PRODUCT SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006,
Regulation (EC) No. 1272/2008 and Regulation (EU) 2020/878

KERAMOST akciová společnost	PRODUCT NAME: **Activated bentonite with addition of carbon**	ISO 9001 ISO 14001 ISO 45001 CERTIFIED ZÚS 792/2022

Date of publication:	December 1, 2008	**Date of printing:**	December 23, 2022	**Date of revision:**	November 21, 2022

SECTION 1: IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY

1.1 Product identifier: Soda activated bentonite with addition of carbon.
CAS number: 1302-78-9
EG number (EINECS): 215-108-5
REACH Registration number: Exempted in accordance with Annex V.7

1.2 Relevant identified uses of the substance or mixture:
Bentonite can be used as a rheology modifier, binding agent, adsorbent and filler for foundry industry.
Uses advised against:
There are no uses advised against.

1.3 Details of the supplier of the safety data sheet:

Name:	KERAMOST, a.s.
Address:	Žatecká 1899/25, 434 30 Most, CZ
Identification number:	49901222
Phone:	+420 476 442 511
Fax:	+420 476 704 405
E-mail:	reach@keramost.cz

1.4 Emergency telephone number:
Toxicology information centre (TIC) +420 224 919 293, +420 224 915 402 (non-stop)

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:
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.

Regulation EC 1907/2006 (REACH)	Not classified – is not hazardous substance.
Regulation EC 1272/2008 (CLP)	Doesn’t meet the criteria for classification.
Directive 67/548/EEC	It is not classified as a dangerous substance or mixture.

2.2 Label elements: Not applicable – not required.

2.3 Other hazards:
Inorganic material of natural origin. The substance does not meet the criteria for PBT or vPvB substance. No other hazards identified. Bentonite is not known to have an adverse effect on the endocrine system in accordance with the criteria stated within Regulation (EU) 2017/2100 or Regulation (EU) 2018/605.

SECTION 3: COMPOSITION / INFORMATION ON ENGREDIENTS

3.1 Substances:
Bentonite is a UVCB substance sub-type 4 (substances of Unknown or Variable composition, Complex reaction products or Biological materials). Mineral clay containing montmorillonite.

The substance / mixture is not classified according to Regulation (EC) 1272/2008. There is no multiplication coefficient (M-factor) or specific concentration limit (SCL).

CAS number:	1302-78-9
EG number (EINECS):	215-108-5

3.2 General component: Montmorillonite

CAS number:	1318-93-0
EG number (EINECS):	215-288-5
Content (%)	65 - 80 %

3.3 Additional component:

	Sodium carbonate, Na_2CO_3	Carbon, C
CAS number:	497-19-8	7440-44-0
EG number (EINECS):	207-838-8	231-153-3
Content (%):	Max. 4	12 – 50
Hazard symbol:	GHS07 - Harmful	-
Risk and safety phrases, GHS statement:	H319 – Causes serious eye irritation	-

SECTION 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.

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:
If health problems occur or in case of doubts, seek medical help and provide information contained in this safety data sheet.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:
Suitable extinguishing media: No restrictions. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media: No restrictions.

5.2 Special hazards arising from the substance or mixture:
The material is not flammable and does not support fire. Incomplete combustion involves the generation of carbon monoxide.

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.

SECTION 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 inhalation of dust and contact with skin, eyes, and clothing – wear suitable protective equipment (see section 8). Take care of wet product on floor, which presents a slip hazard.

6.2 Environmental precaution:
No special requirement.

6.3 Methods and material for containment and cleaning up:

Avoid dust formation (avoid dry sweeping). Remove mechanically dust free (use vacuum suction unit, or shovel into bags) and wash down the surface with water.

6.4 Reference to other sections:

For more information please check sections 7, 8 and 13 of this safety data sheet.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

Protective measures:

Avoid dust generation and contact with eyes. Provide appropriate exhaust ventilation or wear suitable respiratory protective equipment at places where airborne dust is generated. The composition of the mixture ensures the explosion-proofing and incombustibility. Handle packaged products carefully to prevent accidental bursting.

Advice on general occupational hygiene:

Regular cleaning with suitable cleaning devices. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. No drinking, eating and smoking at the workplace.

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. Storage in dry storehouse or shed without direct attack of climatic influence.

7.3 Specific end use(s):

Not relevant.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters:

According to Government regulation No. 361/2007, and Government regulation No. 93/2012.

Permissible exposure limit (8 hours TWA)	PELr (respirable fraction)	PELt (total amount)
Quartz	0,1 mg/m^3	---
Bentonite	---	6 mg/m^3

8.1.1 Components with occupational exposure limit values:

a) Exposure limit values in the air:

The binding European occupational exposure limit for respirable crystalline quartz dust is set at 0.1 mg / m^3 by Directive (EU) 2017/2398. Observe occupational exposure below the limit value for all types of airborne dust (e.g. respirable dust, fine dust, fine quartz dust, fine cristobalite dust) as required by national regulations. Contact the responsible hygienist or local regulatory authority to check the applicable national limits.

