

**TC75000 - STERNHEIMER AND MALBIN
dye for microscopy**

Safety Data Sheet

According to Annex II to REACH - Regulation (EU) 2020/878 and to Annex II to UK REACH

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

1.1. Product identifierCode: TC75000
Product name: STERNHEIMER AND MALBIN dye for microscopy**1.2. Relevant identified uses of the substance or mixture and uses advised against**

Intended use: Reagent for laboratory, dye for microscopy

1.3. Details of the supplier of the safety data sheetName: TITOLCHIMICA SPA
Full address: VIA S.PIETRO MARTIRE 1054
District and Country: 45030 PONTECCHIO POLESINE (RO)
ITALIA
Tel. +39425492644

e-mail address of the competent person

responsible for the Safety Data Sheet: utecnico@titolchimica.it
Supplier: TITOLCHIMICA SPA**1.4. Emergency telephone number**For urgent inquiries refer to:
Pavia - National Center for Toxicological Information 0382/24444;
Milan - Hosp. Niguarda Ca' Granda 02/66101029;
Bergamo - Hosp. "Pope John XXIII" 800/883300;
Verona - Hosp. Integrated Verona 800/011858
Florence - Hosp. "Careggi" U.O. Medical Toxicology 055/7947819;
Rome - "A. Gemelli" Polyclinic 06/3054343;
Rome - "Umberto I" Polyclinic 06/49978000;
Rome - "Bambino Gesù Pediatric Hospital" 06/68593726
Naples - Hosp. "A. Cardarelli" 081/5453333;
Foggia - Hosp. University of Foggia 800/183459

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP). However, since the product contains hazardous substances in concentrations such as to be declared in section no. 3, it requires a safety data sheet with appropriate information, compliant to (EU) Regulation 2020/878.

Hazard classification and indication: --

2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms: --

Signal words: --

Hazard statements:

EUH210 Safety data sheet available on request.

Precautionary statements: --

Product not intended for uses provided for by Directive 2004/42/EC.

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2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage \geq than 0,1%.

The product does not contain substances with endocrine disrupting properties in concentration \geq 0.1%.

SECTION 3. Composition/information on ingredients
3.2. Mixtures

Contains:

Identification	Conc. %	Classification (EC) 1272/2008 (CLP)
Ethanol		
INDEX 603-002-00-5	5 - 10	Flam. Liq. 2 H225, Eye Irrit. 2 H319
EC 200-578-6		Eye Irrit. 2 H319: \geq 50%
CAS 64-17-5		
REACH Reg. 01-2119457610-43-XXXX		
Ethylene glycol		
INDEX 603-027-00-1	2 - 5	Acute Tox. 4 H302, STOT RE 2 H373
EC 203-473-3		STA Oral: 500 mg/kg
CAS 107-21-1		
REACH Reg. 01-2119456816-28-XXXX		

The full wording of hazard (H) phrases is given in section 16 of the sheet.

Ethanol

The classification reported is more severe than the "minimum" classification set out in Annex VI of Regulation (EC) 1272/2008 (CLP). Companies that have already submitted a registration dossier and in possession of the CSR should adopt the most severe classification which includes eye irritation. Based on the available data, a specific concentration limit of 50% can be applied to the classification of mixtures containing ethanol, for the eye irritation end-point.

SECTION 4. First aid measures
4.1. Description of first aid measures

No episodes of harm to the staff authorised to use the product have been reported. The following general measures should be adopted as necessary:
 INHALATION: Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention.
 INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Do not give anything by mouth to an unconscious person.
 EYES and SKIN: Wash with plenty of water. In the event of persistent irritation, get medical advice/attention.

4.2. Most important symptoms and effects, both acute and delayed

No episodes of damage to health ascribable to the product have been reported.

Ethylene glycol

Acute dose-dependent effects.

Skin: irritation

Nervous system: depression, convulsions, coma if ingested

Eyes: irritation

Upper airways: irritation

Lungs: irritation

Digestive system: nausea, vomiting, abdominal colic if ingested

Urogenital system: kidney damage

Chronic effects.

