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

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

1.1 Product identifier.

Product Name: PLM - M Product Code: 4200300

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

CONSERVING RESTORATION

Uses advised against:

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.

Company: **Deffner & Johann GmbH**

Address: Mühläckerstraße 13 City: 97520 Röthlein

Telephone: +49 09723 9350-0 E-mail: info@deffner-johann.de

1.4 Emergency telephone number: +49 09723 9350-0 (Only available during office hour)

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the substance or mixture.

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

Eye Dam. 1 : Causes serious eye damage.

STOT RE 1: Causes damage to the respiratory tract through prolonged or repeated exposure by inhalation

STOT SE 3 : May cause respiratory irritation.

Skin Corr. 1 : Causes severe skin burns and eye damage. Skin Sens. 1 : May cause an allergic skin reaction.

2.2 Label elements.

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

Pictograms:







Signal Word:

Danger

Hazard statements:

H314 Causes severe skin burns and eye damage. H317 May cause an allergic skin reaction. H335 May cause respiratory irritation.

H372 Causes damage to the respiratory tract through prolonged or repeated exposure by inhalation

Precautionary statements:

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P280 Wear gloves, protective clothing, goggles and a mask.

P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or

shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and

easy to do. Continue rinsing.

P314 Get medical advice/attention if you feel unwell.
P363 Wash contaminated clothing before reuse.

P501 Dispose the contents / container in accordance with the regulations on hazardous waste or packaging and

packaging waste respectively.

Contains:

calcium oxide

crystalline silica: Quartz (SiO2) (respirable fraction)

Cement, portland, chemicals

2.3 Other hazards.

The mixture does not contain substances classified as PBT.

The mixture does not contain substances classified as vPvB.

The mixture does not contain any endocrine disrupting properties substances.

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

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

3.1 Substances.

Not Applicable.

3.2 Mixtures.

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

			(*)Classification - Regulation (EC) No 1272/2008	
Identifiers	Name	Concentrate	Classification	Specifics concentration limits and Acute toxicity estimate
CAS No: 65997-15-1 EC No: 266-043-4	[2] Cement, portland, chemicals	20 - 75 %	Eye Dam. 1, H318 - STOT SE 3, H335 - Skin Irrit. 2, H315 - Skin Sens. 1B, H317	-
CAS No: 14808-60-7 EC No: 238-878-4	[2] crystalline silica: Quartz (SiO2) (respirable fraction)	10 - 75 %	STOT RE 1, H372	STOT RE 2, H373: 1% ≤ C < 10% STOT RE 1, H372: C ≥ 10%
CAS No: 1305-78-8 EC No: 215-138-9 Registration No: 01- 2119475325-36-XXXX	[1] [2] calcium oxide	3 - 10 %	Eye Dam. 1, H318 - STOT SE 3, H335 - Skin Irrit. 2, H315	-

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

^[1] Substance with a European Union exposure limit in the workplace (see section 8.1).

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

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SECTION 4: FIRST AID MEASURES.

4.1 Description of first aid measures.

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

Eve contact.

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.

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

Inaestion.

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

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

Corrosive Product, contact with eyes or skin can cause burns; ingestion or inhalation can cause internal damage, if this occurs immediate medical assistance is required.

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

Contact with eyes may cause irreversible damage.

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. 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.

5.3 Advice for firefighters.

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

Fire protection equipment.

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

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SECTION 6: ACCIDENTAL RELEASE MEASURES.

6.1 Personal precautions, protective equipment and emergency procedures.

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

6.2 Environmental precautions.

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

6.3 Methods and material for containment and cleaning up.

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

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

6.4 Reference to other sections.

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

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

Do not inject at temperatures below 5°C and protect the applied material from frost in the first 48/72 hours after application.

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.

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

7.3 Specific end use(s).

Consolidation of structures.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

8.1 Control parameters.

Work exposure limit for:

Name	CAS No.	Country	Limit value	ppm	mg/m³
		United Kingdom [1]	Eight hours	dust) 4	10 (inhalable dust) 4 (respirable dust)
Cement, portland, chemicals	65997-15-1		Short term		
		Éire [2]	Eight hours		1 (Respirable fraction)
			Short term	<u> </u>	