Permissible dust exposure limits (8 hours TWA) in mg/m^3	Unspecified (inert) dust INHALABLE	Unspecified (inert) dust RESPIRABLE
Austria	10	5
Belgium	10	3
Bulgaria		4
Denmark	10	5
Finland	10	/
France	10	5
Germany	10	0,5 *
Greece	10	5
Ireland	10	4
Italy	10	3
Lithuania		10
Luxembourg	10	6
Holland	10	5
Norway	10	5
Poland	10	/
Portugal	10	5
Romania		10
Slovakia	10	
Spain	10	3

Permissible dust exposure limits (8 hours TWA) in mg/m³	Unspecified (inert) dust INHALABLE	Unspecified (inert) dust RESPIRABLE
Sweden	5	2,5
Switzerland		6
Great Britain	10	4

∗ *Defined for a density of 1 g/cm³, i.e. for minerals with a common density of 2,5 g/cm³, a calculated OEL of 1,25 mg/m³ applies.*

Further information on national exposure limit values:
https://www.nepsi.eu/sites/nepsi.eu/files/content/document/file/oel_full_table_january_2021_europe.pdf

b) Biological limit values: None

8.1.2 Appropriate technical control: None

8.1.3 Exposure limit values and / or biological limit values for contaminated air: Not available

8.1.4 Values of DNEL/DMEL and PNEC: 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, 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:
Eye / face protection:
Do not wear contact lenses. If there is an increased risk of eyes contact, use tight fitting goggles with side shields. Ensure accessibility of eyewash equipment and safety showers close to the work place.
Skin and hands protection:
Wear suitable work clothes with long sleeves, gloves. At the end of each work session wash skin with soap and water. Eventually use a greasy cream – the material dries the skin.
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 - Category 2 or 3 (FP2 - FP3). See EN 143:2000 - Respiratory protective equipment.

8.2.3 Environmental exposure controls:
All ventilation systems should be filtered before discharge to atmosphere. Avoid releasing to the environment. Ensure that spilled material is removed.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

Appearance (at 20 ˚C): Solid state – as a fine powder or granular.
Color: Grey, Greyish black.
Odour: No specific odour.
pH value: 9 – 10
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: Hardly inflammable.
Auto ignition temperature: No relative self-ignition temperature below 400 ˚C (study result, EU A.16 method).
Decomposition temperature: Incomplete combustion involves the generation of carbon monoxide (over 300°C without access of air).

Explosive limits:
Non explosive (void of any chemical structures commonly associated with explosive properties).
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).
Vapour pressure: Not applicable (solid with a melting point > 450 ˚C).

Vapour density:	Not applicable.
Relative density:	2,6 g/cm^3
Viscosity:	Not applicable (solid with a melting point > 450 ˚C).

9.2 Other information:

Solubility:	
- in water	Bentonite compound makes a suspension.
- in grease	Not known.
Distributing coefficient n-octanol/water:	Not known.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:	Inert and not reactive material.
10.2 Chemical stability:	The substance is stable under normal conditions.
10.3 Possibility of hazardous reactions:	Not known.
10.4 Conditions to avoid:	Slippery when wet. Minimise exposure to air and dust generation. Infusion with possibility of temperature rise over 300°C.
10.5 Incompatible materials:	Not reactive. Avoid storing together with materials that may be affected by dust.
10.6 Hazardous decomposition products:	Incomplete combustion involves the generation of carbon monoxide (over 300°C without access of air).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:

a) Acute toxicity:
Oral – LD_{50} > 2000 mg/kg bw (OECD 425, rat).
Dermal – No data available. Bentonite is almost insoluble and has a low absorption through the skin.
Inhalation – LC_{50} > 5,27 mg/L (OECD 436, rat).
Bentonite is not considered as harmful. Classification for acute toxicity is not warranted.

b) Skin corrosion/irritation:
Bentonite is not irritating to skin (OECD 404, rabbit).

c) Serious eye damage / irritation:
Bentonite is not irritating to eye (OECD 405, rabbit). Slightly irritating to the eyes (according to modified Kay and Calandra criteria).

d) Respiratory or skin sensitization:
No adverse effects were observed in accordance with the local lymph node test (OECD 429, mouse).

e) Germ cell mutagenicity:
Negative according to tests in mammalian cells - chrom abb, micronucleus assay (OECD 471, 473 and 476).

f) Carcinogenicity:
Based on the available tests, bentonite was assessed as non-carcinogenic. Classification for carcinogenicity is not warranted (IARC - sepiolite comparison).

g) Toxicity for reproduction:
The studies did not reveal any effects on maternity / fetus according to studies (Abdel-Wahhab et al 1999; Wiles et al 2004).

h) STOT – single exposure:
Classification criteria are not met according to the available tests.

i) STOT – repeated exposure:
According to available tests, the criteria for classification are not met.

j) Aspiration hazard:
Classification criteria are not met according to available information.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity:

12.1.1 Toxicity to fish:
LC_{50} (96 h) for freshwater fish (rainbow trout): 16000 mg/l.
LC_{50} (24 h) for marine water fish (black bass): 2800 - 3200 mg/l.

