

SECTION 1. Identification of the substance/mixture and of the company/enterprise

1.1. Product identifier

Product name : BENTOGRAN
Product code: refer to sales department
Chemical Name: Bentonite CAS: 1302-78-9 - EC No: 215-108-5

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

Clarifying Agents
Sectors of use:
Manufacture of food products[SU4]
Product category:
Technological adjuvant for limited food use

Not recommended uses
Do not use for purposes other than those listed

1.3. Details of the supplier of the safety data sheet

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SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

CAS 1302-78-9 EINECS 215-108-5

2.1.1 Classification according to Regulation (EC) No 1272/2008:

This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

Pictograms:
None

Hazard Class and Category Code(s):
Non hazardous

Hazard statement Code(s):
Non hazardous

2.2. Label elements

Labelling according to Regulation (EC) No 1272/2008:

Pictogram, Signal Word Code(s):
None

Hazard statement Code(s):
Non hazardous

Supplemental Hazard statement Code(s):
not applicable

Precautionary statements:
None in particular.

Contains:
Ingredients: activated bentonite.

Food use. Also for oenological use. Not intended for the final consumer. In accordance with current regulations on the specific matter.

2.3. Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII

SECTION 3. Composition/information on ingredients

3.1 Substances

No dangerous substance to report.

Substance	Concentration[w/w]	Classification	Index	CAS	EINECS	REACH
Bentonite substance for which there are Community workplace exposure limits	100%			1302-78-9	215-108-5	

3.2 Mixtures

Irrilevant

SECTION 4. First aid measures

4.1. Description of first aid measures

Inhalation:

Ventilate the area. Move immediately the contaminated patient from the area and keep him at rest in a well ventilated area. If you feel unwell seek medical advice.

Direct contact with skin (of the pure product):

Wash thoroughly with soap and running water.

Direct contact with eyes (of the pure product):

Wash immediately and thoroughly with running water for at least 10 minutes.

Ingestion:

Not dangerous. In case of malaise consult a doctor.

4.2. Most important symptoms and effects, both acute and delayed

No data available.

4.3. Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5. Firefighting measures

5.1. Extinguishing media

Suggested extinguishing media:

Water spray, CO₂, foam, dry chemical, depending on the materials involved in the fire.

Extinguishing media to avoid:

Water jets. Use water jets only to cool the surfaces of the containers exposed to fire.

5.2. Special hazards arising from the substance or mixture

No data available.

5.3. Advice for firefighters

Use protection for the breathing apparatus

Safety helmet and full protective clothing.

The water spray can be used to protect the people involved in the extinction.

You may also use self-contained breathing apparatus, especially when working in confined and poorly ventilated areas.

Keep containers cool with water spray

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel:

Leave the area surrounding the spill or release. Do not smoke

Wear gloves and protective clothing

6.1.2 For emergency responders:

Eliminate all unguarded flames and possible sources of ignition. No smoking.

Provide a sufficient ventilation.

Evacuate the danger area and, in case, consult an expert.

6.2. Environmental precautions

Contain spills

Inform the competent authorities.

Dispose of the waste material in compliance with the regulations

6.3. Methods and material for containment and cleaning up

6.3.1 Containment:

Recover the product for reuse, if possible, or for elimination.

6.3.2 Cleaning up:

After wiping up, wash with water the area and materials involved

6.3.3 Other information:

None in particular.

6.4. Reference to other sections

Refer to paragraphs 8 and 13 for more information

SECTION 7. Handling and storage

7.1. Precautions for safe handling

At work do not eat or drink.

See also paragraph 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep in original container closed tightly. Do not store in open or unlabelled containers.
Keep containers upright and safe by avoiding the possibility of falls or collisions.
Store in a cool and dry place, away from heat sources and direct exposure to sunlight.

7.3. Specific end use(s)

Manufacture of food products:
Handle with care.
Store in a clean, dry, ventilated area away from heat and direct sunlight.
Keep container tightly closed.

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

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Related to contained substances:
Bentonite:
INHALABLE, DUST

Limit value – Eight hours
(ppm)/(mg/m³)
Austria: x/10
Belgium: x/10
Denmark: x/10
France: x/4 (1)
Germany (AGS): x/10(1)(2)(3)
Germany (DFG): x/4
Hungary: x/10
Ireland: x/10
Italy: x/10
Poland: x/10
Singapore: x/10
Spain: x/10
Sweden: x/10
Switzerland: x/10
UK: x/10

Limit value – Short term
(ppm)/(mg/m³)
Austria: x/20
Denmark: x/20
Germany (AGS): x/20(1)(2)(3)

Remarks:
France: (1) Bold type: Restrictive statutory limit values
Germany (AGS): (1) Insoluble particulates (2) not applicable for ultra-fine dusts and dusts with specific toxicity (3) the limit value is a general upper limit for technical measures, as long as no specific regulations for toxic or carcinogenic substances are available.

