

SAFETY DATA SHEET

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

93890-KETOCONAZOLE



Version 1 Date of compilation: 27/04/2016

Version 6 (replaces version 5)

Revision date: 28/02/2023

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

1.1 Product identifier.

Product Name: KETOCONAZOLE
Product Code: 93890
Chemical Name: ketoconazole; 1-[4-[4-[[[(2SR, 4RS)-2-(2,4-dichlorophenyl)-2-(imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]piperazin-1-yl]ethanone
Index No: 613-283-00-6
CAS No: 65277-42-1
EC No: 265-667-4

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

Active pharmaceutical ingredient

Uses advised against:

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.

Company: **GUINAMA**
Address: C/ Praga, s/n. P.I. Gutenberg
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:

Acute Tox. 3 : Toxic if swallowed.

Aquatic Acute 1 : Very toxic to aquatic life.

Aquatic Chronic 1 : Very toxic to aquatic life with long lasting effects.

Repr. 1B : May damage fertility or the unborn child.

STOT RE 2 : May cause damage to organs through prolonged or repeated exposure.

2.2 Label elements.

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

Pictograms:



Signal Word:

Danger

Hazard statements:

H301 Toxic if swallowed.

H360F May damage fertility.

H373 May cause damage to organs through prolonged or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

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Precautionary statements:

| | |
|-----------|--------------------------------------------------------------------------------------------------|
| P201 | Obtain special instructions before use. |
| P202 | Do not handle until all safety precautions have been read and understood. |
| P260 | Do not breathe dust/fume/gas/mist/vapours/spray. |
| P264 | Wash ... thoroughly after handling. |
| P270 | Do not eat, drink or smoke when using this product. |
| P273 | Avoid release to the environment. |
| P280 | Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/... |
| P301+P310 | IF SWALLOWED: Immediately call a POISON CENTER/doctor/... |
| P308+P313 | IF exposed or concerned: Get medical advice/attention. |
| P314 | Get medical advice/attention if you feel unwell. |
| P321 | Specific treatment (see ... on this label). |
| P330 | Rinse mouth. |
| P391 | Collect spillage. |
| P405 | Store locked up. |
| P501 | Dispose of contents/container to ... |

2.3 Other hazards.

The substance is not PBT

The substance is not vPvB

Substance does not have endocrine disrupting properties.

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.

| Identifiers | Name | Concentrate | (*)Classification - Regulation (EC) No 1272/2008 | |
|------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|-------------|----------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| | | | Classification | Specifics concentration limits and Acute toxicity estimate |
| Index No: 613-283-00-6 CAS No: 65277-42-1 EC No: 265-667-4 | ketoconazole, 1-[4-[4-[[[(2SR, 4RS)-2-(2,4-dichlorophenyl)-2-(imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]piperazin-1-yl]ethanone | 100 | Acute Tox. 3 *, H301 - Aquatic Acute 1, H400 - Aquatic Chronic 1, H410 - Repr. 1B, H360F*** - STOT RE 2 *, H373** | - |

*, **, *** See Regulation (EC) No. 1272/2008, Annex VI, section 1.2.

3.2 Mixtures.

Not Applicable.

SECTION 4: FIRST AID MEASURES.

4.1 Description of first aid measures.

Immediate medical attention is required. Delayed effects may occur after the exposure to the product.

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.

Skin contact.

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

Ingestion.

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If accidentally ingested, seek immediate medical attention. Keep calm. NEVER induce vomiting. The use of personal protective equipment is recommended for people providing first aid (see section 8).

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

Toxic Product, accidental contact may result in serious respiratory difficulties, alteration of the central nervous system and in extreme cases, unconsciousness. Immediate medical assistance is required.

Long-term chronic exposure may result in injury to certain organs or tissues.

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

Request immediate medical attention. Never administer anything orally to persons who are unconscious. Do not induce vomiting. If the person vomits, clear the respiratory tract. Keep the person comfortable. Turn him/her over to the left side and stay there while waiting for medical care.

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.

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

- Toxic 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.

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. 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.

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 (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.

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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.

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.

Classification and threshold amount of storage in accordance with Annex I to Directive 2012/18/EU (SEVESO III):

| Code | Description | Qualifying quantity (tonnes) for the application of | |
|------|-----------------------------------------------------------------------------------------------|-----------------------------------------------------|-------------------------|
| | | Lower-tier requirements | Upper-tier requirements |
| E1 | ENVIRONMENTAL HAZARDS - Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1 | 100 | 200 |

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.

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: | | Active pharmaceutical ingredient | |
| Breathing protection: | | | |
| PPE: | Particle filter mask | | |
| Characteristics: | «CE» marking, category III. Made of filtering material, it covers nose, mouth and chin. | | |
| 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 |

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| 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: white or almost white

Odour: characteristic

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

Melting point: 148-152 °C

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: nonflammable

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

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

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: insoluble

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

Partition coefficient n-octanol/water (log value): Log Pow octanol 4,35

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

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.

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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.

No further information available

10.6 Hazardous decomposition products.

Under normal conditions of storage and use, hazardous decomposition products should not be generated.

SECTION 11: TOXICOLOGICAL INFORMATION.

