

 	STEELCO S.P.A.	Revision nr. 4 Dated 21/05/2021
	Steelcoxide-DT	Printed on 31/05/2021 Page n. 1/23 Replaced revision:3 (Printed on: 15/09/2020)

Safety Data Sheet

According to Annex II to REACH - Regulation 2015/830

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

1.1. Product identifier

Product name **Steelcoxide-DT**

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

Intended use **Concentrated decontaminating disinfectant product. Compatible with thermolabile medical devices and latest generation optical fibers. FOR PROFESSIONAL USE ONLY.**

Uses advised against: Uses other than those indicated.

1.3 Details of the supplier of the safety data sheet

Name **STEELCO S.p.A.**
Full address **Via Balegante, 27**
District and Country **31039 Riese Pio X (TV)**
ITALY

tel. +39 0423 7561

fax +39 0423 755528

e-mail address of the competent person
responsible for the Safety Data Sheet **info@steelcogroup.com**

1.4. Emergency telephone number

For urgent inquiries refer to **Centros de Orientação de Doentes Urgentes (CODU): 800250250**

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 2015/830. 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 2 H225 Highly flammable liquid and vapour.

2.2. Label elements

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

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Hazard pictograms:



Signal words: **Danger**

Hazard statements:

H225 Highly flammable liquid and vapour.
EUH208 Contains: SUBTILISINE
May produce an allergic reaction.

Precautionary statements:

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 Keep container tightly closed.

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%.

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification 1272/2008 (CLP)
ETHANEDIOL		
CAS 107-21-1	$6 \leq x < 10$	Acute Tox. 4 H302, STOT RE 2 H373
EC 203-473-3		
INDEX 603-027-00-1		
Reg. no. 01-2119456816-28-xxxx		
PROPAN-2-OL		
CAS 67-63-0	$6 \leq x < 10$	Flam. Liq. 2 H225, Eye Irrit. 2 H319, STOT SE 3 H336
EC 200-661-7		
INDEX 603-117-00-0		
Reg. no. 01-2119457558-25-XXXX		
ETHANOL		
CAS 64-17-5	$1 \leq x < 3$	Flam. Liq. 2 H225, Eye Irrit. 2 H319
EC 200-578-6		
INDEX 603-002-00-5		

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Reg. no. 01-2119457610-43-XXXX

SUBTILISINE

CAS 9014-01-1 $0,2 \leq x < 0,6$ Acute Tox. 4 H302, Eye Dam. 1 H318, Skin Irrit. 2 H315, STOT SE 3 H335, Resp. Sens. 1 H334, Aquatic Acute 1 H400 M=1, Aquatic Chronic 2 H411

EC 232-752-2

INDEX 647-012-00-8

Reg. no. 01-2119480434-38-xxxx

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

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.

PROTECTION MEASURES FOR FIRST AID: for the PPE necessary for first aid interventions refer to section 8.2 of the present safety data sheet.

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

Specific information on symptoms and effects caused by the product are unknown.

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

Treat symptomatically.

In the event of an accident or discomfort, consult a doctor immediately (if possible show the instructions for use or the safety data sheet).

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

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

PROPAN-2-OL

Carbon oxides.

5.3. Advice for firefighters

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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.

6.1.1 For those who do not intervene directly

Do not take any action involving any personal risk or without proper training. Evacuate the surrounding areas. Don't touch either walk on the spilled material.

Wear suitable protective equipment (including personal protective equipment referred to in section 8 of this Safety Data Sheet) to prevent contamination of skin, eyes and personal clothing. Wear an appropriate respirator when ventilation is inadequate.

Do not inhale the mists / vapors / fumes. Avoid the dispersion of the product into the environment. Follow the appropriate internal procedures provided for non-personnel authorized to intervene directly in the event of accidental release.

6.1.2 For those who intervene directly

Stop the leak if there is no danger.

Evacuate unauthorized personnel. Wear suitable protective equipment (see section 8 of this Safety Data Sheet).

Follow the appropriate internal procedures for authorized personnel. Isolate the danger area and deny entry. Ventilate enclosed spaces before to come in.

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.

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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 use(s)

No use other than that indicated in section 1.2 of this safety data sheet.

