

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

CEBOGEL® OCMA

Version number: 7.0
Replaces version of: 09.08.2021 (6)

Revision: 05.10.2023

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name

CEBOGEL® OCMA

Identification of the substance

Bentonite

Registration number (REACH)

Bentonite is exempted from REACH registration in accordance with Annex V. A hazard assessment has been conducted under the umbrella of the European Bentonite Association (EUBA) and the outcome was that bentonite is not a hazardous substance

EC number

215-108-5

CAS number

1302-78-9

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

Relevant identified uses

Industrial use

Uses advised against

Do not use for private purposes (household)

1.3 Details of the supplier of the safety data sheet

Cebo Holland BV
Westerduinweg 1
1976 BV IJmuiden
Netherlands

Telephone: +31 (0) 255-546262
e-mail: info@cebo.com
Website: www.cebo.com

e-mail (competent person)

msds@cebo.com (HSEQ Department)

1.4 Emergency telephone number

Emergency information service

+31 (0) 255-546262
This number is only available during the following of-
fice hours: Mon-Fri 08:30 - 17:00

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

This substance does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP)

Not required.

2.3 Other hazards

Depending on the type of handling and use (e.g. grinding, drying), airborne respirable crystalline silica may be generated. Prolonged and/or massive inhalation of respirable crystalline silica dust may cause lung fibrosis, commonly referred to as silicosis.

Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB

Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in a concentration of $\geq 0.1\%$.

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

CEBOGEL® OCMA

Version number: 7.0
Replaces version of: 09.08.2021 (6)

Revision: 05.10.2023


SECTION 3: Composition/information on ingredients

3.1 Substances

Name of substance	Bentonite
Identifiers	
CAS No	1302-78-9
EC No	215-108-5

Impurities and additives, classification acc. to EU regulation

Bentonite is a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB, type 4) according to REACH & CLP Regulations.

Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Specific Conc. Limits	M-Factors
respirable silica, crystalline (quartz)	CAS No 14808-60-7 EC No 238-878-4	< 1	STOT RE 1 / H372			

Remarks

For full text of H-phrases: see SECTION 16. All the percentages given are percentages by weight unless stated otherwise.

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes

Do not leave affected person unattended. Remove victim out of the danger area. In case of unconsciousness place person in the recovery position. Never give anything by mouth. In all cases of doubt, or when symptoms persist, seek medical advice.

Following inhalation

Provide fresh air. If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. In case of respiratory tract irritation, consult a physician.

Following skin contact

Brush off loose particles from skin. Rinse skin with water/shower. Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention.

Following eye contact

Rinse immediately carefully and thoroughly with eye shower or water. If eye irritation persists: Get medical advice/attention.

Following ingestion

Rinse mouth with water (only if the person is conscious). Let water be drunk in little sips (dilution effect). In all cases of doubt, or when symptoms persist, seek medical advice.

4.2 Most important symptoms and effects, both acute and delayed

Acute symptoms can be: pain in the eyes because of dust. No delayed effects are anticipated if first aid treatment is applied effectively.

4.3 Indication of any immediate medical attention and special treatment needed

None.

CEBOGEL® OCMA

Version number: 7.0
Replaces version of: 09.08.2021 (6)

Revision: 05.10.2023

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

The product is not combustible; Co-ordinate firefighting measures to the fire surroundings

Unsuitable extinguishing media

None.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products

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

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Fight fire with normal precautions from a reasonable distance. Avoid dust formation. Slippery surface in combination with water.

Special protective equipment for firefighters

Self-contained breathing apparatus (EN 133). Standard protective clothing for firefighters.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove persons to safety. Ventilate affected area. Control of dust.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases. Use personal protective equipment as required. Keep unprotected persons away. Ventilate affected area.

6.2 Environmental precautions

Keep away from drains or surface water.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains.

Advice on how to clean up a spill

Vacuuming or wet sweeping may be used to avoid dust dispersal.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

CEBOGEL® OCMA

Version number: 7.0
Replaces version of: 09.08.2021 (6)

Revision: 05.10.2023

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Specific notes/details

Dust deposits may accumulate on all deposition surfaces in a technical room. Avoid dust formation.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities

Managing of associated risks

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.

- Explosive atmospheres

Removal of dust deposits.

Control of effects

Protect against external exposure, such as

High temperatures. Moisture.

Consideration of other advice

Store in a well-ventilated place. Keep container tightly closed.

- Ventilation requirements

Use local and general ventilation.