Nervous system: depression, ocular nystagmus

Eyes: irritation

Lungs: irritation

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Signs and symptoms of poisoning include anion deficiency in metabolic acidosis, central nervous system depression, kidney damage, and possible end-stage cranial nerve involvement. Respiratory symptoms, including pulmonary edema, may occur with a delayed effect. People who are subjected to significant exposure should be observed for 24-48 hours in case any respiratory problems develop. In case of severe poisoning, mechanical ventilation support with positive expiratory pressure may be required. Maintain an adequate level of ventilation and oxygen delivery to the patient. If gastric lavage is performed, endotracheal and / or esophageal control is suggested. Pulmonary aspiration hazards should be weighed against toxicity when gastric lavage is considered. If there is a burn, treat as a thermal burn, after decontamination. Treatment in the event of exposure should be aimed at symptom control and the clinical condition of the patient

Ethanol

Acute dose-dependent effects.

Skin: irritation, delipidization

Nervous system: in case of depression ingestion

Eyes: irritation, corneal damage

Upper airways: irritation

Lungs: irritation

Chronic effects.

Skin: irritation, delipidization

Nervous system: headache, asthenia, depression

Upper airways: irritation

Lungs: irritation.

4.3. Indication of any immediate medical attention and special treatment needed

Information not available.

SECTION 5. Firefighting measures**5.1. Extinguishing media****SUITABLE EXTINGUISHING EQUIPMENT**

Extinguishing substances are: carbon dioxide, foam, chemical powder. For product loss or leakage that has not caught fire, water spray can be used to disperse flammable vapours and protect those trying to stem the leak.

UNSUITABLE EXTINGUISHING EQUIPMENT

Do not use jets of water. Water is not effective for putting out fires but can be used to cool containers exposed to flames to prevent explosions.

5.2. Special hazards arising from the substance or mixture**HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE**

Avoid breathing combustion products (carbon oxides).

5.3. Advice for firefighters**GENERAL INFORMATION**

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Stop the leak if there is no danger.

Wear appropriate protective equipment (including personal protective equipment referred to in Section 8 of the safety data sheet) to prevent contamination of skin, eyes and personal clothing. These indications are valid both for workers and for emergency interventions.

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

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Vacuum the spilled product into a suitable container. Assess the compatibility of the vessel to be used with the product by checking Section 10. Absorb the remaining with inert absorbent material.
 Ensure sufficient ventilation of the place affected by the loss. Disposal of contaminated material shall be carried out in accordance with point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage
7.1. Precautions for safe handling

Do not store or handle near open flame, heat or other sources of ignition. Do not smoke. Use only with adequate ventilation. Avoid inhalation of vapors and contact with skin and eyes. Use personal protective equipment recommended in section 8 of the safety data sheet. Wash thoroughly after use. Handle and open the container carefully.

7.2. Conditions for safe storage, including any incompatibilities

Keep away from heat, sparks and open flame. Store in a cool, well ventilated place. Keep containers tightly closed.
 Keep in an area equipped with sprinkler systems. Store this material away from foodstuffs, beverages and feed for animals. Proper use/keep.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection
8.1. Control parameters

Regulatory References:

