Safety Data Sheet

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

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

1.1. Product identifier

Code: **TC54005**
Product name **PHENOLPHTHALEIN 0.5% hydroalcoholic solution**

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

Intended use **Laboratory reagent**

1.3. Details of the supplier of the safety data sheet

Name **TITOLCHIMICA SPA**
Full address **VIA DELL'ARTIGIANATO, 2**
District and Country **45030 VILLAMARZANA (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 classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Flammable liquid, category 3	H226	Flammable liquid and vapour.
Eye irritation, category 2	H319	Causes serious eye irritation.

2.2. Label elements

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

Hazard pictograms:

Signal words: Warning

Hazard statements:

H226	Flammable liquid and vapour.
H319	Causes serious eye irritation.

Precautionary statements:

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280	Wear protective gloves/ protective clothing / eye protection / face protection.
P337+P313	If eye irritation persists: Get medical advice / attention.
P370+P378	In case of fire: use carbon dioxide, foam, chemical powder to extinguish.

2.3. Other hazards

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

The product does not contain substances with endocrine disrupting properties in concentration ≥ 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	30 - 50	Flam. Liq. 2 H225, Eye Irrit. 2 H319
EC 200-578-6		Eye Irrit. 2 H319: ≥ 50%
CAS 64-17-5		
REACH Reg. 01-2119457610-43-XXXX		
2-Propanol		
INDEX 603-117-00-0	1 - 5	Flam. Liq. 2 H225, Eye Irrit. 2 H319, STOT SE 3 H336
EC 200-661-7		
CAS 67-63-0		
REACH Reg. 01-2119457558-25-XXXX		
Phenolphthalein		
INDEX 604-076-00-1	0,1 – 0,9	Carc. 1B H350, Muta. 2 H341, Repr. 2 H361f
EC 201-004-7		Carc. 1B H350: ≥ 1%
CAS 77-09-8		
REACH Reg. 01-2119498295-24-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

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.
SKIN: Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.
INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.

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

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.

2-Propanol
Acute dose-dependent effects.
Skin: irritation.
Nervous system: ingestion and inhalation cause depression.
Eyes: irritation.
Nose: irritation.
Lungs: irritation.
Chronic effects.
Skin: irritation, sensitization, delipidization.

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

Useful urgent medical intervention.

SECTION 5. Firefighting measures

Closed containers exposed to fire heat can generate overpressure and explode.

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
None in particular.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE
Do not breathe combustion products. The product is combustible and, when the powder is released into the air in sufficient concentrations and in the presence of a source of ignition, it can create explosive mixtures with air. Fires may start or get worse by leakage of the solid product from the container, when it reaches high temperatures or through contact with sources of ignition.

Ethanol
Hazardous decomposition products: carbon oxides.

5.3. Advice for firefighters

Water may not be effective in extinguishing the fire, however it should be used to cool flammable containers and prevent bursts and explosions. For leakages and spills that have not burned, water spray can be used to disperse flammable vapors and protect people committed to stop the loss.
It is not advisable to use direct jet jets.
Equipment: wear complete equipment with visor helmet and neck protector, self-contained breathing apparatus or demand, fire jacket and trousers with bands around your arms, legs and waist.

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ethanol
For those who do not intervene directly
The following indications are addressed to duly trained personnel operating in the plant units in which the substance is normally used and are intended to ensure, when this is possible without risk, the preliminary safety operations before leaving and waiting for the intervention. of the emergency team.
Stop the leak if the operation is safe.
Keep people not involved in emergency intervention away from the area affected by the spreading.
Whenever possible, operate above wind.
The vapors that develop are flammable and heavier than air and therefore tend to stratify downwards, they could ignite even far from the point of release and cause a backfire.
Eliminate all possible sources of ignition.

For those who intervene directly
The following indications are addressed to expert personnel such as personnel belonging to the emergency team and, for this purpose, specially trained; they are added to the indications referred to in the point referring to personnel who do not intervene directly; the same personnel refer to the indications relating to environmental precautions and methods of containment and remediation.
As a precaution, wear the special fire-fighting equipment referred to in point 5.
All equipment used during the operation must be grounded.
Use antistatic clothing and equipment during operations.
To limit evaporation and minimize the area affected by the dispersion of vapors, place barriers to contain the spilled substance; the use of filming foams can also be effective.
It can also be effective to dilute the spread with water.

6.2. Environmental precautions

Prevent product from entering sewers, surface water, ground water and confined areas. If the product has run into watercourses, inform the relevant authorities.

