

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

0001327 - SANIT LOCION VIRUGEL

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

1.1 Product identifier:

0001327 - SANIT LOCION VIRUGEL

Other means of identification:

SANIT LOCION VIRUGEL - ANTISEPTIC FOR HEALTHY SKIN № Reg. AEMPS: 1472-DES

UFI: 6XN3-J06N-U002-M18G

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

Relevant uses (Consumer use): Hygienic cleaner Relevant uses (Professional users): Hygienic cleaner Relevant uses (Industrial user): Hygienic cleaner Uses advised against: All uses not specified in this section or in section 7.3

1.3 Details of the supplier of the safety data sheet:

S.A. PRODER Paseo Sanllehy 64, 08213 POLINYÀ - BARCELONA - ESPAÑA Phone: 93 713 20 25 - Fax: 93 713 15 68 info@proderpharma.com www.proderpharma.com

1.4 Emergency telephone number: 915620420

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

CLP Regulation (EC) No 1272/2008:

Classification of this product has been carried out in accordance with CLP Regulation (EC) No 1272/2008.

Eye Irrit. 2: Eye irritation, Category 2, H319 Flam. Liq. 2: Flammable liquids, Category 2, H225

2.2 Label elements:

CLP Regulation (EC) No 1272/2008:

Danger



Hazard statements:

Eye Irrit. 2: H319 - Causes serious eye irritation. Flam. Liq. 2: H225 - Highly flammable liquid and vapour.

Precautionary statements:

P102: Keep out of reach of children.

P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue

rinsing.

P337+P313: If eye irritation persists: Get medical advice/attention.

P403+P233: Store in a well-ventilated place. Keep container tightly closed.

P501: Dispose of contents/container according to the separated collection system used in your municipality.

2.3 Other hazards:

Product does not meet PBT/vPvB criteria

Endocrine-disrupting properties: The product does not meet the criteria.

External use. Do not eat.

Do not inhale.

Do not use in people sensitive to its components, or in large areas of the skin, or for a long time.

Use with caution in children under 2 years.

Avoid contact with the eyes, mucous membranes, sensitive or diseased areas of the skin. In order to avoid risks to people and the environment, follow the instructions for use.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS



SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS (continued)

3.1 Substance:

Not relevant

3.2 Mixture:

Chemical description: Miscellaneous products

Components:

In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

	Identification	Chemical name/Classification				
CAS:	64-17-5	ethanol ⁽¹⁾	Self-classified			
EC: Index: REACH:	200-578-6 603-002-00-5 01-2119457610-43-XXXX	Regulation 1272/2008	Eye Irrit. 2: H319; Flam. Liq. 2: H225 - Danger	75 - <100 %		

(1) Substances presenting a health or environmental hazard which meet criteria laid down in Regulation (EU) No. 2020/878

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

Other information:

Identification	Specific concentration limit
ethanol	
CAS: 64-17-5	% (w/w) >=50: Eye Irrit. 2 - H319
EC: 200-578-6	

Acute toxicity estimate for the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or as determined in accordance with Annex I to that Regulation:

Identification	Acute toxicity		Genus
ethanol	LD50 oral	Not relevant	
	LD50 dermal	Not relevant	
EC: 200-578-6	LC50 inhalation vapour	124,7 mg/L	Rat

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

This product does not contain substances classified as hazardous for inhalation, however, in case of symptoms of intoxication remove the person affected from the exposure area and provide with fresh air. Seek medical attention if the symptoms get worse or persist.

By skin contact:

In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of changes to the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Safety Data Sheet

By eye contact:

Rinse eyes thoroughly with lukewarm water for at least 15 minutes. Do not allow the person affected to rub or close their eyes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, in which case this could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS of the product.

By ingestion/aspiration:

In case of consumption, seek immediate medical assistance showing the SDS for the product.

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

Acute and delayed effects are indicated in sections 2 and 11.