DEU	Deutschland	Technischen Regeln für Gefahrstoffe (TRGS 900) - Liste der Arbeitsplatzgrenzwerte und Kurzzeitwerte. MAK- und BAT-Werte-Liste 2020, Ständige Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe, Mitteilung 56
ESP	España	Límites de exposición profesional para agentes químicos en España 2021
FRA	France	Valeurs limites d'exposition professionnelle aux agents chimiques en France. ED 984 - INRS
HRV	Hrvatska	Pravilnik o izmjenama i dopunama Pravilnika o zaštiti radnika od izloženosti opasnimkemijskim tvarima na radu, graničnim vrijednostima izloženosti i biološkim graničnim vrijednostima (NN 1/2021)
ROU	România	Hotărârea nr. 53/2021 pentru modificarea hotărârii guvernului nr. 1.218/2006, precum și pentru modificarea și completarea hotărârii guvernului nr. 1.093/2006
SVN	Slovenija	Pravilnik o varovanju delavcev pred tveganji zaradi izpostavljenosti kemičnim snovem pri delu (Uradni list RS, št. 100/01, 39/05, 53/07, 102/10, 43/11 – ZVZD-1, 38/15, 78/18 in 78/19)
GBR	United Kingdom	EH40/2005 Workplace exposure limits (Fourth Edition 2020)
EU	OEL EU	Directive (EU) 2022/431; Directive (EU) 2019/1831; Directive (EU) 2019/130; Directive (EU) 2019/983; Directive (EU) 2017/2398; Directive (EU) 2017/164; Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC; Directive 98/24/EC; Directive 91/322/EEC.
	TLV-ACGIH	ACGIH 2022

Ethylene glycol
Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
OEL	EU	52	20	104	40	SKIN
Predicted no-effect concentration - PNEC						
Normal value in fresh water				10	mg/l	
Normal value in marine water				1	mg/l	
Normal value for fresh water sediment				37	mg/kg	
Normal value for marine water sediment				3,7	mg/kg	

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2-Propanol
Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m ³	ppm	mg/m ³	ppm	
AGW	DEU	500	200	1000	400	
MAK	DEU	500	200	1000	400	
VLA	ESP	500	200	1000	400	
VLEP	FRA			980	400	
GVI/KGVI	HRV	999	400	1250	500	
TLV	ROU	200	81	500	203	
MV	SVN	500	200	1000	400	
WEL	GBR	999	400	1250	500	
TLV-ACGIH		492	200	983	400	

Predicted no-effect concentration - PNEC

Normal value in fresh water	140,9	mg/l
Normal value in marine water	140,9	mg/l
Normal value for fresh water sediment	552	mg/kg
Normal value for marine water sediment	552	mg/kg
Normal value for the terrestrial compartment	28	mg/kg

Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers			Effects on workers				
	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation								500 mg/kg
Skin								880 mg/kg/d

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified ; LOW = low hazard ; MED = medium hazard ; HIGH = high hazard.

Sampling methods

The following sampling methods are suggested for the substances mentioned in the previous tables.

Ethylene glycol

<http://amcaw.ifa.dguv.de/substance/methoden/011-L-Ethane-12-diol.pdf>

Ethanol

http://amcaw.ifa.dguv.de/substance/methoden/063-Ethanol_2016.pdf.

8.2. Exposure controls

The product is not classified as hazardous to health under the provisions of Annex I, Part 3 of Reg. (EC) 1272/2008 (CLP) and as such would not require specific measures for exposure control. However, the following measures are provided as a precautionary measure.

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

HAND PROTECTION

In case of prolonged contact with the product, it is advisable to protect the hands with penetration-resistant work gloves (ref. EN 374).

For the final choice of material for work gloves (ref. EN 374) the following must be considered: compatibility, degradation, breaking time and permeation.

SKIN PROTECTION

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Wear category I professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION

Wear airtight protective goggles (see standard EN 166) in case of handling large quantities of product.

RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type A filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	clear liquid	
Colour	Red - purple	
Odour	characteristic	
Melting point / freezing point	not available	
Initial boiling point	not available	
Flammability	not flammable	
Lower explosive limit	not applicable	
Upper explosive limit	not applicable	
Flash point	not available	
Auto-ignition temperature	not applicable	
Decomposition temperature	not available	
pH	not available	
Kinematic viscosity	not available	
Solubility	in water	
Partition coefficient: n-octanol/water	not available	
Vapour pressure	not available	
Density and/or relative density	1	
Relative vapour density	not available	
Particle characteristics	not applicable	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Information not available

9.2.2. Other safety characteristics

VOC (Directive 2010/75/EU)	7,57 % - 75,66 g/litre
VOC (volatile carbon)	3,92 % - 39,20 g/litre

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Explosive properties

Not applicable (absence of chemical groups associated with explosive properties in accordance with the provisions of Annex I, Part 2, Chapter 2.1.4.3 of Reg. (EC) 1272/2008 - CLP).