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 2019
FRA	France	Valeurs limites d'exposition professionnelle aux agents chimiques en France. ED 984 - INRS
ITA	Italia	Decreto Legislativo 9 Aprile 2008, n.81
GBR	United Kingdom	EH40/2005 Workplace exposure limits (Fourth Edition 2020)
EU	OEL EU	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 2020

ETHANEDIOL

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
AGW	DEU	26	10	52	20	SKIN
MAK	DEU	26	10	52	20	SKIN
VLA	ESP	52	20	104	40	SKIN
VLEP	FRA	52	20	104	40	SKIN
VLEP	ITA	52	20	104	40	SKIN
WEL	GBR	52	20	104	40	SKIN
OEL	EU	52	20	104	40	SKIN
TLV-ACGIH			25		50	
TLV-ACGIH				10		INHAL
Predicted no-effect concentration - PNEC						
Normal value in fresh water				10		mg/l
Normal value in marine water				1		mg/l
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

Effects on
consumers

Effects on
workers

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Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral		NPI		NPI				
Inhalation	NPI	NPI	7 mg/m3	NPI	NPI	NPI	35 mg/m3	NPI
Skin	NPI	NPI	NPI	53 mg/kg bw/d	NPI	NPI	NPI	106 mg/kg bw/d

PROPAN-2-OL

Threshold Limit Value

Type	Country	TWA/8h	STEL/15min	Remarks / Observations
		mg/m3	ppm	
AGW	DEU	500	200	1000
MAK	DEU	500	200	1000
VLA	ESP	500	200	1000
VLEP	FRA			980
WEL	GBR	999	400	1250
TLV-ACGIH		492	200	983

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 water, intermittent release	140,9	mg/l
Normal value of STP microorganisms	2,251	g/l
Normal value for the food chain (secondary poisoning)	160	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
Oral					VND	VND	VND	26 mg/kg bw/d
Inhalation	VND	VND	VND	89 mg/m3	VND	VND	VND	500 mg/m3
Skin	VND	VND	VND	319 mg/kg bw/d	VND	VND	VND	888 mg/kg bw/d

ETHANOL

Threshold Limit Value

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

Predicted no-effect concentration - PNEC

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Normal value in fresh water	960	µg/L
Normal value in marine water	790	mg/l
Normal value for fresh water sediment	3,6	mg/kg
Normal value for marine water sediment	2,9	mg/kg
Normal value for water, intermittent release	2,75	mg/l
Normal value of STP microorganisms	580	mg/l
Normal value for the food chain (secondary poisoning)	380	mg/kg food
Normal value for the terrestrial compartment	630	µg/kg soil dw

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
Oral						NPI		87 mg/kg bw/d
Inhalation	950 mg/m3	NPI	NPI	114 mg/m3	1900 mg/m3	NPI	NPI	950 mg/m3
Skin	NPI	NPI	NPI	206 mg/kg bw/d	NPI	NPI	NPI	343 mg/kg bw/d

SUBTILISINE					
Threshold Limit Value					
Type	Country	TWA/8h	STEL/15min	Remarks / Observations	
		mg/m3	ppm	mg/m3	ppm
VLA	ESP		6E-05		
WEL	GBR	4E-05			

Predicted no-effect concentration - PNEC		
Normal value in fresh water	1,7	µg/L
Normal value in marine water	170	ng/L
Normal value for water, intermittent release	900	ng/L
Normal value of STP microorganisms	65	mg/l
Normal value for the terrestrial compartment	568	µg/kg soil

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
Oral		3,6 mg/kg bw/d		1,8 mg/kg bw/d				
Inhalation	NPI	NPI	15 ng/m3	NPI	NPI	NPI	60 ng/m3	NPI
Skin					VND	NPI	VND	NPI

Substances that could be released in case of decomposition:

FORMALDHEYDE					
Type	Country	TWA/8h	STEL/15min	Remarks / Observations	
		Mg/m3	ppm	mg/m3	ppm
VLEP	ITA	0,37	0,3	0,74	0,6
OEL	EU	0,37	0,3	0,74	0,6
TLV-ACGIH			0,1	0,74	0,3 (C)

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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.

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.

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 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 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, wear a mask with a type AX filter, whose limit of use will be defined by the manufacturer (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.