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		United States	Eight hours		10 (Total dust) 5 (Respirable
	[3] (Cal/OSHA) United States				fraction)
			Short term		
					fraction) 10 (Total dust) 5 (Respirable fraction) 15 (Total dust) 5 (Respirable fraction) 50 (mppcf:Millions of particles per cubic foot of air, based on impinger samples counted by light-field techniques. Conversion factors - mppcf X 35.3 = million particles per
		Eight hours	5 (Respirable		
		[4] (NIOSH)			fraction)
			Short term		
		United States [5] (OSHA)	Eight hours		5 (Respirable fraction) 50 (mppcf:Millions of particles per cubic foot of air, based on impinger samples counted by light-field techniques. Conversion factors - mppcf X 35.3 = million particles per cubic meter =
			Short term		c.c.)
		,	Eight hours		0.1
		Éire [2] Short term			
		United States	Eight hours		0.05
		[3] (Cal/OSHA)	Short term		fraction) 10 (Total dust) 5 (Respirable fraction) 15 (Total dust) 5 (Respirable fraction) 50 (mppcf:Millions of particles per cubic foot of air, based on impinger samples counted by light-field techniques. Conversion factors - mppcf X 35.3 = million particles per cubic meter = particles per
		, ,			
		United States [4] (NIOSH)	Eight hours		
					0.05
			Short term		
crystalline silica: Quartz (SiO2) (respirable fraction)	14808-60-7	United States [5] (OSHA)	Eight hours		+2), 250/(%SiO2+5) (mppcf:Millions of particles per cubic foot of air, based on impinger samples counted by light-field techniques. Conversion factors - mppcf X 35.3 = million particles per cubic meter = particles per

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		European	Eight hours	1 (Respirable fraction)
		Union [6]	Short term	4 (Respirable fraction)
		United	Eight hours	2
		Kingdom [1]	Short term	
	1205 70 0	Éire [2]	Eight hours	1 (Respirable fraction)
calcium oxide	1305-78-8		Short term	4 (Respirable fraction)
		United States	Eight hours	2
		[3] (Cal/OSHA)	Short term	
		United States	Eight hours	2
		[4] (NIOSH)	Short term	
		United States	Eight hours	5
		[5] (OSHA)	Short term	

^[1] According Limit Value (IOELV) list in 2nd Indicative Occupational Exposure adobted by Health and Safety Executive.

The product does NOT contain substances with Biological Limit Values.

Concentration levels DNEL/DMEL:

Name	DNEL/DMEL	Туре	Value
calcium oxide	DNEL	Inhalation, Chronic, Local effects	3,5
CAS No: 1305-78-8	(Workers)		(mg/m³)
EC No: 215-138-9	DNEL	Inhalation, Chronic, Systemic effects	3,5
LC NO. 213-130-9	(Workers)		(mg/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.

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:	CONSERVING RESTORATION
Breathing protecti	on:
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:	
PPF:	Non-disposable protective gloves against chemicals.

^[2] According Code of Practice for the Safety, Health and Welfare at Work (Chemicals Agents) Regulations adopted by Health and Safety Authority (HSA).

^[3] California Division of Occupational Safety and Health (Cal/OSHA) Permissible Exposure Limits (PELs).

^[4] 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.

^[5] 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).

^[6] 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).

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«CE» marking, category III. Check the list of chemicals for which the glove has been Characteristics: CEN standards: EN 374-1, En 374-2, EN 374-3, EN 420 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 Maintenance: than not using gloves, since the pollutant can gradually accumulate in the glove's material. They are to be replaced whenever tears, cracks or deformations are observed or when exterior dirt could Observations: reduce their strength. Eye protection: Protective goggles against particle impacts. Characteristics: «CE» marking, category II. Eye protector against dust and smoke. EN 165, EN 166, EN 167, EN 168 CEN standards: Visibility through lenses should be ideal. Therefore, these parts should be cleaned daily. Protectors should Maintenance: be disinfected periodically following the manufacturer's instructions. Some signs of wear and tear include: yellow colouring of the lenses, superficial scratching of the lenses, Observations: scraping etc. Skin protection: Chemical protective clothing PPF: «CE» marking, category III. Clothing should fit properly. The level of protection Characteristics: 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 In order to guarantee uniform protection, follow the washing and maintenance instructions provided by Maintenance: the manufacturer. The protective clothing's design should facilitate correct positioning, staying in place without moving for Observations: 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. «CE» marking, category III. Check the list of chemicals against which the footwear Characteristics: is resistant. EN ISO 13287, EN 13832-1, EN 13832-2, EN 13832-3, EN ISO 20344, EN ISO 20345 CEN standards: For correct maintenance of this kind of safety footwear, it is necessary to observe the instructions Maintenance: specified by the manufacturer. The footwear should be replaced as soon as any sign of damage is observed. The footwear should be cleaned regularly and dried when damp, although it should not be placed too Observations: 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 - Dust Color: Grayish white Odor: Characteristic Odor threshold: Not available Melting point: Not available Freezing point: Not available

Boiling point or initial boiling point and boiling range: Not applicable

Flammability: Non-flammable Lower explosion limit: Not available Upper explosion limit: Not available Flash point: Not applicable

Auto-ignition temperature: Not available Decomposition temperature: Not available

pH: 12.0 +- 1.0

Kinematic viscosity: Not available

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Solubility: Not available Hydrosolubility: Not available Liposolubility: Not available

Partition coefficient n-octanol/water (log value): Not available

Vapor pressure: Not available Absolute density: Not available Relative density: > 1

Relative vapor density: Not available Particle characteristics: Not available

9.2 Other information

Viscosity: Not available

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

Dropping point: Not available

Blink: Not available

SECTION 10: STABILITY AND REACTIVITY.