Oxidising properties

Not applicable (absence of the requirements related to the presence of atoms and / or chemical bonds associated with oxidizing properties in the molecules of the components in accordance with the provisions of Annex I, Part 2, 2.13.4 of Regulation (EC) 1272/2008 - CLP).

SECTION 10. Stability and reactivity

In the absence of information on the mixture, the literature information on the components is reported. This information is not characteristic of the solution but of the dangerous components.

10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

Ethylene glycol

Reacts violently with chlorosulfonic acid, oleum, perchloric acid, P2S5.

Ethanol

Vapors can form an explosive mixture with air. Ethanol can react violently with strong oxidizing agents.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

Ethylene glycol

It is very hygroscopic.

10.3. Possibility of hazardous reactions

The vapours may also form explosive mixtures with the air.

Ethanol

Risk of explosion on contact with: alkali metals, alkali oxides, calcium hypochlorite, sulfur monofluoride, acetic anhydride (with acids), concentrated hydrogen peroxide, perchlorates, perchloric acid, perchloronitrile, mercury nitrate, nitric acid, silver and acid nitric, silver nitrate, silver and ammonia nitrate, silver oxide and ammonia, strong oxidizing agents, nitrogen dioxide. It can react dangerously with: bromine acetylene, chlorine acetylene, bromine trifluoride, chromium trioxide, cromyl chloride, oxiranes, fluorine, potassium tert-butoxide, lithium hydride, phosphorus trioxide. Forms explosive mixtures with air.

10.4. Conditions to avoid

Avoid overheating. Avoid bunching of electrostatic charges. Avoid all sources of ignition.

Ethylene glycol

Temperature above 40 ° C. Avoid humidity. Avoid daylight. Failure to comply with the aforementioned conditions can cause unwanted decomposition reactions.

Ethanol

Flow or agitation of the substance can generate electrostatic charges due to low conductivity (Pohanish, 2009).

Heating, open flames and sparks.

No ventilation.

Exposure to air.

Containers not properly closed.

10.5. Incompatible materials

Ethylene glycol

strong acids, carbon oxides, oxidising agents, combustible, moisture.

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Ethanol

Strong oxidizing agents, sulfuric acid, nitric acid, alkali and alkaline earth metals, alkaline oxides, peroxides, ammonia, sodium hypochlorite, calcium hypochlorite, perchlorates.

10.6. Hazardous decomposition products

In the event of thermal decomposition or fire, gases and vapours that are potentially dangerous to health may be released.

Ethylene glycol

carbon oxides.

Possible decomposition products: carbonyl compounds, dioxolane derivatives.

Ethanol

Burning ethanol creates carbon monoxide.

SECTION 11. Toxicological information

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.

It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008Metabolism, toxicokinetics, mechanism of action and other information

Ethylene glycol

The substance is rapidly absorbed orally and by inhalation, distributed in the body and metabolized. In rats and dogs, approximately 20-30% of the absorbed dose is excreted by the kidneys. Metabolism occurs in the kidneys and liver 2-4 hours after exposure and metabolites appear in the urine within 24-48 hours. In humans it is initially metabolized by alcohol dehydrogenase into glycoaldehyde and then into glycolic acid which subsequently undergoes conversion into oxalic acid by glycolic acid oxidase. The toxic action of the substance, especially at the kidney level, is attributed to its metabolites, in particular glycolic acid and oxalate. The neurotoxicity of the substance is probably caused by the formation of calcium oxalate crystals, which can lead to a disturbance of intracellular calcium homeostasis with membrane abnormalities, associated with cell damage and even cell death.

