essedielle srl
Loc. Macinini Fraz. Caldari
66026 Ortona (CH)
Num. REA CH-72915
P.IVA e CF: 00639090695
Codice Univoco SUBM70N
Capitale Sociale € 100.000,00

SAFETY DATA SHEET

BENTGEL

Revision No. 6, October 2023; Complies with Reg (EU) 2020/878

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE MANIFACTURING COMPANY

1.1 Product identification
Chemical name: Sodium bentonite; calcic bentonite; montmorillonite; activated sodium bentonite
Trade names and synonyms: Bentgel
CAS Number: 1302-78-9
EC Number: 215-108-5
REACH number: substance is not classified and is not subject to REACH registration

1.2 Relevant identified uses of the substance/mixture and uses not recommended
Bentonite is used in the following industrial fields:

- food additive in human and animal nutrition
- environment
- paper
- ceramics
- detergency
- construction
- oenology
- pharmaceutical and cosmetics
- filtration (e.g., oil, beer, wine)
- foundry
- geotechnics
- civil engineering
- cat litter
- drilling
- paints and varnishes
- plastics
- water treatment

1.3 Information about the supplier of the safety data sheet
essedielle srl
S.P. 538 km. 6,950 - CALDARI
66026 ORTONA (CH)
ITALY
Phone: +39 (0) 85 9031315
Qualified persons responsible for the safety data sheet: laboratorio@essedielle.com

1.4 Emergency telephone number: essedielle srl +39 (0) 85 9031315 – 0039 3668134126
Poison Control Center
S.S. Annunziata Hospital – Chieti +39 0871 1551219

2. HAZARD IDENTIFICATION

2.1 Classification of the substance or mixture
Criteria EC Regulation 1272/2008 (CLP): not classified

2.2 Label elements
Labeling according to Regulation (EC) 1272/2008 [CLP]: the substance does not have to be labeled according to CLP Regulation (EC) 1272/2008
Symbols: none
Hazard statements:
H315 Causes skin irritation.

H319 Causes severe eye irritation.
Cautionary Statements:
P264 Wash hands thoroughly after use.
P280 Wear protective gloves/protective clothing/eye/face protection.
P302+P352 IF ON SKIN: Wash thoroughly with water. P305+P351+P338 IF EYE CONTACT: rinse thoroughly for several minutes. Remove any contact lenses if it is convenient to do so. Continue to rinse.
P337+P313 If eye irritation persists, seek medical attention.
P332+P313 If skin irritation occurs seek medical attention.
Special provisions: none
Special provisions according to Annex XVII of REACH and subsequent adaptations: none

2.3 Other hazards
The substance does not meet the criteria for PBT or vPvB classification according to REACH Regulation (EC) 1907/2006.
During handling and use, the product can potentially generate respirable dust.
The dust may contain respirable crystalline silica.
Prolonged or massive inhalation of respirable crystalline silica may cause pulmonary fibrosis, commonly referred to as silicosis.
The main symptoms of pulmonary fibrosis are coughing and difficulty breathing.
Occupational exposure of respirable dust and respirable crystalline silica should be monitored and controlled.

3. COMPOSITION/INGREDIENT INFORMATION

3.1 Substances
Chemical name: sodium bentonite; calcic bentonite; montmorillonite; activated sodium bentonite
Trade names and synonyms: Sodium bentonite
CAS Number: 1302-78-9
EC Number: 215-108-5
REACH number: substance is not classified and is not subject to REACH registration

3.2 Mixtures
Bentonite is a substance of variable and/or unknown composition, produced by complex reactions or biological materials (UVCB) according to REACH and CLP regulations.
The purity of the product is 100% w/w.
The composition of the substance consists mainly of smectite (CAS 1318-93-0) together with other ancillary materials.

4. FIRST AID MEASURES

4.1 Description first aid measures
In case of inhalation: no actions to be avoided, no special instructions for rescuers.
In case of skin contact: none in particular.
In case of eye contact: immediately flush with running water with open eyelids for at least 15 minutes. Consult an ophthalmologist. Protect the uninjured eye.
In case of ingestion: none in particular.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing means
Suitable extinguishing means
All standard firefighting equipment.

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Extinguishing media that should not be used for safety reasons
None in particular.

5.2 Special hazards from combustion products
In case of prolonged exposure or high level of suspended dust, wear respiratory protection in accordance with national legislation.

5.3 Recommendations for fire suppression operators
Avoid dry sweeping by spraying water or using a vacuum system to prevent dust formation. Keep in mind that wet bentonite can be slippery.

