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

ABSONET MULTIZORB



Version 1 Date of compilation: 12/08/2019

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

1.1 Product identifier.

Product Name: ABSONET MULTIZORB

Chemical Name: Sepiolite CAS No: 63800-37-3 EC No: 264-465-3

Registration No: Exempt according to Annex V.7 of Regulation (EC) 1907/2006

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

This material should only be used for industrial purposes

Uses advised against:

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.

TOLSA Company:

Address: C/Nuñez de Balboa, 51 City: E-28001 MADRID (Spain)

Province: Madrid Telephone: +34913220100

E-mail: reach@tolsa.com Web: www.tolsa.com

1.4 Emergency telephone number: TOLSA +34 91 360 69 00 (Only available during office hours; Monday-Friday; 08:00-

18:00)

National Poisons Information Service (NPIS): 111 National Poisons Information Centre +35318092566

European emergency number: 112

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the substance or mixture.

The product is not classified as hazardous within the meaning of Regulation (EU) No 1272/2008.

2.2 Label elements.

2.3 Other hazards.

The substance is not PBT The substance is not vPvB

Substance does not have endocrine disrupting properties.

The product may have the following additional risks:

Dustiness during handling and use.

The substance is not included in the list stablished in accordance with Article 59(1) for having endocrine disrupting properties, and is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

3.1 Substances.

Mono-constituent.

Chemical Name: Sepiolite CAS No: 63800-37-3 EC No: 264-465-3 Registration No: Exempt

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Impurities or additives that affect the classification:

•	Name	Concentrate	(*)Classification - Regulation (EC) No 1272/2008	
Identifiers			Classification	Specifics concentration limits and Acute toxicity estimate
CAS No: 14808-60-7 EC No: 238-878-4	[1] Quartz (SiO2)	0 - 5 %	-	-

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

3.2 Mixtures.

Not Applicable.

SECTION 4: FIRST AID MEASURES.

4.1 Description of first aid measures.

Due to the composition and type of the substances present in the product, no particular warnings are necessary.

Inhalation.

No special measure; Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

Eve contact.

No special measure; 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.

No special measure; Remove contaminated clothing.

Ingestion.

No special measure; Keep calm. NEVER induce vomiting.

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

The acute symptoms would be pain in the eyes because of dust entry.

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.

5.1 Extinguishing media.

Suitable extinguishing media:

The product is not combustible. Use a dry water, powder, foam or CO2 fire extinguisher to extinguish the surrounding fire. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media:

No restriction on the extinguishing media to be used in cases of fire in its vicinity.

5.2 Special hazards arising from the substance or mixture.

Special risks.

The material is not flammable and it does not support fire. No hazardous thermal decomposition products.

5.3 Advice for firefighters.

Avoid generation of dust. Use breathing apparatus.

Product on floor when wetted will become slippery and may present a hazard; wear anti-slip boots.

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

^[1] Substance with a Community workplace exposure limit (see section 8.1).

^[1] The product contains fine fraction of quartz (CAS: 14808-60-7) below 1% (w/w).

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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.

6.1.1. For non-emergency personnel

Ensure adequate ventilation.

Keep dust levels to a minimum.

Keep unprotected persons away.

Avoid contact with skin, eyes, and clothing - wear suitable protective equipment (see section 8).

Avoid inhalation of dust – ensure that sufficient ventilation or suitable respiratory protective equipment is used, wear suitable protective equipment (see section 8).

Take care of wet product on floor, which presents a slip hazard.

6.1.2. For emergency responders

Keep dust levels to a minimum.

Ensure adequate ventilation.

Keep unprotected persons away.

Avoid contact with skin, eyes, and clothing - wear suitable protective equipment (see section 8).

Avoid inhalation of dust – ensure that sufficient ventilation or suitable respiratory protective equipment is used, wear suitable protective equipment (see section 8).

Take care of wet product on floor, which presents a slip hazard.

6.2 Environmental precautions.

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

If product is released from trucks in roads, place signposts to divert traffic and remove the spill using vacuum cleaning systems

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). Avoid dust formation: avoid dry sweeping.

Use vacuum suction unit, or shovel into bags.

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 product does not require special handling measures, the following general measures are recommended:

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.

Protective measures

Keep dust levels to a minimum.

Minimize dust generation.

Provide appropriate exhaust ventilation at places where airborne dust is generated. In case of insufficient ventilation, wear suitable respiratory protective equipment refer to section 8 of this safety data sheet. Handle packaged products carefully to prevent accidental bursting. If you require advice on safe handling techniques, please contact your supplier or check the Good Practice Guide referred to in section 16.

Measures to prevent fire

The product is not flammable. No special protective measures against fire required.

Advice on general occupational hygiene

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Keep dust levels to a minimum.

Minimize dust generation.

General occupational hygiene measures are required to ensure safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no drinking, eating and smoking at the workplace. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home.

7.2 Conditions for safe storage, including any incompatibilities.

The product does not require special storage measures. As general storage measures, sources of heat, radiation, electricity and contact with food should be avoided.

Keep away from oxidising agents and from highly acidic or alkaline materials.