Ethanol

It is rapidly absorbed by ingestion and by inhalation, poorly by skin contact (INRS, 2011).

It is distributed in all the body's tissues and liquids, in particular the brain, lungs and liver (INRS, 2011).

About 80-90% of the ingested quantity is metabolized in the liver to acetaldehyde and then in acetic acid.

Acetaldehyde is rapidly metabolized to acetic acid by liver aldehyde dehydrogenase. Acetic acid is subsequently oxidized in the peripheral tissues in carbon dioxide and water. A small amount of absorbed ethanol (2 to 5%) is eliminated unchanged in the urine and exhaled air. It can also be eliminated in breast milk at a concentration comparable to that of breast blood (INRS, 2011).

Its effects are due to the inhibition of synaptic transmission in the brain and depresses the central nervous system with a mainly analgesic and anesthetic action (INRS, 2011).

It also has action on lipid metabolism (INRS, 2011).

Information on likely routes of exposure

Ethylene glycol

The main routes of exposure in the occupational field are inhalation and skin contact. The general population can be exposed by inhalation from the ambient air or by skin contact with products containing the substance.

Ethanol

Professional exposure can take place by inhalation and skin contact with ethanol in the workplaces where it is produced or used (HSDB, 2015).

For the general population, the main potential routes of exposure are ingestion (consumption of alcoholic beverages containing ethanol), inhalation and skin contact (HSDB, 2015).

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Ethylene glycol

The digestive substance is more toxic to humans than animals. The clinical symptomatology develops in 4 phases. In the 1st phase (30 minutes-12 hours after ingestion) there is nausea, vomiting, agitation, stupor, inhibition of reflexes, epileptic seizures and convulsions. Causes of death in this phase can be central respiratory paralysis, coma and cardiocirculatory arrest. Other symptoms are: acute gastritis, meningoencephalitis, metabolic acidosis, leukocytosis, proteinuria. Ocular level shows: nystagmus, ophthalmoplegia, papilledema and optic atrophy. In the 2nd phase (12-24 hours) the main

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symptoms are affecting the cardio-respiratory system: tachycardia, tachypnea, bronchopneumonia, pulmonary edema and respiratory arrest within 72 hours. In the 3rd phase (24-72 hours) renal damage occurs mainly: initially polyuria followed by oliguria and anuria. Kidney changes usually subside within 50 days. In one case, chronic renal failure was observed. In the 4th phase (6-14 days) there are symptoms of CNS degeneration: facial paralysis, dysphagia, hyperreflexia, ataxia, cerebral edema and calcium oxalate deposits in the brain tissue. Hepatic necrosis is also reported. The available data are insufficient to pronounce on the possibility of neurological or immunological effects due to long-term exposure

Ethanol

Acute toxicity is mild both by ingestion and by inhalation. By the dermal route it is minimal (INRS, 2011).

In humans, in the case of acute intoxication by ingestion, the manifestations are essentially neuropsychic (intellectual and psychic arousal with motor incoordination of the cerebellar type, then more or less deep coma and possible paralysis of the respiratory centers). These disorders are closely related to the blood sugar level (INRS, 2011).

Industrial alcohol that has denaturation additives, for concentrations equal to 70% of ethanol, causes serious gastric lesions (INRS, 2011).

In case of inhalation of ethanol vapors, the risk of serious intoxication is slight (INRS, 2011).

The chronic effects of ethylism by ingestion are: neuropsychics (polyneuritis, cerebellar atrophy, memory disorders), digestive (steatosis and cirrhosis of the liver, chronic gastritis, pancreatitis) cardiovascular (myocardiopathy, high blood pressure) and hematological (INRS, 2011).

In case of repeated inhalations of ethanol vapors there are irritation of the eyes, upper airways, headaches, fatigue, decreased concentration and alertness (INRS, 2011).

Studies show that excessive alcohol consumption is a factor that causes arteriosclerosis, while moderate consumption has a protective power (INRS, 2011).