5.4 Other information
None in particular.

6. MEASURES IN CASE OF ACCIDENTAL RELEASE

6.1 Personal precautions, personal protective equipment and emergency procedures
Wear personal protective equipment. Move people to a safe place. Refer to the protective measures set out in section 7 and 8.

6.2 Environmental precautions
Prevent penetration into the soil/subsoil. Prevent runoff into the sewer system.

6.3 Methods and materials for containment and remediation
Small quantities: wash with plenty of water.

6.4 Reference to other sections
See also paragraph 8 and 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling
Avoid dust formation. Provide adequate ventilation in rooms where dust is formed. In case of insufficient ventilation, wear suitable respiratory protective equipment.

7.2 Conditions for safe storage, including any incompatibilities
No special precautions are required. Provide proper ventilation and store by preventing accidental damage. Keep away from moisture.

7.3 Specific end uses
No special technical measures or precautions are required. Indicate mode of use before use in case of mixture with other substances.

8. EXPOSURE CONTROL/INDIVIDUAL PROTECTION

8.1 Control parameters
Depending on the treatment and use (grinding, drying, bagging), respirable dust may be generated in the air. The dust contains respirable crystalline silica. Prolonged and massive inhalation or respirable crystalline silica can cause pulmonary fibrosis, commonly referred to as silicosis. The main symptoms of silicosis are cough and shortness of breath. Occupational exposure to respirable dust should be monitored and controlled. The product should be handled with methods and techniques that minimize or eliminate dust formation. The product contains less than 1% w/w RCS (crystalline silica) as determined by the SWERF method. Respirable crystalline silica content can be measured by the "Size-Weighted Respirable Fraction - SWERF"

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method. Full details of the SWERF method are available at www.crystallinesilica.eu The data are based on our latest knowledge but do not constitute any guarantee of product characteristics and do not motivate any contractual legal relationship.

8.2 Exposure controls
Provide appropriate ventilation and filtration in workplaces where dust may be generated. Wash hands before intervals and at the end of the workday. Remove and wash soiled clothing.

Eye protection
Not necessary. However, operate according to good working practices.

Skin protection
No special precautions are required for normal use.

Hand protection
No special precautions are required for normal use.

Respiratory protection
In case of prolonged exposure to dust wear personal respiratory protection in accordance with national legislation (refer to the appropriate CEN standard).

Thermal hazards
None.

Environmental exposure controls
None.

9. PHISICAL AND CHEMICAL PROPERTIES

9.1 Information on general physical and chemical properties

Appearance	White powder
Shape	Powder
Color	White
Odor	Odorless
Olfactory threshold	Not determined
Ph value	Not determined
CHANGE OF STATE	
Melting point/interval	> 450°C (study result, EU A.1 method)
Boiling point/interval	> 450°C (study result, EU A.1 method)
Flash point	Non flammable
Flammability (solids, gases)	Non flammable
Auto-ignition temperature	Not determined
Decomposition temperature	Not determined
Explosive properties	Non explosive
Lower flammability limits	Greater than 150 °C
Upper flammability limits	Not determined
Vapor pressure at 20°C	Not determined
Density at 20°C	0,9 – 1,4 g/ml
Relative density	2,6 g/cm^3 a 20°C

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Vapor density at 20°C	Not determined
Evaporation rate	Not determined
Solubility in/Miscibility with water	< 0,9 mg/l a 20 °C (secondo EU A.6 method)
Specific rotation	Not determined
Partition coefficient: n-octanol/water	Not determined
Dynamic Viscosity at 20 °C	Not determined
Kinematic Viscosity	Not determined

9.2 Other information

Molecular mass	Not determined
Conductivity	Not determined
Liposolubility	Not determined
Particular properties groups of substances	None
Other Useful Information	None

10. STABILITY AND RESPONSIVENESS

10.1 Responsiveness
Under normal conditions, it is completely stable to air and light.

10.2 Chemical stability
Under normal conditions, it is completely stable to air and light.

10.3 Possibility of dangerous reactions
Stable under normal conditions.

10.4 Conditions to be avoided
Stable under normal conditions.

10.5 Incompatible materials
None in particular.

10.6 Hazardous decomposition products
None.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects
Toxicological information regarding the main substances in the mixture
Toxicological information regarding substance: Bentonite Powder
Oral LD50 > 2000 mg/kg bw (OECD 420 rat).
Derma data not available. Bentonite is insoluble and has low absorption through the skin
Inhalation LC50 > 5.27 mg/l) OECD 436 rat).
Classification for acute toxicity is not warranted.
Unless otherwise specified, the data required by Regulation 453/2010/EC below are intended to be undetermined:

(a) acute toxicity: bentonite does not exhibit acute toxicity.

