ADR	
 	
Class:	3 (F1) Flammable liquids.
Label:	3
IMDG	
 	
Class:	3 Flammable liquids.
Label:	3
IATA	
	
Class:	3 Flammable liquids.
Label:	3

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14.4 Packing group ADR, IMDG, IATA	II
14.5 Environmental hazards	Product contains environmentally hazardous substances: C.I. Basic Violet 3
Marine pollutant:	Yes
Special marking (ADR):	Symbol (fish and tree) Symbol (fish and tree)
14.6 Special precautions for user	Persons employed in transporting dangerous goods must be trained. All persons involved in transporting must observe safety regulations. Precautions must be taken to prevent damage. Warning: Flammable liquids.
Hazard identification number (Kemler code):	33
EMS Number:	F-E, <u>S</u> -E
Stowage Category:	B
14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
Transport/Additional information:	
ADR	
Limited quantities (LQ):	1L
Excepted quantities (EQ):	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
Transport category:	2
Tunnel restriction code:	D/E
IMDG	
Limited quantities (LQ):	1L
Excepted quantities (EQ):	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
UN "Model Regulation":	UN 1993 FLAMMABLE LIQUID, N.O.S., SPECIAL PROVISION 640D (ETHANOL (ETHYL ALCOHOL)), 3, II, ENVIRONMENTALLY HAZARDOUS

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.

Seveso category:

E2 Hazardous to the Aquatic Environment

P5c FLAMMABLE LIQUIDS

Qualifying quantity (tonnes) for the application of lower-tier requirements: 200 t

Qualifying quantity (tonnes) for the application of upper-tier requirements: 500 t

REGULATION (EC) No 1907/2006 ANNEX XVII: Conditions of restriction for the group No 3, 72.

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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Safety data sheet

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

Printing date: 26.05.2021
Revision date: 26.05.2021
Version number: 4 (replaces version 3)

Trade name: Crystal violet solution

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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.
H302 Harmful if swallowed.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H351 Suspected of causing cancer.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

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:	
Flammable liquids	On basis of test data
Serious eye damage/eye irritation Carcinogenicity Hazardous to the aquatic environment - long-term (chronic) aquatic hazard	Calculation method

Department issuing SDS:

Ing. Karel Královec, Studio2K
Phone: +420 777 145 808, E-mail: info@studio2k.cz, Websites: www.studio2k.cz / www.bezpecnostni-listy.eu

First issue of SDS: 15.04.2014

Date of previous version: 04.05.2018

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, 14, 15, 16.

Internal code formula: 810.007

Documents used to prepare SDS:

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

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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

Printing date: 26.05.2021
Revision date: 26.05.2021
Version number: 4 (replaces version 3)

Trade name: **Crystal violet solution**

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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
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. 4: Acute toxicity – Category 4
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Carc. 2: Carcinogenicity – Category 2
Aquatic Acute 1: Hazardous to the aquatic environment - Acute Hazard, Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – 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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