

ENGLISH

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

1.1 Product identifiers

Product name: Crystal Violet Solution
 Product Number: 80299

1.2 Identified uses of the relevant substance or mixture and uses advised against

Identified uses relevant: Professional uses, Health Services, scientific research and development

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier: Liofilchem®
 Address: Via Scozia, 64026 - Roseto degli Abruzzi (TE)
 Telephone number: 085/8930745
 Fax number: 085/8930330
 E-mail address: liofilchem@liofilchem.com

1.4 Emergency telephone number

Poison control centers
 Pavia - 038224444;
 Milano - 0266101029;
 Bergamo - 800883300;
 Verona - 800011858;
 Firenze - 0557947819;
 Roma - Gemelli 063054343;
 Roma - Umberto I 0649978000;
 Roma - Bambino Gesù 0668593726;
 Napoli - 0815453333;
 Foggia - 800183459.

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

The product is classified as dangerous pursuant to the provisions of Regulation (EC) 1272/2008 (CLP) (and subsequent amendments and adjustments). The product therefore requires a safety data sheet compliant with the provisions of Regulation (EC) 1907/2006 and subsequent amendments. Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]

Flam. Liq. 3, Flammable liquids (Category 3); H226
 Eye Irrit. 2, Eye irritation (Category 2); H319
 Carc. 2, Carcinogenicity (Category 2); H351
 STOT RE 2, Specific target organ toxicity — repeated exposure (Category 2); H373
 Aquatic Chronic 3, Chronic toxicity to the aquatic environment (Category 3); H412

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008 [CLP]

Pictogram



Signal word

Danger

Hazard statement(s)

H226 Flammable liquid and vapour.
 H351 Suspected of causing cancer
 H373 May cause damage to organs through prolonged or repeated exposure.
 H319 Causes serious eye irritation.
 H412 Harmful to aquatic life with long lasting effects.

Precautionary statement(s)

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.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

Supplemental Hazard Statements - none

2.3 Other hazards - none

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

3.2 Mixtures:

Hazardous substances

CAS n°	EC n°	Index n°	Registration number REACH	Concentration	Classification according Regulation (EC) No 1272/2008
Ethylene glycol					
107-21-1	203-473-3	603-027-00-1	01-2119456816-28-XXXX	20.0 – 25.0 %	Acute Tox. 4 H302, STOT RE 2 H373
Ethanol					
64-17-5	200-578-6	603-002-00-5	01-2119457610-43-XXXX	12.0 – 15.0 %	Flam. Liq. 2 H225, Eye Irrit. 2 H319
Gentian Violet					
548-62-9	208-953-6	612-204-00-2	-	1.0 – 2.5 %	Carc. 2 H351, Acute Tox. 4 H302, Eye Dam. 1 H318, Skin Irrit. 2 H315, Aquatic Acute 1 H400 M=1, Aquatic Chronic 1 H410 M=1

Additional Information:

For full text of H-statements, see SECTION 16

SECTION 4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice: Consult a physician. Show this safety data sheet to the doctor in attendance.

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 30-60 minutes, opening the eyelids fully. Get medical advice/attention.

SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention.

INGESTION: Have the subject drink as much water as possible. Get medical advice/attention. Do not induce vomiting unless explicitly authorised by a doctor.

INHALATION: Get medical advice/attention immediately. Remove victim to fresh air, away from the accident scene. If the subject stops breathing, administer artificial respiration. Take suitable precautions for rescue workers.

4.2 Most important symptoms and effects, both acute and delayed

For symptoms and effects due to the substances contained, see chap. 11..

ETHYLENE GLYCOL

Signs and symptoms of poisoning include anion deficiency in metabolic acidosis, central nervous system depression, kidney damage and possible late stage cranial nerve involvement. Respiratory symptoms may occur, including edema pulmonary, with delayed effect. People who are subjected to significant exposure should be kept under observation for 24-48 hours, in case of any breathing problems. In case of severe poisoning, support may be required mechanical ventilation with positive expiratory pressure. Maintain an adequate level of ventilation and oxygen supply to the patient. If gastric lavage is performed, endotracheal and / or esophageal control is suggested. Dangers from pulmonary aspiration must be evaluated for toxicity when gastric lavage is considered. If there is a burn, treat as thermal burn, after decontamination. Treatment in the event of

exposure should be aimed at symptom control and treatment 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