PROPAN-2-OL

IBE (Biological Indicators of Exposure - ACGIH 2020): acetone in urine = 40 mg / L (end of shift)

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	liquid
Colour	straw yellow
Odour	mild
Odour threshold	Not determined
pH	9,5
Melting point / freezing point	Not available
Initial boiling point	106 °C

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Boiling range	Not available	
Flash point	35 °C	
Evaporation rate	Not determined	
Flammability (solid, gas)	not applicable	Reason for missing data: Based on the physical state
Lower inflammability limit	Not available	
Upper inflammability limit	Not available	
Lower explosive limit	Not available	
Upper explosive limit	Not available	
Vapour pressure	Not available	
Vapour density	Not determined	
Relative density	1,022 g/cm ³	
Solubility	soluble in water	
Partition coefficient: n-octanol/water	Not determined	
Auto-ignition temperature	Not available	
Decomposition temperature	Not determined	
Viscosity	Not determined	
Explosive properties	Not Explosive	
Oxidising properties	Not Oxidizing	

9.2. Other information

Information not available

SECTION 10. Stability and reactivity

10.1. Reactivity

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

ETHANEDIOL

In the air absorbs moisture. Decomposes at temperatures above 200°C/392°F.

It can absorb atmospheric moisture up to twice its own weight. It decomposes at temperatures above 200 ° C.

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.

ETHANEDIOL

Risk of explosion on contact with: perchloric acid. May react dangerously with: chlorosulphuric acid, sodium hydroxide, sulphuric acid, phosphorus pentasulphide, chromium (III) oxide, chromyl chloride, potassium perchlorate, potassium dichromate, sodium peroxide, aluminium. Forms explosive mixtures with: air.

Risk of explosion on contact with: perchloric acid. It can react dangerously with: chlorosulfuric acid, sodium hydroxide, sulfuric acid, phosphorus pentasulphide, chromium (III) oxide, chromyl chloride, potassium perchlorate, potassium dichromate, sodium peroxide, aluminum. Forms explosive mixtures with air.

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ETHANOL

Risk of explosion on contact with: alkaline metals,alkaline oxides,calcium hypochlorite,sulphur monofluoride,acetic anhydride,acids,concentrated hydrogen peroxide,perchlorates,perchloric acid,perchloronitrile,mercury nitrate,nitric acid,silver,silver nitrate,ammonia,silver oxide,ammonia,strong oxidising agents,nitrogen dioxide.May react dangerously with: bromoacetylene,chlorine acetylene,bromine trifluoride,chromium trioxide,chromyl chloride,fluorine,potassium tert-butoxide,lithium hydride,phosphorus trioxide,black platinum,zirconium (IV) chloride,zirconium (IV) iodide.Forms explosive mixtures with: air.

10.4. Conditions to avoid

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

ETHANEDIOL

Avoid exposure to: sources of heat,naked flames.
Avoid exposure to heat sources and naked flames.

PROPAN-2-OL

Heat, flames and sparks. Extreme temperatures and direct sunlight.

ETHANOL

Avoid exposure to: sources of heat,naked flames.
Avoid high temperatures and proximity to ignition sources

10.5. Incompatible materials

PROPAN-2-OL

Oxidizing agents, acid anhydrides, aluminum, halogenated compounds, acids.

ETHANOL

Strong mineral acids, oxidizing agents. High temperature aluminum.

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.

ETHANEDIOL

May develop: hydroxyacetaldehyde, glyoxal, acetaldehyde, methane, carbon monoxide, hydrogen.
Due to thermal decomposition or in the event of fire, gases and vapors potentially harmful to health can be released.

SECTION 11. Toxicological information

11.1. Information on toxicological effects

In the absence of experimental toxicological data on the product itself, the possible health hazards of the product have been assessed on the basis of the properties of the substances contained, according to the criteria established by the reference legislation for classification.
Therefore, consider the concentration of the individual dangerous substances possibly mentioned in sect. 3, to evaluate the resulting toxicological effects from exposure to the product.

Metabolism, toxicokinetics, mechanism of action and other information

PROPAN-2-OL

It is readily absorbed following inhalation exposure and rapidly spreads to tissues. However, it is also readily excreted in the urine, essentially in the form of the 2-methoxyacetic acid metabolite. (Arch Toxicol, 68, -588-94 - Johanson G, 1994)

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Information on likely routes of exposure

Information not available

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

ETHANEDIOL

Ingestion initially stimulates the central nervous system; later replaced by a phase of depression. There may be kidney damage, with anuria and uremia. Over-exposure symptoms are: vomiting, drowsiness, difficulty in breathing, convulsions. The lethal dose for humans is approx. 1.4 ml/kg.