At the skin level, repeated contact can cause erythema and edema in particular if there is an occlusion that determines the evaporation of ethanol (INRS, 2011).

Interactive effects
Ethanol

In the industrial field, hepatotoxic synergistic effects can occur due to simultaneous exposure to chlorinated solvents and to interactions with amides, oximes, thiurams and carbonates, inhibitors of aldehyde dehydrogenase.

ACUTE TOXICITY

ATE (Inhalation) of the mixture:	Not classified (no significant component)
ATE (Oral) of the mixture:	>2000 mg/kg
ATE (Dermal) of the mixture:	Not classified (no significant component)

Ethylene glycol

LD50 (Dermal):	> 3500 mg/kg topo - Studio di tossicità dello sviluppo (sper.)
LD50 (Oral):	7712 mg/kg ratto (sper.)
STA (Oral):	500 mg/kg estimate from table 3.1.2 of Annex I of the CLP (figure used for calculation of the acute toxicity estimate of the mixture)
LC50 (Inhalation mists/powders):	> 2,5 mg/l/6h ratto. Studio di teratogenicità. (sper.)

Ethanol

LD50 (Dermal):	> 20000 mg/kg coniglio (INRS, 2011)
LD50 (Oral):	3400 mg/kg topo (HSDB, 2015)
LC50 (Inhalation mists/powders):	20000 ppm/10h (HSDB, 2015)

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

Ethylene glycol

It has mild irritating power on the skin.

Ethanol

The substance is not irritating (OECD, 2004).

Mild transient irritation was observed on rabbit skin after prolonged contact for 24 hours under occlusive dressing (INRS, 2011).

In rabbits it was not irritating in a study conducted in accordance with OECD TG 404 (OECD, 2004).

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

Ethylene glycol

In volunteers, exposure to vapors and aerosols of substance equal to 137 mg / m³ caused irritation of the ocular mucous membranes. Above 200 mg / m³ the intensity of irritation has made it impossible to continue the exposure. In rabbits, the instillation of a 0.4% isotonic solution has no effect. 4%

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solutions are moderately irritating. Higher concentrations cause caustic lesions.

Ethanol

Moderately irritating (OECD, 2004).

In humans, direct contact with ethanol causes pain, watery eyes, corneal epithelial lesions and conjunctival hyperemia; the sensation of a foreign body in the eye can last 1 or 2 days but, in general, healing is spontaneous, rapid and complete (INRS, 2011; OECD, 2004).

On rabbit eyes, pure ethanol causes moderate eye irritation which is manifested by a mild opacity of the cornea and moderate to severe conjunctivitis. These effects are reversible in less than 14 days [OECD TG 405] (INRS, 2011; OECD, 2004).

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

Skin sensitization**Ethanol**

The substance has not shown sensitizing properties (OECD, 2004).

No reaction was observed in a guinea pig maximization test at a 75% v / v concentration of ethanol and in the mouse ear swelling test at a 95% v / v concentration (INRS, 2011; OECD, 2004).

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

Ethylene glycol

Available studies do not show mutagenic power.

Ethanol

In vitro it determines an increase in exchanges between sister chromatids in cultures of hamster ovary cells or human lymphocytes (INRS, 2011).

In vivo there is an increase in exchanges between sibling chromatids in rats and mice exposed orally to massive doses (> 7 g / kg / day) of ethanol for several weeks. It also determines dominant lethal mutations in rats and mice, exposed orally to 1240 mg / kg / day for 3 days and micronucleus formation in bone marrow erythrocytes in the mouse starting from doses of 620 mg / kg intraperitoneally (INRS, 2011).

Chromosomal aberration assays were negative (INRS, 2011).

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

Ethylene glycol

The available studies have not shown carcinogenic power. In a two-year carcinogenicity study of NTP, in which ethylene glycol was administered in feeding, "no evidence of carcinogenic activity" was observed in male and female B6C3F1 mice (NTP, 1993).

