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

1.1 Product identifier.

Product Name:	ZINC OXIDE
Product Code:	93363
Chemical Name:	zinc oxide
Index No:	030-013-00-7
CAS No:	1314-13-2
EC No:	215-222-5
Registration No:	01-2119463881-32-XXXX

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

cosmetic use
Food 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:
Aquatic Acute 1 : Very toxic to aquatic life.
Aquatic Chronic 1 : Very toxic to aquatic life with long lasting effects.

2.2 Label elements.
Labelling in accordance with Regulation (EC) No 1272/2008:
Pictograms:

Signal Word:
Warning
Hazard statements:
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:
P273 Avoid release to the environment.
P391 Collect spillage.
P501 Dispose of contents/container to …

-Continued on next page.-

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: 030-013-00-7 CAS No: 1314-13-2 EC No: 215-222-5	zinc oxide	>=95%->=99,9%	Aquatic Acute 1, H400 - Aquatic Chronic 1, H410	-

3.2 Mixtures.
Not applicable.

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.

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.
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.

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:

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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. 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.

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.

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 15 and 25 º 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.

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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
zinc oxide CAS No: 1314-13-2 EC No: 215-222-5	DNEL (Workers)	Inhalation, Chronic, Systemic effects	5 (mg/m³)
	DNEL (Workers)	Inhalation, Chronic, Systemic effects	1 (mg Zn/m3)
	DNEL (Consumers)	Inhalation, Short term, Systemic effects	1,3 (mg Zn/m3)
	DNEL (Consumers)	Inhalation, Chronic, Systemic effects	2,5 (mg Zn/m3)

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
zinc oxide CAS No: 1314-13-2 EC No: 215-222-5	STP	100 (µg/L)
	Sedimento de agua dulce	117,8 (mg/Kg sedimento base seca. Se aplica por defecto un factor genérico del factor de biodisponibilidad de 0.5: PNEC= 325.6 mg/kg sedimento base seca)
	Sedimento de agua marina	56,6 (mg/kg sedimento base seca. Se aplica por defecto un factor genérico del factor de biodisponibilidad de 0.5: PNEC=113 mg/kg sediment d.w.)
	Soil	35,6 (mg/kg suelo base seca. Se aplica por defecto un factor genérico del factor de biodisponibilidad/envejecimiento de 3)
	Oral	(No hay potencial de bioacumulación)

-Continued on next page.-

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:	**cosmetic use** **Food use**
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:	Work gloves.
Characteristics:	«CE» marking, category I.
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:	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
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:	Work footwear.
Characteristics:	«CE» marking, category II.
CEN standards:	EN ISO 13287, EN 20347
Maintenance:	This product adapts to the first user's foot shape. That is why, as well as for hygienic reasons, it should not be used by other people.
Observations:	Work footwear for professional use includes protection elements aimed at protecting users against any injury resulting from an accident

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.
Physical state: Solid

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Colour: White
Odour: Odourless
Odour threshold: Not applicable/Not available due to the nature/properties of the product
Melting point: Zinc oxide is very stable. It does not melt and no exothermic or endothermic peaks are observed. No decomposition reactions observed. ºC
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: Zinc oxide dust is not considered flammable.
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:)
Kinematic viscosity: Not applicable/Not available due to the nature/properties of the product
Solubility: The water solubility of Zn in ZnO is 2.9mg/l
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: 5.68
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.

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

Toxicological information.

Name	Acute toxicity			
	Type	Test	Kind	Value
zinc oxide	Oral	DL50 DL50 [1] Löser 1972 [2] Löser 1977	Rat Rat	15000 mg/kg [1] >5000 mg/kg [2]
	Dermal			

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CAS No: 1314-13-2 EC No: 215-222-5	Inhalation	CL50 Rat >5.7 mg/l (4h) [1] [1] Klimisch et al. (1982)	

a) Acute toxicity

With LD50 values greater than 2,000 mg/kg body weight, slightly soluble compounds such as ZnO (LD50 between 5,000 and 15,000 mg/kg) show a low level of acute oral toxicity that does not lead to their classification.
ZnO shows low acute inhalation toxicity (LC50(4h) > 5.7 mg/l) which does not lead to its classification.

b) Skin corrosion or irritation
Non-irritating (Löser, 1977; Lansdown, 1991)

c) Serious eye damage or eye irritation
Non-irritating (Van Huygevoort, 1999e; Thijssen, 1978; Löser, 1977)

d) Respiratory or skin sensitization
No sensitizing effects known (Van Huygevoort 1999 g,h)
Non-irritating to the respiratory tract (Klimish et al., 1982)

e) Germ cell mutagenicity
No biologically relevant genotoxic activity (cross-read with Zn compounds; no mutagenicity classification required) (Zinc Oxide Chemical Safety Report 2010).

f) Carcinogenicity
There is no experimental or epidemiological evidence to justify classification of zinc compounds for carcinogenic activity (cross-read with Zn compounds; no carcinogenicity classification required) (2010 Zinc Oxide Chemical Safety Report).

g) Reproductive toxicity
There is no experimental or epidemiological evidence to justify classification of zinc compounds for reproductive or developmental toxicity (cross-read with Zn compounds; no reproductive toxicity classification required) (CSSR) zinc oxide 2010).

h) Specific target organ toxicity (single exposure)
There is insufficient experimental or epidemiological evidence for specific target organ toxicity (single exposure; STOT-SE) (no classification) (Heydon and Kagan, 1990; Gordon et al., 1992; Mueller and Seger, 1985 [Cited in Report on the Chemical Safety (ISQ) of zinc oxide 2010]).

i) Specific target organ toxicity (repeated exposure)
There is insufficient experimental or epidemiological evidence for specific target organ toxicity (repeated exposure; STOT-RE) (no classification) (Lam et al., 1985, 1988; Conner et al., 1988 [Cited in Safety Report Chemistry (ISQ) of zinc oxide 2010]).

j) Aspiration hazard
Not available

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.

SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.
No information is available regarding the ecotoxicity.
Chronic Aquatic Toxicity: Marine Water
The Zinc Chronic Aquatic Toxicity Database contains high-quality NOEC EC10 values for 39 species (9 taxonomic groups) obtained under varied conditions. These data, specified in the Chemical Safety Report (CSR), were compiled into a species sensitivity distribution, from which the PNEC (expressed as Zn++ ion concentration) was derived. This PNEC is an added value, that is, it will be added to the previous zinc content in the water (see section 8.1.3).
Sediment toxicity
The chronic toxicity of zinc to organisms in freshwater sediments was evaluated from a database containing high-quality NOEC EC10 values on 7 benthic species, obtained under varied conditions. These data, specified in the Chemical Safety Report (CSR),

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were compiled into a species sensitivity distribution, from which the PNEC (expressed as total Zn contained in the sediment) was derived. This PNEC is an added value, that is, it will be added to the previous zinc content in the water.
For marine sediments, a PNEC was derived using the partition equilibrium approximation (see section 8.1.3).
soil toxicity
The chronic toxicity of zinc to soil organisms in freshwater was evaluated from a database containing high quality NOEC EC10 values on 18 plant species, 8 invertebrate species and 17 microbial processes, obtained under varied conditions. . These data, specified in the Chemical Safety Report (ISQ), were compiled into a species sensitivity distribution, from which the PNEC (expressed as total Zn contained in the soil) was derived. This PNEC is an added value, that is, it will be added to the previous zinc content in the water, see section 8.1.3.
Toxicity for microorganisms in WWTP
The PNEC for WWTP was obtained by applying an assessment factor to the lowest relevant toxicity value: 5.2 mg Zn_l (Dutka et al., 1983).

12.2 Persistence and degradability.
Zinc is an element and as such the persistence criterion is not relevant for the metal and its inorganic compounds in the same way as it is for organic substances. An analysis on the removal of zinc from a water column as a surrogate for persistence has been presented. The rapid removal of zinc from the water column is documented in the Chemical Safety Report (CSR). Thus, neither zinc nor its compounds meet this criterion.

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

12.3 Bioaccumulative potential.
Zinc is an essential natural element, necessary for the optimal growth and development of all living organisms, including man. All living organisms have homeostasis mechanisms that actively regulate zinc uptake and absorption/excretion from the body. Due to this regulation, zinc and its compounds do not bioaccumulate or biomagnify.

12.4 Mobility in soil.
For zinc (as for other metals), transport and distribution in different environmental compartments, for example water (dissolved fraction, fraction bound to suspended matter), soil (fraction bound or complexed with zinc particles). soil, fraction in the water of the soil pores,...) is described and quantified by means of the metal distribution coefficient between these different fractions. In the Chemical Safety Report (ISQ), a solid-water partition coefficient of 158.5 l/kg (2.2 logarithmic value) was applied for zinc in soils (Chemical Safety Report (ISQ) of oxide of zinc 2010).

12.5 Results of PBT and vPvB assessment.
According to the previous points, zinc and its compounds are not PBT or vPvB

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.

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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 or ID number.
UN No: UN3077

14.2 UN proper shipping name.
Description:
ADR/RID: UN 3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (CONTAINS ZINC OXIDE), 9, PG III, (-)
IMDG: UN 3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (CONTAINS ZINC OXIDE), 9, PG III, MARINE POLLUTANT
ICAO/IATA: UN 3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (CONTAINS ZINC OXIDE), 9, PG III

14.3 Transport hazard class(es).
Class(es): 9

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-F

14.6 Special precautions for user.
Labels: 9

Hazard number: 90
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.
Proceed in accordance with point 6.
ADR LQ: 5 kg
IMDG LQ: 5 kg
ICAO LQ: 30 kg B

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.

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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:

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

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]:

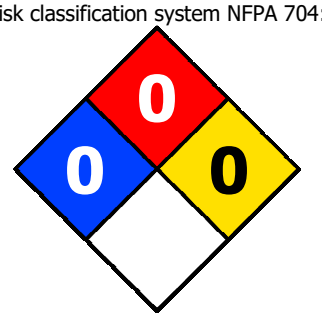
Physical hazards	On basis of test data
Health hazards	Calculation method
Environmental hazards	Calculation method

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
1314-13-2	zinc oxide	Registered

Risk classification system NFPA 704:



Health hazard: 0 (Normal Material)

Flammability: 0 (Will not burn)

Reactivity: 0 (Stable)

Abbreviations and acronyms used:

ADR: 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.
PNEC: Predicted No Effect Concentration, concentration of the substance below which adverse effects are not expected in the environmental compartment.
RID: Regulations Concerning the International Transport of Dangerous Goods by Rail.

Key literature references and sources for data:

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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.

-End of safety data sheet.-