Interactive effects

Information not available

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)

ETHANEDIOL

LD50 (Oral): 7712 mg/kg Ratto

LD50 (Dermal): 9530 mg/kg Coniglio

LC50 (Inhalation): 2,5 mg/l/6h Ratto

ETHANOL

LD50 (Oral): 1187 mg/kg Ratto

LC50 (Inhalation): 115,9 mg/l/4h

PROPAN-2-OL

LD50 (Oral): 4710 mg/kg Rat

LD50 (Dermal): 12800 mg/kg Rat

LC50 (Inhalation): 72,6 mg/l/4h Rat

SUBTILISINE

LD50 (Oral): 1800 mg/kg Rat

ETHANEDIOL

Harmful if swallowed (Harmonized classification, Annex VI, CLP Reg.)

Reference: Evaluation of the Developmental Toxicity of Ethylene Glycol Aerosol in the CD Rat and CD-1 Mouse by Whole-Body Exposure. (Fundamental and Applied Toxicology 24: 57-75 (1995))

Reliability (Klimisch score): 2

Species: rat (Sprague-Dawley; Male/Female)

Routes of exposure: inhalation (aerosol)

Results: LC50> 2.5 mg / L

Reference: Assessment of the Developmental Toxicity of Ethylene Glycol Applied Cutaneously to CD-1 Mice. (Fundamental and Applied Toxicology 27: 155-166 (1995)) "

Reliability (Klimisch score): 2

Species: mouse (CD-1; Male/Female)

Routes of exposure: cutaneous

Results: LD50> 3500 mg / kg.

PROPAN-2-OL

Method: equivalent or similar to OECD 401

Reliability (Klimisch score): 2

Species: Rat (Sherman)



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Routes of exposure: oral
Results: LD50 = 5840 mg / kg

Method: equivalent or similar to OECD 402
Reliability (Klimisch score): 2
Species: Rabbit
Routes of exposure: cutaneous
Results: LC50 = 16.4 ml / kg

Method: equivalent or similar to OECD 403
Reliability (Klimisch score): 1
Species: Rat (Fischer 344; Male/Female)
Routes of exposure: inhalation (vapors)
Results: LD50> 10000 ppm / 6h

ETHANOL
Method: OECD 401
Reliability (Klimish score): 1
Species: rat (Cox CD; Male/Female)
Route of exposure: oral
Results: LD50: 10470 mg / kg

Method: OECD 403
Reliability (Klimish score): 2
Species: rat (Sprague-Dawley; Male/Female)
Route of Exposure: inhalation (vapors)
LC50 results (male): 116.9 mg / l 4h

Reference: Schechter, M. et al, Pharmacol Biochem Behav 52 (1): 245-248, 1995
Reliability (Klimisch score): 2
Species: Mouse (HS; Male/Female)
Routes of exposure: intraperitoneal
Results: LD50 = 9450 mg / kg body weight

SUBTILISINE
Method: OECD 401
Reliability (Klimisch score): 1
Species: rat (Wistar; Male/Female)
Routes of exposure: oral
Results LD50: 1800 mg / kg body weight / day
The substance is classified as harmful by inhalation.

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

ETHANEDIOL
Method: BASF-internal standards
Reliability (Klimisch score): 2
Species: rabbit (Vienna White)
Routes of exposure: cutaneous
Results: non-irritating

PROPAN-2-OL
Reliability (Klimisch score): 2
Species: Rabbit
Routes of exposure: cutaneous
Results: Not irritating
Reference: Nixon G et al, Toxicology and Applied Pharmacology 31, 481-490 (1975)

ETHANOL

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Method: OECD 404
Reliability (Klimisch score): 1
Species: Rabbit (New Zealand White)
Routes of exposure: cutaneous
Results: non-irritating.

SUBTILISINE
The substance causes skin irritation Harmonized classification, Annex VI, CLP Reg.)

