

SAFETY DATA SHEET

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

22-ORANGE ESSENTIAL OIL

LABDASSENCE

Version 1 Date of compilation: 16/01/2017

Version 4 (replaces version 3)

Revision date: 24/02/2023

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Print date: 25/05/2023

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

1.1 Product identifier.

Product Name: ORANGE ESSENTIAL OIL
Product Code: 22
Chemical Name: Orange oil, sweet
Botanical Name: *Citrus sinensis* L.
INCI Name: Citrus sinensis peel oil expressed
CAS No: 8028-48-6
EC No: 232-433-8
Registration No: 01-2119493353-35-XXXX

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

Ingredient for use in cosmetics, perfumery, pharmacy and aromatherapy.

Uses advised against:

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.

Company: **SL DE PLANTAS AROMÁTICAS INDUSTRIALIZADAS**
Address: C/ Antonio Gómez Millán, nº 29, Parque Tecnológico Citec
City: 41120, Gelves
Province: Sevilla
Telephone: +34 955439492
E-mail: labdassence@labdassence.com

1.4 Emergency telephone number: +34 955439492 (Only available during office hours; Monday-Friday; 09:00-18:30)
+34 915620420 (National Institute of Toxicology. Available 24 hours)

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the substance or mixture.

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

Aquatic Chronic 2 : Toxic to aquatic life with long lasting effects.

Asp. Tox. 1 : May be fatal if swallowed and enters airways.

Flam. Liq. 3 : Flammable liquid and vapour.

Skin Irrit. 2 : Causes skin irritation.

Skin Sens. 1 : May cause an allergic skin reaction.

2.2 Label elements.

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

Pictograms:



Signal Word:

Danger

H statements:

H226	Flammable liquid and vapour.
H304	May be fatal if swallowed and enters airways.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H411	Toxic to aquatic life with long lasting effects.

P statements:

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P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P273	Avoid release to the environment.
P280	Wear protective gloves and eye protection.
P301+P310	IF SWALLOWED: Call a POISON CENTER or doctor immediately.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P370+P378	In case of fire: Use appropriate extinguisher for extinction.
P501	Dispose of contents/container in accordance with all local and national regulations

2.3 Other hazards.

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.

UVCB (Substance of Unknown or Variable composition, Complex reaction products or Biological materials).

Chemical Name:	Orange oil, sweet
CAS No:	8028-48-6
EC No:	232-433-8
Registration No:	01-2119493353-35-XXXX

Composition:

Identifiers	Name	Concentrate	(*)Classification - Regulation (EC) No 1272/2008	
			Classification	specific concentration limit
CAS No: 80-56-8 EC No: 201-291-9 Registration No: 01-2119519223-49-XXXX	alpha-Pinene	0,4% - 0,8%	Asp. Tox. 1, H304 - Flam. Liq. 3, H226 - Skin Irrit. 2, H315 - Skin Sens. 1, H317	-
CAS No: 78-70-6 EC No: 201-134-4 Registration No: 01-2119474016-42-XXXX	Linalool	0,15% - 0,7%	Eye Irrit. 2, H319 - Skin Irrit. 2, H315 - Skin Sens. 1, H317	-
Index No: 601-029-00-7 CAS No: 5989-27-5 EC No: 227-813-5 Registration No: 01-2119529223-47-XXXX	(R)-p-mentha-1,8-diene, d-limonene	93% - 96%	Aquatic Acute 1, H400 - Aquatic Chronic 1, H410 - Asp. Tox. 1, H304 - Flam. Liq. 3, H226 - Skin Irrit. 2, H315 - Skin Sens. 1, H317	-
CAS No: 123-35-3 EC No: 204-622-5 Registration No: 01-2119514321-56-XXXX	7-methyl-3-methylenecycloocta-1,6-diene	1,3% - 3,5%	Asp. Tox. 1, H304 - Flam. Liq. 3, H226 - Skin Irrit. 2, H315	-
CAS No: 127-91-3 EC No: 204-872-5 Registration No: 01-2119519230-54-XXXX	beta-Pinene	0,02% - 15%	Asp. Tox. 1, H304 - Flam. Liq. 3, H226 - Skin Irrit. 2, H315 - Skin Sens. 1, H317	-

3.2 Mixtures.

Not Applicable.