7.3 Specific end use(s)

If you require advice on specific uses check the Good Practice Guide referred to in section 16.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

National limit values

Occupational exposure limit values (Workplace Exposure Limits)									
Country	Name of substance	CAS No	Identifier	TWA [ppm]	TWA [mg/m ³]	STEL [ppm]	STEL [mg/m ³]	Notation	Source
EU	respirable silica, crystalline (quartz)	14808-60-7	IOELV		0,1			r	2017/2398/EU
NL	respirable silica, crystalline (quartz)	14808-60-7	GW		0,075			r, dust	SC-SZW

Notation

dust	as dust
r	respirable fraction
STEL	short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)
TWA	time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average (unless otherwise specified)

Relevant DNELs/DMELs/PNECs and other threshold levels

No data available.

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

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CEBOGEL® OCMA

Version number: 7.0
Replaces version of: 09.08.2021 (6)

Revision: 05.10.2023

8.2 Exposure controls

Appropriate engineering controls

Keep formation of airborne dusts to a minimum. Provide appropriate exhaust ventilation at places where dust is formed. Read and understand the manufacturer's instruction and the possible precautionary label on the product. Provide eyewash stations and safety showers at the workplace.

Individual protection measures (personal protective equipment)

Eye/face protection



Do not wear contact lenses when handling this product. Use safety goggles with side protection (EN 166).

Skin protection



Protective clothing (EN 340 & EN ISO 13688).

- Hand protection



Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- Type of material

PVC: polyvinyl chloride, NR: natural rubber, latex, NP: neoprene

- Breakthrough time of the glove material

Use gloves with a minimum breakthrough time of the glove material: >10 minutes (permeation: level 1).

- Other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

Respiratory protection

In case of inadequate ventilation wear respiratory protection. P2 (filters at least 94 % of airborne particles, colour code: White).

Environmental exposure controls

All ventilation systems should be filtered before discharge to atmosphere.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	solid (powder)
Colour	light grey
Odour	odourless - characteristic
Melting point/freezing point	>450 °C (melting/freezing temperature)
Boiling point or initial boiling point and boiling range	not determined
Flammability	non-combustible
Lower and upper explosion limit	not applicable
Flash point	not applicable

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

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CEBOGEL® OCMA

Version number: 7.0
Replaces version of: 09.08.2021 (6)

Revision: 05.10.2023

Auto-ignition temperature	not applicable
Decomposition temperature	no data available
pH (value)	9 – 10,5 (in aqueous solution: 5 % (w/w))
Kinematic viscosity	not relevant

Solubility

Water solubility	<0,9 mg/l at 20 °C (water solubility)
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Partition coefficient n-octanol/water (log value)	not relevant (inorganic)
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Vapour pressure	not determined
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Density and/or relative density

Density	2,6 g/cm ³ at 20 °C
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Particle characteristics	no data available
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9.2 Other information

Information with regard to physical hazard classes	hazard classes acc. to GHS (physical hazards): not relevant
Other safety characteristics	there is no additional information

SECTION 10: Stability and reactivity

10.1 Reactivity

This material is not reactive under normal ambient conditions.

10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

10.3 Possibility of hazardous reactions

No known hazardous reactions.

10.4 Conditions to avoid

Minimise exposure to air. Slippery when wet.

10.5 Incompatible materials

Do not store together with materials that may be affected by dust.

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

CEBOGEL® OCMA

Version number: 7.0
Replaces version of: 09.08.2021 (6)

Revision: 05.10.2023

SECTION 11: Toxicological information

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

Classification according to GHS (1272/2008/EC, CLP)

This substance does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC.

Acute toxicity

Shall not be classified as acutely toxic.

Acute toxicity			
Exposure route	Endpoint	Value	Species
oral	LD50	>2.000 mg/kg	rat
inhalation: dust/mist	LC50	>5,27 mg/l/4h	rat

Skin corrosion/irritation

Bentonite is not irritating to skin (in vivo, OECD 404, rabbit). .

Serious eye damage/eye irritation

Bentonite is not irritating to eye (in vivo, OECD 405, rabbit). Bentonite is classified as a mild irritant to eyes (according to the modified Kay & Calandra criteria).

Respiratory or skin sensitisation

Bentonite is not a skin sensitiser in accordance with the local lymph node assay (OECD 429, mouse) .

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Sepiolite was evaluated by IARC as class 3 ("Cannot be classified as to carcinogenicity to humans"). Based on read-across with sepiolite, bentonite was assessed as non-carcinogenic.

Therefore classification of bentonite for carcinogenicity is not warranted.

Reproductive toxicity

Shall not be classified as a reproductive toxicant. Bentonite is not toxic to reproduction.