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

ETHANEDIOL
Method: BASF-internal standards
Reliability (Klimisch score): 2
Species: rabbit (Vienna White)
Routes of exposure: ocular
Results: non-irritating

PROPAN-2-OL
Method: equivalent or similar to OECD 405
Reliability (Klimisch score): 1
Species: Rabbit (New Zealand White)
Routes of exposure: ocular
Results: irritating

ETHANOL
Method: OECD 405
Reliability (Klimisch score): 2
Species: Rabbit
Routes of exposure: ocular
Results: irritating.

SUBTILISINE
The substance causes serious eye damage (Harmonized Classification, Annex VI, CLP Reg.)

RESPIRATORY OR SKIN SENSITISATION

May produce an allergic reaction.Contains:SUBTILISINE

ETHANEDIOL
Reference: Evaluation of Skin Irritation and Sensitization of Two Diol Solutions used as Experimental Dentin Primers in Humans and Guinea Pigs. (Dental Materials Journal 15 (2): 226-232 (1996))
Reliability (Klimisch score): 2
Species: Guinea Pig (Dunkin-Hartley; Female)
Routes of exposure: cutaneous
Results: not sensitizing.

PROPAN-2-OL
Method: OECD 406
Reliability (Klimisch score): 1
Species: Guinea pig (Dunkin-Hurtley; Male/Female)
Routes of exposure: cutaneous
Results: not sensitizing

ETHANOL
Method: equivalent or similar OECD 406
Reliability (Klimisch score): 2

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Species: Guinea pig (Pirbright White; Female)
Routes of exposure: cutaneous
Results: not sensitizing.

SUBTILISINE

The substance causes respiratory sensitization (Harmonized Classification, Annex VI, CLP Reg.)

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

ETHANEDIOL

Method: OECD 471 - In vitro test
Reliability (Klimisch score): 1
Species: S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and E. coli WP2
Results: negative

Method: Publication 1986 - In vivo testing
Reliability (Klimisch score): 2
Species: rat (Fischer 344; Male/Female)
Routes of exposure: oral
Results: negative.

PROPAN-2-OL

Based on available data, the substance has no mutagenic effects and is not classified under the relevant hazard class CLP.

ETHANOL

Method: equivalent or similar to OECD 471 - In vitro test
Reliability (Klimisch score): 1
Species: S. typhimurium
Results: negative with and without metabolic activation

Method: equivalent or similar to OECD 474 - In vivo test
Species: mouse (NMRI; Male/Female)
Routes of exposure: intraperitoneal
Results: negative.

SUBTILISINE

Method: OECD 473 - Test in vitro
Reliability (Klimisch score): 1
Species: human (lymphocytes)
Results: negative with and without metabolic activation

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

ETHANEDIOL

Available studies have shown no carcinogenic potential. In a carcinogenicity study lasting two years, carried out by the US National Toxicology Program (NTP), in which ethylene glycol was administered in the feed, "no evidence of carcinogenic activity" in male and female B6C3F1 mice was observed (NTP, 1993).

PROPAN-2-OL

Based on available data, the substance has no carcinogenic effects and is not classified under the relevant hazard class CLP.

ETHANOL

Method: equivalent or similar to OECD 453
Reliability (Klimisch score): 1
Species: rat (Fischer 344 / DuCrj; Male/Female)



Routes of exposure: inhalation (vapors)
Results: negative.

SUBTILISINE
No data available.

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

ETHANEDIOL

Reference: Chronic Toxicity and Oncogenicity Studies of Ethylene Glycol in Rats and Mice. (Fundamental and Applied Toxicology 7: 547-565 (1986))

Reliability (Klimisch score): 2

Species: mouse (CD-1; Male/Female)

Routes of exposure: oral

Results: negative.

PROPAN-2-OL

Method: equivalent or similar to OECD 416

Reliability (Klimisch score): 1

Species: Rat (Sprague-Dawley; Male/Female)

Routes of exposure: Oral

Results: negative. NOAEL = 1000 mg / kg bw / day.

SUBTILISINE

No data available.

Adverse effects on sexual function and fertility

PROPAN-2-OL

Method: equivalent or similar to OECD 416

Reliability (Klimisch score): 1

Species: rat (Sprague-Dawley Male/Female)

Routes of exposure: oral

Results: negative.