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SECTION 4: FIRST AID MEASURES.

IRRITANT MIXTURE. Its repeated or prolonged contact with the skin or mucous membranes can cause irritant symptoms such as reddening of the skin, blisters, or dermatitis. Some of the symptoms may not be immediate. They can cause allergic reactions on the skin.

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. Do not administer anything orally. If unconscious, place them in a suitable position and seek medical assistance.

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.

Skin contact.

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.

Irritant Product, repeated or prolonged contact with skin or mucous membranes can cause redness, blisters or dermatitis, inhalation of spray mist or particles in suspension may cause irritation of the respiratory tract, some symptoms may not be immediate.

Harmful Product, prolonged exposure due to inhalation may cause anaesthetic effects and the need for immediate medical assistance.

It may cause an allergic reaction, dermatitis, redness or inflammation of the skin.

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. Do not induce vomiting. If the person vomits, clear the respiratory tract.

SECTION 5: FIREFIGHTING MEASURES.

Flammable product, the necessary prevention measures should be taken in order to avoid risks, In case of fire, the following measures are recommended:

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.

Fire can cause thick, black smoke. As a result of thermal decomposition, dangerous products can form: carbon monoxide, carbon dioxide. Exposure to combustion or decomposition products can be harmful to your health.

During a fire and depending on its magnitude the following may occur:

- Flammable vapors or gases.

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. Product residues and extinguishing media may contaminate the aquatic environment. Follow the instructions given in the emergency or fire evacuation plan or plans if available.

Fire protection equipment.

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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. During extinction and depending on the magnitude and proximity to the fire, additional protective equipment such as chemical protection gloves, heat-reflecting suits or gas-tight suits may be required.

SECTION 6: ACCIDENTAL RELEASE MEASURES.

6.1 Personal precautions, protective equipment and emergency procedures.

Eliminate possible ignition points and ventilate the area. No smoking. Avoid breathing fumes. For exposure control and individual protection measures, see section 8.

6.2 Environmental precautions.

Product dangerous for the environment, in case of large spills or if the product contaminates lakes, rivers, or sewers, inform the responsible authorities according to local legislation. Prevent the contamination of drains, surface or subterranean waters, and the ground.

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

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.

The fumes are heavier than air and can spread across the ground. They can form explosive mixtures with air. Prevent the creation of flammable or explosive fume concentrations in the air; prevent fume concentrations above work exposure limits. The product must only be used in areas where all unprotected flames and other ignition points have been eliminated. Electrical equipment has to be protected according to applicable standards.

The product can be electrostatically charged: always use earth grounds when transferring the product. Operators must use anti-static footwear and clothing, and floors must be conductors.

Keep the container tightly closed and isolated from heat sources, sparks, and fire. Do not use tools that can cause sparks. For personal protection, see section 8.

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

Follow legislation on occupational health and safety.

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 5 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:

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Name	DNEL/DMEL	Type	Value
Orange oil, sweet CAS No: 8028-48-6 EC No: 232-433-8	DNEL (Workers)	Inhalation, Long-term, Systemic effects	31,1 (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.

