

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2020/878)

10155-Cold cream wo

Version 1 Date of compilation: 16/10/2022

Version 4 (replaces version 3)

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

1.1 Product identifier.

Product Name: Cold cream wo
Product Code: 10155
UFI: JP80-100V-H00N-NQUT

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

Excipient pharmaceutical use

Uses advised against:

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.

Company: **GUINAMA S.L**
Address: C/ Oslo Nº3
City: 46185 - La Pobla de Vallbona
Province: Valencia
Telephone: +34961869090 / 902119816
Fax: +34961850352
E-mail: ventas@guinama.com
Web: www.guinama.com

1.4 Emergency telephone number: +34961869090 / 902119816 (Only available during office hours; Monday-Friday; 08:00-18:00)

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the substance or mixture.

In accordance with Regulation (EC) No 1272/2008:

Eye Irrit. 2 : Causes serious eye irritation.

2.2 Label elements.

Labelling in accordance with Regulation (EC) No 1272/2008:

Pictograms:



Signal Word:

Warning

Hazard statements:

H319 Causes serious eye irritation.

Precautionary statements:

P201 Obtain special instructions before use.
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...
P308+P313 IF exposed or concerned: Get medical advice/attention.
P321 Specific treatment (see ... on this label).
P337+P313 If eye irritation persists: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.
P501 Dispose of contents/container to ...

EUH statements:

Restricted to professional users.

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Contains:

petrolatum, Petrolatum, [A complex combination of hydrocarbons obtained as a semi-solid from dewaxing paraffinic residual oil. It consists predominantly of saturated crystalline and liquid hydrocarbons having carbon numbers predominantly greater than C25.]

2.3 Other hazards.

The mixture does not contain substances classified as PBT.

The mixture does not contain substances classified as vPvB.

The mixture does not contain any endocrine disrupting properties substances.

In normal use conditions and in its original form, the product itself does not involve any other risk for health and the environment.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

3.1 Substances.

Not applicable.

3.2 Mixtures.

Substances posing a danger to health or the environment in accordance with the Regulation (EC) No. 1272/2008, assigned a Community exposure limit in the workplace, and classified as PBT/vPvB or included in the Candidate List:

Identifiers	Name	Concentrate	(*)Classification - Regulation (EC) No 1272/2008	
			Classification	Specifics concentration limits and Acute toxicity estimate
Index No: 649-254-00-X CAS No: 8009-03-8 EC No: 232-373-2 Registration No: 01-2119490412-42-XXXX	petrolatum, Petrolatum, [A complex combination of hydrocarbons obtained as a semi-solid from dewaxing paraffinic residual oil. It consists predominantly of saturated crystalline and liquid hydrocarbons having carbon numbers predominantly greater than C25.]	0.1 - 50 %	Carc. 1B, H350	-
CAS No: 142-91-6 EC No: 205-571-1 Registration No: 01-2119541808-31-XXXX	isopropyl palmitate	10 - 25 %	-	-
CAS No: 56-81-5 EC No: 200-289-5 Registration No: 01-2119471987-18-XXXX	glycerol	2.5 - 10 %	-	-
Index No: 605-019-00-3 CAS No: 5392-40-5 EC No: 226-394-6 Registration No: 01-2119462829-23-XXXX	citral	0 - 1 %	Skin Irrit. 2, H315 - Skin Sens. 1, H317	-

(*) The complete text of the H phrases is given in section 16 of this Safety Data Sheet.

[2] Substance with a national workplace exposure limit (see section 8.1).

SECTION 4: FIRST AID MEASURES.

4.1 Description of first aid measures.

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

Inhalation.

Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

Eye contact.

Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance. Dont let the person to rub the affected eye.

Skin contact.

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Remove contaminated clothing. Wash skin vigorously with water and soap or a suitable skin cleaner. NEVER use solvents or thinners.

Ingestion.

If accidentally ingested, seek immediate medical attention. Keep calm. NEVER induce vomiting.

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

No known acute or delayed effects from exposure to the product.

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

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious. Cover the affected area with a dry sterile bandage. Protect the affected area from pressure or friction.

SECTION 5: FIREFIGHTING MEASURES.

The product is NOT classified as flammable, in case of fire the following measures should be taken:

5.1 Extinguishing media.

Suitable extinguishing media:

Extinguisher powder or CO₂. In case of more serious fires, also alcohol-resistant foam and water spray.