ETHYLENE GLYCOL

If a quantity of ethylene glycol of about 60 - 100 ml has been ingested, the rapid administration of ethanol can counteract the toxic effects (metabolic acidosis, kidney damage). Consider hemodialysis or peritoneal dialysis and administration of thiamine 100 mg e pyridoxine 50 mg intravenously every 6 hours. If ethanol is used, a therapeutically effective blood concentration in the range 100-150 mg / dl can be achieved with a rapid attack dose followed by continuous intravenous infusion. Consult the literature available for treatment details. 4-methyl pyrazole is an effective alcoholic dehydrogenase blocker and is available as Fomepizole (Antizol (R)) and should be used in the treatment, if available, of poisoning by mono-, di- or tri-ethylene glycol, methanol and ethylene glycol butyl ether. Fomepizole protocol (Brent J. et al., New EngJ Med, Feb 8 2001 244: 6, p 424-9): attack dose 15 mg / kg for intravenously, followed by a maintenance dose of 10 mg / kg every 12 hours. After 48 hours increase the dose to 15 mg / kg every 12 hours. Continue administration of Fomepizole until serum from methanol, mono, di or triethylene glycol is no longer present.

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

CO₂, foam, chemical powder for flammable liquids.

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

Excess pressure may form in containers exposed to fire at a risk of explosion. Do not breathe combustion products.

Ethylene glycol: If possible, move the containers of the substance away from the fire or cool, since if exposed to thermal adiation or if directly involved it can give rise to toxic fumes. Vapors can cause dizziness, fainting or choking.

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

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

Send away individuals who are not suitably equipped. Use explosion-proof equipment. Eliminate all sources of ignition (cigarettes, flames, sparks, etc.) from the leakage site.

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

Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in 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

Keep away from heat, sparks and naked flames; do not smoke or use matches or lighters. Without adequate ventilation, vapours may accumulate at ground level and, if ignited, catch fire even at a distance, with the danger of backfire. Avoid bunching of electrostatic charges. When performing transfer operations involving large containers, connect to an earthing system and wear antistatic footwear. Vigorous stirring and flow through the tubes and equipment may cause the formation and accumulation of electrostatic charges. In order to avoid the risk of fires and explosions, never use compressed air when handling. Open containers with caution as they may be pressurised. Do not eat, drink or smoke during use. Avoid leakage of the product into the environment.

7.2 Conditions for safe storage, including any incompatibilities

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Store in a cool and well ventilated place, keep far away from sources of heat, naked flames and sparks and other sources of ignition. Keep containers away from any incompatible materials, see section 10 for details.

7.3 Specific end uses

Apart from the uses described in section 1.2 are not covered other specific uses.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

- **ETHYLENE GLYCOL**

Threshold limit value.								
Type	Country	TWA/8h		STEL/15min				
		mg/m ³	ppm	mg/m ³	ppm			
VLEP	ITA	52	20	104	40			
TLV-ACGIH				100 (C)		Aerosol		
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				20,9	mg/kg			
Normal value for water, intermittent release				10	mg/l			
Normal value of STP microorganisms				199,5	mg/l			
Normal value for the terrestrial compartment				1,53	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			VND	7 mg/m ³			VND	35 mg/m ³
Skin			VND	53 mg/kg/d			VND	106 mg/kg/d

- **ETHANOL**

Threshold Limit Value								
Type	Country	TWA/8h		STEL/15min		Remarks / Observations		
		mg/m ³	ppm	mg/m ³	ppm			
WEL	GBR	1920	1000					
TLV-ACGIH				1884	1000			(ir TRS)
Predicted no-effect concentration - PNEC								
Normal value in fresh water				0.96				mg/l
Normal value in marine water				0.79				mg/l
Normal value for fresh water sediment				3.6				mg/kg
Normal value for marine water sediment				2.9				mg/kg
Normal value of STP microorganisms				580				mg/l
Normal value for the food chain (secondary poisoning)				0.72				mg/kg
Normal value for the terrestrial compartment				0.63				mg/kg/d
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
Skin							VND	343 mg/m ³
Inhalation				1900 mg/m ³			VND	VND 950 mg/m ³

8.2 Exposure controls

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. When choosing personal protective equipment, ask your chemical substance supplier for advice. Personal protective equipment must be CE marked, showing that it complies with applicable standards. Provide an emergency shower with face and eye wash station. Exposure levels must be kept as low as possible to avoid significant build-up in the organism. Manage personal protective equipment so as to guarantee maximum protection (e.g. reduction in replacement times).