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

There are no tested data available on the product.

a) acute toxicity;

Product classified:

Acute toxicity (Oral), Category 3: Toxic if swallowed.

b) skin corrosion/irritation;

Not conclusive data for classification.

c) serious eye damage/irritation;

Not conclusive data for classification.

d) respiratory or skin sensitisation;

Not conclusive data for classification.

e) germ cell mutagenicity;

Not conclusive data for classification.

f) carcinogenicity;

Not conclusive data for classification.

g) reproductive toxicity;

Product classified:

Reproductive toxicant, Category 1B: May damage fertility or the unborn child.

h) STOT-single exposure;

Not conclusive data for classification.

i) STOT-repeated exposure;

Product classified:

Specific target organ toxicity following a repeated exposure, Category 2: May cause damage to organs through prolonged or repeated exposure.

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.

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.

Information about the bioaccumulation.

| Name | Bioaccumulation | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|-----|-------|----------|
| | Log Pow | BCF | NOECs | Level |
| ketoconazole, 1-[4-[4-[(2SR, 4RS)-2-(2,4-dichlorophenyl)-2-(imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]piperazin-1-yl]ethanone CAS No: 65277-42-1 EC No: 265-667-4 | Log Pow octanol 435 | - | - | 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.

No information is available.

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.

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14.1 UN number or ID number.

UN No: UN2811

14.2 UN proper shipping name.

Description:

ADR/RID: UN 2811, TOXIC SOLID, ORGANIC, N.O.S. (CONTAINS KETOCONAZOLE 1-[4-[4-[(2SR, 4RS)-2-(2,4-DICHLOROPHENYL)-2-(IMIDAZOL-1-YLMETHYL)-1,3-DIOXOLAN-4-YL]METHOXY]PHENYL]PIPERAZIN-1-YL]ETHANONE), 6.1, PG III, (E)

IMDG: UN 2811, TOXIC SOLID, ORGANIC, N.O.S. (CONTAINS KETOCONAZOLE 1-[4-[4-[(2SR, 4RS)-2-(2,4-DICHLOROPHENYL)-2-(IMIDAZOL-1-YLMETHYL)-1,3-DIOXOLAN-4-YL]METHOXY]PHENYL]PIPERAZIN-1-YL]ETHANONE), 6.1, PG III, MARINE POLLUTANT

ICAO/IATA: UN 2811, TOXIC SOLID, ORGANIC, N.O.S. (CONTAINS KETOCONAZOLE 1-[4-[4-[(2SR, 4RS)-2-(2,4-DICHLOROPHENYL)-2-(IMIDAZOL-1-YLMETHYL)-1,3-DIOXOLAN-4-YL]METHOXY]PHENYL]PIPERAZIN-1-YL]ETHANONE), 6.1, PG III

14.3 Transport hazard class(es).

Class(es): 6.1

14.4 Packing group.

Packing group: III

14.5 Environmental hazards.

Marine pollutant: Yes



Dangerous for the environment

Transport by ship, FEM – Emergency sheets (F – Fire, S – Spills): F-A, S-A

14.6 Special precautions for user.

Labels: 6.1



Hazard number: 60

ADR LQ: 5 kg

IMDG LQ: 5 kg

ICAO LQ: 10 kg

Provisions concerning carriage in bulk ADR:

VC1 Carriage in bulk in sheeted vehicles, sheeted containers or sheeted bulk containers is permitted.

VC2 Carriage in bulk in closed vehicles, closed containers or closed bulk containers is permitted.

AP7 Carriage in bulk shall only be as a full load.

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): E1

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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.

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:

Acute Tox. 3 : Acute toxicity (Oral), Category 3

Aquatic Acute 1 : Acute toxicity to the aquatic environment, Category 1

Aquatic Chronic 1 : Chronic effect to the aquatic environment, Category 1

Repr. 1B : Reproductive toxicant, Category 1B

STOT RE 2 : Specific target organ toxicity following a repeated exposure, Category 2

Changes regarding to the previous version:

- Changes in the composition of the product (SECTION 3.2).

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

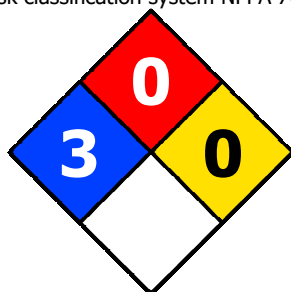
Environmental hazards Calculation method

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 |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------|-------|
| 65277-42-1 | ketoconazole, 1-[4-[4-[[[(2SR, 4RS)-2-(2,4-dichlorophenyl)-2-(imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]piperazin-1-yl]ethanone | |

Risk classification system NFPA 704:



Health hazard: 3 (Extreme Danger)

Flammability: 0 (Will not burn)

Reactivity: 0 (Stable)

Abbreviations and acronyms used:

ADR/RID: European Agreement concerning the International Carriage of Dangerous Goods by Road.

BCF: Bioconcentration factor.

CEN: European Committee for Standardization.

EC50: Half maximal effective concentration.

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PPE: Personal protection equipment.
IATA: International Air Transport Association.
ICAO: International Civil Aviation Organization.
IMDG: International Maritime Code for Dangerous Goods.
LC50: Lethal concentration, 50%.
LD50: Lethal dose, 50%.
NOEC: No observed effect concentration.
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) 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.