Store the containers between 5 and 35 °C, in a dry and well-ventilated place.

Store according to local legislation. Observe indications on the label. 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).

Minimise airborne dust generation and prevent wind dispersal during loading and unloading. Keep containers closed and store packaged products so as to prevent accidental bursting.

7.3 Specific end use(s).

Raw mineral Technological Additive for Animal Feed Absorbent Pet Litter Animal Bedding Rheological Additive Agro

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

8.1 Control parameters.

Work exposure limit for:

Name	CAS No.	Country	Limit value	ppm	mg/m³
		European Union [1]	Eight hours Short term		0,1
		United	Eight hours		0,1
		Kingdom [2]	Short term		
		Éire [3]	Eight hours		0,1
			Short term		
		United States [4] (Cal/OSHA)	Eight hours		0.05 respirable dust, 0.3 (Total Dust)
			Short term		
Quartz (SiO2)	14808-60-7	United States [5] (NIOSH)	Eight hours		Potential occupational carcinogens 0.05 respirable dust, lowest feasible concentration (LFC).
			Short term		
		United States [6] (OSHA)	Eight hours		(Total Dust) 30 mg/m3/(%SiO2 +2)
			Short term		

^[1] According both Binding Occupational Esposure Limits (BOELVs) and Indicative Occupational Exposure Limits (IOELVs) adopted by Scientific Committee for Occupational Exposure Limits to Chemical Agents (SCOEL).

^[2] According Limit Value (IOELV) list in 2nd Indicative Occupational Exposure adobted by Health and Safety Executive.

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[3] According Code of Practice for the Safety, Health and Welfare at Work (Chemicals Agents) Regulations adopted by Health and Safety Authority (HSA).

[4] California Division of Occupational Safety and Health (Cal/OSHA) Permissible Exposure Limits (PELs).

[5] National Institute for Occupational Safety and Health. NIOSH Recommendations for occupational safety and health, Compendium of Policy Documents and Statements, January, 1992, DHHS (NIOSH) Publication No. 92-100.

[6] Occupational Safety and Health Administration, United States Department of Labor. Permissible Exposure limits (PELs), California Division of Occupational Safety and Health (Cal/OSHA) Permissible Exposure Limits (PELs).

The product does NOT contain substances with Biological Limit Values.

Maintain personal exposure below occupational exposure limit for all types of airborne dust (e.g. inhalable dust, respirable dust, respirable quartz, respirable cristobalite) as dictated in the national legislation.

A European Binding OEL (Occupational Exposure Limit) for respirable crystalline silica dust is set at 0.1 mg/m^3 in the Directive (EU) 2017/2398, measured as an 8-hour TWA (Time Weighted Average)

For the equivalent limits in other countries, please consult a competent occupational hygienist or the local regulatory authority.

8.2 Exposure controls.

Measures of a technical nature:

Concentration:	100 %						
Uses:	This material should only be used for industrial purposes						
Breathing protect	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:	Type FFP1 or FFP3 (European Norm 143) or that complies with the requirements of national legislation is recommended.						
Hand protection:							
PPE: Characteristics:	Protective gloves. «CE» marking, category II.						
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.): Material thickness (mm): 0,35						
Eye protection:							
PPE: Characteristics:	- Proceeding goggines against particle impacts.						
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:	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						

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.

Physical state: Solid - Granules Colour: Cream to greyish Odour: Odourless

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

Melting point: >1550 °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: Non 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: 8-9

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

Solubility: Insoluble Hydrosolubility: Insoluble Liposolubility: Insoluble

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: 2,1

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

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

Explosive properties: Non explosive

Oxidizing properties: Not applicable/Not available due to the nature/properties of the product Dropping point: Not applicable/Not available due to the nature/properties of the product Blink: 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. Minimise exposure to air Slippery when wet

10.5 Incompatible materials.

Avoid storing together with materials that may be affected by dust

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.

There are no tested data available on the product.

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a) acute toxicity;

Not conclusive data for classification.

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;

In vitro test (OECD 487) negative

f) carcinogenicity;

Sepiolite was evaluated by IARC as class 3 ("Cannot be classified as to carcinogenicity to humans").

g) reproductive toxicity;

Not conclusive data for classification.

h) STOT-single exposure;

Not conclusive data for classification.

i) STOT-repeated exposure;

Animal and in vitro data indicate a difference between crystalline quartz and the quartz-content of bentonite, that can be extrapolated to sepiolite. A quantitative assessment based on the animal data is not possible as no relevant repeated-dose inhalation study is available.

Human data is restricted to case reports that suggest a relationship between high bentonite exposure (exposures in the early 20th century without state-of-the-art protective measures and maximum dust exposure limits). The link between bentonite exposure and silicosis is not considered to be demonstrated sufficiently.

With regards to classification and labelling of bentonite, the evidence is not considered adequate to come to a conclusion on specific classification of bentonite with specific target organ toxicity upon repeated exposure (STOT-RE). The lung can be affected at repeated high-dose exposure which has been suggested by case reports in humans. Whether this effect occurs only at concentrations overloading the lung's clearance capacity and is not relevant to humans since establishment of general dust exposure limits.

j) aspiration hazard;

Not conclusive data for classification.