Ethanol

Alcohol consumption can cause cancer of the oral cavity, pharynx, larynx, esophagus, colorectal, liver (hepatocellular carcinoma) and, in women, breast cancer. There was also an association between alcohol consumption and pancreatic cancer. There is sufficient epidemiological evidence showing that individuals who consume alcohol and who have deficiencies in the oxidation of acetaldehyde to acetate have a substantially increased risk of developing cancer, particularly of the esophagus and upper respiratory and digestive tract (IARC, 2012).

- The International Agency for Research on Cancer (IARC) allocates ethanol in alcoholic beverages in group 1 (proven carcinogen for humans) on the basis of evidence of sufficient carcinogenicity both in humans (as regards alcohol consumption) and in laboratory animals (regarding ethanol) (IARC, 2012).

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

Adverse effects on sexual function and fertility**Ethylene glycol**

Animal studies have shown no reproductive toxicity.

Ethanol

Ingestion of the substance alters male fertility: testicular atrophy, decreased libido and testosterone (INRS, 2011).

In women there are changes in the menstrual cycle. There is also a decrease in the incidence of conception per cycle in cases of substance consumption in quantities of 5 glasses per week (INRS, 2011).

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Ethylene glycol

Studies in rats and mice have shown teratogenic effects with skeletal abnormalities and external malformations

Ethanol

Alcohol consumption leads to multiple congenital anomalies: growth retardation, CNS changes, external malformations. The frequency of these anomalies depends on the daily dose of alcohol absorbed (INRS, 2011).

In women who took daily doses of 10 to 20 g, an increase in spontaneous abortions, intellectual (reduced IQ) and behavioral delays (INRS, 2011) was observed.

Effects on or via lactation

Ethanol

Ethanol crosses the placental barrier (INRS, 2011).

Excessive consumption of alcoholic beverages during breastfeeding in women who were already drinking alcohol during pregnancy can increase the negative effects (INRS, 2011).

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

Ethylene glycol

The vapors and the aerosol of the substance are highly irritating to the respiratory system. In volunteers, exposure to vapors and aerosols of 137 mg / m³ substance caused irritation of the upper airways. Above 200 mg / m³ the intensity of irritation has made it impossible to continue the exposure. Available studies indicate the kidney as a target organ in acute poisoning.

Ethanol

In humans, in cases of acute intoxication by ingestion, the manifestations are essentially neuropsychic (intellectual and psychic arousal with cerebellar motor incoordination, then more or less deep coma and possible paralysis of the respiratory centers) (INRS, 2011).

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

Ethylene glycol

The available data are insufficient to pronounce on the possibility of neurological or immunological effects due to long-term exposure.

Ethanol

Repeated exposure if swallowed causes toxicity of the nervous system (polyneuritis, cerebellar atrophy, memory disorders), of the digestive system (steatosis and cirrhosis of the liver, chronic gastritis, pancreatitis) of the cardiovascular system (myocardiopathy, arterial hypertension) (INRS, 2011).

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

11.2. Information on other hazards

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

SECTION 12. Ecological information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity

Ethanol

LC50 - for Fish

Chronic NOEC for Algae / Aquatic Plants

> 100 mg/l/96h Pimephales promelas (OECD, 2004)

280 mg/l/7d Lemna gibba (OECD, 2004)

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Short-term effects

Fish (*Pimephales promelas*) LC50-96 hours > 100 mg/l (OECD, 2004);
Crustaceans (*Artemia salina*) LC50-24 hours: 1833 mg/l (OECD, 2004);
Crustaceans (*Paramecium caudatum*) LC50-4 hours: 5980 mg/l (OECD, 2004);
Algae (*Chlorella vulgaris*) EC50-96 hours: 1000 mg/l (growth inhibition) (OECD, 2004).

Long term effects

Crustaceans (*Ceriodaphnia* sp.) NOEC-10 days: 9.6 mg/l (effects on reproduction) (OECD, 2004)
Algae (*Lemna gibba*) NOEC-7 days: 280 mg/l (OECD, 2004).