ETHANOL

Method: equivalent or similar to OECD 416

Reliability (Klimisch score): 1

Species: mouse (CD-1; Male/Female)

Routes of exposure: oral

Results: No effect on fertility at doses equivalent to 20.7 g / kg / day

Adverse effects on development of the offspring

PROPAN-2-OL

Method: equivalent or similar to OECD 414

Reliability (Klimisch score): 1

Species: rat (Sprague-Dawley)

Routes of exposure: oral

Results: negative.

ETHANOL

Method: equivalent or similar to OECD 414

Reliability (Klimisch score): 2

Species: rat (Sprague-Dawley)

Routes of exposure: inhalation

Results: negative. NOAEL (maternal) = 16000 ppm. NOAEL (fetus) > = 20,000 ppm

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STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

ETHANEDIOL

Based on available data, the substance has no specific target organ toxicity effects for single exposure and is not classified under the relevant CLP hazard class.

PROPAN-2-OL

Method: OECD 426

Reliability (Klimisch score): 1

Species: Rat (Sprague-Dawley; Female)

Routes of exposure: oral.

Results: May cause drowsiness or dizziness.

Based on available data, the substance exhibits specific target organ toxicity effects from single exposure and is classified under the relevant CLP hazard class.

ETHANOL

Based on available data, the substance has no specific target organ toxicity effects for single exposure and is not classified under the relevant CLP hazard class.

SUBTILISINE

Based on available data, the substance exhibits specific target organ toxicity effects from single exposure and is classified under the relevant CLP hazard class. (Harmonized classification, Annex VI, CLP Reg.)

Target organ

SUBTILISINE

Lungs.

Route of exposure

SUBTILISINE

Inhalation.

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ETHANEDIOL

Method: equivalent or similar to OECD 452

Reliability (Klimisch score): 2

Species: Rat (Wistar; Male)

Routes of exposure: oral

Results: observed toxicity towards the kidneys and bladder. NOAEL = 150 mg / kg bw / day

PROPAN-2-OL

Based on available data, the substance has no specific target organ toxicity effects on repeated exposure and is not classified under the relevant CLP hazard class.

ETHANOL

Method: equivalent or similar OECD 408

Reliability (Klimisch score): 2

Species: Rat (Sprague-Dawley; Male/Female)

Routes of exposure: oral

Results: negative. NOAEL: 1730 mg / kg body weight / day

**SUBTILISINE**

Based on available data, the substance has no specific target organ toxicity effects on repeated exposure and is not classified under the relevant CLP hazard class.

Target organ

ETHANEDIOL
Kidneys

Route of exposure

ETHANEDIOL
Oral

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

ETHANEDIOL

No data on aspiration hazard are available

PROPAN-2-OL

No data on aspiration hazard are available

ETHANOL

No data are available on the hazard in case of aspiration.

SUBTILISINE

No data on aspiration hazard are available

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**ETHANEDIOL**

LC50 - for Fish

> 72,86 g/l/96h Pimephales promelas (EPA 600/4-90/027)

EC50 - for Crustacea

> 100 mg/l/48h Daphnia magna (OECD 202)

EC50 - for Algae / Aquatic Plants

> 10940 mg/l/72h Pseudokirchneriella subcapitata (EPA/600/4-89/001)

Chronic NOEC for Fish

> 15,38 g/l/7 d

Chronic NOEC for Crustacea

> 8,59 g/l/7 d

Chronic NOEC for Algae / Aquatic Plants

100 mg/l/72h

ETHANOL

LC50 - for Fish

14,2 g/l/96h Pimephales promelas (US EPA E03-05)

EC50 - for Crustacea

5012 mg/l/48h Ceriodaphnia dubia (ASTM E729-80)

EC50 - for Algae / Aquatic Plants

275 mg/l/72h Chlorella vulgaris (OECD 201)

Chronic NOEC for Fish

250 mg/L/5 d

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PROPAN-2-OL

LC50 - for Fish

9640 mg/l/96h Pimephales promelas (equivalent or similar to OECD 203)

EC50 - for Crustacea

> 10000 mg/l/48h Daphnia magna (equivalent or similar to OECD 202)

SUBTILISINE

LC50 - for Fish

8,2 mg/l/96h Oncorhynchus mykiss; (OECD 203)

