

B-SanySafe C

Safety Data Sheet

According to Annex II to REACH - Regulation 2020/878

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

1.1. Product identifier

Code: **BES**
Product name: **B-SanySafe C**
UFI: **CH00-Y0NJ-K00U-MUWN**

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

Intended use: **Concentrated decontaminant and disinfectant for Medical Devices. For professional use only.**

1.3. Details of the supplier of the safety data sheet

Name: **FIS & DM S.R.L.**
Full address: **Strada di Sabbione, 27/a**
District and Country: **05100 Terni (Terni)**
Italia
tel. **+39 07444555503**

e-mail address of the competent person

responsible for the Safety Data Sheet: **dir.tech@fisindustry.it**
Product distribution by: **FIS&DM srl**

1.4. Emergency telephone number

For urgent inquiries refer to

Emergency number (24\7):

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	Flammable liquid and vapour.
Acute toxicity, category 4	H302	Harmful if swallowed.
Eye irritation, category 2	H319	Causes serious eye irritation.
Specific target organ toxicity - single exposure, category 2	H371	May cause damage to organs.
Hazardous to the aquatic environment, chronic toxicity, category 3	H412	Harmful to aquatic life with long lasting effects.

La classificazione del prodotto, si basa sui risultati di un adeguato test in vitro che esclude la classificazione H290 (Method MT 37.4, Manual of test and Criteria of the Transport of Dangerous Goods of United nations. Study Report No. 21179-01C; results: not corrosive for steel and aluminium).

The classification of the compound, featuring an extreme pH value, is based on the results of an appropriate in vitro test.

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.
H302	Harmful if swallowed.
H319	Causes serious eye irritation.
H371	May cause damage to organs.
H412	Harmful to aquatic life with long-lasting effects.

Precautionary statements:

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280	Wear protective gloves and eye protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P403+P235	Store in a well-ventilated place. Keep cool.
P261	Avoid breathing vapours/spray.
P312	Call a POISON CENTRE if you feel unwell.

Contains: TETRAMETHYLAMMONIUM CHLORIDE

2.3. Other hazards

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

The product does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Reg. (EU) 2017/2100 or Reg. (EU) 2018/605 in a percentage equal to or greater than 0.1% by weight.

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

Identificazione	x = Conc. %	Classification 1272/2008 (CLP)
PROPAN-2-OL		
CAS 67-63-0	$15 \leq x < 25$	Flam. Liq. 2 H225, Eye Irrit. 2 H319, STOT SE 3 H336
CE 200-661-7		
INDEX 603-117-00-0		
Nr. Reg. 01-2119457558-25-XXXX		
TETRAMETHYLAMMONIUM CHLORIDE		
CAS 75-57-0	$4 \leq x < 10$	Acute Tox. 2 H300, Acute Tox. 3 H311, STOT SE 1 H370, Skin Irrit. 2 H315, Aquatic Chronic 2 H411
CE 200-880-8		
ETHANOL		
CAS 64-17-5	$2 \leq x < 5$	Flam. Liq. 2 H225, Eye Irrit. 2 H319
CE 200-578-6		
INDEX 603-002-00-5		
Nr. Reg. 01-2119457610-43-XXXX		
HYDROCHLORIC ACID		
CAS 7647-01-0	$0,05 \leq x < 0,2$	Met. Corr. 1 H290, Skin Corr. 1B H314, Eye Dam. 1 H318, STOT SE 3 H335, Classification note/notes according to Annex VI to the CLP Regulation: B
CE 231-595-7		
INDEX 017-002-01-X		
Nr. Reg. 01-2119484862-27-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. Rinse skin with a shower immediately. Get medical advice/attention immediately. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention immediately.

INGESTION: Get medical advice/attention immediately. Do not induce vomiting. Do not administer anything not explicitly authorised by a doctor.

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

Information not available

SECTION 5. Firefighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

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

UNSUITABLE EXTINGUISHING EQUIPMENT

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

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

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

GENERAL INFORMATION

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

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

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

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Block the leakage if there is no hazard.

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

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

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

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

Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

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

SECTION 7. Handling and storage

7.1. Precautions for safe handling

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

7.2. Conditions for safe storage, including any incompatibilities

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

7.3. Specific end 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 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

PROPAN-2-OL 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	
WEL	GBR	999	400	1250	500	
TLV-ACGIH		492	200	983	400	
Predicted no-effect concentration - PNEC						
				140,9		mg/l
				140,9		mg/l
				552		mg/kg

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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

TETRAMETHYLAMMONIUM CHLORIDE

Predicted no-effect concentration - PNEC

Normal value in fresh water	600	ng/L
Normal value in marine water	60	ng/L
Normal value for fresh water sediment	35	µg/kg
Normal value for marine water sediment	35	µg/kg
Normal value for water, intermittent release	36	µg/kg
Normal value of STP microorganisms	6	mg/l
Normal value for the food chain (secondary poisoning)	NEA	
Normal value for the terrestrial compartment	66	µg/kg
Normal value for the atmosphere	NPI	