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:		Ingredient used in cosmetic or pharmaceutical preparations			
Breathing protection:					
PPE:	Filter mask for protection against gases and particles.				
Characteristics:	«CE» marking, category III. The mask must have a wide field of vision and an anatomically designed form in order to be sealed and watertight.				
CEN standards:	EN 136, EN 140, EN 405				
Maintenance:	Should not be stored in places exposed to high temperatures and damp environments before use. Special attention should be paid to the state of the inhalation and exhalation valves in the face adaptor.				
Observations:	Read carefully the manufacturer's instructions regarding the equipment's use and maintenance. Attach the necessary filters to the equipment according to the specific nature of the risk (Particles and aerosols: P1-P2-P3, Gases and vapours: A-B-E-K-AX), changing them as advised by the manufacturer.				
Filter Type needed:	A2				
Hand protection:					
PPE:	Protective gloves against chemicals.				
Characteristics:	«CE» marking, category III.				
CEN standards:	EN 374-1, En 374-2, EN 374-3, EN 420				
Maintenance:	Keep in a dry place, away from any sources of heat, and avoid exposure to sunlight as much as possible. Do not make any changes to the gloves that may alter their resistance, or apply paints, solvents or adhesives.				
Observations:	Gloves should be of the appropriate size and fit the user's hand well, not being too loose or too tight. Always use with clean, dry hands.				
Material:	PVC (polyvinyl chloride)	Breakthrough time (min.):	> 480	Material thickness (mm):	0,35
Eye protection:					
PPE:	Protective goggles with built-in frame.				
Characteristics:	«CE» marking, category II. Eye protector with built-in frame for protection against dust, smoke, fog and vapour.				
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:	Anti-static protective clothing.				
Characteristics:	«CE» marking, category II. Protective clothing should not be too tight or loose in order not to obstruct the user's movements.				
CEN standards:	EN 340, EN 1149-1, EN 1149-2, EN 1149-3, EN 1149-5				
Maintenance:	In order to guarantee uniform protection, follow the washing and maintenance instructions provided by the manufacturer.				
Observations:	The protective clothing should offer a level of comfort in line with the level of protection provided in terms of the hazard against which it protects, bearing in mind environmental conditions, the user's level of activity and the expected time of use.				
PPE:	Anti-static safety footwear.				
Characteristics:	«CE» marking, category II.				
CEN standards:	EN ISO 13287, EN ISO 20344, EN ISO 20346				
Maintenance:	The footwear should be checked regularly				

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Observations:	The level of comfort during use and acceptability are factors that are assessed very differently depending on the user. Therefore, it is advisable to try on different footwear models and, if possible, different widths.
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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.

Appearance: Clear mobile liquid
Colour: Yellow to reddish yellow
Odour: Characteristic, orange peel smell
Odour threshold: N.A./N.A.
pH: N.A./N.A.
Melting point: N.A./N.A.
Boiling Point: 175 °C
Flash point: 43 °C
Evaporation rate: N.A./N.A.
Inflammability (solid, gas): N.A./N.A.
Lower Explosive Limit: N.A./N.A.
Upper Explosive Limit: N.A./N.A.
Vapour pressure: N.A./N.A.
Vapour density: N.A./N.A.
Relative density: 0,842-0,850
Solubility: N.A./N.A.
Liposolubility: N.A./N.A.
Hydrosolubility: N.A./N.A.
Partition coefficient (n-octanol/water): N.A./N.A.
Auto-ignition temperature: N.A./N.A.
Decomposition temperature: N.A./N.A.
Viscosity: N.A./N.A.
Explosive properties: N.A./N.A.
Oxidizing properties: N.A./N.A.
N.A./N.A. = Not Available/Not Applicable due to the nature of the product

9.2 Other information.

Dropping point: N.A./N.A.
Blink: N.A./N.A.
Kinematic viscosity: N.A./N.A.
N.A./N.A. = Not Available/Not Applicable due to the nature of the product

SECTION 10: STABILITY AND REACTIVITY.

10.1 Reactivity.

If the storage conditions are satisfied, does not produce dangerous reactions.

10.2 Chemical stability.

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

10.3 Possibility of hazardous reactions.

Flammable liquid and vapour.

10.4 Conditions to avoid.

Avoid the following conditions:

- High temperature.
- Static discharge.
- Contact with incompatible materials.
- Avoid temperatures near or above the flash point. Do not heat closed containers. Avoid direct sunlight and heat, as these may cause a risk of fire.

10.5 Incompatible materials.

Avoid the following materials:

- Explosives materials.
- Toxic materials.
- Oxidizing materials.

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10.6 Hazardous decomposition products.

In case of fire, dangerous decomposition products can be generated, such as carbon monoxide and dioxide and nitrogen fumes and oxides.

SECTION 11: TOXICOLOGICAL INFORMATION.

IRRITANT MIXTURE. Its repeated or prolonged contact with the skin or mucous membranes can cause irritant symptoms such as reddening of the skin, blisters, or dermatitis. Some of the symptoms may not be immediate. They can cause allergic reactions on the skin.

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

There are no tested data available on the product.