6.3. Methods and material for containment and cleaning up

Aspirate in suitable container (in material incompatible with the product) and absorb the spilled product with inert absorbent material (sand, vermiculite, diatomaceous earth, Kieselguhr, etc.). Collect most of the resulting material with non-sparking equipment and deposit it in containers for disposal. Ensure adequate ventilation of the place affected by the loss. Disposal of contaminated material must be made in accordance with point 13.

6.4. Reference to other sections

Any information regarding personal protection and disposal are reported in sections 8 and 13.

SECTION 7. Handling and storage

7.1. Precautions for safe handling

The product is flammable and may form explosive mixtures of steam/water even at normal ambient temperatures. Do not store or handle near open flame, heat or other sources of ignition. Do not smoke. Avoid the accumulation of electrostatic charges. All equipment used when handling the product must be properly grounded. Use tools that non-sparking and explosion proof equipment. 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 handling. Handle and open container with care.

7.2. Conditions for safe storage, including any incompatibilities

Store away from heat, sparks and open flames. Store in a cool, well-ventilated place. Keep containers tightly closed.
Keep in an area with fire sprinkler systems. Keep this material away from food, drink and animal feed. Handle/store with care.

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 opasnimkemikalijama 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)
	TLV-ACGIH	ACGIH 2022

Ethanol

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
AGW	DEU	380	200	1520	800	
MAK	DEU	380	200	1520	800	
VLA	ESP			1910	1000	
VLEP	FRA	1900	1000	9500	5000	
GVI/KGVI	HRV	1900	1000			
TLV	ROU	1900	1000	9500	5000	
MV	SVN	960	500	1920	1000	
WEL	GBR	1920	1000			
TLV-ACGIH				1884	1000	

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	g/kg
Normal value for the terrestrial compartment	0,63	mg/kg/d

Health - Derived no-effect level - DNEL / DMEL

	Effects on consumers				Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation					1900 mg/m3			950 mg/m3
Skin								343 mg/kg/d

2-Propanol

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	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

	Effects on consumers				Effects on workers			
Route of exposure	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.

Ethanol
https://amcaw.ifa.dguv.de/amcaw/substances/methods/c3a4176e-652d-4a93-9b89-fc1f4f6f03c9

2-Propanol
https://amcaw.ifa.dguv.de/amcaw/substances/methods/14f00262-fa4c-428a-9237-29b91a15f159

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.

HAND PROTECTION
Protect hands with category III work gloves.
The following should be considered when choosing work glove material (see standard EN 374): compatibility, degradation, permeability time.
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 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.

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 ISO 16321).

RESPIRATORY PROTECTION
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. Use a mask with a type AX filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387).
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	liquid	
Colour	colourless	
Odour	sweet	
Melting point / freezing point	not available	
Initial boiling point	> 60 °C	
Flammability	not available	
Lower explosive limit	2 % (v/v)	Substance:2-Propanol
Upper explosive limit	12 % (v/v)	Substance:2-Propanol
Flash point	23 < T < 60 °C	
Auto-ignition temperature	> 400 °C	Substance:2-Propanol
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	0,9	
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)	42,25 %	-	380,24	g/litre
VOC (volatile carbon)	21,89 %	-	197,01	g/litre
Risk of explosion	Non-explosive, it is possible to form explosive vapor / air mixtures.			

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.

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

2-Propanol
It has the properties of secondary alcohols (oxidation reactions, dehydrogenation, dehydration, esterification ....).

10.2. Chemical stability

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

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.

2-Propanol
Forms explosive mixtures with air. Reacts violently with oxidants. At high temperatures it can react vigorously with oxygen in the air.

Phenolphthalein
Dust is potentially explosive when mixed with air.
Reacts with oxidants.

10.4. Conditions to avoid

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

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.

2-Propanol
Exposure to sunlight. Heating and open flames. No ventilation. Exposure to air.

Phenolphthalein
Avoid the accumulation of dust in the environment.
Danger of dust explosion in the presence of air in case of enrichment of fine dust.

10.5. Incompatible materials

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

2-Propanol
Aluminum and oxidants. Plastic and rubbers.

Phenolphthalein
oxidising agents.

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.

Ethanol
Burning ethanol creates carbon monoxide.

2-Propanol
In the event of a fire, toxic gases and vapors (carbon oxides) may be released.

Phenolphthalein
carbon oxides.