Unsuitable extinguishing media:

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

5.2 Special hazards arising from the substance or mixture.

Special risks.

Exposure to combustion or decomposition products can be harmful to your health.

5.3 Advice for firefighters.

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account. Prevent the products used to fight the fire from going into drains, sewers, or waterways.

Fire protection equipment.

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

SECTION 6: ACCIDENTAL RELEASE MEASURES.

6.1 Personal precautions, protective equipment and emergency procedures.

For exposure control and individual protection measures, see section 8.

6.2 Environmental precautions.

Product not classified as hazardous for the environment, avoid spillage as much as possible.

6.3 Methods and material for containment and cleaning up.

Contain and collect spillage with inert absorbent material (earth, sand, vermiculite, Kieselguhr...) and clean the area immediately with a suitable decontaminant.

Deposit waste in closed and suitable containers for disposal, in compliance with local and national regulations (see section 13).

6.4 Reference to other sections.

For exposure control and individual protection measures, see section 8.

For later elimination of waste, follow the recommendations under section 13.

SECTION 7: HANDLING AND STORAGE.

7.1 Precautions for safe handling.

For personal protection, see section 8.

In the application area, smoking, eating, and drinking must be prohibited.

Follow legislation on occupational health and safety.

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Never use pressure to empty the containers. They are not pressure-resistant containers. Keep the product in containers made of a material identical to the original.

7.2 Conditions for safe storage, including any incompatibilities.

Store according to local legislation. Observe indications on the label. Store the containers between 15 and 25 ° C, in a dry and well-ventilated place, far from sources of heat and direct solar light. Keep far away from ignition points. Keep away from oxidising agents and from highly acidic or alkaline materials. Do not smoke. Prevent the entry of non-authorised persons. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.

The product is not affected by Directive 2012/18/EU (SEVESO III).

7.3 Specific end use(s).

Not available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

8.1 Control parameters.

The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

Concentration levels DNEL/DMEL:

Name	DNEL/DMEL	Type	Value
isopropyl palmitate CAS No: 142-91-6 EC No: 205-571-1	DNEL (Workers)	Inhalation, Chronic, Systemic effects	25,85 (mg/m ³)
glycerol CAS No: 56-81-5 EC No: 200-289-5	DNEL (Workers)	Inhalation, Chronic, Local effects	56 (mg/m ³)
	DNEL (Consumers)	Inhalation, Chronic, Local effects	33 (mg/m ³)
citral CAS No: 5392-40-5 EC No: 226-394-6	DNEL (Workers)	Inhalation, Chronic, Systemic effects	9 (mg/m ³)

DNEL: Derived No Effect Level, level of exposure to the substance below which adverse effects are not anticipated.

DMEL: Derived Minimal Effect Level, exposure level corresponding to a low risk, that risk should be considered a tolerable minimum.

Concentration levels PNEC:

Name	Details	Value
glycerol CAS No: 56-81-5 EC No: 200-289-5	Fresh water	0,885 (mg/l)
	Agua del mar	0,088 (mg/l)
	Intermitente, agua dulce	8,85 (mg/l)
	Sedimentos agua dulce	3,3 (mg/kg)
	Sedimentos agua de mar	0,33 (mg/kg)
	Tierra	0,141 (mg/kg)
	Estación depuradora	1000 (mg/l)

PNEC: Predicted No Effect Concentration, concentration of the substance below which adverse effects are not expected in the environmental compartment.

8.2 Exposure controls.

Measures of a technical nature:

Provide adequate ventilation, which can be achieved by using good local exhaust-ventilation and a good general exhaust system.

Concentration:	100 %
Uses:	Excipient pharmaceutical use
Breathing protection:	
PPE:	Particle filter mask
Characteristics:	«CE» marking, category III. Made of filtering material, it covers nose, mouth and chin.



