



Bentonite

- Safety Data Sheet - Bentonite PELLETS

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1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

Product name: Bentonite Clay, Sodium, Calcium and Activated Calcium

REACH registration number: Exempt

Product Code: 6084

Relevant identified uses of the substance or mixture:

Construction and civil engineering

Details of the supplier of the safety data sheet:

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2 COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Characterization

Product / Ingredient Name	CAS	EC number	Concentration range
Bentonite	1302-78-9	215-108-5	>99%
Quartz (SiO ₂)	148-60-7	238-878-4	<1%
Cristobalite (SiO ₂)	14464-46-1	238-455-4	<1%



3 HAZARDS IDENTIFICATION

CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

The product does not meet the criteria for classification as hazardous according to EC Regulation 1272/2008 and Directive 67/548/EC as amended. Handling and use may generate airborne respirable dust. Dust contains respirable crystalline silica. Prolonged and or massive inhalation of respirable crystalline silica dust may cause lung fibrosis, commonly referred to as silicosis. The product contains less than 1% w/w RCS (respirable crystalline silica)

Classification (67/548/EEC): Not classified

Classification (EC) 1272/2008: Not classified

LABEL ELEMENTS

Labelling according to Directive 67/548/EEC No pictogram required.

Label in accordance with (EC) 1272/2008 No pictogram required.

OTHER HAZARDS

The substance does not meet the criteria for PBT or vPvB substance. No other hazards identified.



4 FIRST AID MEASURES

DESCRIPTION OF FIRST AID MEASURES

- Inhalation:** Move the exposed person to fresh air at once. Get medical attention if any discomfort continues.
- Ingestion:** Rinse mouth thoroughly. Get medical attention if any discomfort continues.
- Skin contact:** Wash skin with soap and water. Get medical attention if irritation persists after washing.
- Eye contact:** Make sure to remove any contact lenses from the eyes before rinsing. Rinse eye with water immediately. Get medical attention if any discomfort continues.

MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

The acute symptoms would pain in the eyes because of dust entry. No delayed effects are anticipated if first aid treatment is applied and is effective. Handling and use may generate airborne respirable dust. Dust contains respirable crystalline silica. Prolonged and or massive inhalation of respirable crystalline silica dust may cause lung fibrosis, commonly referred to as silicosis. The product contains less than 1% w/w RCS (respirable crystalline silica) Principal symptoms of silicosis are cough and breathlessness. Occupational exposure to respirable dust should be monitored and controlled.

The product should be handled using methods and techniques that minimize or eliminate dust generation.

5 FIREFIGHTING MEASURES

- Extinguishing media:** This product is not flammable. Use fire extinguishing media appropriate for surrounding materials.

SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

- Hazardous combustion products:** None under normal conditions

ADVICE FOR FIREFIGHTERS

- Special fire fighting procedures:** Avoid generation of dust. Use breathing apparatus. Product on floor when wetted will become slippery and may present a hazard; wear anti-slip boots.



6 ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Ensure adequate ventilation. Keep dust levels to a minimum. Keep unprotected persons away. Avoid contact with skin, eyes, and clothing – wear suitable protective equipment. Avoid inhalation of dust – ensure that sufficient ventilation or suitable respiratory protective equipment is used, wear suitable protective equipment. Take care of wet product on floor, which presents a slip hazard.

ENVIRONMENTAL PRECAUTIONS

No special requirement. Contain the spillage. If product is released from trucks in roads, place signposts to divert traffic and remove the spill using vacuum cleaning systems

METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Avoid dust formation; avoid dry sweeping. Use vacuum suction unit, or shovel into bags.

REFERENCE TO OTHER SECTIONS

For more information on exposure controls/personal protection or disposal considerations, please check sections 8 and 13 of this safety data sheet.



PRECAUTIONS FOR SAFE HANDLING

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.

ADVICE ON GENERAL OCCUPATIONAL HYGIENE

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.

CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

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.

SPECIFIC END USE

Intended for use in construction and civil engineering.

Maintain personal exposure below occupational exposure limit for inhalable and respirable dust as dictated in the national legislation. Occupational Exposure Limits in mg/m³ 8 hours TWA – Respirable Dust:

Inert dust 5 mg /m³ Quarts 0,1 mg/m³ Cristobalite 0,1 ng/m³ Tridynite 0,1 mg/m³

EXPOSURE CONTROLS**Appropriate engineering controls**

Minimise airborne dust generation. Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne levels below specified exposure limits. If user operations generate dust, fumes or mist, use ventilation to keep exposure to airborne particles below the exposure limit. Apply organisational measures e.g. by isolating personnel from dusty areas. Remove and wash soiled clothing.