SECTION 11. Toxicological information

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

Metabolism, toxicokinetics, mechanism of action and other information

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).

2-Propanol
In humans, the substance is rapidly absorbed from the lungs and the gastrointestinal tract, on the contrary the absorption through the skin is slow. It is metabolized into acetone from aldehyde dehydrogenase, but a large part is excreted unchanged with exhaled air and urine.

Information on likely routes of exposure

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).

2-Propanol
The main routes of potential exposure are expected to be skin contact and inhalation in workers exposed during manufacture and use of the substance. Potential exposure of the general population can occur through ingestion of contaminated food or water, from ambient air and from contact with products containing the substance.

Delayed and immediate effects as well as chronic effects from short and 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).

2-Propanol
Ingestion of a massive dose causes digestive disturbances (repeated vomiting) and, after 30-60 minutes, a euphoric syndrome that can progress to coma, with respiratory depression, hypotension and areflexia. Complications are: digestive bleeding and acute renal failure. Fatal cases are reported. Exposure to 400 ppm for 3 minutes in the form of vapor causes irritation of the eyes, nose and throat. Inhalation of high concentrations causes narcotic effects that can complicate with coma, rhabdomyolysis, renal failure and, in some cases, death from respiratory failure. The liquid has degreasing characteristics of the skin.
In rats, long-term inhalation and / or digestive exposure essentially causes CNS depression and kidney injury.

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.

2-Propanol
In humans, the simultaneous ingestion of an equal dose of ethanol cancels the effects of the substance. The substance enhances the toxicity of carbon tetrachloride. Simultaneous exposure to the two substances caused acute hepatitis and renal failure. In one case there was pulmonary edema (INRS, 2009).

ACUTE TOXICITY

ATE (Inhalation) of the mixture:	Not classified (no significant component)
ATE (Oral) of the mixture:	Not classified (no significant component)
ATE (Dermal) of the mixture:	Not classified (no significant component)

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)
Rat LD50 (oral):	7000 mg/kg (HSDB, 2015)
Mouse LC50-4 hours	39 mg/m3 (HSDB, 2015).

2-Propanol

LD50 (Dermal):	12870 mg/kg coniglio (INRS, 2009)
LD50 (Oral):	> 4396 mg/kg ratto (INRS, 2009) 4396-5500 mg/kg
LC50 (Inhalation vapours):	72600 mg/m3 ratto (INRS, 2009)
Mouse LC50-4 hours (inhalation):	27200 mg/m3 (INRS, 2009)

Phenolphthalein

LD50 (Oral):	> 1000 mg/kg ratto

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

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).

2-Propanol
It is scarcely irritating to intact or abraded skin of rabbits and guinea pigs (INRS, 2009).

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye irritation

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).

2-Propanol
In humans, exposure to isopropanol vapors (3 minutes of exposure at 400 ppm) caused mild eye irritation (INRS, 2009).
In rabbit eyes a 70% solution (0.1 ml) caused moderate to severe reversible irritation in 14 days; an instillation of the substance can induce ocular lesions that persist for more than 21 days (INRS, 2009).

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

Respiratory sensitization

2-Propanol
No experimental data or evidence based on practical experience are available in the open literature.

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).

2-Propanol
The substance has no skin sensitizing power in the Buelher test on guinea pig (INRS, 2009).
Isolated cases of sensitization following repeated contact have been reported in the literature.

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

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).

2-Propanol
Negative results in mutagenesis assays performed "in vivo" (gene mutation in S. typhimurium TA97, TA98, TA100, TA1535, TA1537 and TA1538 both in the presence and absence of metabolic activation, in E. coli both in the presence and absence of metabolic activation, in N. crassa in the absence of metabolic activation; cellular transformation in Chinese hamster ovary cells both in the presence and absence of metabolic activation; cellular transformation in Syrian hamster embryonic cells in the absence of metabolic activation; exchanges between sister chromatids in Syrian hamster V79 cells both in the presence and absence of metabolic activation) and “
in vitro”
(micronucleus assay on mice) (INRS, 2009).

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

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).

2-Propanol
There is evidence from epidemiological studies that exposure during isopropanol production from strong acid processes causes sinus cancer.
- The International Agency for Research on Cancer (IARC) allocates it in group 1 (confirmed carcinogen for humans), based on evidence of sufficient carcinogenicity in humans and identifies the nasal cavity and paranasal sinuses as target organs for which the evidence of carcinogenicity is certain.

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

Adverse effects on sexual function and fertility

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).