Repeated or prolonged contact with the product can cause the elimination of oil from the skin, giving rise to non-allergic contact dermatitis and absorption of the product through the skin.

a) acute toxicity;

Not conclusive data for classification.

b) skin corrosion/irritation;

Product classified:

Skin irritant, Category 2: Causes skin irritation.

c) serious eye damage/irritation;

Not conclusive data for classification.

d) respiratory or skin sensitisation;

Product classified:

Skin sensitizer, Category 1: May cause an allergic skin reaction.

e) germ cell mutagenicity;

Not conclusive data for classification.

f) carcinogenicity;

Not conclusive data for classification.

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;

Product classified:

Aspiration toxicity, Category 1: May be fatal if swallowed and enters airways.

11.2 Information on other hazards.

Not available.

SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.

No information is available regarding the ecotoxicity.

12.2 Persistence and degradability.

No information is available regarding the biodegradability.

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

12.3 Bioaccumulative potential.

No information is available regarding the bioaccumulation.

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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.

No information is available about endocrine disrupting properties.

12.7 Other adverse effects.

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.

Transport following ADR rules for road transport, RID rules for railway, ADN for inner waterways, IMDG for sea, and ICAO/IATA for air transport.

Land: Transport by road: ADR, Transport by rail: RID.

Transport documentation: Consignment note and written instructions

Sea: Transport by ship: IMDG.

Transport documentation: Bill of lading

Air: Transport by plane: ICAO/IATA.

Transport document: Airway bill.

14.1 UN number.

UN No: UN1197

14.2 UN proper shipping name.

Description:

ADR: UN 1197, EXTRACTS, LIQUID, 3, PG III, (D/E)

IMDG: UN 1197, EXTRACTS, LIQUID (ORANGE OIL, SWEET), 3, PG III (43°C), MARINE POLLUTANT

ICAO/IATA: UN 1197, EXTRACTS, LIQUID, 3, PG III

14.3 Transport hazard class(es).

Class(es): 3

14.4 Packing group.

Packing group: III

14.5 Environmental hazards.

Marine pollutant: Yes



Dangerous for the environment

14.6 Special precautions for user.

Labels: 3

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Hazard number: 30

ADR LQ: 5 L

IMDG LQ: 5 L

ICAO LQ: 10 L

Provisions concerning carriage in bulk ADR: Not authorized carriage in bulk in accordance with ADR.

Transport by ship, FEm – Emergency sheets (F – Fire, S - Spills): F-E,S-D

Proceed in accordance with point 6.

14.7 Maritime transport in bulk according to IMO instruments.

The product is not transported in bulk.

SECTION 15: REGULATORY INFORMATION.

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

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.

Product classification according to Annex I of Directive 2012/18/EU (SEVESO III): N/A

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.

The product is affected by Annex II, Sec III to Directive 2009/48/EC - Allergic Fragrances Banned/Restricted in Toys.

15.2 Chemical safety assessment.

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

SECTION 16: OTHER INFORMATION.

Classification codes:

Aquatic Chronic 2 : Chronic effect to the aquatic environment, Category 2

Asp. Tox. 1 : Aspiration toxicity, Category 1

Flam. Liq. 3 : Flammable liquid, Category 3

Skin Irrit. 2 : Skin irritant, Category 2

Skin Sens. 1 : Skin sensitiser, Category 1

Changes regarding to the previous version:

- Change of the name of the product (SECTION 1.1).
- Change of the uses of the product (SECTION 1.2).
- Changes in the information of the supplier (SECTION 1.3).
- Change in the emergency number (SECTION 1.4).
- Removal of precautionary statements/hazard statements/pictograms/signal word (SECTION 2.2).
- Addition of precautionary statements/hazard statements/pictograms/signal word (SECTION 2.2).
- Modification in the values of the physical and chemical properties (SECTION 9).
- Update in accordance with Regulation (EU) 2020/878.

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

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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.

Abbreviations and acronyms used:

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
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.
PPE: Personal protection equipment.
IATA: International Air Transport Association.
ICAO: International Civil Aviation Organization.
IMDG: International Maritime Code for Dangerous Goods.
RID: Regulations Concerning the International Transport of Dangerous Goods by Rail.

Key literature references and sources for data:

<http://eur-lex.europa.eu/homepage.html>

<http://echa.europa.eu/>

Regulation (EU) No 2020/878.

Regulation (EU) No 2015/830.

Regulation (EC) No 1907/2006.

Regulation (EU) 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 Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

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.