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CEN standards:	EN 149		
Maintenance:	Check for any tears, defects, etc. before use. Since it is disposable individual protection equipment, it should be replaced after use.		
Observations:	Does not protect worker unless properly adjusted. Follow the manufacturer's instructions regarding suitable use of the equipment.		
Filter Type needed:	P2		
Hand protection:			
PPE:	Non-disposable protective gloves against chemicals.		
Characteristics:	«CE» marking, category III. Check the list of chemicals for which the glove has been tested.		
CEN standards:	EN 374-1, En 374-2, EN 374-3, EN 420		
Maintenance:	A schedule for the periodical replacement of gloves should be established in order to guarantee their replacement before pollutants permeate them. The use of contaminated gloves could be more dangerous than not using gloves, since the pollutant can gradually accumulate in the glove's material.		
Observations:	They are to be replaced whenever tears, cracks or deformations are observed or when exterior dirt could reduce their strength.		
Material:	PVC (polyvinyl chloride)	Breakthrough time (min.): > 480	Material thickness (mm): 0,35
Eye protection:			
PPE:	Protective goggles against particle impacts.		
Characteristics:	«CE» marking, category II. Eye protector against dust and smoke.		
CEN standards:	EN 165, EN 166, EN 167, EN 168		
Maintenance:	Visibility through lenses should be ideal. Therefore, these parts should be cleaned daily. Protectors should be disinfected periodically following the manufacturer's instructions.		
Observations:	Some signs of wear and tear include: yellow colouring of the lenses, superficial scratching of the lenses, scraping etc.		
Skin protection:			
PPE:	Chemical protective clothing		
Characteristics:	«CE» marking, category III. Clothing should fit properly. The level of protection must be set according to a test parameter called BT (Breakthrough Time), which indicates how long it takes for the chemical to pass through the material.		
CEN standards:	EN 464, EN 340, EN 943-1, EN 943-2, EN ISO 6529, EN ISO 6530, EN 13034		
Maintenance:	In order to guarantee uniform protection, follow the washing and maintenance instructions provided by the manufacturer.		
Observations:	The protective clothing's design should facilitate correct positioning, staying in place without moving for the period of use expected, bearing in mind environmental factors as well as any movement or position the user might adopt while carrying out the activity.		
PPE:	Anti-static safety footwear against chemicals.		
Characteristics:	«CE» marking, category III. Check the list of chemicals against which the footwear is resistant.		
CEN standards:	EN ISO 13287, EN 13832-1, EN 13832-2, EN 13832-3, EN ISO 20344, EN ISO 20345		
Maintenance:	For correct maintenance of this kind of safety footwear, it is necessary to observe the instructions specified by the manufacturer. The footwear should be replaced as soon as any sign of damage is observed.		
Observations:	The footwear should be cleaned regularly and dried when damp, although it should not be placed too close to a source of heat in order to avoid any sharp changes in temperature.		

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.

Physical state: Solid

Colour: light white

Odour: Characteristic

Odour threshold: Not applicable/Not available due to the nature/properties of the product

Melting point: Not applicable/Not available due to the nature/properties of the product

Freezing point: Not applicable/Not available due to the nature/properties of the product

Boiling point or initial boiling point and boiling range: Not applicable/Not available due to the nature/properties of the product

Flammability: Not applicable/Not available due to the nature/properties of the product

Lower explosion limit: Not applicable/Not available due to the nature/properties of the product

Upper explosion limit: Not applicable/Not available due to the nature/properties of the product

Flash point: > 60 °C

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Auto-ignition temperature: Not applicable/Not available due to the nature/properties of the product
Decomposition temperature: Not applicable/Not available due to the nature/properties of the product
pH: Not applicable (Substance/mixture is non-soluble (in water)).
Kinematic viscosity: Not applicable/Not available due to the nature/properties of the product
Solubility: Not applicable/Not available due to the nature/properties of the product
Hydrosolubility: Not applicable/Not available due to the nature/properties of the product
Liposolubility: Not applicable/Not available due to the nature/properties of the product
Partition coefficient n-octanol/water (log value): Not applicable/Not available due to the nature/properties of the product
Vapour pressure: Not applicable/Not available due to the nature/properties of the product
Absolute density: Not applicable/Not available due to the nature/properties of the product
Relative density: 0,9-1,1
Relative vapour density: Not applicable/Not available due to the nature/properties of the product
Particle characteristics: Not applicable/Not available due to the nature/properties of the product

9.2 Other information

Not applicable/Not available due to the nature/properties of the product

SECTION 10: STABILITY AND REACTIVITY.

10.1 Reactivity.

The product does not present hazards by their reactivity.

10.2 Chemical stability.

Stable under the recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions.

The product does not present possibility of hazardous reactions.

10.4 Conditions to avoid.

Avoid any improper handling.

10.5 Incompatible materials.

Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

10.6 Hazardous decomposition products.

No decomposition if used for the intended uses.