(b) skin corrosion/irritation: bentonite is not irritating to the skin (in vivo, OECD 404, rabbit)
(c) severe eye injury/serious eye irritation: bentonite is not irritating to eyes (in vivo, OECD 405, rabbit). Bentonite is classified as mild eye irritant (according to Kay&Calandra criteria) classification for irritation/corrosion is not warranted
(d) respiratory or skin sensitization: Bentonite is not a skin sensitizer (OECD 429, mouse)
(e) germ cell mutagenicity: in vivo tests (OECD 471,473 and 476) NEGATIVE
(f) carcinogenicity: Sepiolite has been evaluated by IARC as Class 3 ("Cannot be classified as carcinogenic to humans"). Based on read-across with sepiolite, bentonite has been evaluated as non-carcinogenic. Therefore, the classification of bentonite for carcinogenicity is not warranted
(g) Reproductive toxicity: two studies are available -Abdel-Wahhab et al (1999): bentonite had no effect on maternal and fetal parameters at the dietary level of 0.5% w/w (equivalent to 250 mg/kg body weight). -Wiles et al (2004) Calcium montmorillonite 2% or sodium montmorillonite in the diet had no effect on maternal and maternal organ weights, offspring weights, embryonic implants, or resorptions. In both animal studies, no effects on maternal/fetal parameters were found. Classification for reproductive toxicity under Regulation (EC) 1272/2008 is not warranted.
(h) Specific target organ toxicity (STOT) - single exposure: No organ toxicity was observed in acute testing.
(i) Specific target organ toxicity (STOT) - repeated exposure - Oral. The short-term repeated dose toxicity study (28 days) and toxicity sub-study (90 days) on mice were conducted with bentonite. Mice were fed 10%, 25%, and 50% bentonite for 61 days. Hepatoma was observed in mice treated with 50% bentonite diet. This is because bentonite being an exchange silicate goes on to remove choline from the intestinal contents after more than 200 days of feeding based on a 50% bentonite diet. Hepatomas developed in 11 out of 12 mice. The liver of the mice was severely damaged. The liver damage observed in the group that ingested bentonite is speculated to be related to prolonged choline deficiency, partially explaining the development of hepatomas in the mice in these experiments. However, studies have been conducted by exposing mice to a very high concentration of bentonite, and the observed effects are considered secondary due to digestive dysfunction. Therefore, the classification of bentonite for toxicity upon prolonged oral exposure is not justified.
(j) Specific Target Organ Toxicity (STOT) - Repeated Exposure - Inhalation data obtained from animal and in vitro experiments indicate a difference between crystalline quartz and the quartz content of bentonite. A quantitative assessment based on animal data is not possible because no relevant study with repeated inhalation administration is available. Human data is limited to clinical cases suggesting a relationship with high bentonite exposure (exposures in the 20th century without state-of-the-art protective measures and dust exposure ceilings). The link between bentonite exposure and silicosis is not considered to be sufficiently demonstrated. Regarding the classification and labeling of bentonite, the evidence is not considered to be sufficient to reach a conclusion on the specific classification of bentonite with the specific target organ toxicity on repeated exposure (STOT-RE). Lung may be applicable to repeated high-dose exposure, which has been suggested by human case studies. Although this effect happens only at concentrations beyond the lung purification capacity and is not relevant to humans, given the general exposure limits established. Therefore, the classification of bentonite for toxicity during prolonged inhalation exposure is not justified.
(k) Aspiration hazard: no aspiration hazard is expected.

12. ECOLOGICAL INFORMATION

12.1 Toxicity
(a) Acute aquatic toxicity
12.1.1 Acute/prolonged toxicity to fish
LC50 (96h) for freshwater fish (rainbow trout): 16000 mg/l

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LC50 (24h) for marine water fish (black bass, bass warmouth, bluegill and sunfish): 2800-3200 mg/l
12.1.2 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
LC50 (24h) for C. dubia and H. limbata:> 500 mg / L
12.1.3 acute/prolonged toxicity on aquatic plants
EC50 (72h) for freshwater algae:> 100 mg / l
12.1.4 toxicity on microorganisms (e.g., bacteria)
EC50 (48h) for Daphnia magna (OECD 202) :> 100 mg / l
12.1.5. chronic toxicity to aquatic organisms
Data not available
12.1.6 toxicity to soil-dwelling organisms
Data not 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 effects
No specific adverse effects known