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		250		250 µg/kg/d				
Inhalation	NEA	NEA	NEA	1,76 mg/m3	NEA	NEA	NEA	2,9 mg/m3
Skin				250 µg/kg/d	VND	VND	NEA	400 µg/kg/d

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	
WEL	GBR	1920	1000			
TLV-ACGIH				1884	1000	
Predicted no-effect concentration - PNEC						
Normal value in fresh water				960	µg/L	

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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			Chronic systemic	Effects on workers			Chronic systemic
	Acute local	Acute systemic	Chronic local		Acute local	Acute systemic NPI	Chronic local	
Oral								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

HYDROCHLORIC ACID Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
AGW	DEU	3	2	6 (C)	4 (C)	
VLA	ESP	7,6	5	15	10	
VLEP	FRA			7,6	5	
VLEP	ITA	8	5	15	10	
WEL	GBR	2	1	8	5	
OEL	EU	8	5	15	10	
TLV-ACGIH				2,9 (C)	2 (C)	

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.

Provide an emergency shower with face and eye wash station.

HAND PROTECTION

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

The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

SKIN PROTECTION

Wear category II professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap

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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).

In the presence of risks of exposure to splashes or squirts during work, adequate mouth, nose and eye protection should be used to prevent accidental absorption.

RESPIRATORY PROTECTION

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

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

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

ENVIRONMENTAL EXPOSURE CONTROLS

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

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

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	green	
Odour	Citrus	
Odour threshold	Not determined	
pH	7 +/- 0,3	
Melting point / freezing point	Not determined	
Initial boiling point	103 °C	
Flash point	31 °C	
Vapour pressure	2569 Pa a 20 °C	
Vapour density	Not determined	
Relative density	0,971 g/cm ³	
Solubility	soluble in water	
Partition coefficient: n-octanol/water	0,16 (Propan-2-olo)	Substance: PROPAN-2-OL
Auto-ignition temperature	324 °C	
Decomposition temperature	Not determined	
Viscosity	1,26 cP	Substance: WATER
Explosive properties	Not explosive	
Oxidising properties	Not oxydant	

9.2. Other information

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VOC (Directive 2010/75/EC) : 21,07 % - 204,55 g/litre

SECTION 10. Stability and reactivity

10.1. Reactivity

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

TETRAMETHYLAMMONIUM CHLORIDE

Hygroscopic.

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: 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.

HYDROCHLORIC ACID

Risk of explosion on contact with: alkaline metals,aluminium powder,hydrogen cyanide,alcohol.

10.4. Conditions to avoid

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

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.

HYDROCHLORIC ACID

Incompatible with: alkalis,organic substances,strong oxidants,metals.

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.

HYDROCHLORIC ACID

In decomposition develops: hydrochloric acid fumes.

SECTION 11. Toxicological information

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

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

11.1. Information on toxicological effects

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)

Information on likely routes of exposure

Information not available

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

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

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

ATE (Oral) of the mixture: 522,22 mg/kg

ATE (Dermal) of the mixture: >2000 mg/kg

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

TETRAMETHYLAMMONIUM CHLORIDE

LD50 (Oral) 47 mg/kg Ratto

LD50 (Dermal) > 200 mg/kg coniglio

PROPAN-2-OL

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Method: equivalent or similar to OECD 401
Reliability (Klimisch score): 2
Species: Rat (Sherman)
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

TETRAMETHYLAMMONIUM CHLORIDE

Method: equivalent or similar to OECD401
Reliability: 2
Species: Rat (Wistar, male / female)
Routes of exposure: oral
Results: highly toxic
Bibliographic reference: Fundam Appl Toxicol 5: 727-736.

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

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

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)

TETRAMETHYLAMMONIUM CHLORIDE

Method: equivalent or similar to OECD402
Reliability: 1
Species: Rabbit (male / female)
Routes of exposure: cutaneous

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Results: Irritant Category 3

ETHANOL

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

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye irritation

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

TETRAMETHYLAMMONIUM CHLORIDE

Method: equivalent or similar to OECD439
Reliability: 1
Species: man (male / female)
Routes of exposure: cutaneous
Results: irritating

Method: equivalent or similar to OECD405
Reliability: 1
Species: Rabbit (New Zealand White, male / female)
Routes of exposure: ocular
Results: non-irritating

ETHANOL

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

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

PROPAN-2-OL

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

TETRAMETHYLAMMONIUM CHLORIDE

Method: equivalent or similar to OECD429
Reliability: 1

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Species: Mouse (CBA / J, female)
Routes of exposure: cutaneous
Results: not sensitizing
Details on the substance used: 5% -25% soluzoins in propylene glycol

ETHANOL

Method: equivalent or similar OECD 406
Reliability (Klimisch score): 2
Species: Guinea pig (Pirbright White; Female)
Routes of exposure: cutaneous
Results: not sensitizing.