HAND PROTECTION

Protect hands with category III work gloves (see standard EN 374).

The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability. The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

SKIN PROTECTION

Wear category II 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.

Consider the appropriateness of providing antistatic clothing in the case of working environments in which there is a risk of explosion.

EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

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.

Product residues must not be indiscriminately disposed of with waste water or by dumping in waterways.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance

Form Clear Liquid
Color Violet

Odour

characteristic

pH

No data available

Melting point/ freezing point

No data available

Initial boiling point and boiling range

No data available

Evaporation rate

No data available

Flammability (solid, gas)

No data available

Upper / lower flammability or explosive limits	No data available
Flash point	38°C
Auto-ignition temperature	Not applicable
Decomposition temperature	Not applicable
Vapour pressure	No data available
Vapour density	No data available
Relative density	No data available
Water solubility	Soluble
Partition coefficient: n-octanol/water	Not applicable
Viscosity	No data available
Explosive properties	No data available
Oxidizing properties	No data available

9.2 Other safety information

VOC (Directive 2010/75 / EC): 38.04%

VOC (volatile carbon): 0

Explosion hazard Product is not explosive. However, formation of explosive air / vapor mixtures are possible.

SECTION 10. STABILITY AND REACTIVITY

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.

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

Forms explosive mixtures with air (Pohanish, 2009).

It can react violently with strong oxidants and strong acids; bases, strong peroxides; acetic anhydride, acetyl bromide, acetyl chloride, aliphatic amines, bromine pentafluoride, calcium oxide (quicklime), cesium oxide, chloryl perchlorate, disulphoryl difluoride, ethylene glycol methyl ether, iodine heptafluoride, isocyanates, nitrosyl perchlorate, platinum ally black diplomat; potassium-tert-butoxide, potassium, potassium oxide, potassium peroxide, potassium superoxide; phosphorus (III) oxide, silver nitrate, silver oxide, sulfuric acid, oleum, sodium, sodium hydrazide, sodium peroxide, sulfinyl yanamide, tetrachlorosilane, s-triazine-2,4,6-triol, triethoxy aluminum tribromide, triethylaluminium, uranium fluoride, xenon tetrafluoride (Pohanish, 2009).

The mixture with concentrated hydrogen peroxide forms powerful explosives. The mixture with mercury nitrate (II) forms explosive fulminate mercury. Forms explosive complexes with perchlorates, magnesium perchlorate (form ethyl perchlorate), silver perchlorate (Pohanish, 2009).

Reacts with hypochlorous acid or chlorine to form explosive and heat sensitive ethyl hypochlorite (which can decompose when cold) (Pohanish, 2009).

10.4 Conditions to avoid

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

Ethylene glycol

No ventilation. Heating and open flames. Avoid build-up of static electricity

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 oxidants. Strong bases

ETHANOL

Strong oxidants. Perchlorates, peroxides, silver oxide, hydrogen peroxide, potassium, sodium, chlorine, permanganate or chromate in acid solutions, ruthenium oxide, uranium hexafluoride, iodine or bromine pentafluoride, chromyl chloride, iodine heptafluoride, bromide or chloride of acetyl, disulfuryl difluoride, platinum, nitric acid, peroxides, calcium hypochlorite, chlorine oxides, silver nitrate, dipotassium dioxide, hexoxide tetraphosphorus, chromium trioxide, fluorine nitrate, strong oxidants.

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

Possible decomposition products: carbonyl compounds, dioxolane derivatives.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

ETHYLENE GLYCOL

Metabolism, kinetics, mechanism of action and other information

The substance is rapidly absorbed orally and inhaled, 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 man 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 in the kidney, 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.

Acute toxicity

LD50 (Oral). 7712 mg / kg rat

LD50 (Dermal). > 3500 mg / kg mouse

LC50 (Inhalation). > 2.5 mg / l / 6h rat (aerosol)

Skin corrosion / irritation

It has a mild skin irritant effect.

Corrosion to the respiratory tract

Date not available.

Serious eye damage / eye irritation

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 the irritation made it impossible to continue the exposure. In rabbits, instillation of a 0.4% isotonic solution has no effect. 4% solutions are moderately irritating. Higher concentrations cause caustic lesions.

Germ cell mutagenicity

The available studies do not show mutagenic power.