12.2 Persistence and degradability
Not relevant for inorganic substances

12.3 Bioaccumulation potential
Not relevant for inorganic substances

12.4 Mobility in soil
Bentonite is nearly insoluble and therefore has low mobility in soils.

12.5 Results of PBT and vPvB assessment vPvB substances: None **- PBT substances:** None

12.6 Other adverse effects
No adverse effects found. According to the criteria of the European classification and labeling system, the substance does not require classification as environmentally hazardous.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods
PRODUCT
Inorganic product not to be disposed of through biological treatment systems. Dispose of residues in accordance with current regulations through authorized disposers.
Recover if possible. Operate in accordance with current local and national regulations.
CONTAMINATED PACKAGING
Empty as best as possible by fully opening them. Dispose of in accordance with the constituent material.

13.2 HP Phrases
None

14. TRANSPORTATION INFORMATION

14.1 UN number
Non-dangerous goods within the meaning of transport regulations.

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14.2 UN shipping name
N.A.

14.3 Transport hazard class(es)
N.A.

14.4 Packing group
N.A.

14.5 Environmental hazards Marine pollutant
N.A.

14.6 Special precautions for users
N.A.

14.7 Transport of bulk according to MARPOL Annex II and the IBC Code
N.A.

15. REGULATORY INFORMATION

15.1 Health, safety and environmental laws and regulations specific to the substance or mixture
Legislative Decree 3/2/1997 No. 52 (Classification, packaging and labeling of dangerous substances)
Legislative Decree 14/3/2003 No. 65 (Classification, packaging and labeling of dangerous preparations)
D.M. Labor 26/02/2004 (Occupational exposure limits)
Ministerial Decree 03/04/2007 (Implementation of Directive No. 2006/8/EC)
Regulation (EC) No. 1907/2006 (REACH)
Regulation (EC) No. 1272/2008 (CLP)
Regulation (EC) No. 790/2009 (ATP 1 CLP)
Regulation (EU)No 453/2010 (Annex I)
Regulation (EU) No 286/2011 (ATP 2 CLP)
Restrictions related to the product or the contained substances according to Annex XVII of Regulation (EC) 1907/2006 (REACH) and subsequent adaptations: none
Where applicable, please refer to the following regulations:
Ministerial Circulars 46 and 61 (Aromatic Amines)
Legislative Decree No. 238 of September 21, 2005 (Seveso Ter Directive)
EC Regulation No. 648/2004 (Detergents).
Royal Decree No. 147 of January 9, 1927 (Toxic Gases)
D.L. 3/4/2006 n. 152 Environmental regulations

15.2 Chemical safety assessment
No

16. OTHER INFORMATION

This sheet cancels and replaces any previous edition.

This document was prepared by a technician competent in SDS and who has received appropriate training.
The information contained herein is based on our knowledge as of the date above.
It relates only to the product indicated and does not constitute a guarantee of any quality. The user is responsible for ensuring the suitability and completeness of this information in relation to the specific use to be made of it.

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Main bibliographic sources

ECDIN - Environmental Chemicals Data and Information Network - Joint Research Centre, Commission of the European Communities
SAX's DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS - Eight Edition -Van Nostrand Reinold
CCNL - Annex 1
Istituto Superiore di Sanità - National Inventory of Chemical Substances.

LEGENDA SIGLES

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS: Service of the Chemical Abstract (division of the American Chemical Society).CLP: Classification, Labeling, Packaging.
DNEL: Derived no-effect level.
EINECS: European Inventory of Existing Commercial Chemical Substances.
GefStoffVO: Ordinance on hazardous substances, Germany.
GHS: General harmonized system of classification and labeling of chemicals.
IATA: International Air Transport Association.
IATA-DGR: Regulations for the Transport of Dangerous Goods of the "International Air Transport Association"(IATA).
ICAO: International Civil Aviation Organization.
ICAO-TI: Technical Instructions of the "International Civil Aviation Organization"(ICAO).
IMDG: International Maritime Dangerous Goods Code.
INCI: International nomenclature of cosmetic ingredients.
KSt: Coefficient of explosion.
LC50: Lethal concentration for 50 percent of the population tested.
LD50: Lethal dose for 50 percent of the population tested.
N.A.: Not Available
PNEC: Predicted no-effect concentration.
RID: Regulations concerning the international transport of dangerous goods by rail.
STE: Short-term exposure.
STEL: Short-term exposure limit.
STOT: Specific target organ toxicity.TLV: Threshold limit value.
TWATLV: Threshold limit value for an 8-hour weighted average exposure per day. (ACGIH standard).
WGK: German water hazard class.