EC50 - for Crustacea

0,17 mg/l/48h Daphnia Magna; OECD 202

EC50 - for Algae / Aquatic Plants

0,29 mg/l/72h Pseudokirchnerella subcapitata (OECD 201)

Chronic NOEC for Fish

0,042 mg/l/34d Pimphales promelas; (OECD 210)

Chronic NOEC for Crustacea

0,019 mg/l/14d Daphnia magna; (OECD 211)

Chronic NOEC for Algae / Aquatic Plants

0,041 mg/l/72h Pseudokirchnerella subcapitata; (OECD 201)

12.2. Persistence and degradability

ETHANEDIOL

Rapidly degradable, 90-100% in 10 days (OECD 301 A)

Solubility in water 1000 - 10000 mg/l

PROPAN-2-OL

Rapidly degradable, 53% in 5 days (equivalent or similar to EU C.5)

ETHANOL

Readily biodegradable, 60% in 10 days (BOD - Standard methods for the examination of water and waste water 1971. 13th ed, American Public Health Assoc, NY)

SUBTILISINE

Rapidly degradable, 79% in 28 days (OECD 301 B).

12.3. Bioaccumulative potential

ETHANEDIOL

Partition coefficient: n-octanol/water

-1,36 Log Kow (ACS Professional Reference Book, 1995)

ETHANOL

Partition coefficient: n-octanol/water

-0,35 Log Kow 24°C (OECD 107)

PROPAN-2-OL

Partition coefficient: n-octanol/water

0,05

12.4. Mobility in soil

Information not available

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. Other adverse effects

Information not available

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SECTION 13. Disposal considerations

13.1. Waste treatment methods

Reuse if possible. Product residues are to be considered special hazardous waste. The dangerousness of the waste that partially contains this product must be evaluated according to the laws in force. (Ref. Annex D - Part IV of Legislative Decree no. 152/2006 and subsequent amendments and adjustments).

Disposal must be entrusted to an authorized waste management company, in compliance with national and possibly local regulations.

The legal responsibility for disposal lies with the producer / holder of the waste.

Different CER (European Waste Code) codes could be applied to this mixture according to the specific circumstances that generated the waste, any alterations and contaminations.

The product as it is, out of specification in the original packaging, or poured into a suitable container for disposal as waste, or the product in specification but no longer usable (for example following an accidental spill), is to be classified with a code CER compatible with the description of use indicated in section 1.2.

The appropriate final destination of the waste will be assessed by the manufacturer according to the chemical-physical characteristics of the waste itself compatible with the authorized plant to which it will be conferred for recovery, treatment or final disposal in the manner prescribed by current regulations. Disposal via the wastewater drain is not permitted.

For hazardous substances registered according to EC Regulation 1907/2006 (REACH) for which a chemical safety report has been prepared, refer to the specific information contained in the exposure scenarios attached to this SDS.

CONTAMINATED PACKAGING

Contaminated packaging must be sent, properly labeled, for recovery or disposal in compliance with national regulations on waste management and must be classified with the following EWC code:

15 01 10 *: packaging containing residues of dangerous substances or contaminated by these substances

SECTION 14. Transport information

14.1. UN number

ADR / RID, IMDG, 1993
IATA:

14.2. UN proper shipping name

ADR / RID: FLAMMABLE LIQUID, N.O.S. (Propan-2-ol; Ethanol) MIXTURE
IMDG: FLAMMABLE LIQUID, N.O.S. (Propan-2-ol; Ethanol) MIXTURE
IATA: FLAMMABLE LIQUID, N.O.S. (Propan-2-ol; Ethanol) MIXTURE

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, III
IATA:

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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: -		
IMDG:	EMS: F-E, S-E	Limited Quantities: 5 L	
IATA:	Cargo:	Maximum quantity: 220 L	Packaging instructions: 366
	Pass.:	Maximum quantity: 60 L	Packaging instructions: 355
	Special provision:	A3	