Sepiolite produced by TOLSA has no carcinogenic effects as it has been demonstrated by epidemiological, in vitro and in vivo studies.

Sepiolite is classified by IARC as class 3 ("Cannot be classified as to carcinogenicity to humans").

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.

Name	Ecotoxicity				
Name	Туре	Test	Kind	Value	
Sepiolite	Fish	LC50 [1] (OECD	fish 203)	>14000 mg/l (96h) [1]	

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		Aquatic invertebrates			
		Aquatic plants	EC50	algae	>300 mg/l (96h) [1]
CAS No: 63800-37-3	EC No: 264-465-3	Aquatic plants		C 147/SC 5WG 5 N85)	

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.

Not relevant for inorganic substances

12.3 Bioaccumulative potential.

No information is available regarding the bioaccumulation.

Not relevant for inorganic substances

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.

Product is almost insoluble and thus presents a low mobility in most soils.

12.5 Results of PBT and vPvB assessment.

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

This substance does not meet the criteria for classification as PBT or vPvB.

12.6 Endocrine disrupting properties.

This product doesn't contain components with environmental 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.

Waste classification according to the European Waste Catalogue:

01 WASTES RESULTING FROM EXPLORATION, MINING, QUARRYING, AND PHYSICAL AND CHEMICAL TREATMENT OF MINERALS

01 04 wastes from physical and chemical processing of non-metalliferous minerals

01 04 09 waste sand and clays

Method of treatment according to Directive 2008/98/EC:

Disposal

D13 Blending or mixing prior to submission to any of the operations numbered D 1 to D 12

Dispose in such a way to avoid dust generation. Where possible, recycling should be preferred to disposal.

SECTION 14: TRANSPORT INFORMATION.

The material is not classified as dangerous in terms of transport regulations and no restrictions apply for land/sea/air transportation. Avoid dust spreading

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.

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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.

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

14.6 Special precautions for user.

Transportation is not dangerous.

Avoid any release of dust during transportation, by using air-tight tanks for powders and covered trucks for pebbles

14.7 Maritime transport in bulk according to IMO instruments.

Transportation is not dangerous.

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.

Kind of pollutant to water (Germany): nwg: Non-hazardous to water. (Autoclassified according to the AwSV Regulations)

15.2 Chemical safety assessment.

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

SECTION 16: OTHER INFORMATION.

16.1. Indication of changes/revision

The SDS has been revised to comply with Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of REACH.

16.2 Other relevant information

This product contains quartz (fine fraction) classified as STOT RE1 according to criteria defined in the Regulation EC 1272/2008 in quantity below 1%.

Workers must be informed of the presence of crystalline silica and trained in the proper use and handling of this product as required under applicable regulations.

Depending on the handling and use (grinding, drying, bagging), airborne respirable dust may be generated. Dust contains respirable crystalline silica. Prolonged and/or massive exposure to respirable crystalline silica-containing dust may cause silicosis, a nodular pulmonary fibrosis caused by deposition in the lungs of fine respirable particles of crystalline silica. Principal symptoms of silicosis are cough and breathlessness. Occupational exposure to respirable crystalline silica dust should be monitored and controlled. The product should be handled using methods and techniques that minimize or eliminate dust generation.

In 1997, IARC (the International Agency for Research on Cancer) concluded that crystalline silica inhaled from occupational sources can cause lung cancer in humans (human carcinogen category 1). However it pointed out that not all industrial circumstances, nor all crystalline silica types, were to be incriminated. (IARC Monographs on the evaluation of the carcinogenic risks of chemicals to humans, Silica, silicates dust and organic fibres, 1997, Vol. 68, IARC, Lyon, France.). In 2009, in the Monographs 100 series, IARC confirmed its classification of Silica Dust, Crystalline, in the form of Quartz and Cristobalite (IARC Monographs, Volume 100C, 2012).

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In June 2003, SCOEL (the EU Scientific Committee on Occupational Exposure Limits) concluded that the main effect in humans of the inhalation of respirable crystalline silica dust is silicosis. "There is sufficient information to conclude that the relative risk of lung cancer is increased in persons with silicosis (and, apparently, not in employees without silicosis exposed to silica dust in quarries and in the ceramic industry). Therefore preventing the onset of silicosis will also reduce the cancer risk..." (SCOEL SUM Doc 94-final, June 2003). So there is a body of evidence supporting the fact that increased cancer risk would be limited to people already suffering from silicosis. Worker protection against silicosis should be assured by respecting the existing regulatory occupational exposure limits and implementing additional risk management measures where required (see section 16).

For further information, please visit: www.safesilica.eu

16.3 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 recommended that the product only be employed for the purposes advised.

16.4. Abbreviations and acronyms used:

AwSV: Facility Regulations for handling substances that are hazardous for the water.

CEN: European Committee for Standardization.
EC50: Half maximal effective concentration.
PPE: Personal protection equipment.
LC50: Lethal concentration, 50%.

LD50: Lethal dose, 50%. WGK: Water hazard classes.

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 (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 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.