SECTION 11: TOXICOLOGICAL INFORMATION.

IRRITANT MIXTURE. Splashes in the eyes can cause irritation.

11.1 Information on hazard classes as defined in Regulation (EC) N° 1272/2008.

Repeated or prolonged eye contact may cause stinging, tearing, redness, swelling, and blurred vision.

Toxicological information about the substances present in the composition.

Name	Acute toxicity			
	Type	Test	Kind	Value
isopropyl palmitate CAS No: 142-91-6 EC No: 205-571-1	Oral	LD50	Rat	> 5000 mg/kg bw [1]
		[1] Food and Chemical Toxicology. Vol. 20, Pg. 727, 1982.		
	Dermal	LD50	Rabbit	> 5000 mg/kg bw [1]
[1] Food and Chemical Toxicology. Vol. 20, Pg. 727, 1982.				
glycerol	Oral	LD50	Rat	27200 mg/kg bw [1]
		LD50	Rat	15750 mg/kg bw [2]
		LD50	Rat	12600 mg/kg bw [3]

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CAS No: 56-81-5 EC No: 200-289-5		[1] Janssen P., de Rooy C., Evaluation of the toxicity and metabolism of glycerine, polyglycerines and polyglycerine esters, Solvay-Duphar (Weesp) (5) [2] Janssen P., de Rooy C., Evaluation of the toxicity and metabolism of glycerine, polyglycerines and polyglycerine esters, Solvay-Duphar (Weesp) (5) [3] Federation Proceedings, Federation of American Societies for Experimental Biology (Bethesda, MD) USA V 4, page 142, 1945. (Via RTECS database).
	Dermal	LD50 Rabbit > 10000 mg/kg bw [1] [1] BIOFAX Industrial Bio-Test Laboratories, Inc., Data Sheets. Vol. 9-4/1970
	Inhalation	LC50 Rat > 2.75 mg/l (4h) [1] [1] Valor experimental
citral CAS No: 5392-40-5 EC No: 226-394-6	Oral	LD50 Rat 6800 mg/kg bw [1] [1] BASF AG, Abteilung Toxikologie. unveroeffentlichte Untersuchung (77/170), 23.11.1978
	Dermal	LD50 Rat 2000 mg/kg bw [1] [1] BASF AG, Abteilung Toxikologie. unveroeffentlichte Untersuchung (77/170), 23.11.1978
	Inhalation	

a) acute toxicity;

Not conclusive data for classification.

b) skin corrosion/irritation;

Based on available data, the classification criteria are not met.

c) serious eye damage/irritation;

Product classified:

Eye irritation, Category 2: Causes serious eye irritation.

d) respiratory or skin sensitisation;

Based on available data, the classification criteria are not met.

e) germ cell mutagenicity;

Not conclusive data for classification.

f) carcinogenicity;

Based on available data, the classification criteria are not met.

g) reproductive toxicity;

Not conclusive data for classification.

h) STOT-single exposure;

Not conclusive data for classification.

i) STOT-repeated exposure;

Not conclusive data for classification.

j) aspiration hazard;

Not conclusive data for classification.

11.2 Information on other hazards.

Endocrine disrupting properties

This product does not contain components with endocrine-disrupting properties with effects on human health.

Other information

There is no information available on other adverse health effects.

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SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.