Carcinogenicity

Available studies have not shown carcinogenic potential. In a two-year NTP carcinogenicity study in which ethylene glycol as administered in the feed, "no evidence of carcinogenic activity" was observed in male and female B6C3F1 mice (NTP, 1993).

Reproductive toxicity

- Adverse Effects on Sexual Function and Fertility: Animal studies have not shown reproductive toxicity.

- Adverse Developmental Effects: Studies in rats and mice have shown teratogenic effects with skeletal abnormalities and external malformations.

- Effects on lactation or through lactation: Data not available.

Specific target organ toxicity (STOT) - single exposure

The vapors and aerosol of the substance are strongly irritating to the respiratory system. In volunteers, exposure to vapors and aerosols of the substance equal to 137 mg / m³ caused irritation of the upper airways. Above 200 mg / m³ the intensity of the irritation made it impossible to continue the exposure.

Available studies indicate the kidney as a target organ in acute poisoning.

Specific target organ toxicity (STOT) - repeated exposure

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

Aspiration hazard

Date not available.

Likely routes of exposure

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

Delayed, immediate and chronic effects from short and long term exposure

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. Cause of death at this stage 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 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 not sufficient to pronounce on the possibility of effect

ETHANOL

Metabolism, kinetics, mechanism of action and other information

It is rapidly absorbed by ingestion and by inhalation, poorly by skin contact. It is distributed throughout the body's tissues and fluids, especially the brain, lungs and liver. About 90-98% of the ingested amount is metabolized in the liver to acetaldehyde and then to acetic acid. Acetaldehyde is rapidly metabolised to acetic acid by liver aldehyde dehydrogenase. The acetic acid is subsequently oxidized in the peripheral tissues to carbon dioxide and water. A small amount of ethanol is excreted unchanged in urine, sweat and exhaled air. Its effects are due to the inhibition of synaptic transmission in the brain.

It also has an action on lipid metabolism.

Acute toxicity

Rat LD50 (oral): 7060 mg / kg

Rabbit LD50 (cutaneous): > 20000 mg / kg

Rat LC50-10 hours (by inhalation): 20000 ppm

Skin corrosion / irritation

The substance is not irritating.

Corrosion to the respiratory tract

Date not available.

Serious eye damage / eye irritation

The substance is irritating to the eyes, but resolution is generally quick and complete.

The substance causes pain, tearing, corneal epithelial lesions and conjunctival hyperemia.

Germ cell mutagenicity

In vitro it leads to increased sister chromatid exchanges in hamster or hamster ovary cell cultures

human lymphocytes. In vivo, increased sister chromatid exchanges are observed in rats and mice exposed orally to massive doses of ethanol for several weeks. It also determines dominant lethal mutations in rats and mice exposed orally at 1240 mg / kg / day for 3 days and the formation of micronuclei in bone marrow erythrocytes in mice starting at doses of 620 mg / kg intraperitoneally.

Chromosomal aberration assays were negative.

Carcinogenicity

Alcohol consumption can cause cancer of the oral cavity, pharynx, larynx, esophagus, colorectal, liver (hepatocellular carcinoma) and, in women, breast cancer. There has also been 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 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 (known Carcinogen to humans) based on evidence of sufficient carcinogenicity in both humans (regarding alcohol consumption) and in laboratory animals (regarding ethanol) (IARC, 2012)

Reproductive toxicity

- Adverse Effects on Sexual Function and Fertility:

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

In women there are alterations in the menstrual cycle. A decrease in the incidence of conception per cycle is also reported in cases of substance consumption in quantities of 5 glasses per week.

- Adverse effects on development:

The consumption of alcohol causes multiple congenital anomalies: growth retardation, CNS alterations, external malformations. The frequency of these anomalies depends on the daily dose of alcohol absorbed.

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

- Effects on or through lactation: Ethanol crosses the placental barrier.

Excessive consumption of alcoholic beverages during breastfeeding in women who were already drinking alcohol during pregnancy may increase the negative effects.

Specific target organ toxicity (STOT) - single exposure

In humans, in case of acute intoxication due to ingestion, the manifestations are essentially neuropsychic (intellectual and psychic excitation with motor incoordination of the cerebellar type, then more or less deep coma and possible paralysis of the respiratory centers).