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

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Not available

Suitable extinguishing media:



SECTION 5: FIREFIGHTING MEASURES (continued)

Foam extinguisher (AB), Dry Chemical Powder (ABC) Fire Extinguisher, Carbon dioxide extinguisher (BC)

Unsuitable extinguishing media:

Water jet

5.2 Special hazards arising from the substance or mixture:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and Self Contained Breathing Apparatus. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...)

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

For non-emergency personnel:

Isolate leaks provided that there is no additional risk for the people performing this task. Evacuate the area and keep out those without protection. Personal protection equipment must be used against potential contact with the spilt product (See section 8). Above all prevent the formation of any vapour-air flammable mixtures, through either ventilation or the use of an inert medium. Remove any source of ignition. Eliminate electrostatic charges by interconnecting all the conductive surfaces on which static electricity could form, and also ensuring that all surfaces are connected to the ground.

For emergency responders:

Wear protective equipment. Keep unprotected persons away. See section 8.

6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and ground water.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Prevent the entrance of product in drains, sewers or watercourses. Absorb the spill using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. Collect the product in appropriate containers and manage it according to current legislation.

Spillages in water or sea:

Small spillages:

Contain spillage using barriers or similar equipment. Use suitable absorbents for collection and treat the waste in accordance with current regulations.

Large spillages:

If possible, contain spillage in open water using barriers or similar equipment. If this is not possible, try to control its spread and collect the product with suitable mechanical means. Always consult experts before using dispersants and make sure you have the necessary approvals if they are to be used. Treat the waste according to current regulations.

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- General precautions for safe use

Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

B.- Technical recommendations for the prevention of fires and explosions



SECTION 7: HANDLING AND STORAGE (continued)

Transfer in well ventilated areas, preferably through localized extraction. Fully control sources of ignition (mobile phones, sparks,...) and ventilate during cleaning operations. Avoid the existence of dangerous atmospheres inside containers, applying inertization systems where possible. Transfer at a slow speed to avoid the creation of electrostatic charges. Against the possibility of electrostatic charges: ensure a perfect equipotential connection, always use groundings, do not wear work clothes made of acrylic fibres, preferably wearing cotton clothing and conductive footwear. Comply with the essential security requirements for equipment and systems defined in Directive 2014/34/EC (ATEX 100) and with the minimum requirements for protecting the security and health of workers under the selection criteria of Directive 1999/92/EC (ATEX 137). Consult section 10 for conditions and materials that should be avoided.

C.- Technical recommendations on general occupational hygiene

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

- D.- Technical recommendations to prevent environmental risks
- It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

7.2 Conditions for safe storage, including any incompatibilities:

A.- Specific storage requirements

Minimum Temp.:	5 ºC
Maximum Temp.:	40 ºC
Maximum time:	60 Months

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

Other information:

Comply with current legislation regarding storage. Store in the original container. Store in a cool, dry and well-ventilated place, protected from light to preserve the product quality. Keep containers tightly closed. Control spills and waste eliminating them with safe methods (section 6). Maintain order and cleanliness wherever the dangerous products are stored.

7.3 Specific end use(s):

Hydroalcoholic solution for fast and effective disinfection of clean and healthy skin. Suitable for pre-surgical disinfection.

EFFECTIVENESS: see label.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the workplace (European OEL, not country-specific legislation):

There are no applicable occupational exposure limits for the substances contained in the product

DNEL (Workers):

		Short e	xposure	Long ex	posure
Identification		Systemic	Local	Systemic	Local
ethanol	Oral	Not relevant	Not relevant	Not relevant	Not relevant
CAS: 64-17-5	Dermal	Not relevant	Not relevant	343 mg/kg	Not relevant
EC: 200-578-6	Inhalation	Not relevant	Not relevant	950 mg/m³	Not relevant

DNEL (General population):

		Short e	xposure	Long ex	kposure
Identification		Systemic	Local	Systemic	Local
ethanol	Oral	Not relevant	Not relevant	87 mg/kg	Not relevant
CAS: 64-17-5	Dermal	Not relevant	Not relevant	206 mg/kg	Not relevant
EC: 200-578-6	Inhalation	Not relevant	Not relevant	114 mg/m³	Not relevant

PNEC:

