LAVIOTHIX P100

Safety Data Sheet in compliance with REACH title IV / annex 2 and ISO 11014 format

LAVIOTHIX P100

Version: 4
Emission date: November 2012

Section 1 - Identification of the Substance / Compound and Identification of the Company

1.1 – Identification of the Substance / Compound

Substance name : Bentonite

Chemical name / Synonyms: Bentonite, sodian; Bentonite, calcian; Montmorillonite; Sodium-activated bentonite

Trade name: LAVIOTHIX P100

Registration number: The substance is not classified and is exempted from REACH registration

EC No 215-108-5

CAS No 1302-78-9

ID No of the ECHA classification & labelling inventory: Not applicable. The substance is not classified and is exempted from REACH registration

REACH REGISTRATION No: Exempted according to Annex V.7 of Regulation (EC) 1907/2006

1.2 – Use of the substance / compound

Bentonite is used in the following industrial fields:

- Food & feed additives in human and animal nutrition
- environment
- paper
- ceramic
- detergency
- construction
- oenology
- pharmaceuticals and cosmetics
- filtration (e.g. oil, beer, wine)
- foundry
- geotechnics
- civil engineering
- cat litter
- drilling
- paints and varnishes
- plastic
- water treatment

1.3 – Company identification

LAVIOSA CHIMICA MINERARIA S.p.a.
Via Leonardo da Vinci, 21 – 57123 Livorno, ITALY
Tel: +39-0586-434000
Fax: +39-0586-425301
E-mail: lcm@laviosa.com
Website: www.laviosa.com
E-mail of responsible person for SDS in EU: andrea.biasci@laviosa.com

1.4 – Emergency telephone number: tel .+39 0586 434175 cell. +39 335 314779

Section 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. Labelling according to Regulation (EC) 1272/2008 [CLP]: The substance is not labelled according to CLP Regulation (EC) 1272/2008

2.3 Other Hazards

The substance does not meet the criteria for PBT or vPvB substance according to REACH Regulation (EC) 1907/2006.
The product does give potential for generation of breathable dust during handling and use.
Dust may contain breathable crystalline silica. Prolonged and or massive inhalation of breathable crystalline silica dust may cause lung fibrosis, commonly referred to as silicosis. Principal symptoms of lung fibrosis are cough and breathlessness.
Occupational exposure to breathable dust and breathable crystalline silica should be monitored and controlled.

Section 3 – Composition / Information on Ingredients

3.1 Substances

Bentonite is a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB) according to REACH & CLP Regulations. The purity of the product is 100 % w/w. The composition of the substance consists mainly in smectite (CAS: 1318-93-0) together with some other accessory minerals.

Section 4 – First aid measures

No actions to be avoided, no special instructions for rescuers.

Following skin contact: no special measure

Following e contact: no special measure; wash with copious quantities of water and consult medical physician if necessary.

Following inhalation: no special measure

Following ingestion: no special first aid measures

Section 5 – Fire-fighting measures

Not flammable, not explosive. No hazardous releases in case of fire

Section 6 – Accidental release measures

Personal precautions: in case of exposure to prolonged or high level of airborne dust, wear a personal respirator in compliance with national legislation.

Environmental precautions: no special requirements.

Methods for cleaning up: avoid dry sweeping and use water spraying or ventilated vacuum system to prevent dust formation.
Wet bentonite could be slippery.

Section 7 – Handling and Storage

7.1 – Precautions for safe handling

Minimize dust generation.

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

7.2 – Storage

Technical measures / Precautions
No specific requirements. Provide appropriate ventilation and store bags such as to prevent any accidental damage. Prevent clay becoming wet.

7.3 – Specific end use(s)

No special technical measures or precautions. Apply above handling advice when mixing with other substances.

Section 8 – Exposure controls / Personal protection

8.1 – Exposure limit values

Exposure limit value for dust (inhalable fraction): 3 mg/m^3
Exposure limit value for dust (breathable fraction): 10 mg/m^3

Respect regulatory provisions for dust and for breathable crystalline silica dust. Please refer to the annex 1 at the end of section 16 for the appropriate national exposure limit values.

