

# PRODUCT SAFETY DATA SHEET

For Bentonite prepared in accordance with Annex II of the REACH Regulation (EC) 1907/2006 as amended by Commission Regulation (EU) 453/2010), and with CLP Regulation (EC) 1272/2008

Version: 11.0/EN

Revision date: March 2015

Printing Date: March 5, 2015

# Kentish Minerals

A division of Macromin Ltd

## 1. IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY/UNDERTAKING

### 1.1 Product identifier

**Substance name:** Bentonite  
**Synonyms:** Bentonite, sodium; Bentonite, calcium; Montmorillonite; Sodium-activated Bentonite.

**Trade names:** KM2, KM2E, KMSW, KM35, KMSR, KMA, KM Ultra Bore

**EC No** 215-108-5  
**CAS No** 1302-78-9

#### ID No of the ECHA classification & labeling inventory

Not applicable. The substance is not hazardous so is not classified and is exempted from REACH registration

#### REACH REGISTRATION No:

Exempted according to Annex V.7 of Regulation (EC) 1907/2006

#### CLP Regulation

Product not classified (as hazardous) so not classified under (EC) 1272/2008 (see Appendix 2)

### 1.2 Relevant identified uses of the substance and uses advised against

#### 1.2.1 Relevant identified uses

Bentonite has a variety of uses including but not exclusively; as a rheology modifier, binding agent, adsorbent, filler, foundry, iron ore agglomeration, drilling, construction – civil engineering, filtration (i.e. oil, wine, beer), pharmaceutical & cosmetics, cat litter, food processing aids and feed additives.

#### 1.2.2 Uses advised against

There are no identified uses advised against.

### 1.2 Details of the supplier of the safety data sheet

Name:	Kentish Minerals a division of Macromin Ltd
Address:	16-18 High St, Westerham, Kent, TN16 1RF
Country:	UK
Phone N°:	+44 1959 564690
Fax N°:	+44 1959 563722
E-mail of competent person responsible for the SDS:	Paul Adams - paul@mkm.co.uk
National contact:	Paul Adams

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## 1.3 Emergency telephone number

European Emergency N°:	112
National centre for Prevention and Treatment of Intoxications N°:	N/A
Emergency telephone at the company	+44 7767 709454
Available outside office hours:	YES
Other comments (e.g. language(s) of the phone service):	English

## 2. HAZARDS IDENTIFICATION

### 2.1. Classification of the substance

#### 2.1.1. Classification according to CLP Regulation (EC) 1272/2008

Not classified

#### 2.1.2. Classification according to Directive 67/548/EEC

Not classified

### 2.2. Label elements

#### 2.2.1. Labeling according to Regulation (EC) 1272/2008 [CLP]

The substance does not require labeling \*according to CLP Regulation (EC) 1272/2008

### 2.3. Other hazards

The substance does not meet the criteria for PBT(Persistent Bioaccumulative and Toxic ) or vPvB (very Persistent, very Bioaccumulative and/or Toxic ) substance according to REACH Regulation (EC) 1907/2006.

Crystalline Silica Quartz, Cristobalite and Tridymite EC 238-878-4, CAS 14808-60-7, at <10% of which the Respirable Crystalline Silica (<7.1µ) is <1% may be present and at this concentration is not classified (as hazardous). See [www.crystallinesilica.eu](http://www.crystallinesilica.eu) for further information.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substances

Bentonite is a naturally occurring mineral classified as UVCB (Variable composition, Complex reaction products or Biological materials) according to REACH & CLP Regulations. While being of Variable Composition, the purity of the product is 100 % w/w. The composition of the substance consists mainly in Smectite (Montmorillonite, CAS: 1318-93-0) together with some other accessory minerals such as quartz, feldspar, mica and calcite.

## 4. FIRST AID MEASURES

### 4.1 Description of first aid measures

#### General advice

No known delayed effects. Consult a physician for all exposures except for minor instances.

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## Following inhalation

No special measure; move source of dust or move person to fresh air. If respiratory irritation persists or breathing becomes difficult seek medical attention immediately.

## Following skin contact

No special measure; wash affected area with soap and plenty of water. If necessary, seek medical advice.

## Following eye contact

No special measure; rinse eyes immediately with plenty of water. If symptoms persist, seek medical advice.

## Following ingestion

No special measure; clean mouth with water and drink afterwards plenty of water. If symptoms persist, seek medical advice.

## **4.2 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.

## **4.3 Indication of any immediate medical attention and special treatment needed**

No need for immediate medical attention; follow the advice given in section 4.1.