PERSONAL PROTECTIVE EQUIPMENT**Eye/face protection:**

Do not wear contact lenses. For powders, tight fitting goggles with side shields, or wide vision full goggles. It is also advisable to have individual pocket eyewash.

Skin & Hands Protection:

For skin, normal work clothes are appropriate. For hands, appropriate protection (e.g. gloves, barrier cream) is recommended for workers who suffer from dermatitis or sensitive skin. Wash hands at the end of each work session.

Respiratory Protection:

Local ventilation to keep levels below established threshold values is recommended. In case of prolonged exposure to airborne dust concentrations, a suitable particle filter mask that complies with the requirements of national legislation is recommended, depending on the expected exposure levels.



9 PHYSICAL AND CHEMICAL PROPERTIES

INFORMATION ON BASIC AND PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Light grey pellets
Odour:	odourless
Odour threshold:	not applicable
Melting point:	> 450 °C (study result, EU A.1 method)
Boiling point:	not applicable (solid with a melting point > 450 °C)
Flash point:	not applicable (solid with a melting point > 450 °C)
Evaporation rate:	not applicable (solid with a melting point > 450 °C)
Flammability:	non flammable (study result, EU A.10 method)
Explosive limits:	non explosive (void of any chemical structures commonly associated with explosive properties)
Vapour pressure:	not applicable (solid with a melting point > 450 °C)
Vapour density:	not applicable
Relative density:	2.0- 2,5 g/cm ³
Bulk density:	1 – 1.4 g/cm ³
Solubility in water:	<0.9 mg/L at 20°C (study results, EU A.6 method)
Partition coefficient:	not applicable (inorganic substance)
Auto ignition temperature:	no relative self-ignition temperature below 400 °C (study result, EU A.16 method)
Decomposition temperature:	not applicable
Viscosity:	not applicable (solid with a melting point > 450 °C)
Oxidising properties:	no oxidising properties (Based on the chemical structure, the substance does not contain a surplus of oxygen or any structural groups known to be correlated with a tendency to react exothermally with combustible material)



10 STABILITY AND REACTIVITY

Reactivity:	No specific reactivity hazards associated with this product.
Chemical stability:	Stable under normal temperature conditions.
Possibility of hazardous reactions:	Not relevant
Conditions to avoid:	Minimise exposure to air, Slippery when wet

INCOMPATIBLE MATERIALS

Materials to avoid:	No specific, or groups of materials, are likely to react to produce a hazardous situation.
Hazardous decomposition products:	None under normal circumstances



INFORMATION ON TOXICOLOGICAL EFFECTS

The product does not meet the criteria for classification as hazardous according to EC Regulation 1272/2008 and Directive 67/548/EC as amended.

The product contains less than 1% w/w RCS (respirable crystalline silica)

Absorption: Bentonite is not classified as a hazardous substance. Therefore, absorption is not a relevant parameter for the effects assessment.

Acute toxicity: Bentonite is not acutely toxic.

Oral LD50 > 2000 mg/kg bw (OECD 425, rat) Dermal Data not available. Bentonite is almost insoluble and has a low absorption through the skin. Inhalation No data available. Classification for acute toxicity is not warranted.

Irritation / corrosion: Bentonite is not irritating to skin (in vivo, OECD 404, rabbit).
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).

Classification for Irritation/corrosion is not warranted

Sensitisation: No data available. Bentonite is considered not to be a skin sensitiser based on experience in handling and low absorption through the skin.

Classification for sensitisation is not warranted.

Repeated dose toxicity - 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 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 disruption of digestion.
Therefore, classification of bentonite for toxicity upon prolonged exposure by oral route is not warranted.

Mutagenicity: In vitro gene mutation in bacteria (Ames) – negative
In vivo cytogenicity test in mammalian cells (chrom abb) – negative
In vivo cytogenicity test in mammalian cells (micronucleus assay) –negative

Classification for genotoxicity is not warranted.

Repeated dose toxicity - 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.

Carcinogenicity:

No data available.

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. Classification for carcinogenicity is not warranted.

Toxicity for 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 according to regulation (EC) 1272/2008 is not warranted.