RESPIRABLE DUST

Limit value – Eight hours
(ppm)/(mg/m³)
Austria: x/5
Belgium: x/3
France: x/0.9 (1)

Germany (AGS): x/1,25 (1)(2)(3)(4)(5)
Germany (DFG): x/0.3 (1)
Hungary: x/6
Ireland: x/4
Italy: x/3
Spain: x/3
Switzerland: x/3
UK: x/4
USA – OSHA: x/5

Limit value – Short term
(ppm)/(mg/m³)
Austria: x/10
Germany (DFG): x/2.4 (1)(2)

Remarks:

Austria: STV 15 minutes average value
France: (1) Bold type: Restrictive statutory limit values
Germany (AGS): (1) Insoluble particulates (2) not applicable for ultra-fine dusts and dusts with specific toxicity (3) the limit value is a general upper limit for technical measures, as long as no specific regulations for toxic or carcinogenic substances are available (4) the limit value was derived for dusts with an average density of 2.5 mg/m³ (5) at work areas where all technical and further measures are state of the art but the LV is still not adhered, the old LV can be applied for a transitional period until 31st December 2018 (8 h-LV: 3.0 mg/m³, 15 minutes average value: 6.0 mg/m³)
Germany (DFG): (1) For granular, bio-resistant dusts, except ultra-fine particles (2) 15 minutes average value

8.2. Exposure controls

Appropriate engineering controls:

Manufacture of food products:

No specific monitoring foreseen (act according to good practice and specific rules for the type of risk associated)

8.2.2 Individual protection measures:

(a) Eye / face protection

Not needed for normal use, unless otherwise provided by the employer and / or by assessments of environmental hygiene investigations

(b) Skin protection

(i) Hand protection

Not needed for normal use, unless otherwise provided by the employer and / or by assessments of environmental hygiene investigations

(ii) Other

Wear normal work clothing.

(c) Respiratory protection

Not needed for normal use, unless otherwise provided by the employer and / or by assessments of environmental hygiene investigations

(d) Thermal hazards

No hazard to report

Environmental exposure controls:

Use according to good working practices and avoid to disperse the product into the environment.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical and chemical properties	Value	Determination method
Physical state	Granular powder	
Colour	Beige	
Odour	odorless	
Odour threshold	not determined as it is considered not relevant for the characterization of the product	
Melting point/freezing point	not determined as it is considered not relevant for the characterization of the product	
Boiling point or initial boiling point and boiling range	not determined as it is considered not relevant for the characterization of the product	
Flammability	not determined as it is considered not relevant for the characterization of the product	
Lower and upper explosion limit	not determined as it is considered not relevant for the characterization of the product	
Flash point	not determined as it is considered not relevant for the characterization of the product	ASTM D92
Auto-ignition temperature	not determined as it is considered not relevant for the characterization of the product	
Decomposition temperature	not determined as it is considered not relevant for the characterization of the product	
pH	8,5 - 10 (20°C; sol. 5%)	
Kinematic viscosity	not determined as it is considered not relevant for the characterization of the product	
Solubility	not determined as it is considered not relevant for the characterization of the product	
Water solubility	not determined as it is considered not relevant for the characterization of the product	
Partition coefficient n-octanol/water (log value)	not determined as it is considered not relevant for the characterization of the product	
Vapour pressure	not determined as it is considered not relevant for the characterization of the product	
Density and/or relative density	0,85 ± 0,05 (20°C)	
Relative vapour density	not determined as it is considered not relevant for the characterization of the product	
Particle characteristics	not determined as considered not relevant for the characterization of the product	

9.2. Other information

9.2.1 Information with regard to physical hazard classes

No data available.

9.2.2 Other safety characteristics

No data available.

SECTION 10. Stability and reactivity

10.1. Reactivity

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Related to contained substances:

Bentonite:

Inert

10.2. Chemical stability

Stable under normal conditions of use and storage

10.3. Possibility of hazardous reactions

No dangerous reactions

10.4. Conditions to avoid

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Related to contained substances:

Bentonite:

Dust generation in enclosed and confined areas

10.5. Incompatible materials

No one in particular

10.6. Hazardous decomposition products

Not known

SECTION 11. Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

(a) acute toxicity: Bentonite: Ingestion - LD50 rat (mg/kg/24h bw): >2000

Contact with skin - LC50 rat / rabbit (mg/kg/24h bw): nd

Inhalation - LD50 rat (mg/l/4h): >5.27

(b) skin corrosion/irritation: Bentonite: Non-corrosive

Bentonite: Non-irritating

(c) serious eye damage/irritation: Bentonite: Non-corrosive

Bentonite: Moderately irritating

(d) respiratory or skin sensitisation: Bentonite: Non-sensitizing

(e) germ cell mutagenicity: Bentonite: In vitro tests (OECD 471, 473 and 476) negative

(f) carcinogenicity: Bentonite: 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.

(g) reproductive toxicity: Bentonite: 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/fetal parameters were detected.

Classification for reproductive toxicity according to regulation (EC) 1272/2008 is not warranted.

(h) specific target organ toxicity (STOT) single exposure: Bentonite: Not available

(i) specific target organ toxicity (STOT) repeated exposure Bentonite: Oral: 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 disruptor of digestion.

