

Safety Data Sheet

Pharmabent N

Safety Data Sheet dated 29/12/2022 version 3

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Identification of the substance:

Trade name: Pharmabent N

Chemical name: Bentonite

CAS number: 1302-78-9

EC number: 215-108-5

Registration Number N.A.

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

Recommended use: FOR PROFESSIONAL USE

FOR ENOLOGICAL USE

Uses advised against: N.A.

1.3. Details of the supplier of the safety data sheet

Company:

ESSECO S.r.l. Via San Cassiano 99

28069 - Trecate (NO)

Italy

Enartis - Phone n. +39-0321-790300

Competent person responsible for the safety data sheet: vino@enartis.it

1.4. Emergency telephone number

Enartis - Phone n. +39-0321-790300

Malta: 112

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) n. 1272/2008 (CLP)

The product is not classified as dangerous according to Regulation EC 1272/2008 (CLP).

Adverse physicochemical, human health and environmental effects:

No other hazards

2.2. Label elements

The product is not classified as dangerous according to Regulation EC 1272/2008 (CLP).

Special provisions according to Annex XVII of REACH and subsequent amendments:

None.

2.3. Other hazards

This substance has no PBT, vPvB or endocrine disrupting properties

Other Hazards: No other hazards

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance Identifications: BENTONITE

CAS number: 1302-78-9

EC number: 215-108-5

3.2. Mixtures

N.A.

SECTION 4: First aid measures

4.1. Description of first aid measures

In case of skin contact:

Wash with plenty of water and soap.

In case of eyes contact:

Wash immediately with water.

In case of Ingestion:

Induce vomiting. SEEK A MEDICAL EXAMINATION IMMEDIATELY and present the safety-data sheet.

In case of Inhalation:

Remove casualty to fresh air and keep warm and at rest.

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

N.A.

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

N.A.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

Water.

Carbon dioxide (CO₂).

Extinguishing media which must not be used for safety reasons:

None in particular.

5.2. Special hazards arising from the substance or mixture

Do not inhale explosion and combustion gases.

5.3. Advice for firefighters

Wear suitable protective clothing (helmet, protective clothings, goggles, fire resistant gloves, boots) and protect respiratory organs (self contained breathing apparatus).

Use suitable breathing apparatus .

Move undamaged containers from immediate hazard area if it can be done safely.

Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

Fire residues and contaminated firefighting water must be disposed of in accordance within the local regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear personal protection equipment.

Remove persons to safety.

See protective measures under point 7 and 8.

6.2. Environmental precautions

If the product has escaped into a water course, into the drainage system, or has contaminated the ground or vegetation, notify the competent authorities.

6.3. Methods and material for containment and cleaning up

Suitable material for taking up: absorbing material, organic, sand

Dispose of the collected material in accordance with the current regulations.

Wash with plenty of water.

Retain contaminated washing water and dispose it.

6.4. Reference to other sections

See also section 8 and 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on general occupational hygiene:

Do not eat or drink while working.

See also section 8 for recommended protective equipment.

7.2. Conditions for safe storage, including any incompatibilities

Keep away from food, drink and feed.

Incompatible materials:

None in particular.

Instructions as regards storage premises:

Adequately ventilated premises.

7.3. Specific end use(s)

Recommendation(s)

None in particular

Industrial sector specific solutions:

None in particular

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

OEL Type	Long Term mg/m ³	Long Term ppm	Short Term mg/m ³	Short Term ppm	Notes
ACGIH	3.000				(Inhalable fraction)
ACGIH	10.000				(respirable fraction)

8.2. Exposure controls

Individual protection measures:

Personal protective equipment selections vary based on potential exposure conditions and working conditions.

The final choice of protective equipment will depend upon a risk assessment.

Personal protective equipment (PPE) should meet recommended national standards. Check with PPE suppliers.

Please see both sections 5 and 6 for information about personal protective equipment to be worn in an emergency (e.g.: fire or unintentional release of the substance).

Eye protection:

Not needed for normal use. Anyway, operate according good working practices.

Protection for skin:

No special precaution must be adopted for normal use.

Protection for hands:

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Glove suitability and breakthrough time will differ depending on the specific use conditions.

Contact the glove manufacturer for specific advice on glove selection and breakthrough times for your use conditions.

Not needed for normal use.

Respiratory protection:

Depending on the potential for exposure, select respiratory protective equipment suitable for the specific conditions of use and in compliance with current legislation.