Identification				
ethanol	STP	580 mg/L	Fresh water	0,96 mg/L
CAS: 64-17-5	Soil	0,63 mg/kg	Marine water	0,79 mg/L
EC: 200-578-6	Intermittent	2,75 mg/L	Sediment (Fresh water)	3,6 mg/kg
	Oral	0,38 g/kg	Sediment (Marine water)	2,9 mg/kg

8.2 Exposure controls:



SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

A.- Individual protection measures, such as personal protective equipment

As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<CE marking>> in accordance with Regulation (EU) 2016/425. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1. All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection

If the working conditions and/or safety measures adopted do not allow keeping the airborne concentration of the product below the exposure limits (if any) or at acceptable levels (if no exposure limits exist), suitable respiratory protection equipment chosen by a qualified professional should be used.

C.- Specific protection for the hands

Not relevant

D.- Eye and face protection

Not relevant

E.- Body protection

Not relevant

F.- Additional emergency measures

It is advised to implement additional emergency equipments in workplaces that are particularly exposed to the product or in situations where risk assessments highlight the necessity of such equipments.

It is not necessary to take additional emergency measures.

Environmental exposure controls:

To comply with environmental protection regulations, it is recommended to prevent any spillage of the product and its container. For more detailed information, please refer to subsection 7.1.D.

Volatile organic compounds:

With regard to Directive 2010/75/EU, this product has the following characteristics:

V.O.C. (Supply):	76,8 % weight
V.O.C. density at 20 °C:	652,8 kg/m³ (652,8 g/L)
Average carbon number:	2
Average molecular weight:	46,1 g/mol

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:					
Physical state at 20 ºC:	Liquid				
Appearance:	Fluid				
Colour:	Colourless				
Odour:	Alcohol				
Odour threshold:	Not relevant *				
Volatility:					
Boiling point at atmospheric pressure:	82 ºC				
Vapour pressure at 20 ºC:	5057 Pa				
Vapour pressure at 50 ºC:	24182,6 Pa (24,18 kPa)				
Evaporation rate at 20 ºC:	Not relevant *				
Product description:					
Density at 20 ºC:	800 - 900 kg/m³				
Relative density at 20 ºC:	0,795 - 0,895				
*Not relevant due to the nature of the product, not providing information property of its hazards.					



SECT	ION 9: PHYSICAL AND CHEMICAL PROPERTIES (co	ntinued)
	Dynamic viscosity at 20 ºC:	Not relevant *
	Kinematic viscosity at 20 ºC:	Not relevant *
	Kinematic viscosity at 40 °C:	Not relevant *
	Concentration:	Not relevant *
	pH:	5 - 6 (at 100 %)
	Vapour density at 20 ºC:	Not relevant *
	Partition coefficient n-octanol/water 20 °C:	Not relevant *
	Solubility in water at 20 ºC:	Not relevant *
	Solubility properties:	Not relevant *
	Decomposition temperature:	Not relevant *
	Melting point/freezing point:	Not relevant *
	Flammability:	
	Flash Point:	20 ºC
	Flammability (solid, gas):	Not relevant *
	Autoignition temperature:	360 ºC
	Lower flammability limit:	Not relevant *
	Upper flammability limit:	Not relevant *
	Particle characteristics:	
	Median equivalent diameter:	Not relevant *
9.2	Other information:	
	Information with regard to physical hazard classes:	
	Explosive properties:	Not relevant *
	Oxidising properties:	Not relevant *
	Corrosive to metals:	Not relevant *
	Heat of combustion:	Not relevant *
	Aerosols-total percentage (by mass) of flammable components:	Not relevant *
	Other safety characteristics:	
	Surface tension at 20 °C:	Not relevant *
	Refraction index:	20 - 24

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7 from Safety Data Sheet.

10.2 Chemical stability:

Chemically stable under the indicated conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Risk of combustion	Avoid direct impact	Not applicable

10.5 Incompatible materials:

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Avoid direct impact	Not applicable	Avoid alkalis or strong bases



SECTION 10: STABILITY AND REACTIVITY (continued)

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO_2) , carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

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

The experimental information related to the toxicological properties of the product itself is not available

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

A- Ingestion (acute effect):

- Acute toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for consumption. For more information see section 3

- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for inhalation. For more information see section 3.

- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- C- Contact with the skin and the eyes (acute effect):
 - Contact with the skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for skin contact. For more information see section 3.
 - Contact with the eyes: Produces eye damage after contact.
- D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):
 - Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for the effects mentioned. For more information see section 3.

IARC: ethanol (1)

- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- E- Sensitizing effects:
 - Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous with sensitising effects. For more information see section 3.

- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

F- Specific target organ toxicity (STOT) - single exposure:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

- G- Specific target organ toxicity (STOT)-repeated exposure:
 - Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

Other information:

Not relevant



SECTION 11: TOXICOLOGICAL INFORMATION (continued)

Specific toxicology information on the substances:

Identification Acute toxicity		Genus	
ethanol	LD50 oral	6200 mg/kg	Rat
CAS: 64-17-5	LD50 dermal	20000 mg/kg	Rabbit
EC: 200-578-6	LC50 inhalation vapour	124,7 mg/L	Rat

11.2 Information on other hazards:

Endocrine disrupting properties

Endocrine-disrupting properties: The product does not meet the criteria.

Other information

Not relevant

SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

12.1 Toxicity:

Acute toxicity:

Identification	Concentration		Species	Genus
ethanol	LC50	11000 mg/L (96 h)	Alburnus alburnus	Fish
CAS: 64-17-5		9268 mg/L (48 h)	Daphnia magna	Crustacean
EC: 200-578-6	EC50	1450 mg/L (192 h)	Microcystis aeruginosa	Algae

Chronic toxicity:

Identification	Concentration		Species	Genus
ethanol	NOEC	250 mg/L	Danio rerio	Fish
CAS: 64-17-5 EC: 200-578-6		2 mg/L	Ceriodaphnia dubia	Crustacean

12.2 Persistence and degradability:

Substance-specific information:

Identification	Degradability		Biodegradability	
ethanol	BOD5	Not relevant	Concentration	100 mg/L
CAS: 64-17-5	COD	Not relevant	Period	14 days
EC: 200-578-6	BOD5/COD	Not relevant	% Biodegradable	89 %

12.3 Bioaccumulative potential:

Substance-specific information:

	Identification		nulation potential
ethanol		BCF	3
CAS: 64-17-5		Pow Log	-0.31
EC: 200-578-6		Potential	Low

12.4 Mobility in soil:

Identification	Absorption/desorption		Volatility	
ethanol	Кос	1	Henry	4,61E-1 Pa·m³/mol
CAS: 64-17-5	Conclusion	Very High	Dry soil	Yes
EC: 200-578-6	Surface tension	2,339E-2 N/m (25 ºC)	Moist soil	Yes

12.5 Results of PBT and vPvB assessment:

Product does not meet PBT/vPvB criteria

12.6 Endocrine disrupting properties:

Endocrine-disrupting properties: The product does not meet the criteria.

12.7 Other adverse effects:

Not described



SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Code	Description	Waste class (Regulation (EU) No 1357/2014)	
20 01 29*	detergents containing hazardous substances	Hazardous	

Type of waste (Regulation (EU) No 1357/2014):

HP3 Flammable, HP4 Irritant — skin irritation and eye damage

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-hazardous residue. Waste should not be disposed of to drains. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) No 1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

Transport of dangerous goods by land:

With regard to ADR 2023 and RID 2023:

	14.1	UN number or ID number:	UN1993
	14.2	UN proper shipping name:	FLAMMABLE LIQUID, N.O.S. (ethanol)
	14.3	Transport hazard class(es):	3
$\langle \simeq \rangle$		Labels:	3
	14.4	Packing group:	111
3	14.5	Environmental hazards:	No
	14.6	Special precautions for user	
		Special regulations:	274, 601
		Tunnel restriction code:	D/E
		Physico-Chemical properties:	see section 9
		Limited quantities:	5 L
	14.7	Maritime transport in bulk according to IMO instruments:	Not relevant
Transport of dan	gerous g	oods by sea:	
With regard to IN	1DG 41-2	22:	
	14.1	UN number or ID number:	UN1993
	14.2	UN proper shipping name:	FLAMMABLE LIQUID, N.O.S. (ethanol)
, de	14.3	Transport hazard class(es):	3
		Labels:	3