Name	Ecotoxicity			
	Type	Test	Kind	Value
glycerol	Fish	LC0	Leuciscus idus	250 mg/L (48 h) [1]
		LC100	Leuciscus melanotus	10000 mg/L [2]
glycerol	Fish	LC50	Carassius auratus	>5000 mg/L (24 h) [3]
		LC50	Carassius auratus	184000 mg/L (96 h) [4]
glycerol	Fish	LC100	Oncorhynchus	51000 mg/L (96 h) [5]
		LC50	mykiss	>1000 mg/l (96h)
glycerol	Fish	-	Pesacado	54000 mg/l (-) [6]
		-	Salmo gairdneri	
glycerol	Aquatic invertebrates	[1] Wierich, Glycerin (Henkel KGaA Reg. no. 1518), 1968 (rewrite) of September 1996) (110).		
		[2] Juhnke I. & Luedemann D., Ergebnisse der Untersuchung von 200 chemischen Verbindungen auf akute Fischtoxizität mit dem Goldorfenfisch, Z.f. Wasser- und Abwasser-Forschung 11(5) 161-164, 1978 (71)		
glycerol	Aquatic invertebrates	[3] Bridie A., Wolff C. & Winter M., The acute toxicity of some petrochemicals to goldfish, Water Res. 13: 623-626, 1979(90)		
		[4] EPIWIN v3.04, 1994-1999.		
glycerol	Aquatic invertebrates	[5] Johnson, W.W. et al. (1980). Handbook of acute toxicity of chemicals to fish and aquatic invertebrates. Resour. Publ. 137, Fish. Wildl. Serv., U.S.D.I., Washington, D.C.		
		[6] -		
glycerol	Aquatic invertebrates	EC100	Daphnia magna	10000 mg/L (24 h) [1]
		EC50	Daphnia magna	>10000 mg/L (24 h) [2]
glycerol	Aquatic invertebrates	EC0	Daphnia magna	500 mg/L (24 h) [3]
		LC50	Daphnia	153000 mg/L (48 h) [4]
glycerol	Aquatic invertebrates	[1] Bringmann G. & Kuehn R., Ergebnisse der Schadwirkung wassergefährdender Stoffe gegen Daphnia magna in einem weiterentwickelten standardisierten Testverfahren, Z. Wasser/Abwasser Forsch. 15 (1): 1-6, 1982 (73)		
		[2] Bringmann, G. & Kuehn, R., Z. Wasser Abwasser Forsch. 10(1977), 161-166 (72).		
glycerol	Aquatic invertebrates	[3] Henkel KGaA, unpublished data (Reg. no. 1518)		
		[4] EPIWIN v3.04, 1994-1999.		
glycerol	Aquatic plants	EC3	Microcystis aeruginosa	2900 mg/L (8 d) [1]
		EC3	Scenedesmus	10000 mg/L (8 d) [2]
glycerol	Aquatic plants	EC50	quadricauda	77712 mg/L (96 h) [3]
		EC50	Green Algae	77712 mg/L (96 h) [4]
glycerol	Aquatic plants	[1] Bringmann and Kuehn, Vergleichende Befunde der Schadwirkung wassergefährdender Stoffe gegen Bakterien (Pseudomonas putida) und Blaualgen (Microcystis aeruginosa), Gwf-wasser/abwasser 117 (9): 410-413, 1976 (98)		
		[2] Bringmann G. & Kuehn R., Grenzwerte der Schadwirkung wassergefährdender Stoffe gegen Blaualgen (Microcystis aeruginosa) und Gruenalgen (Scenedesmus quadricauda) im Zellvermehrungshemmtest. Vom Wasser 50: 45-60, 1978 (75)		
glycerol	Aquatic plants	[3] EPIWIN v3.04, 1994-1999.		
		[4] EPIWIN v3.04, 1994-1999.		
CAS No: 56-81-5	EC No: 200-289-5			

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12.2 Persistence and degradability.

No information is available regarding the biodegradability of the substances present.

No information is available on the degradability of the substances present.

No information is available about persistence and degradability of the product.

12.3 Bioaccumulative potential.

Information about the bioaccumulation of the substances present.

Name	Bioaccumulation			
	Log Pow	BCF	NOECs	Level
glycerol CAS No: 56-81-5 EC No: 200-289-5	-1,76	-	-	Very low

12.4 Mobility in soil.

No information is available about the mobility in soil.

The product must not be allowed to go into sewers or waterways.

Prevent penetration into the ground.

12.5 Results of PBT and vPvB assessment.

No information is available about the results of PBT and vPvB assessment of the product.

12.6 Endocrine disrupting properties.

This product doesn't contain components with environmental endocrine disrupting properties.

12.7 Other adverse effects.

The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.

No information is available about other adverse effects for the environment.

SECTION 13: DISPOSAL CONSIDERATIONS.

13.1 Waste treatment methods.

Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.

Follow the provisions of Directive 2008/98/EC regarding waste management.

SECTION 14: TRANSPORT INFORMATION.

Transportation is not dangerous. In case of road accident causing the product's spillage, proceed in accordance with point 6.

14.1 UN number or ID number.

Transportation is not dangerous.

14.2 UN proper shipping name.

Description:

ADR/RID: Not classified as hazardous for transport.

IMDG: Not classified as hazardous for transport.

ICAO/IATA: Not classified as hazardous for transport.