Thermal Hazards:

N.A.

Environmental exposure controls:

N.A.

Hygienic and Technical measures

N.A.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical State: Solid

Color: N.A.

Odour: None

Odour threshold:

pH: N.A.

Kinematic viscosity: N.A.

Melting point / freezing point: >450°C

Initial boiling point and boiling range: N.A.

Flash point: N.A.

Upper/lower flammability or explosive limits: N.A.

Vapour density: N.A.

Vapour pressure: N.A.

Relative density: 2.6 g/cm³ a 20°C

Solubility in water: 0,9 mg/l a 20°C

Solubility in oil: N.A.

Partition coefficient (n-octanol/water): N.A.

Auto-ignition temperature: N.A.

Decomposition temperature: N.A.

Flammability: N.A.

Volatile Organic compounds - VOCs = N.A.

Particle characteristics:

Particle size: N.A.

9.2. Other information

Miscibility: N.A.
Conductivity: N.A.
Evaporation rate: N.A.
No other relevant information

SECTION 10: Stability and reactivity

10.1. Reactivity

Data not available.

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

10.4. Conditions to avoid

Data not available.

10.5. Incompatible materials

None in particular.

Data not available.

10.6. Hazardous decomposition products

None

SECTION 11: Toxicological information

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

Toxicological Information of the Substance

a) acute toxicity	Not classified Based on available data, the classification criteria are not met LD50 Oral Rat > 2000 mg/kg - OECD 420 LC50 Inhalation Rat > 5.27 mg/l
b) skin corrosion/irritation	Not classified Based on available data, the classification criteria are not met Skin Irritant Skin Negative
c) serious eye damage/irritation	Not classified Based on available data, the classification criteria are not met
d) respiratory or skin sensitisation	Not classified Based on available data, the classification criteria are not met
e) germ cell mutagenicity	Not classified Based on available data, the classification criteria are not met
f) carcinogenicity	Not classified Based on available data, the classification criteria are not met
g) reproductive toxicity	Not classified Based on available data, the classification criteria are not met
h) STOT-single exposure	Not classified Based on available data, the classification criteria are not met
i) STOT-repeated exposure	Not classified Based on available data, the classification criteria are not met
j) aspiration hazard	Not classified Based on available data, the classification criteria are not met

11.2. Information on other hazards

Endocrine disrupting properties:

This substance has no endocrine disrupting properties

SECTION 12: Ecological information

12.1. Toxicity

Adopt good working practices, so that the product is not released into the environment.

Eco-Toxicological Information:

List of Eco-Toxicological properties of the product

Not classified for environmental hazards.

Based on available data, the classification criteria are not met

- a) Aquatic acute toxicity : LC50 Fish > 2800 mg/l 24h
- a) Aquatic acute toxicity : EC50 Crustaceans > 24.8 mg/l 96h
- e) Plant toxicity : EC50 Algae > 100 mg/l 72h
- a) Aquatic acute toxicity : EC50 Daphnia > 100 mg/l 48h - OECD 202

12.2. Persistence and degradability

N.A.

12.3. Bioaccumulative potential

N.A.

12.4. Mobility in soil

N.A.

12.5. Results of PBT and vPvB assessment

This substance has no PBT, vPvB or endocrine disrupting properties

12.6. Endocrine disrupting properties

This substance has no endocrine disrupting properties

12.7. Other adverse effects

N.A.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Recover if possible. In so doing, comply with the local and national regulations currently in force.

SECTION 14: Transport information

Not classified as dangerous in the meaning of transport regulations.

14.1. UN number or ID number

N.A.

14.2. UN proper shipping name

N.A.

14.3. Transport hazard class(es)

N.A.

14.4. Packing group

N.A.

14.5. Environmental hazards

N.A.

14.6. Special precautions for user

N.A.

Road and Rail (ADR-RID):

N.A.

Air (IATA):

N.A.

Sea (IMDG):

N.A.

14.7. Maritime transport in bulk according to IMO instruments

N.A.