## **5. FIREFIGHTING MEASURES**

### **5.1 Extinguishing media**

#### Suitable extinguishing media

The product is not combustible. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

By preference use a dry powder, foam or CO<sub>2</sub> fire extinguisher to extinguish the surrounding fire as the Bentonite becomes very slippery and hard to clean up when wet.

#### Unsuitable extinguishing media

No restriction on the extinguishing media to be used in cases of fire in its vicinity – though it should be noted that Bentonite becomes very slippery when wet.

### **5.2 Special hazards arising from the substance**

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

### **5.3 Advice for fire fighters**

Avoid generation of dust. Use breathing apparatus.

Product on floor when wetted will become slippery and may present a significant slip hazard; wear anti-slip boots Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

## **6. ACCIDENTAL RELEASE MEASURES**

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## 6.1 Personal precautions, protective equipment and emergency procedures

### 6.1.1. For non-emergency personnel

Ensure adequate ventilation.

Keep dust levels to a minimum respect Workplace Exposure Limits (WEL)

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).

Try not to wet, and 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).

Try not to wet and take care of wet product on floor, which presents a slip hazard.

## 6.2 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, or shovel into bags – do not attempt to wash away.

## 6.3 Methods and material for containment and cleaning up

Avoid dust formation; avoid dry sweeping where possible.

Use vacuum suction unit, or shovel into bags.

Do not use water.

## 6.4 Reference to other sections

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

## 7. HANDLING AND STORAGE

### 7.1 Precautions for safe handling

#### Protective measures

Keep dust levels to a minimum and Minimize dust generation.

Respect Workplace Exposure Limits (WEL)

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.

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## Measures to prevent fire

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

## Advice on general occupational hygiene

Keep dust levels to a minimum. Minimize dust generation.  
Keep dry.

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

Minimize airborne dust generation and prevent wind dispersal during loading and unloading. Keep containers closed and store packaged products so as to prevent accidental bursting.  
Keep dry and do not use water for clean up as becomes slippery when wet.

## 7.3 Specific end use(s)

If you require advice on specific uses, please contact your supplier or check the Good Practice Guide referred to in section 16.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### 8.1 Control parameters

#### 8.1.1 Components with occupational exposure limits and/or biological occupational exposure limits requiring monitoring

##### Air limits values:

Maintain personal exposure below occupational exposure limit for inhalable and respirable dust as according to COSHH E40/ 2005 amended Oct 2007 (For data on EU TWA for dust see Appendix 1)

Substance	Description	Inhalable Dust WEL – (Workplace Exposure Limit) 8 hr TWA (Time weighted average)	Respirable Dust WEL – (Workplace Exposure Limit) 8 hr TWA (Time weighted average)
Bentonite	Nuisance dust	10mg/m <sup>3</sup>	4mg/m <sup>3</sup>
Crystalline Silica	Respirable Dust <7.1µ		0.1mg/m <sup>3</sup>

For further information see “The occupational exposure limit for respirable crystalline silica in EU countries given in: <http://www.crystallinesilica.eu/115-what-are-regulatory-measures-taken-eu-member-states>

##### Biological limit values:

None

#### 8.1.2 Recommended monitoring procedures

None

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## 8.1.3 Occupational exposure limits and/or biological limits for air contaminants

Not applicable

## 8.1.4 DNEL/DMEL and PNEC values

Not available

## 8.2 Exposure controls

### 8.2.1 Appropriate engineering controls

Minimize 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 organizational measures e.g. by isolating personnel from dusty areas. Remove and wash soiled clothing

### 8.2.2 Individual protection measures, such as personal protective equipment

Personal Protective Equipment - PPE recommended



#### 8.2.2.1 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.

#### 8.2.2.2 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.

#### 8.2.2.3 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

#### 8.2.2.4 Thermal hazards

The substance does not represent a thermal hazard, thus special consideration is not required.

### 8.2.3 Environmental exposure controls

All ventilation systems should be filtered before discharge to atmosphere.

Avoid releasing to the environment. Contain the spillage.

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## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

Appearance:	Light grey/ yellow or red / brown solid material of varying sizes: Lump, granular or fine powder
Odour:	odourless
Odour threshold:	not applicable
pH:	7.0 - 10.5 (5% solids in water suspension) typically 7.0 - 9.5
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, Method1 of the United Nations, Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, fourth revised edition 2003)
Explosive limits:	non explosive (explosive properties predicted in accordance with Regulation (EC) No 1272/2008, using Appendix 6, screening procedures, specified in the United Nations, Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, fourth revised edition 2003 (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:	2.5 g/cm <sup>3</sup> at 20 °C
Bulk density:	1 – 1.4 g/cm <sup>3</sup>
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 self-ignition temperature below 400 °C (study result, Method 4 of the United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth revised edition, 2003)
Decomposition temperature:	not applicable
Viscosity:	not applicable (solid with a melting point > 450 °C)
Oxidizing properties:	no oxidizing properties predicted from the structure in accordance with Appendix 6 section 6 of the United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth revised edition 2003

### 9.2. Other information

None

## 10. STABILITY AND REACTIVITY

### 10.1. Reactivity

Inert, not reactive.