14.3 Transport hazard class(es).

Transportation is not dangerous.

14.4 Packing group.

Transportation is not dangerous.

14.5 Environmental hazards.

Transportation is not dangerous.

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Transport by ship, FEm – Emergency sheets (F – Fire, S - Spills): Not applicable.

14.6 Special precautions for user.

Transportation is not dangerous.

14.7 Maritime transport in bulk according to IMO instruments.

Not classified as hazardous for transport.

SECTION 15: REGULATORY INFORMATION.

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

The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles:

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
28. Substances which are classified as carcinogen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 1 or Appendix 2, respectively.	<p>Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30:</p> <p>1. Shall not be placed on the market, or used,</p> <p>as substances,</p> <p>as constituents of other substances, or,</p> <p>in mixtures,</p> <p>for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:</p> <p>either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or,</p> <p>the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008.</p> <p>Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows:</p> <p>'Restricted to professional users'.</p> <p>2. By way of derogation, paragraph 1 shall not apply to:</p> <p>(a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC;</p> <p>(b) cosmetic products as defined by Directive 76/768/EEC;</p> <p>(c) the following fuels and oil products:</p> <p>motor fuels which are covered by Directive 98/70/EC,</p> <p>mineral oil products intended for use as fuel in mobile or fixed combustion plants,</p> <p>fuels sold in closed systems (e.g. liquid gas bottles);</p>

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	(d) artists' paints covered by Regulation (EC) No 1272/2008; (e) the substances listed in Appendix 11, column 1, for the application or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date; (f) devices covered by Regulation (EU) 2017/745.
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15.2 Chemical safety assessment.

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16: OTHER INFORMATION.

Complete text of the H phrases that appear in section 3:

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H350	May cause cancer.

Classification codes:

Carc. 1B : Carcinogen, Category 1B
Eye Irrit. 2 : Eye irritation, Category 2
Skin Irrit. 2 : Skin irritant, Category 2
Skin Sens. 1 : Skin sensitiser, Category 1

Changes regarding to the previous version:

- Changes in the information of the supplier (SECTION 1.3).
- Changes in the composition of the product (SECTION 3.2).
- Modification of the symptoms (SECTION 4.2).
- Modification in the values of the physical and chemical properties (SECTION 9).

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

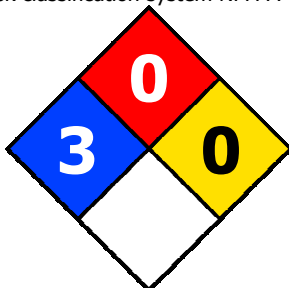
Physical hazards	On basis of test data
Health hazards	Calculation method
Environmental hazards	Calculation method

It is advisable to carry out basic training with regard to health and safety at work in order to handle this product correctly.

Information on the TSCA Inventory (Toxic Substances Control Act) USA:

CAS No	Name	State
8009-03-8	petrolatum, Petrolatum, [A complex combination of hydrocarbons obtained as a semi-solid from dewaxing paraffinic residual oil. It consists predominantly of saturated crystalline and liquid hydrocarbons having carbon numbers predominantly greater than C25.]	Registered
142-91-6	isopropyl palmitate	Registered
56-81-5	glycerol	Registered
5392-40-5	citral	Registered

Risk classification system NFPA 704:



Health hazard: 3 (Extreme Danger)

Flammability: 0 (Will not burn)

Reactivity: 0 (Stable)

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Abbreviations and acronyms used:

- BCF: Bioconcentration factor.
- CEN: European Committee for Standardization.
- DMEL: Derived Minimal Effect Level, exposure level corresponding to a low risk, that risk should be considered a tolerable minimum.
- DNEL: Derived No Effect Level, level of exposure to the substance below which adverse effects are not anticipated.
- EC50: Half maximal effective concentration.
- PPE: Personal protection equipment.
- LC50: Lethal concentration, 50%.
- LD50: Lethal dose, 50%.
- NOEC: No observed effect concentration.
- PNEC: Predicted No Effect Concentration, concentration of the substance below which adverse effects are not expected in the environmental compartment.

Key literature references and sources for data:

- <http://eur-lex.europa.eu/homepage.html>
- <http://echa.europa.eu/>
- Regulation (EU) 2020/878.
- Regulation (EC) No 1907/2006.
- Regulation (EC) No 1272/2008.

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemical substances and mixtures (REACH).

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.