Specific target organ toxicity (STOT) - repeated exposure

Repeated exposure by ingestion causes toxicity to the nervous system (polyneuritis, cerebellar atrophy, memory disorders), to the digestive system (fatty liver and cirrhosis of the liver, chronic gastritis, pancreatitis) of the cardiovascular system (myocardopathy, arterial hypertension).

Aspiration hazard

Date not available.

Likely routes of exposure

The main routes of occupational exposure are ingestion, inhalation and skin contact.

Delayed, immediate and chronic effects from short and long term exposure

Acute toxicity is mild both by ingestion and by inhalation. Through the skin it is minimal.

In humans, in case of acute intoxication due to ingestion, the manifestations are essentially neuropsychic (intellectual and psychic excitation 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 alcohol level.

Industrial alcohol which has denaturation additives, for concentrations equal to 70% of ethanol, causes serious gastric lesions. In case of inhalation of ethanol vapors, the risk of severe intoxication is small.

The chronic effects of alcoholism by ingestion are: neuropsychic (polyneuritis, cerebellar atrophy, memory disorders), digestive (fatty liver and cirrhosis of the liver, chronic gastritis, pancreatitis), cardiovascular (myocardiopathy, arterial hypertension) and haematological.

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

In case of repeated inhalation of ethanol vapors there is irritation of the eyes, upper airways, headaches, fatigue, decreased ability to concentrate and alertness.

Studies show that excessive alcohol consumption is a factor that causes arteriosclerosis, while moderate consumption has a protective power. At the skin level, repeated contact can cause erythema and edema in particular if there is an occlusion that determines evaporation.

VIOLET GENTIAN

ACUTE TOXICITY

LC50 (Inhalation - vapors) of the mixture: Not classified (no relevant component).

LC50 (Inhalation - mists / powders) of the mixture: Not classified (no relevant component).

LD50 (Oral) of the mixture: 23212.389 mg / kg

LD50 (Dermal) of the mixture: Not classified (no relevant component).

SKIN CORROSION / SKIN IRRITATION.

It does not meet the classification criteria for this hazard class.

SERIOUS EYE DAMAGE / EYE IRRITATION.

Causes serious eye irritation.

RESPIRATORY OR SKIN SENSITIZATION.

It does not meet the classification criteria for this hazard class.

MUTAGENICITY ON GERMINAL CELLS.

It does not meet the classification criteria for this hazard class.

CARCINOGENICITY.

Suspected of causing cancer.

REPRODUCTION TOXICITY.

It does not meet the classification criteria for this hazard class.

SPECIFIC TOXICITY FOR TARGET ORGANS (STOT) - SINGLE EXPOSURE.

It does not meet the classification criteria for this hazard class.

SPECIFIC TARGET ORGAN TOXICITY (STOT) - REPEATED EXPOSURE.

It can cause damage to organs.

DANGER IN CASE OF SUCTION.

It does not meet the classification criteria for this hazard class.

SECTION 12. ECOLOGICAL INFORMATION

12.1 Toxicity

ETHANOL

EC50 - Crustaceans. > 10 mg / l / 48h

EC50 - Algae / Aquatic Plants. > 10 mg / l / 72h

EC10 Algae / Aquatic Plants. > 11 mg / l / 72h

Chronic NOEC for Pisces. 12.34 mg / l

Chronic NOEC for Algae / Aquatic Plants. > 3 mg / l

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*) 4-hour LC50: 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).

VIOLET GENTIAN

EC50 - Crustaceans. 0.24 mg / l / 48h (0.24-5 mg / l) *Daphnia magna*

EC50 - Algae / Aquatic Plants. 0.025 mg / l / 72h (0.025-0.8 mg / l) *Pseudokirchneriella subcapitata*

ETHYLENE GLYCOL

LC50 - Pisces.

72860 mg / l / 96h *Pimephales promelas*

EC50 - Crustaceans.

> 100 mg / l / 48h *Daphnia magna*

Chronic NOEC for Pisces.

15830 mg / l *Pimephales promelas* (7 days)

12.2 Persistence and degradability

ETHYLENE GLYCOL

Biodegrades to the soil. In water it biodegrades both aerobically and anaerobically. Photodegrades in the air.

ETHANOL

The vapor pressure (7906 Pa at 25 ° C) indicates that when released into the atmosphere, ethanol exists only as vapor in the atmosphere where it degrades by reaction with photochemically produced hydroxyl radicals; for this reaction in air is Estimated to have a half-life of 36 hours (HSDB, 2015).