SECTION 15: Regulatory information

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

Regulation (EU) n. 2020/878

Regulation (EC) n. 1907/2006 (REACH)

Regulation (EC) n. 1272/2008 (CLP)

Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013

Dir. 98/24/EC (Risks related to chemical agents at work)

Dir. 2000/39/EC (Occupational exposure limit values)

Regulation (EU) n. 286/2011 (ATP 2 CLP)

Regulation (EU) n. 618/2012 (ATP 3 CLP)

Regulation (EU) n. 487/2013 (ATP 4 CLP)

Regulation (EU) n. 944/2013 (ATP 5 CLP)
Regulation (EU) n. 605/2014 (ATP 6 CLP)
Regulation (EU) n. 2015/1221 (ATP 7 CLP)
Regulation (EU) n. 2016/918 (ATP 8 CLP)
Regulation (EU) n. 2016/1179 (ATP 9 CLP)
Regulation (EU) n. 2017/776 (ATP 10 CLP)
Regulation (EU) n. 2018/669 (ATP 11 CLP)
Regulation (EU) n. 2018/1480 (ATP 13 CLP)
Regulation (EU) n. 2019/521 (ATP 12 CLP)
Regulation (EU) n. 2020/217 (ATP 14 CLP)
Regulation (EU) n. 2020/1182 (ATP 15 CLP)
Regulation (EU) n. 2021/643 (ATP 16 CLP)
Regulation (EU) n. 2021/849 (ATP 17 CLP)

Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006 (REACH) and subsequent modifications:

Restrictions related to the product: None.

Restrictions related to the substances contained: None.

Provisions related to directive EU 2012/18 (Seveso III):

N.A.

Regulation (EU) No 649/2012 (PIC regulation)

No substances listed

Where applicable, refer to the following regulatory provisions :

NWG: Not hazardous for water

SVHC Substances:

No data available

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for the substance.

SECTION 16: Other information

This document was prepared by a competent person who has received appropriate training.

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

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality.

It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

This MSDS cancels and replaces any preceding release.

Legend to abbreviations and acronyms used in the safety data sheet:

ACGIH: American Conference of Governmental Industrial Hygienists

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.

AND: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

ATE: Acute Toxicity Estimate

ATEmix: Acute toxicity Estimate (Mixtures)

BCF: Biological Concentration Factor

BEI: Biological Exposure Index

BOD: Biochemical Oxygen Demand

CAS: Chemical Abstracts Service (division of the American Chemical Society).

CAV: Poison Center

CE: European Community

CLP: Classification, Labeling, Packaging.

CMR: Carcinogenic, Mutagenic and Reprotoxic

COD: Chemical Oxygen Demand

COV: Volatile Organic Compound

CSA: Chemical Safety Assessment

CSR: Chemical Safety Report

DMEL: Derived Minimal Effect Level

DNEL: Derived No Effect Level.

DPD: Dangerous Preparations Directive

DSD: Dangerous Substances Directive
EC50: Half Maximal Effective Concentration
ECHA: European Chemicals Agency
EINECS: European Inventory of Existing Commercial Chemical Substances.
ES: Exposure Scenario
GefStoffVO: Ordinance on Hazardous Substances, Germany.
GHS: Globally Harmonized System of Classification and Labeling of Chemicals.
IARC: International Agency for Research on Cancer
IATA: International Air Transport Association.
IATA-DGR: Dangerous Goods Regulation by the "International Air Transport Association" (IATA).
IC50: half maximal inhibitory concentration
ICAO: International Civil Aviation Organization.
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO).
IMDG: International Maritime Code for Dangerous Goods.
INCI: International Nomenclature of Cosmetic Ingredients.
IRCCS: Scientific Institute for Research, Hospitalization and Health Care
KAFH: KAFH
KSt: Explosion coefficient.
LC50: Lethal concentration, for 50 percent of test population.
LD50: Lethal dose, for 50 percent of test population.
LDLo: Leathal Dose Low
N.A.: Not Applicable
N/D: Not defined/ Not available
NIOSH: National Institute for Occupational Safety and Health
NOAEL: No Observed Adverse Effect Level
OSHA: Occupational Safety and Health Administration.
PBT: Persistent, Bioaccumulative and Toxic
PGK: Packaging Instruction
PNEC: Predicted No Effect Concentration.
PSG: Passengers
RID: Regulation Concerning the International Transport of Dangerous Goods by Rail.
STEL: Short Term Exposure limit.
STOT: Specific Target Organ Toxicity.
TLV: Threshold Limiting Value.
TWATLV: Threshold Limit Value for the Time Weighted Average 8 hour day. (ACGIH Standard).
vPvB: Very Persistent, Very Bioaccumulative.
WGK: German Water Hazard Class.

Paragraphs modified from the previous revision:

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