3 3 III No 274, 223, 955 F-E, S-E see section 9 5 L Not relevant Not relevant

Transport of dangerous goods by air:

14.7

With regard to IATA/ICAO 2024:

- CONTINUED ON NEXT PAGE -

Physico-Chemical properties:

Maritime transport in bulk

according to IMO instruments:

Limited quantities:

Segregation group:



SECTION 14: TRANSPORT INFORMATION (continued)

14.

14.



1	UN number or ID number:	UN1993
2	UN proper shipping name:	FLAMMABLE LIQUID, N.O.S. (ethanol)
3	Transport hazard class(es):	3
	Labels:	3
4	Packing group:	111
5	Environmental hazards:	No
6	Special precautions for user	
	Physico-Chemical properties:	see section 9
7	Maritime transport in bulk according to IMO instruments:	Not relevant

SECTION 15: REGULATORY INFORMATION

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

- Article 95, REGULATION (EU) No 528/2012: ethanol (64-17-5) PT: (1,2,4,6)
- Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): Not relevant
- Regulation (EU) 2019/1021 on persistent organic pollutants: Not relevant
- Regulation (EU) No 2024/590, about substances that deplete the ozone layer: Not relevant
- REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Not relevant
- Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Not relevant

Regulation (EC) No 648/2004 on detergents:

In accordance with this regulation the product complies with the following:

The tensoactives contained in this mixture comply with the biodegradibility criteria stipulated in Regulation (EC) nº648/2004 on detergents. The information to prove this is available to the relevant authorities of the Member States and will be shown to them by direct request or the request of a detergent manufacturer.

Seveso III:

Section	Description	Lower-tier requirements	Upper-tier requirements
P5c	FLAMMABLE LIQUIDS	5000	50000

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc):

Shall not be used in:

-ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays, -tricks and jokes,

-games for one or more participants, or any article intended to be used as such, even with ornamental aspects.

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

Other legislation:

The product could be affected by sectorial legislation

- Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products
- Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents
- Commission Regulation (EC) No 907/2006 of 20 June 2006 amending Regulation (EC) No 648/2004 of the European Parliament and of the Council on detergents, in order to adapt Annexes III and VII
- Commission Regulation (EC) No 551/2009 of 25 June 2009 amending Regulation (EC) No 648/2004 of the European Parliament and of the Council on detergents, in order to adapt Annexes V and VI thereto (surfactant derogation)

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

The SDS shall be supplied in an official language of the country where the product is placed on the market. This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (COMMISSION REGULATION (EU) 2020/878).

Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:



SECTION 16: OTHER INFORMATION (continued)

Not relevant

Texts of the legislative phrases mentioned in section 2:

H319: Causes serious eye irritation. H225: Highly flammable liquid and vapour.

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) No 1272/2008:

Eye Irrit. 2: H319 - Causes serious eye irritation. Flam. Liq. 2: H225 - Highly flammable liquid and vapour.

Classification procedure:

Eye Irrit. 2: Calculation method Flam. Liq. 2: Calculation method (2.6.4.3)

Advice related to training:

Training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

http://echa.europa.eu http://eur-lex.europa.eu

Abbreviations and acronyms:

ADR: European agreement concerning the international carriage of dangerous goods by road IMDG: International maritime dangerous goods code IATA: International Air Transport Association ICAO: International Civil Aviation Organisation COD: Chemical Oxygen Demand BOD5: 5day biochemical oxygen demand BCF: Bioconcentration factor LD50: Lethal Dose 50 LC50: Lethal Concentration 50 EC50: Effective concentration 50 LogPOW: Octanolwater partition coefficient Koc: Partition coefficient of organic carbon UFI: unique formula identifier IARC: International Agency for Research on Cancer

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.