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

PROPAN-2-OL

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

TETRAMETHYLAMMONIUM CHLORIDE

Method: equivalent or similar to OECD471
Reliability: 1
In vitro test
Results: no effect observed

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.

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

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.

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

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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.

TETRAMETHYLAMMONIUM CHLORIDE

Method: equivalent or similar to OECD421
Reliability: 2
Species: Rat (Sprague-Dawley, male / female)
Routes of exposure: oral
Results: no effect observed
NOAEL:> 20 mg / kg bw / day

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

STOT - SINGLE EXPOSURE

May cause damage to organs

PROPAN-2-OL

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Metodo: OECD 426

Affidabilità (Klimisch score): 1

Specie: Ratto (Sprague-Dawley; Femmina)

Vie d'esposizione: orale.

Risultati: Può provocare sonnolenza o vertigini.

In base ai dati disponibili, la sostanza presenta effetti di tossicità specifica per organi bersaglio per esposizione singola ed è classificata sotto la relativa classe di pericolo CLP.

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.

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

PROPAN-2-OL

In base ai dati disponibili, la sostanza non presenta effetti di tossicità specifica per organi bersaglio per esposizione ripetuta e non è classificata sotto la relativa classe di pericolo CLP.

TETRAMETHYLAMMONIUM CHLORIDE

Method: equivalent or similar to OECD408

Reliability: 1

Species: Rat (CrI: WI (Han), male / female)

Routes of exposure: oral

Results: observed effect

NOAEL: 10 mg / kg bw / day

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

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

PROPAN-2-OL

Non sono disponibili dati sulla pericolosità in caso di aspirazione.

ETHANOL

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

SECTION 12. Ecological information

This product is dangerous for the environment and the aquatic organisms. In the long term, it have negative effects on aquatic environment.

12.1. Toxicity

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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

PROPAN-2-OL

LC50 - for Fish	9640 mg/l/96h Pimephales promelas (equivalente o similare a OECD 203)
EC50 - for Crustacea	> 10000 mg/l/48h Daphnia magna (equivalente o similare a OECD 202)

TETRAMETHYLAMMONIUM CHLORIDE

LC50 - for Fish	462 mg/l/96h Pimephales promelas (Cavedano americano)
EC50 - for Algae / Aquatic Plants	96,3 mg/l/72h

12.2. Persistence and degradability

PROPAN-2-OL

Rapidamente degradabile, 53% in 5 giorni (equivalente o similare a 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)

HYDROCHLORIC ACID

Solubility in water > 10000 mg/l

ETHANOL

Rapidly degradable

PROPAN-2-OL

Rapidly degradable

12.3. Bioaccumulative potential

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

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

Waste transportation may be subject to ADR restrictions.

CONTAMINATED PACKAGING

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

SECTION 14. Transport information

14.1. UN number

ADR / RID, IMDG, IATA: 1993

14.2. UN proper shipping name

ADR / RID: FLAMMABLE LIQUID, N.O.S. (Propan-2-Ol, Ethanol, Quaternary Ammonium Compounds) MIXTURE

IMDG: FLAMMABLE LIQUID, N.O.S. (Propan-2-Ol, Ethanol, Quaternary Ammonium Compounds) MIXTURE

IATA: FLAMMABLE LIQUID, N.O.S. (Propan-2-Ol, Ethanol, Quaternary Ammonium Compounds) 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, 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: -

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IMDG:	EMS: F-E, <u>S-E</u>	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 - 40

Contained substance

Point	75	HYDROCHLORIC ACID Reg. no.: 01-2119484862-27-XXXX
Point	75	Colorante Verde Alcali Reg. no.: 01-2120757373-51-XXXX

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

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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.

Dispositivo Medico di classe IIb secondo il regolamento 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
Flam. Liq. 3	Flammable liquid, category 3
Met. Corr. 1	Substance or mixture corrosive to metals, category 1
Acute Tox. 2	Acute toxicity, category 2
Acute Tox. 3	Acute toxicity, category 3
STOT SE 1	Specific target organ toxicity - single exposure, category 1
Acute Tox. 4	Acute toxicity, category 4
Skin Corr. 1B	Skin corrosion, category 1B
Eye Irrit. 2	Eye irritation, category 2
Skin Irrit. 2	Skin irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
STOT SE 2	Specific target organ toxicity - single exposure, category 2
Aquatic Chronic 2	Hazardous to the aquatic environment, chronic toxicity, category 2
Aquatic Chronic 3	Hazardous to the aquatic environment, chronic toxicity, category 3
H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H290	May be corrosive to metals.
H300	Fatal if swallowed.
H311	Toxic in contact with skin.
H370	Causes damage to organs.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H371	May cause damage to organs.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

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)
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 15. Regulation (EU) 2018/1480 (XIII Atp. CLP)
 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

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

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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.

Changes to previous review:

The following sections were modified:

01 / 02 / 03 / 04 / 05 / 06 / 07 / 08 / 09 / 10 / 11 / 12 / 13 / 14 / 15 / 16.