10.1 Reactivity.

The product does not present hazards by their reactivity.

10.2 Chemical stability.

Unstable in contact with:

- Acids.

10.3 Possibility of hazardous reactions.

Neutralization can occur on contact with acids.

10.4 Conditions to avoid.

- Avoid contact with acids.

10.5 Incompatible materials.

Avoid the following materials:

- Acids.

10.6 Hazardous decomposition products.

Depending on conditions of use, can be generated the following products:

- Corrosive vapors or gases.

SECTION 11: TOXICOLOGICAL INFORMATION.

IRRITANT MIXTURE. The inhalation of spray mist or suspended particulates can irritate the respiratory tract. It can also cause serious respiratory difficulties, central nervous system disorders, and in extreme cases, unconsciousness.

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

There are no tested data available on the product.

Splatters in the eyes can cause irritation and reversible damage.

a) acute toxicity;

Not conclusive data for classification.

b) skin corrosion/irritation;

Product classified:

Skin Corrosive, Category 1: Causes severe skin burns and eye damage.

c) serious eye damage/irritation;

Product classified:

Serious eye damage, Category 1: Causes serious eye damage.

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d) respiratory or skin sensitisation;

Product classified:

Skin sensitiser, 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;

Product classified:

Specific target organ toxicity following a single exposure, Category 3: May cause respiratory irritation.

i) STOT-repeated exposure;

Product classified:

Specific target organ toxicity following a repeated exposure, Category 1: Causes damage to the respiratory tract through prolonged or repeated exposure by inhalation

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.

SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.

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

12.2 Persistence and degradability.

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

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

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

12.3 Bioaccumulative potential.

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

12.4 Mobility in soil.

No information is available about the mobility in soil.

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

Prevent penetration into the ground.

12.5 Results of PBT and vPvB assessment.

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

12.6 Endocrine disrupting properties.

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

12.7 Other adverse effects.

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

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SECTION 13: DISPOSAL CONSIDERATIONS.

13.1 Waste treatment methods.

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

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

SECTION 14: TRANSPORT INFORMATION.

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

14.1 UN number or ID number.

Transportation is not dangerous.

14.2 UN proper shipping name.

Description:

ADR/RID: Not classified as hazardous for transport.

IMDG: Not classified as hazardous for transport. ICAO/IATA: Not classified as hazardous for transport.

14.3 Transport hazard class(es).

Transportation is not dangerous.

14.4 Packing group.

Transportation is not dangerous.

14.5 Environmental hazards.

Transportation is not dangerous.

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

14.6 Special precautions for user.

Transportation is not dangerous.

14.7 Maritime transport in bulk according to IMO instruments.

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.

15.2 Chemical safety assessment.

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

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SECTION 16: OTHER INFORMATION.

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

H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H335 May cause respiratory irritation.

H372 Causes damage to the respiratory tract through prolonged or repeated exposure by inhalation

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

Classification codes:

Eye Dam. 1: Serious eye damage, Category 1

STOT RE 1 : Specific target organ toxicity following a repeated exposure, Category 1 STOT SE 3 : Specific target organ toxicity following a single exposure, Category 3

Skin Corr. 1: Skin Corrosive, Category 1 Skin Irrit. 2: Skin irritant, Category 2 Skin Sens. 1: Skin sensitiser, Category 1 Skin Sens. 1B: Skin sensitiser, Category 1B

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 hazard classification (SECTION 2.1).
- 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 of specific hazards (SECTION 2.3).
- Changes in the composition of the product (SECTION 3.2).
- Changes in the composition of the product (SECTION 3.2).
- Changes in the composition of the product (SECTION 3.2).
- Modification of the symptoms (SECTION 4.2).
- Modification in the firefighting measures (SECTION 5.2).
- Modifications in the accidental release measures (SECTION 6.1).
- Modifications in the handling and storage precautions (SECTION 7.1).
- Modifications in the handling and storage precautions (SECTION 7.2).
- Elimination of exposure data (SECTION 8.1).
- Addition of exposure data (SECTION 8.1).
- Modification of exposure data (SECTION 8.1).
- Modification in the values of the physical and chemical properties (SECTION 9).
- Modification of the information of the stability and reactivity conditions (SECTION 10.2).
- Modification of the information of the stability and reactivity conditions (SECTION 10.3).
 Modification of the information of the stability and reactivity conditions (SECTION 10.4).
- Modification of the information of the stability and reactivity conditions (SECTION 10.5).
- Modification of the information of the stability and reactivity conditions (SECTION 10.6).
- Change in the hazard classification (SECTION 11.1).
- Modification of the classification ADR/IMDG/ICAO/IATA/RID (SECTION 14).

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

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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:

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.

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.