12 ECOLOGICAL INFORMATION**Acute / prolonged fish toxicity:**

LC50 (96h) for freshwater fish (rainbow trout): 16000 mg/l
LC50 (24h) for marine water fish (black bass, warmouth bass, blue gill and sunfish): 2800-3200 mg/l

Acute / Prolonged toxicity to aquatic invertebrates:

EC50 (96h) for freshwater invertebrates (Dungeness crab): 81.6 mg/l
EC50 (96h) for freshwater invertebrates (dock shrimp): 24.8 mg/l

Acute/Prolonged toxicity to aquatic plants:

EC50 (72h) for freshwater algae: > 100 mg/l

Toxicity to micro-organisms e.g. bacteria:

EC50 (48h) for daphnia magna (OECD 202): > 100 mg/l

Chronic toxicity to aquatic organisms:

No data available

Toxicity to soil dwelling organisms:

No data available



Toxicity to terrestrial plants:	No effect was observed on the growth of beans (<i>Phaseolus vulgaris</i>) or corn (<i>Zea mays</i>) when bentonite was added at a concentration of 135 g/1.6 kg soil
General effect:	No specific adverse effects known
Further information:	None
Persistence and degradability:	Not relevant for inorganic substances
Bioaccumulative potential:	Not relevant for inorganic substances
Mobility in soil:	Bentonite is almost insoluble and thus presents a low mobility in most soils.
Results of PBT and vPvB assessment:	Not relevant for inorganic substances
Other adverse effects:	No other adverse effects are identified



13 DISPOSAL CONSIDERATIONS

The residues/unused product can be disposed in landfills following national and local regulations. Dispose in such a way to avoid dust generation. Where possible, recycling should be preferred to disposal.

Packaging: No specific requirements. In all cases dust formation from residues in the packaging should be avoided and suitable protection be assured.

14 TRANSPORT INFORMATION

The material is not classified as a dangerous substance and no restrictions apply for land/sea/air transportation. Avoid dust spreading

UN-Number: Not relevant
UN proper shipping name: Not relevant

TRANSPORT HAZARD CLASS(ES)

ADR: Not classified
IMDG: Not classified
ICAO/IATA: Not classified
RID: Not classified

Packing group: Not applicable

Environmental hazards: Not relevant

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

Transport in bulk according to Annex II of: Not regulated
MARPOL73/78 and the IBC Code



SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE

- Authorisations:** Not required
- Restrictions on use:** None
- Other EU regulations:** Bentonite is not a SEVESO substance, not an ozone depleting substance and not a persistent organic pollutant.
- International legislation requirements:** Bentonite is not separately classified by the Occupational Health and Safety Administration (OSHA). The product has not been classified as a human carcinogen by OSHA, the International Agency for Research on Cancer (IARC) and the National Toxicology Program (NTP).

Occupational exposure limits for bentonite and crystalline silica

	OSHA, PEL - TWA (mg/m ³)	ACGIH, TLV - TWA (mg/m ³)	NIOSH, REL - TWA (mg/m ³)
Bentonite			
Respirable Dust	5	3	
Total Dust	15		
Inhalable Dust		10	
Quartz			
Respirable Dust	10/(2+% SiO ₂)	0.05	0.05
Total Dust	30/(2+% SiO ₂)		

Chemical safety assessment: Bentonite is exempted from REACH registration in accordance with Annex V.7. 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 substances. Therefore, in absence of identified hazard, the substance is safe and presents no risk.

Data are based on our latest knowledge but do not constitute a guarantee for any specific product features and do not establish a legally valid contractual relationship.

- Hazard Statements:** Not relevant
- Precautionary Statements:** Not relevant
- Risk Phrases:** Not relevant
- Safety Phrases:** Not relevant

Abbreviations

- | | |
|---|---|
| EC50: median effective concentration | vPvB: very persistent, very bioaccumulative chemical |
| LC50: median lethal concentration | LD50: median lethal dose |
| NOEC: no observable effect concentration | OEL: occupational exposure limit |
| PBT: persistent, bioaccumulative, toxic chemical | PNEC: predicted no-effect concentration |
| STEL: short-term exposure limit | TWA: time weighted average |



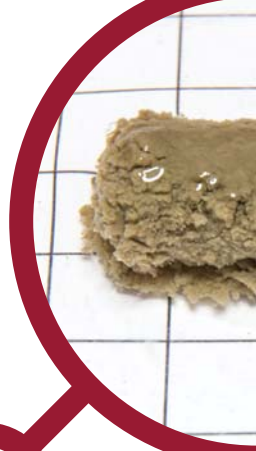
Revision: The Safety Data Sheet is prepared in accordance with Annex II of the REACH Regulation EG 1907/2006, Regulation (EG) 1272/2008 and Regulation (EU) 453/2010.

OTHER RELEVANT INFORMATION

Training: 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.

Social Dialogue on Respirable Crystalline Silica 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, 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. 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.



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