### 10.2. Chemical stability

Bentonite is chemically stable under normal conditions of use and storage

### 10.3. Possibility of hazardous reactions

No hazardous reactions

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## 10.4. Conditions to avoid

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

None

## 11. TOXICOLOGICAL INFORMATION

### 11.1. Information on toxicological effects

Toxicity endpoints	Outcome of the effects assessment
<b>Acute toxicity</b>	Bentonite is not acutely toxic. Oral LD <sub>50</sub> > 2000 mg/kg bw (OECD 420, rat) Dermal Data not available. Bentonite is almost insoluble and has a low absorption through the skin. Inhalation LC <sub>50</sub> > 5,27 mg/L (OECD 436, rat) Classification for acute toxicity is not warranted.
<b>Irritation / corrosion</b>	Bentonite is not irritating to skin ( <i>in vivo</i> , OECD 404, rabbit). Bentonite is not irritating to eye ( <i>in vivo</i> , 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
<b>Sensitisation</b>	Bentonite is not a skin sensitizer in accordance with the local lymph node assay (OECD 429, mouse) Classification for sensitization is not warranted.
<b>STOT Single exposure</b>	No organ toxicity observed in acute tests
<b>STOT Repeated exposure - Oral</b>	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.



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Toxicity endpoints	Outcome of the effects assessment
<b>STOT Repeated exposure - Inhalation</b>	<p>Animal and <i>in vitro</i> 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 20<sup>th</sup> 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.</p> <p>With regards to classification and labeling 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.</p> <p>Therefore, classification of Bentonite for toxicity upon prolonged exposure by</p>
<b>Aspiration hazard</b>	No aspiration hazard envisaged
<b>Mutagenicity</b>	<i>In vitro tests (OECD 471, 473 and 476) negative</i>
<b>Carcinogenicity</b>	<p>No data available.</p> <p>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.</p> <p>Therefore classification of Bentonite for carcinogenicity is not warranted.</p>
<b>Toxicity for reproduction</b>	<p>Two developmental studies are available:  <u>Abdel-Wahhab et al (1999)</u>            Bentonite had no effect on maternal and fetal parameters at a dietary level of 0.5% w/w (equivalent to 250 mg/kg bw).  <u>Wiles et al (2004)</u>            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.</p>

## 12. ECOLOGICAL INFORMATION

### 12.1. Toxicity

#### 12.1.1. Acute/Prolonged toxicity to fish

LC<sub>50</sub> (96h) for freshwater fish (rainbow trout): 16000 mg/l

LC<sub>50</sub> (24h) for marine water fish (black bass, warmouth bass, blue gill and sunfish): 2800-3200 mg/l

#### 12.1.2. Acute/Prolonged toxicity to aquatic invertebrates

EC<sub>50</sub> (96h) for freshwater invertebrates (Dungeness crab): 81.6 mg/l

EC<sub>50</sub> (96h) for freshwater invertebrates (dock shrimp): 24.8 mg/l

LC<sub>50</sub> (24h) for *C. dubia* and *H. limbata*: >500 mg/L

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## 12.1.3. Acute/Prolonged toxicity to aquatic plants

EC<sub>50</sub> (72h) for freshwater algae: > 100 mg/l

## 12.1.4. Toxicity to micro-organisms e.g. bacteria

EC<sub>50</sub> (48h) for daphnia magna (OECD 202): > 100 mg/l

## 12.1.5. Chronic toxicity to aquatic organisms

No data available

## 12.1.6. Toxicity to soil dwelling organisms

No data available

## 12.1.7. Toxicity to terrestrial plants

No effect was observed on the growth of beans (*Phaseolus vulgaris*) or corn (*Zea mays*) when Bentonite was added at a concentration of 135 g/1.6 kg soil

## 12.1.8. General effect

No specific adverse effects known

## 12.1.9. Further information

None

## 12.2. Persistence and degradability

Not relevant for inorganic substances

## 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.

## 12.5. Results of PBT and vPvB assessment

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

## 12.6. Other adverse effects

No other adverse effects are identified. According to the criteria of the European classification and labeling system, the substance does not require classification as hazardous for the environment.

## 13. DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

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

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## Packaging disposal

No specific requirements. In all cases dust formation from residues in the packaging should be avoided and suitable protection be assured. Empty containers, -dispose of as unused product. The empty and clean containers are to be reused in conformity with regulations.