Therefore, classification of bentonite for toxicity up

(j) aspiration hazard: Bentonite: Not available

11.2. Information on other hazards

No data available.

SECTION 12. Ecological information

12.1. Toxicity

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Related to contained substances:

Bentonite:

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): 16000 mg/l EC50 (96h) for freshwater invertebrates (dock shrimp): 24.8 mg/l LC50 (24h) for c. dubia and h. limbata: >500 mg/L.

Acute/Prolonged toxicity to aquatic plants

EC50 (72h) for freshwater algae: >100 mg/l.

Toxicity to micro-organisms e.g. bacteria

EC50 (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.

Use according to good working practices and avoid to disperse the product into the environment.

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 nearly insoluble and therefore has low mobility in most soils.

12.5. Results of PBT and vPvB assessment

Not classified as PBT and vPvB

12.6. Endocrine disrupting properties

No data available.

12.7. Other adverse effects

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

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with the regulations in force. Any remaining product should be disposed of according to applicable regulations by addressing to authorized companies.

Recover if possible. Operate according to local or national regulations

SECTION 14. Transport information

14.1. UN number or ID number

Not included in the field of application of regulations concerning the transport of dangerous goods: by road (ADR); by rail (RID); by air (ICAO / IATA); by sea (IMDG).

14.2. UN proper shipping name

None

14.3. Transport hazard class(es)

None

14.4. Packing group

None

14.5. Environmental hazards

None

14.6. Special precautions for user

No data available.

14.7. Maritime transport in bulk according to IMO instruments

Transport in bulk is not foreseen

SECTION 15. Regulatory information

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

Restrictions relating to the product or contained substances (All. XVII Reg. EC 1907/2006): not applicable
Substances in Candidate List (art. 59 Reg. EC 1907/2006): the product does not contain SVHC in a proportion $\geq 0.1\%$.
Substances subject to authorisation (Ann. XIV Reg. CEC 1907/2006): the product does not contain SVHC in a proportion $\geq 0.1\%$.
Reg. (EU) n. 1169/2011: see 2.2
Regulation (EU) 1332/2008; see p.2.2

15.2. Chemical safety assessment

No chemical safety assessment was carried out by the supplier

SECTION 16. Other information

16.1. Other information

Points modified from previous revision: 8.1. Control parameters, 11.1 Information on toxicological effects, 12.1. Toxicity

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

No hazard to report. Classification procedure: Calculation method

Main normative references:

Reg. (CE) n. 1907 del 18/12/06 REACH (Registration, Evaluation and Authorisation of CHemicals) et seq.

Reg. (CE) 1272/2008 CLP (Classification Labelling and Packaging) et seq.

Regulation (UE) n. 1169/2011 (on the provision of food information to consumers)

Directive 2012/18/EU (on the control of major-accident hazards involving dangerous substances) et seq.

Regulation (EU) 1332/2008 (Food enzymes)

Training required: This document must be submitted to the employer to determine the possible need for appropriate training for workers to ensure protection of human health and the environment.

n.a.: not applicable

n.d.: not available

ADR: Accord européen relative au transport International des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

ATE: Acute Toxicity Estimat

BFC: BioconCentration Factor

BOD: Biochemical Oxigen Demand

CAS: Chemical Abstract Service number

CAP: Centre AntiPoison

CE/EC number EINECS (European Inventory of existing Commercial Substances) e ELINCS (European List of notified Chemical Substances)

CL50/LC50: Lethal Concentration 50

DL50/LD50: Lethal Dose 50

COD: Chemical Oxygen Demand

DNEL: Derived No Effect Level

EC50: half maximal Effective Concentration

ERC: Enviroment Release Classes

EU/UE: European Union

IATA: International Air Transport Association

ICAO: International Civil Aviation Organization

IMDG: International Maritime Dangerous Goods code

Kow: Octanol water partition coefficient

NOEC: No Observed Effect Concentration

OEL: Occupational Exposure Limit

PBT: Persistent Bioaccumulative and Toxic

PC: Product Categories

PNEC: Predicted No Effect Concentration

PROC: Process Categories

RID: Règlement concernant le transport International ferroviaire des marchandises dangereuses (Regulations concerning International rail transport of dangerous goods)

STOT: Target Organ Systemic Toxicity

STOT (RE): Repeated Exposure

STOT (SE): Single Exposure

STP: Sewage Treatment Plants

SU: Sector of Use

SVCH: Substance of Very High Concern

TLV: Threshold Limit Value

vPvB: Very Persistent Very Bioaccumulative

References and Sources:

- ECHA Registered Substances:
- <https://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>
- SDS supplier
- GESTIS DNEL Database: <http://www.dguv.de/ifa/gestis/gestis-dnel-datenbank/index-2.jsp>
- GESTIS International Limit Value: <http://limitvalue.ifa.dguv.de>

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*** this tab annuls and replaces any previous edition. (IIXX)

Changes to the previous edition: documental alignment.