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

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/EC: P5c

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

Product

Point	3	
		<i>Liquid substances or mixtures that meet the criteria relating to one of the following hazard classes or categories as set out in Annex I of Regulation (EC) No. 1272/2008:</i> <i>a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;</i> <i>b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or development, 3.8 effects other than narcotic effects, 3.9 and 3.10;</i> <i>c) hazard class 4.1;</i> <i>d) hazard class 5.1.</i>
Point	40	
		<i>Substances classified as flammable gases of category 1 or 2, flammable liquids of category 1, 2 or 3, flammable solids of category 1 or 2, substances and mixtures which, in contact with water, emit flammable gases of categories 1, 2 or 3, category 1 pyrophoric liquids or category 1 pyrophoric solids, even if not listed in Part 3 of Annex VI to Regulation (EC) No. 1272/2008</i> <i>Contained substance</i>
Point	75	SUBTILISINE Reg. No. 01-2119480434-38-xxxx
		<i>Substances included in one or more of the following:</i>

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a) substances classified in one of the following classes in Annex VI, part 3, of Regulation (EC) no. 1272/2008:

- category 1A, 1B or 2 carcinogenicity, category 1A, 1B or 2 germ cell mutagenicity, but excluding substances classified due to effects following exposure by inhalation only;
- Reproductive toxicity of category 1A, 1B or 2, but excluding substances classified due to effects following exposure by inhalation only;
- skin sensitization of category 1, 1A or 1B;
- skin corrosion of category 1, 1A, 1B or 1C or skin irritation of category 2;
- serious category 1 eye damage or category 2 eye irritation;

b) substances listed in Annex II of Regulation (EC) no. 1223/2009 of the European Parliament and of the Council (*);

c) substances listed in Annex IV of Regulation (EC) no. 1223/2009 for which a condition is indicated in at least one of the columns g, h or i of the table of this annex;

d) substances listed in Appendix 13 of this annex. The ancillary requirements referred to in points 7 and 8 of column 2 of this entry apply to all mixtures intended for tattooing practices, regardless of whether they contain one of the substances referred to in points a) to d) of this column and entry.

Regulation (EC) No. 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

Substances subject to exportation reporting pursuant to (EC) Reg. 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.

Medical device, class IIb according to legislation 93/42.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16. Other information

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

Flam. Liq. 2

Flammable liquid, category 2

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Flam. Liq. 3	Flammable liquid, category 3
Skin Corr. 1A	Skin corrosion, category 1A
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.
H314	Causes severe skin burns and eye damage.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 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 NUMBER: 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: EC Regulation 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 STEL: Short-term exposure limit
- TWA: Time-weighted average 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) 790/2009 (I Atp. CLP) of the European Parliament
4. Regulation (EU) 2015/830 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) 2018/1480 (XIII Atp. CLP)

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16. Regulation (EU) 2019/521 (XII Atp. CLP)
17. Regulation (EU) 2019/1148
18. Regulation (EU) 2020/217 (XIV 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

Training for workers:

The training of workers must include contents, updates and duration according to the risk profiles assigned to the working sectors of membership, according to the procedures provided for by Legislative Decree 81/2008.

Procedure used to derive the classification according to Regulation (EC) 1272/2008 (CLP) in relation to mixtures:

Classification of the mixture according to Regulation (EC) n. 1272/2008	Classification procedure
Flammable liquid, category 2	H225
	Based on experimental data.

Note for the recipient of the Safety Data Sheet (SDS):

It is the recipient of this SDS who must ensure that the information contained is read and understood by all persons who handle, store, use, or otherwise come into contact in any way with the substance or mixture to which this sheet refers. In particular, the recipient must provide adequate training to personnel assigned to the use of dangerous substances or mixtures. The recipient must ensure the suitability and completeness of the information in relation to the specific use of the substance or mixture.

However, the substance or mixture to which this SDS refers must not be used for uses other than those specified in section 1. No responsibility is assumed for improper uses. Since the use of the product does not fall under the direct control of the Supplier, it is the user's obligation to observe, under his own responsibility, the laws and regulations in force regarding national and Community hygiene and safety.

The information contained in this SDS is provided in good faith and is based on the current state of scientific and technical knowledge, at the revision date indicated, available from the Supplier indicated in section 1 of this sheet. The SDS should not be interpreted as a guarantee of any specific property of the substance or mixture. The information refers only to the substance or mixture specifically designated in section 1 and may not be valid for the substance or mixture used in combination with other materials or in other processes not specifically indicated in the text.

This version of the SDS supersedes all previous versions.

Changes from the previous revision.

Changes have been made to the following sections:
01/02/03/04/05/06/07/08/09/10/11/12/13/14/15/16.