DantoPlug



Version: 1.0/EN

Revision date: 15 December / 2010 Printing Date: September 12, 2011

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

1.1 Product identifier

Product name: DantoPlug

REACH Registration number: Exempted in accordance with Annex V.7

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

Identified use: Construction and civil engineering Uses advised against: There are no uses advised against.

1.3 Details of the supplier of the safety data sheet

Name: Dantonit A/S Address: Energivej 30

DK 5260 Odense S

Phone N°. +45 65973263 Fax N°. +45 65973264 E-mail: joh@dantonit.dk

1.4 Emergency telephone number

European Emergency N°. 112

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance

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 according to Regulation (EC) 1272/2008

Not classified. The product does not meet the criteria for hazardous substances.

Classification according to Directive 67/548/EEC

Not classified. The substance does not meet the criteria for dangerous substances.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008

No labelling requirements according to Regulation (EC) 1272/2008





Labelling according to Directive 67/548/EEC

No labelling requirements according to Directive 67/548/EEC

2.3 Other hazards

The substance does not meet the criteria for PBT or vPvB substance.

No other hazards identified.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance

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%

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.

Following inhalation

No special measure; move source of dust or move person to fresh air. Obtain 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.

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.

4.3 Indication of any immediate medical attention and special treatment needed

DantoPlug



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

5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

The product is not combustible. Use a dry water, powder, foam or CO2 fire extinguisher to extinguish the surrounding fire. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. No restriction on the extinguishing media to be used in cases of fire in its vicinity.

5.2 Special hazards arising from the substance or mixture

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 hazard; wear anti-slip boots Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

6. ACCIDENTAL RELEASE MEASURES

6.1 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.

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

6.3 Methods and material for containment and cleaning up

Avoid dust formation; avoid dry sweeping

Use vacuum suction unit, or shovel into bags.

6.4 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.





7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Protective measures

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.

7.2 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.

7.3 Specific end use

Intended for use in construction and civil engineering.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

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

8.2 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.

Individual protection measures, such as 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.

Environmental exposure controls

All ventilation systems should be filtered before discharge to atmosphere.

Avoid releasing to the environment. Contain the spillage.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Light grey/greenish Lumps

Odour: odourless
Odour threshold: not applicable

pH: 9.0 - 10.5 (5% solids in water suspension) Melting point: > 450 $^{\circ}$ C (study result, EU A.1 method)

Boiling point: not applicable (solid with a melting point > 450 $^{\circ}$ C) Flash point: not applicable (solid with a melting point > 450 $^{\circ}$ C) Evaporation rate: not applicable (solid with a melting point > 450 $^{\circ}$ 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 $^{\circ}$ C)

Vapour density: not applicable Relative density: 2.0- 2,5 g/cm³ Bulk density: 1 - 1.4 g/cm³

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 ℃ (study result, EU

A.16 method) not applicable

Decomposition temperature: Viscosity:

not applicable (solid with a melting point > 450 ℃)

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)

9.2 Other information

Not available

10. STABILITY AND REACTIVITY

Reactivity

Inert, not reactive.





Chemical stability

Bentonite is chemically stable

Possibility of hazardous reactions

No hazardous reaction

Conditions to avoid

Minimise exposure to air Slippery when wet

Incompatible materials

Avoid storing together with materials that may be affected by dust

Hazardous decomposition products

None.

11. TOXICOLOGICAL INFORMATION

11.1 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)

Toxicity endpoints	Outcome of the effects assessment:		
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 $LD_{50} > 2000$ 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 a 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 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.

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.

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.

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

12.1 Toxicity

Acute/Prolonged toxicity to fish

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

 EC_{50} (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 (Phaseolus vulgaris) or corn (Zea mays) when bentonite was added at a concentration of 135 g/1.6 kg soil

General effect

No specific adverse effects known

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

Not relevant for inorganic substances

12.6 Other adverse effects

No other adverse effects are identified

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

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.

<u>Packaging:</u> 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

14.1 UN-Number

Not relevant

14.2 UN proper shipping name

Not relevant

14.3 Transport hazard class(es)

ADR: Not classified

IMDG: Not classified

ICAO/IATA: Not classified

RID: Not classified

14.4 Packing group

Not applicable





14.5 Environmental hazards

Not relevant

14.6 Special precautions for user

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

■ 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not regulated.

15. REGULATORY INFORMATION

15.1 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).

Table 1: 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+% SiO2)	0,05	0,05
Total dust	30/(2+% SiO2)		

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





16. OTHER INFORMATION

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

 EC_{50} : median effective concentration LC_{50} : 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

vPvB: very persistent, very bioaccumulative chemical

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 silicacontaining dust may cause silicosis, a nodular pulmonary fibrosis caused by deposition in the lungs of fine respirable particles of crystalline silica.

Iln 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.

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.