Ethylene glycol

LC50 - for Fish 72860 mg/l/96h *Pimepales promelas*
EC50 - for Crustacea > 100 mg/l/48h *Daphnia magna*

12.2. Persistence and degradability
Ethanol

Solubility in water > 1000 mg/l (1000-10000 mg/l)
Rapidly degradable

12.3. Bioaccumulative potential
Ethanol

Partition coefficient: n-octanol/water -0,35

12.4. Mobility in soil
Ethanol

It is not persistent in the environment. The fugacity model (level III) shows that, released into the environment, it is mainly distributed in air and water. The relative distributions between the compartments are 57% in air, 34% in water and 9% in soil. This prediction is supported by the limited data available on prevailing concentrations, which show that ethanol has been detected in outdoor air and in river water (OECD, 2004).

The Koc of 2.75 (determined from the log Kow of 0.44) indicates that if released to soil, ethanol has very high mobility and, if released to water, does not adsorb to suspended solids and sediments (HSDB, 2015).

The Henry's Law constant of 5×10^{-6} atm-m³/mole indicates that volatilization from both wet soil surfaces and water surfaces is an important fate process (for a model river and model lake it has been estimated volatilization half-lives of 5 and 39 days, respectively) (HSDB, 2015).

The vapor pressure indicates that ethanol can volatilize from dry soil surfaces (HSDB, 2015).

12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage \geq than 0,1%.

12.6. Endocrine disrupting properties

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

12.7. Other adverse effects

Information not available

SECTION 13. Disposal considerations
13.1. Waste treatment methods

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

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14.1. UN number or ID number

not applicable

14.2. UN proper shipping name

not applicable

14.3. Transport hazard class(es)

not applicable

14.4. Packing group

not applicable

14.5. Environmental hazards

not applicable

14.6. Special precautions for user

not applicable

14.7. Maritime transport in bulk according to IMO instruments

Information not relevant

SECTION 15. Regulatory information
15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Seveso Category - Directive 2012/18/EU: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006
Product

Point 40

Contained substance

Point 75

Point 72 Gentian violet REACH Reg.: --

Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors

not applicable

Substances in Candidate List (Art. 59 REACH)

 On the basis of available data, the product does not contain any SVHC in percentage \geq than 0,1%.

Substances subject to authorisation (Annex XIV REACH)

None

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Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls

Information not available

15.2. Chemical safety assessment

A chemical safety assessment has been performed for the following contained substances

Ethanol

SECTION 16. Other information

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Flam. Liq. 2	Flammable liquid, category 2
Acute Tox. 4	Acute toxicity, category 4
STOT RE 2	Specific target organ toxicity - repeated exposure, category 2
Eye Irrit. 2	Eye irritation, category 2
H225	Highly flammable liquid and vapour.
H302	Harmful if swallowed.
H373	May cause damage to organs through prolonged or repeated exposure.
H319	Causes serious eye irritation.
EUH210	Safety data sheet available on request.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: Regulation (EC) 1907/2006

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- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA: Time-weighted average exposure limit
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
 2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
 3. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
 4. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
 5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
 6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
 7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
 9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
 10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
 11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
 12. Regulation (EU) 2016/1179 (IX Atp. CLP)
 13. Regulation (EU) 2017/776 (X Atp. CLP)
 14. Regulation (EU) 2018/669 (XI Atp. CLP)
 15. Regulation (EU) 2019/521 (XII Atp. CLP)
 16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
 17. Regulation (EU) 2019/1148
 18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
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 20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)
 21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)
 22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)
- The Merck Index. - 10th Edition
 - Handling Chemical Safety
 - INRS - Fiche Toxicologique (toxicological sheet)
 - Patty - Industrial Hygiene and Toxicology
 - N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
 - IFA GESTIS website
 - ECHA website
 - Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

CALCULATION METHODS FOR CLASSIFICATION

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.

Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.

Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

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