## 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

## 15. REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/legislation specific for the substance

Other EU regulations: Bentonite is not a SEVESO substance (*SEVESO III is the latest EU legislation that deals specifically with the control of on-shore major accident hazards involving dangerous substances*), it is not an ozone depleting substance and not a persistent organic pollutant.

National regulations: EH / COSH limits for Workplace Exposure Limits (WEL)

International legislation requirements:

The product (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).

### 15.2. 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 substance. Therefore, in absence of identified hazard, the substance is safe and presents no risk.

## 16. OTHER INFORMATION

Depending on the handling and use (grinding, drying, bagging), airborne respirable dust may be generated. Dust contains respirable crystalline silica. 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. 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.

The product contains less than 1% w/w RCS (respirable crystalline silica) as determined by the SWERF method. The respirable crystalline silica content can be measured using the "Size-Weighted Respirable Fraction – SWERF" method. All details about the SWERF method is available at [www.crystallinesilica.eu](http://www.crystallinesilica.eu)

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.

### 16.1. Indication of changes

See Section 16.5 below

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## 16.2. Abbreviations and acronyms

ACGIH =	American Conference of Industrial Hygienists
DMEL =	Derived maximum effect level
DNEL =	Derived no effect level
EC50 =	Median effect concentration
EU =	European Union
EWC =	European waste catalogue
IARC =	International agency for Research on Cancer
LC50 =	Median lethal concentration
LD50 =	Medial lethal dose
NIOSH =	National Institute of Occupational Safety & Health
OECD =	Organisation for Economic Co-operation and Development
OEL =	Occupational exposure level
OSHA =	Occupational Safety and Health Administration
PBT =	Persistent bioaccumulative toxic
PEL =	Permissible exposure limit
PNEC =	Predicted no effect level
REL =	Recommended exposure limit
SCOEL =	Scientific Committee on Occupational Exposure Limits
SDS =	Safety data sheet
STOT =	Specific target organ toxicity
STOT RE=	Specific target organ toxicity upon repeated exposure
TLV =	Threshold limit value
TWA =	Time-Weighted Average
vPvB	Very persistent very bioaccumulative

## 16.3. Key literature references and sources for data

For any information on literature references or toxicity and ecotoxicity studies, please contact Kentish Minerals

## 16.4. Relevant R-phrases and/or H-statements

Not relevant as Bentonite is not classified under REACH or CLP

## 16.5. Revision

Based on new available information, sections 11 & 12 have been amended.

Other minor changes (mainly format) have been made to comply with the ECHA Guidance on "How to compile a SDS" (September 2011)

## 16.6. Training advice and 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.
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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.

Based on its evaluation in 2011, the International Agency for Research on Cancer (IARC) concluded that crystalline silica inhaled from occupational sources is a carcinogen category 1

In June 2003, the EU Scientific Committee on Occupational Exposure Limits (SCOEL) 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 below).

## Disclaimer

This safety data sheet (SDS) is based on the legal provisions of the REACH Regulation (EC 1907/2006; article 31 and Annex II), as amended. 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. It should not be construed as any guarantee of technical performance, suitability for particular applications, and does not establish a legally valid contractual relationship. This version of the SDS supersedes all previous versions.

# PRODUCT SAFETY DATA SHEET

For Bentonite prepared in accordance with Annex II of the REACH Regulation (EC) 1907/2006 as amended by Commission Regulation (EU) 453/2010), and with CLP Regulation (EC) 1272/2008

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## Appendix 1

Occupational Exposure Limits in mg/m <sup>3</sup> 8 hours TWA dust		
Member State	Non specified (inert) dust INHALABLE	Non specified (inert) dust RESPIRABLE
Austria	15	6
Belgium	10	3
Bulgaria		4
Denmark	10	5
Finland	10	/
France	10	5
Germany	10	3
Greece	10	5
Ireland	10	4
Italy	10	3
Lithuania		10
Luxembourg	10	6
Netherlands	10	5
Norway	10	5
Portugal/	10	5
Romania		10
Slovakia	10	
Spain	10	3
Sweden		5
Switzerland		6
UK	10	4

## Appendix 2

### CLP Regulation (EC No 1272/2008 incorporating the “Globally Harmonised System (GHS) of Classification and labelling of Chemicals”

Parameter 1 of the GHS states that “The GHS covers all **hazardous** chemicals. The mode of application of the hazard communication elements of the GHS (e.g. labels, safety data sheets) may vary by product category or stage in the life cycle. Target audiences for the GHS include consumers, workers, transport workers, and emergency responders. “