Ethanol does not contain chromophores that absorb wavelengths at > 290 nm, and therefore it is not expected to be susceptible to direct photolysis by solar radiation (HSDB, 2015).

Hydrolysis is not expected to be an important environmental fate process since ethanol is devoid of functional groups which hydrolyze in environmental conditions (pH 5 to 9) (HSDB, 2015).

Ethanol was biodegraded with half-lives of the order of a few days using microcosms built with soil sandy with low organic content and groundwater, this indicates that biodegradation is a process of important environmental fate in soil and water (HSDB, 2015).

12.3 Bioaccumulative potential

ETHANOL

An estimated BCF value of 3 suggests low bioconcentration potential in aquatic organisms (HSDB, 2015).

12.4 Mobility in soil

ETHYLENE GLYCOL

High mobility on the ground. Volatilization from wet surfaces and water is not significant; it does not adsorb to sediments and suspended solids. In the atmosphere it exists in the vapor phase.

ETHANOL

Ethanol is not persistent in the environment. The fugacity model (level III) shows that, released in the environment it is mainly distributed in air and water. The relative distributions between the sub-funds 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 river water (OECD, 2004). The Koc of 2.75 (determined by the log Kow of 0.44) indicates that if released to the ground, ethanol has much mobility high and, if released in water, it does not adsorb to suspended solids and sediments (HSDB, 2015).

The Henry's law constant of 5×10^{-6} atm-m³ / mole indicates that the volatilization is from surfaces of moist soil that from water surfaces is an important fate process (for a model river and a lake model were estimated volatilization half-lives, respectively, of 5 and 39 days) (HSDB, 2015). The vapor pressure indicates that ethanol can volatilize from dry soil surfaces (HSDB, 2015).

12.5 Results of PBT and vPvB assessment

This mixture contains no substances evaluated PBT or vPvB

12.6 Endocrine disrupting properties

The mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

None

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations. Waste transportation may be subject to ADR restrictions.

Contaminated packaging

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

SECTION 14. TRANSPORT INFORMATION

14.1 UN number

ADR/RID: 1170 IMDG: 1170 IATA: 1170

14.2 UN proper shipping name

ADR/RID: ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

IMDG: ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

IATA: ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

14.3 Transport hazard class(es)

ADR/RID: 3 IMDG: 3 IATA: 3

14.4 Packaging group

ADR/RID: III IMDG: III IATA: III

14.5 Environmental hazards

ADR/RID: no IMDG: no IATA: no

14.6 Special precautions for user

no data available

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

no data available

15. REGULATORY INFORMATION

This safety datasheet complies with:

- the requirements of European Parliament and of the Council Regulation (EC) No. 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and Commission Regulation (EU) No. 453/2010 amending Commission Regulation (EC) No. 1907/2006.
- the requirements of Commission Regulation EU 2020/878

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

The product is classified, coded and labeled in accordance with EU Regulation on Hazardous Materials.

15.2 Chemical Safety Assessment

This product has not been made a chemical safety assessment.

16. OTHER INFORMATION

Text of H code(s) and R-phrases mentioned in Section 3

Flam. Liq. 2, Flammable liquids (Category 2);

Flam. Liq. 3, Flammable liquids (Category 3);

Eye Dam. 1, Serious eye damage, category 1

Eye Irrit. 2, Eye irritation (Category 2);

Skin Irrit. 2, Skin irritation (Category 2);

Acute Tox. 4, Acute toxicity, category 4

Carc. 2, Carcinogenicity (Category 2);

STOT RE 2, Specific target organ toxicity — repeated exposure (Category 2);

Aquatic Chronic 3, Chronic toxicity to the aquatic environment (Category 3);

H225 Highly flammable liquid and vapour

H226 Flammable liquid and vapour.

H302 Harmful if swallowed

H315 Causes skin irritation

H318 Causes serious eye damage

H319 Causes serious eye irritation.

H351 Suspected of causing cancer.

H373 May cause damage to organs through prolonged or repeated exposure.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

H412 Harmful to aquatic life with long lasting effects.

Abbreviations and acronyms

- 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
- 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

Training advice

The product must be used by qualified personnel. It is recommended to provide basic training with regard to safety and health at work to ensure proper handling of the product.

Further information

The information in this document is based on the present state of our knowledge. The user must ensure the accuracy and completeness of such information in relation to the specific use intended.

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