2-Propanol
No human data are available. In animal studies the substance did not show reproductive toxicity except at toxic doses for the parents (INRS, 2009).

Adverse effects on development of the offspring

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.

2-Propanol
No human data are available. In animal studies the substance did not show toxicity except at doses toxic to the mother (INRS, 2009).

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

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).

2-Propanol
It is irritating to the respiratory system. In high concentrations it causes CNS depression with narcosis.

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

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).

2-Propanol
The liquid has degreasing characteristics of the skin. In rats, long-term inhalation and / or digestive exposure essentially causes CNS depression and kidney injury.

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

2-Propanol
Following aspiration through the oral and nasal cavities, the substance can enter the trachea and deeper lung structures (IPCS, 1990).

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

12.1. Toxicity

Ethanol

LC50 - for Fish	> 100 mg/l/96h Pimephales promelas (OECD, 2004)
Chronic NOEC for Algae / Aquatic Plants	280 mg/l/7d Lemna gibba (OECD, 2004)

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).

2-Propanol

LC50 - for Fish	1400 mg/l/96h Lepomis macrochirus (HSDB, 2015)
EC50 - for Crustacea	1400 mg/l/48h Crangon crangon (HSDB, 2015; OECD, 1997)
EC50 - for Algae / Aquatic Plants	> 1000 mg/l/72h Scenedesmus subspicatus
LC10 for Fish	1500 mg/l/96h Rasbora heteromorpha
Chronic NOEC for Crustacea	141 mg/l/16d Daphnia (crescita)

Terrestrial plant (Lactuca sativa) EC50-3 days : 2100 mg/l
NOEC-21 days : 30 mg/L (OECD, 1997)

12.2. Persistence and degradability

Ethanol

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

Rapidly degradable

2-Propanol

Rapidly degradable

12.3. Bioaccumulative potential

Ethanol

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

2-Propanol

Partition coefficient: n-octanol/water	0,05

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 X 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 ≥ 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. 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 or ID number

ADR / RID, IMDG, IATA: 1987

14.2. UN proper shipping name

ADR / RID:	ALCOHOLS, N.O.S. (ethanol, isopropanol)
IMDG:	ALCOHOLS, N.O.S. (ethanol, isopropanol)
IATA:	ALCOHOLS, N.O.S. (ethanol, isopropanol)

14.3. Transport hazard class(es)

ADR / RID:	Class: 3	Label: 3
IMDG:	Class: 3	Label: 3
IATA:	Class: 3	Label: 3

14.4. Packing group

ADR / RID, IMDG, IATA: III

14.5. Environmental hazards

ADR / RID:	NO
IMDG:	NO
IATA:	NO

14.6. Special precautions for user

ADR / RID: HIN - Kemler: 30 Limited Quantities: 5 L Tunnel restriction code: (D/E)

	Special provision: 274, 601		
IMDG:	EMS: F-E, S-D	Limited Quantities: 5 L	
IATA:	Cargo: Passengers:	Maximum quantity: 220 L Maximum quantity: 60 L	Packaging instructions: 366 Packaging instructions: 355
	Special provision:	A3, A180	

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: P5c

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

Product

Point	3 - 40	

Contained substance

Point	75	
Point	28	Phenolphthalein REACH Reg.: 01-2119498295-24-xxxx

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

not applicable

Substances in Candidate List (Art. 59 REACH)

Phenolphthalein

REACH Reg.: 01-2119498295-24-xxxx

Substances subject to authorisation (Annex XIV REACH)

None

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

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the

workers' health and safety are modest and that the 98/24/EC directive is respected.

15.2. Chemical safety assessment

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

Ethanol

2-Propanol

SECTION 16. Other information

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

Flam. Liq. 2	Flammable liquid, category 2
Flam. Liq. 3	Flammable liquid, category 3
Carc. 1B	Carcinogenicity, category 1B
Muta. 2	Germ cell mutagenicity, category 2
Repr. 2	Reproductive toxicity, category 2
Eye Irrit. 2	Eye irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H350	May cause cancer.
H341	Suspected of causing genetic defects.
H361f	Suspected of damaging fertility.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.

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
- 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
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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)
19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
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21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)
22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)
23. Delegated Regulation (UE) 2023/707
- 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.
Safety Data Sheet No.3 dated 23/02/2024. Full revision of version no.2 of 11/01/2018.
Annexes:
Exposure scenarios for Ethanol and 2-Propanol.