Two developmental studies are available:

Abdel-Wahhab et al (1999)

Bentonite had no effect on maternal and fetal parameters at a dietary level of 0.5% w/w (equivalent to 250 mg/kg bw).

Wiles et al (2004)

2% calcium montmorillonite or sodium montmorillonite in the diet had no effect on maternal weight or maternal organ weights, litter weight, embryonic implantations, or resorptions

In both animal studies no effects on maternal/foetal parameters were detected.

Classification for reproductive toxicity is not warranted.

Summary of evaluation of the CMR properties

The product contains substances that are listed on the "SZW-lijst van kankerverwekkende, mutagene en voor de voortplanting giftige stoffen". See section 15 for more information on the ingredients.

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

STOT Oral:

Short-term repeated dose toxicity study (28 days) and sub-chronic toxicity study (90 day) on mice have been conducted with bentonite.

Bentonite fed to mice at 10%, 25%, or 50% for 61 days. Hepatoma was seen in mice receiving a diet of 50% bentonite. This was due to bentonite being a base-exchange silicate and thus removing choline from the content of the intestine > 200 day feeding study of 50% bentonite. Hepatomas developed in 11 of 12 mice. The livers of mice on 50/50 bentonite-basal diet were severely damaged.

The liver damage noted in the group ingesting bentonite is consistent with that expected during prolonged choline deficiency, a

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

CEBOGEL® OCMA

Version number: 7.0
Replaces version of: 09.08.2021 (6)

Revision: 05.10.2023

base-exchange silicate, is advanced as a partial explanation for the development of the hepatomas in the mice in these experiments
Effect seen on livers. However study were conducted in mice at very high concentration and effects seen are considered secondary due to disrapture of digestion.
Therefore, classification of bentonite for toxicity upon prolonged exposure by oral route is not warranted.

STOT Inhalation:

Animal and in vitro data indicate a difference between crystalline quartz and the quartz-content of bentonite. 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.
Therefore, classification of bentonite for toxicity upon prolonged exposure by inhalation is not warranted.

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

11.2 Information on other hazards

Endocrine disrupting properties

Available data for the substance have been considered against the criteria laid down in Regulations (EC) No 1907/2006, (EU) 2017/2100, (EU) 2018/605) and found not to apply.

Other information

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

Aquatic toxicity (acute)			
Endpoint	Value	Species	Exposure time
LC50	16.000 mg/l	rainbow trout	96 h
LC50	2.800 – 3.200 mg/l	marine fish	24 h
LC50	>500 mg/l	C. dubia and H. limbata	24 h
EC50	>100 mg/l	daphnia magna	48 h
EC50	>100 mg/l	freshwater algae	72 h
EC50	81,6 mg/l	Dungeness crab	96 h
EC50	24,8 mg/l	dock shrimp	96 h

12.2 Persistence and degradability

The substance is inorganic and therefore will not undergo biodegradation.

12.3 Bioaccumulative potential

Not relevant for inorganic substances.

12.4 Mobility in soil

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

Safety Data Sheet

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amended by 2020/878/EU

CEBOGEL® OCMA

Version number: 7.0
Replaces version of: 09.08.2021 (6)

Revision: 05.10.2023

12.5 Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

12.6 Endocrine disrupting properties

Available data for the substance have been considered against the criteria laid down in Regulations (EC) No 1907/2006, (EU) 2017/2100, (EU) 2018/605 and found not to apply.

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

Waste treatment-relevant information

Recycling/reclamation of other inorganic materials.

Waste treatment of containers/packagings

Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself. In all cases dust formation from residues in the packaging should be avoided and suitable protection be assured. Empty containers.

Remarks

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

SECTION 14: Transport information

- | | | |
|------|--|---|
| 14.1 | UN number or ID number | not subject to transport regulations |
| 14.2 | UN proper shipping name | not relevant |
| 14.3 | Transport hazard class(es) | none |
| 14.4 | Packing group | not assigned |
| 14.5 | Environmental hazards | non-environmentally hazardous acc. to the dangerous goods regulations |
| 14.6 | Special precautions for user | Avoid any release of dust during transportation, by using air-tight tanks, big bags, and paper bags for powders and covered trucks for pebbles or granules. |
| 14.7 | Maritime transport in bulk according to IMO instruments | No data available. |

Information for each of the UN Model Regulations

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information

Not subject to ADR, RID and ADN.

International Maritime Dangerous Goods Code (IMDG) - Additional information

Not subject to IMDG.

International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information

Not subject to ICAO-IATA.

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

CEBOGEL® OCMA

Version number: 7.0
Replaces version of: 09.08.2021 (6)

Revision: 05.10.2023

SECTION 15: Regulatory information

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

Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

Not listed.

