

**Safety Data Sheet dated 3/4/2018, version 1**

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

- 1.1. Product identifier  
Trade name: PHARMABENT N
- 1.2. Relevant identified uses of the substance or mixture and uses advised against  
Recommended use:  
FOR PROFESSIONAL USE
- 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

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**SECTION 2: Hazards identification**

- 2.1. Classification of the substance or mixture  
EC regulation criteria 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  
Hazard pictograms:  
None  
Hazard statements:  
None  
Precautionary statements:  
None  
Special Provisions:  
None  
Special provisions according to Annex XVII of REACH and subsequent amendments:  
None
- 2.3. Other hazards  
vPvB Substances: None - PBT Substances: None  
Other Hazards:  
No other hazards

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**SECTION 3: Composition/information on ingredients**

- 3.1. Substances  
N.A.
- 3.2. Mixtures

Hazardous components within the meaning of the CLP regulation and related classification:

Qty	Name	Ident. Number	Classification
>= 90%	BENTONITE	CAS: 1302-78-9 EC: 215-108-5	Substance with a Union workplace exposure limit.

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#### 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:

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

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

None

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

Treatment:

None

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#### SECTION 5: Firefighting measures

##### 5.1. Extinguishing media

Suitable extinguishing media:

Water.

Carbon dioxide (CO<sub>2</sub>).

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

Use suitable breathing apparatus .

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

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

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#### 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

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.

Retain contaminated washing water and dispose it.

In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

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

##### 6.3. Methods and material for containment and cleaning up

Wash with plenty of water.

##### 6.4. Reference to other sections

See also section 8 and 13

## SECTION 7: Handling and storage

- 7.1. Precautions for safe handling  
Avoid contact with skin and eyes, inhalation of vapours and mists.  
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)  
None in particular

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## SECTION 8: Exposure controls/personal protection

- 8.1. Control parameters  
BENTONITE - CAS: 1302-78-9  
ACGIH - TWA: 3 mg/m<sup>3</sup> - Notes: (Inhalable fraction)  
ACGIH - TWA: 10 mg/m<sup>3</sup> - Notes: (respirable fraction)

DNEL Exposure Limit Values  
N.A.

PNEC Exposure Limit Values  
N.A.

### 8.2. Exposure controls

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:

Not needed for normal use.

Respiratory protection:

Not needed for normal use.

Use respiratory protection where ventilation is insufficient or exposure is prolonged.

Thermal Hazards:

None

Environmental exposure controls:

None

Appropriate engineering controls:

None

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## SECTION 9: Physical and chemical properties

- 9.1. Information on basic physical and chemical properties
- |   |        |
|---|--------|
| Appearance and colour:                        | Solid  |
| Odour:  | None   |
| Odour threshold:                              | N.A.   |
| Melting point / freezing point:               | >450°C |
| Initial boiling point and boiling range:      | N.A.   |
| Solid/gas flammability:                       | N.A.   |
| Upper/lower flammability or explosive limits: | N.A.   |
| Vapour density:                               | N.A.   |
| Flash point:                                  | N.A.   |
| Evaporation rate:                             | N.A.   |
| Vapour pressure:                              | N.A.   |

Relative density:	2.6 g/cm <sup>3</sup> 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.
Viscosity:	N.A.
Explosive properties:	N.A.
Oxidizing properties:	N.A.

9.2. Other information

Miscibility:	N.A.
Fat Solubility:	N.A.
Conductivity:	N.A.
Substance Groups relevant properties	N.A.

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## SECTION 10: Stability and reactivity

- 10.1. Reactivity  
Stable under normal conditions
- 10.2. Chemical stability  
Stable under normal conditions
- 10.3. Possibility of hazardous reactions  
None
- 10.4. Conditions to avoid  
Stable under normal conditions.
- 10.5. Incompatible materials  
None in particular.
- 10.6. Hazardous decomposition products  
None.

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## SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicological information of the substance:

PHARMABENT N

a) acute toxicity

Not classified

Based on available data, the classification criteria are not met

Test: LD50 - Route: Oral - Species: Rat > 2000 mg/kg - Notes: OECD 420

Test: LC50 - Route: Inhalation - Species: Rat > 5.27 mg/l

b) skin corrosion/irritation

Not classified

Based on available data, the classification criteria are not met

Test: Skin Irritant - Route: 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

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## **SECTION 12: Ecological information**

- 12.1. Toxicity  
Adopt good working practices, so that the product is not released into the environment.  
PHARMABENT N  
Not classified for environmental hazards  
Based on available data, the classification criteria are not met
  - a) Aquatic acute toxicity:  
Endpoint: LC50 - Species: Fish > 2800 mg/l - Duration h: 24  
Endpoint: EC50 - Species: Crustaceans > 24.8 mg/l - Duration h: 96  
Endpoint: EC50 - Species: Daphnia > 100 mg/l - Duration h: 48 - Notes: OECD 202
  - e) Plant toxicity:  
Endpoint: EC50 - Species: Algae > 100 mg/l - Duration h: 72
- 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  
vPvB Substances: None - PBT Substances: None
- 12.6. Other adverse effects  
None

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## **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.

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## **SECTION 14: Transport information**

- 14.1. UN number  
Not classified as dangerous in the meaning of transport regulations.
- 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  
Marine pollutant: No
- 14.6. Special precautions for user  
N.A.
- 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code  
N.A.

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## **SECTION 15: Regulatory information**

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

Dir. 98/24/EC (Risks related to chemical agents at work)  
Dir. 2000/39/EC (Occupational exposure limit values)  
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  
Regulation (EU) 2015/830  
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)

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:

No restriction.

Restrictions related to the substances contained:

No restriction.

Where applicable, refer to the following regulatory provisions :

Directive 2012/18/EU (Seveso III)

Regulation (EC) nr 648/2004 (detergents).

1999/13/EC (VOC directive)

Dir. 2004/42/EC (VOC directive)

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

Seveso III category according to Annex 1, part 1

None

15.2. Chemical safety assessment

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

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## **SECTION 16: Other information**

Paragraphs modified from the previous revision:

SECTION 3: Composition/information on ingredients

SECTION 7: Handling and storage

SECTION 8: Exposure controls/personal protection

SECTION 10: Stability and reactivity

SECTION 11: Toxicological information

SECTION 12: Ecological information

SECTION 15: Regulatory information

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.

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS:	Chemical Abstracts Service (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:	Globally Harmonized System of Classification and Labeling of Chemicals.
IATA:	International Air Transport Association.
IATA-DGR:	Dangerous Goods Regulation by the "International Air Transport Association" (IATA).
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.
KSt:	Explosion coefficient.
LC50:	Lethal concentration, for 50 percent of test population.
LD50:	Lethal dose, for 50 percent of test population.
N.A.:	Not Available
PNEC:	Predicted No Effect Concentration.
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.
TWA:	Time-weighted average
WGK:	German Water Hazard Class.