12.1.2 Toxicity to aquatic invertebrates:
EC_{50} (96 h) for freshwater invertebrates: Dungeness crab – 81,6 mg/l, Dock shrimp - 24,8 mg/l.
LC_{50} (24 h) for C. dubia and H. limbata: > 500 mg/l.

12.1.3 Toxicity to aquatic plants:
EC_{50} (72 h) for freshwater algae > 100 mg/l.
12.1.4 Toxicity to micro-organisms:
EC_{50} (48 h) 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 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.

12.2 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:	Bentonite doesn't meet the classification criteria for persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances.
12.6 Endocrine disrupting properties:	Adverse effects are not known.
12.7 Other adverse effects:	No other adverse effects are identified.

SECTION 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.
Substance / preparation disposal:
Storage category 0.
Contaminated packing disposal:
Secondary utilization, storing, incineration. In all cases dust formation from residues in the packaging should be avoided and suitable protection be assured.

SECTION 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, IMDG, ICAO/IATA, RID – Not classified. Bentonite is not hazardous in the sense of transport regulations. Material is not explosive. Transport in usual covered transport means protected against climatic influences.

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. Other safety measures according to Section 6 and 8.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code:
Not regulated.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations / legislation specific for the substance:
Bentonite is not hazardous substance. Bentonite is not a SEVESO substance, not ozone depleting substance and not a persistent organic pollutant. Bentonite is not classified according to any Directives or Regulations of the European Union, or local law and has no restrictions on use. 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 substances. Therefore, in absence of identified hazard, the substance is safe and presents no risk.

According to European Bentonite Producers Association (EUBA), based on summary studies, the substance Bentonite does not meet the criteria for hazardous substances and the warranted classification is "not classified" as none of the hazard criteria for physico-chemical properties, human health or environment are met. Alkali activation is a method to enrich bentonite with sodium cations - the resulting bentonite being the same substance. Sodium-activated bentonite should therefore be considered as a not chemically modified substance, namely 'a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities'. Activation does not alter the crystal structure of the separate smectite layers. It changes only the stacking of the successive layers, which, in any case, is not a constant structural parameter and is largely dependent on many factors, such as the water content of smectite. Therefore, sodium exchange induced by activation, should not be considered a structural change of smectite and hence the bentonite. Na+ and Ca+ are not part of the "structure" of bentonite as they are loosely bound in between the smectite platelets, modifying the surface electrical charge of them. Given the above, treatment of bentonite by sodium activation results in no change in its chemical structure and, therefore, sodium activated should be considered as identical to natural one.

SECTION 16: OTHER INFORMATION

16.1 Information about revision of safety data sheet:

Changes in terminology and requirements according to Regulation (EU) 2020/878 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council.

16.2 Disclaimer:

The data herein correspond to the present state of knowledge and experience and they are in conformity with valid legal enactments. They are not however comprehensive. When mixing with other products, it is to control whether further health and safety risks cannot occur. This safety data sheet does not represent a guarantee of product's properties. 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. This version of the SDS supersedes all previous versions.

16.3 Abbreviations:

ADR – European Agreement concerning the International Carriage of Dangerous Goods by Road
CLP – Regulation of European parliament and Council for Classification, Labeling and Packaging of chemicals
EC_{50} – Median Effective Concentration
EUBA – European Bentonite Producers Association
GHS – Globally Harmonized System of Classification and Labeling of Chemicals
IARC – International Agency for Research on Cancer
IBC – International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
ICAO/IATA – International Civil Aviation Organization / International Air Transport Association
IMDG – International Maritime Dangerous Goods Code
LD_{50} – Median Lethal Dose
NTP – National Toxicology Program
OECD – Organisation for Economic Co-operation and Development (test methods)
OSHA – Occupational Health and Safety Administration
PBT – Persistent, Bioaccumulative and Toxic substances
PELt – Permissible Exposure Limit, total amount
PELr – Permissible Exposure Limit, respirable fraction
REACH – EU Regulation about Registration, Evaluation, Authorisation and Restriction of Chemicals
RID – Regulations Concerning the International Carriage of Dangerous Goods by Rail
SEVESO – Council Directive on the control of major-accident hazards involving dangerous substances
STOT – Specific Target Organ Toxicity
SWERF – Size-Weighted Respirable Fraction
TWA – Time-Weighted Average

UN – Numbers that identify hazardous substances, and dangerous articles in the framework of international transport.
UVCB – Substances of Unknown or Variable composition, Complex reaction products or Biological materials
vPvB – very Persistent and very Bioaccumulative substances