8.2 – Exposure controls

8.2.1 – Occupational exposure controls

Provide appropriate exhaust ventilation and filtering at the places where dust can be generated. Wash hands before breaks and at the end of the workday. Remove and wash soiled clothing.

- Respiratory protection: in case of prolonged exposure to dust, wear a personal respirator in compliance with national legislation (make reference to the appropriate CEN standard)

8.2.2 – Environmental exposure controls

No special requirements.

Section 9 – Physical and chemical properties	
9.1 – General information	
Physical state	bulk, powder, lump, pellets, spray dried, or slurry
Colour	Variable from white to grey, green, yellow, red, brown.
Odour	Odourless
9.2 – Important health, safety and environmental information	
Bulk density	0,9 – 1,4 g/ml
Relative density	2,6 g/cm3 at 20℃
Melting point	> 450℃ (study result, EU A.1 method)
Flash point	Not applicable (solid with a melting point > 450 ℃)
Evaporation rate	Not applicable (solid with a melting point > 450 ℃)
Boiling point	Not applicable (solid with a melting point > 450 ℃)
Explosive limits	Not 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)
Solubility in water	< 0,9 mg/l at20 ℃ (study resul ts, EU A.6 method)
Decomposition temperature	Not applicable
Auto ignition temperature	Not applicable
Oxidising properties	No oxidising 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

Section 10 – Stability and Reactivity
Chemically stable, no particular incompatibility, no hazardous decomposition product.

Section 11 – Toxicological information
Acute toxicity Bentonite is not acutely toxic. Oral LD_{50} > 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_{50} > 5,27 mg/L (OECD 436, rat) 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

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

Classification for sensitisation is not warranted

STOT Single exposure

No organ toxicity observed in acute tests

STOT Repeated exposure - Oral

Short-term repeated dose toxicity study (28 days) and sub-chronic toxicity study (90 day) on mices 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 disrupture of digestion.
Therefore, classification of bentonite for toxicity upon prolonged exposure by oral route is not warranted.

STOT Repeated exposure – 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

No aspiration hazard envisaged

Mutagenicity

In vitro tests (OECD 471, 473 and 476) negative

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.

Therefore classification of bentonite 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.

Section 12 – Ecological information

12.1 Toxicity

12.1.1. Acute/Prolonged toxicity to fish
LC_{50} (96h) for freshwater fish (rainbow trout): 16000 mg/l

LC_{50} (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_{50} (96h) for freshwater invertebrates (Dungeness crab): 81.6 mg/l

EC_{50} (96h) for freshwater invertebrates (dock shrimp): 24.8 mg/l
LC_{50} (24h) for C. dubia and H. limbata: >500 mg/L

12.1.3 Acute/Prolonged toxicity to aquatic plants

EC_{50} (72h) for freshwater algae: > 100 mg/l

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

EC_{50} (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

12.2 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 labelling system, the substance does not require classification as hazardous for the environment.

Section 13 – Disposal considerations

13.1 Waste from residues / unused products

Can be land filled in compliance with local regulations. The material should be buried to prevent airborne breathable dust being emitted. Where possible, recycling should be preferred to disposal.

13.2 Packaging

No specific requirements. In all cases dust formation from residues in the packaging should be avoided and suitable worker protection be assured. Recycling and disposal of packaging should be carried out by a suitable waste management company

Section 14 – Transport information

No special precaution required under the regulation on transport of dangerous goods. Avoid dust spreading

Section 15 – Regulatory information

Other EU regulations: Bentonite is not a SEVESO substance, not an ozone depleting substance and not a persistent organic pollutant.

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). Il prodotto (bentonite) non è separatamente classificati per la salute e la Safety Administration (OSHA). Il prodotto non è stato classificato come cancerogeno per l'uomo da OSHA, l'Agenzia Internazionale per la Ricerca sul Cancro (IARC) e il National Toxicology Program (NTP).

Section 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

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

Occupational Exposure Limits in mg/m^3 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**