List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list

Not listed.

Seveso Directive

2012/18/EU (Seveso III)			
No	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the application of lower and upper-tier requirements	Notes
	not assigned		

Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

Not listed.

Water Framework Directive (WFD)

Not listed.

Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors, amending Regulation (EC) No 1907/2006 and repealing Regulation (EU) No 98/2013

Not listed.

Regulation on persistent organic pollutants (POP)

Not listed.

National regulations (Netherlands)

SZW-lijst CMR effects

List of carcinogenic, mutagenic and reproductive toxic substances (SZW-lijst)				
Name of substance	CAS No	Carcinogenicity	Mutagenicity	Reproductive toxicity
respirable silica, crystalline (quartz)	14808-60-7	carc		

Legend

carc Listed in "B List of carcinogenic substances"

List of Substances of Very High Concern, Rijksinstituut voor Volksgezondheid en Milieu (RIVM)

List of Substances of Very High Concern (ZZS-lijst)					
Name acc. to inventory	CAS No	Dust class for air emissions	Remarks	Threshold mass flow	Emission limit value
quartz (SiO ₂)	14808-60-7	SA.2	rem-76 rem-100	2,5 g/uur	0,5 mg/Nm ³

Legend

rem-100 Deze stof wordt als ZZS geïdentificeerd omdat in EU verordening 2017/2398/CE staat dat er voldoende bewijs is dat respirabel kristallijn silicastaof carcinogeen is

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

CEBOGEL® OCMA

Version number: 7.0
Replaces version of: 09.08.2021 (6)

Revision: 05.10.2023

Legend

rem-76

Deze stof staat nog niet als ZZS in bijlage 12a van de Activiteitenregeling milieubeheer. In de toekomst zal deze stof worden ingedeeld in een MVP1 of MVP2 stofklasse met bijbehorende grensmassastroom en emissiegrenswaarde.

15.2 Chemical safety assessment

Bentonite is exempted from REACH registration in accordance with Annex V. A hazard assessment has been conducted under the umbrella of the European Bentonite Association (EUBA) and the outcome was that bentonite is not a hazardous substance.

SECTION 16: Other information

Indication of changes (revised safety data sheet)

Complete revision of the safety data sheet.

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
2017/2398/EU	Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
CMR	Carcinogenic, Mutagenic or toxic for Reproduction
DGR	Dangerous Goods Regulations (see IATA/DGR)
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
IOELV	Indicative occupational exposure limit value
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic

Safety Data Sheet

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CEBOGEL® OCMA

Version number: 7.0
Replaces version of: 09.08.2021 (6)

Revision: 05.10.2023

Abbr.	Descriptions of used abbreviations
PNEC	Predicted No-Effect Concentration
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
SC-SZW	Staatscourant: Regeling van de Minister van Sociale Zaken en Werkgelegenheid tot wijziging van de Arbeidsomstandighedenregeling
STEL	Short-term exposure limit
STOT RE	Specific target organ toxicity - repeated exposure
SVHC	Substance of Very High Concern
TWA	Time-weighted average
vPvB	Very Persistent and very Bioaccumulative

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H372	Causes damage to organs through prolonged or repeated exposure.

Training advice

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 type of handling and use (e.g. grinding, drying), airborne respirable crystalline silica may be generated.

Prolonged and/or massive inhalation of respirable crystalline silica dust may cause lung fibrosis, commonly referred to as silicosis.

Principal symptoms of silicosis are cough and breathlessness.

A multi-sectoral social dialogue agreement on Workers Health Protection through the Good Handling and Use of Crystalline Silica and Products Containing it was signed on 25 April 2006. This autonomous agreement, which receives the European Commission's financial support, is based on a Good Practices Guide. The requirements of the Agreement came into force on 25 October 2006. The Agreement was published in the Official Journal of the European Union (2006/C 279/02). The text of the Agreement and its annexes, including the Good Practices Guide, are available from <http://www.nepsi.eu> and provide useful information and guidance for the handling of products containing respirable crystalline silica. Literature references are available on request from EUROSIL, the European Association of Industrial Silica Producers.

Disclaimer

This safety data sheet (SDS) is based on the legal provisions of the REACH Regulation (EC 1907/2006; article 31 and Annex II). Its contents are intended as a guide to the appropriate precautionary handling of the material. It is the responsibility of recipients of this SDS to ensure that the information contained therein is properly read and understood by all people who may use, handle, dispose or in any way come in contact with the product. Information and instructions provided in this SDS are based on the current state of scientific and technical knowledge at the date of issue indicated.