# **PANCREATIN**

20.07.17 Created on: Revised on: 23.10.19

**Effective from:** 25.10.19

Version: 1.04 1.05 Replace Version:



# Identification of the Substance/Mixture and of the Company

### 1.1 Product Identifier

Chemical/Trade Name: **Pancreatin** 

(from porcine pancreas)

Index no.: EG no.: 232-468-9 CAS no .: 8049-47-6

REACH registry no.: 01-2120758992-38-0001

Other Identifier:

### 1.2 Relevant Identified Uses of the Substance or Mixture and Against Uses Advised

Not known

### **Relevant Identified Uses:**

Biochemical research / analysis, technical purposes, hydrolysis, leather industry

### 1.3 Details of the Supplier of the Safety Data Sheet

### Manufacturer/Supplier

BeSiTo GmbH

### Street/PO-Box

Ruhlsdorfer Straße 95

### **ZIP-Code**

14532 Stahnsdorf; Germany

### **Contact for Technical Information**

kontakt@besito-gmbh.de

# Telephone/E-Mail

+49 3329 6909 877/info@besito-gmbh.de

# 1.4 Emergency Telephone Number

Institute of Toxicology Poison Center Berlin, country advisory center for poisoning and embryonic, Berlin and Brandenburg, D-13437 Berlin, Oranienburger Str. 285, Telephone: +49 (0) 30 19240 (Day and Night), Fax: +49 (0) 30/30686 - 721

Seite: 1 / 15

# **PANCREATIN**

 Created on:
 20.07.17

 Revised on:
 23.10.19

 Effective from:
 25.10.19

Version: 1.05 Replace Version: 1.04



### 2 Hazards Identification

### 2.1 Classification of the Substance or Mixture

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

Category 2, H315, skin corrosion / irritation

Category 2, H319, serious eye damage / irritation

Category 3, H335, specific target organ toxicity (single exposure)

Category 1, H334, respiratory sensitization

Category 1, H317, skin sensitization

Classification according to Directive 67/548 / EEC (substances) or Directive 1999/45 / EC (mixtures):

R42/43; Xn – Harmful \* R36/37/38; Xi – Irritant \*

### 2.2 Label Elements

# Label Elements According to Regulation (EC) No. 1272/2008 Pictograms:





GHS 07

Signal Word: Danger

### **Contains Hazard-Determining Components for Labeling**

### **Hazard Statements**

H315 Causes skin irritation.

H317 May cause allergic skin reactions. H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H335 May irritate the respiratory system.

### **Safety Instructions**

P280 Wear protective gloves / protective clothing / eye protection / face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P304+P341 IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position

comfortable for breathing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. If possible, remove

existing contact lenses and continue rinsing.

P342+P311 Call for respiratory symptoms, poison emergency or doctor (see chapt. 1.4).

Seite: 2 / 15

<sup>\*</sup> Further information on H- and R-sentences can be found in chapter 2.2 and 16.

# **PANCREATIN**

Created on: 20.07.17
Revised on: 23.10.19

Effective from: 25.10.19

Version: 1.05 Replace Version: 1.04



### **Further Labeling Elements**

ASR A1.3 Workplace labeling

### **Mandatory Signs:**





Wear eye protection

Wearing safety gloves

### 2.3 Other Hazards

In general, for solid, combustible organic substances and mixtures:

In a correspondingly fine distribution, in a whirled up condition, a dust explosion potential is generally to be assumed.

The PBT / vPvB criteria are not applicable.

### 3 Composition/Information on Ingredients

### 3.1 Substances

### **Main Component of the Substance**

Chemical: Pancreatin

Index no.:

EG no.: 232-468-9 CAS no.: 8049-47-6

# Impurities, Stabilizing Additives and Individual Constituents

The above-mentioned chemical is a natural product. About additives and constituents we don't have information today.

### 3.2 Mixtures

Substance name: not applicable

EG-No.: - CAS-No.: - Index-No.: - REACH-Registration-No.: -

Proportion of: - %

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

Not applicable

(For the wording of the hazard statements refer to chapter 16)

Seite: 3 / 15

# **PANCREATIN**

 Created on:
 20.07.17

 Revised on:
 23.10.19

 Effective from:
 25.10.19

Version: 1.05 Replace Version: 1.04



### 4 First Aid Measures

# 4.1 Description of First Aid Measures

### **General Hints**

- Move the affected person to fresh air.
- · Immediately remove contaminated clothing and remove it.
- · Loosen constricting clothes.
- Keep the affected person calm.
- Protect the affected person from heat loss.
- Transport and store unconscious persons in stable lateral position.
- Do not leave the data subject unattended.

### **After Inhalation**

- Provide fresh air, consult a doctor if symptoms occur.
- In case of irregular breathing or respiratory arrest, give immediate respiratory support or use ventilator ventilation with oxygen supply.

### **After Skin Contact**

- Wash off the affected skin with plenty of water.
- Immediately remove contaminated clothing with the product.
- If skin irritation persists, seek medical attention.

### **After Eye Contact**

- Rinse the eyes open and rinse thoroughly with eye-bath or running water.
- When eye irritation be certain a doctor.

### **After Swallow**

- Rinse your mouth with water.
- Drink plenty of water.

### With consciousness conserved:

- Allow the affected person to drink plenty of water (max. 2 drinking glasses).
- Take care not to induce vomiting (danger of aspiration).
- Consult a doctor and present the packaging or label. Consult a doctor and present the packaging or label.



To prevent the ingress of fluid into the airways, keep the affected person's head down (for example, spontaneous vomiting).

# 4.2 Most Important Symptoms and Effects, Both Acute and Delayed

Allergic reactions, irritant effects (see chapter 11).

### 4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed

Seite: 4 / 15

# PANCREATIN

20.07.17 Created on: Revised on: 23.10.19

**Effective from:** 25.10.19

Version: 1.05 **Replace Version:** 1.04



### 5 **Firefighting Measures**

### **Extinguishing Media**

Suitable:

- Carbon dioxide (CO2)
- Alcohol resistant foam
- Dry chemical
- Water

Extinguishing measures to the surroundings!

Not suitable: An extinguishing agent restriction does not exist for this substance.

### 5.2 Special Hazards Arising from the Substance or Mixture

- The substance is combustible but acts not oxidizing (oxidizing).
- Dust of the substance forms with air explosive mixtures.
- Set fire extinguishing equipment ready.
- If due to the dust-like distribution and the amounts used, the possibility of Dust explosion, follow-up to the "ATEX Directive".

### In case of a fire:

- Carbon oxides
- Do not breathe fire and explosion gases!

# 5.3 Advice for Firefighters

- Wear a self-contained breathing apparatus in case of fire.
- Avoid skin contact.
- Beat down gases / vapors / mist with a water spray.
- Dispose fire residues and contaminated extinguishing water in accordance with official regulations.

### **Accidental Release Measures** 6

# 6.1 Personal Precautions, Protective Equipment and Emergency Procedures

- Bring innocent and unprotected persons upwind in safety.
- They worry adequate ventilation.
- Avoid dust development.
- Avoid substance contact.
- Do not inhale dust.
- Wear personal protective equipment.
- Go to your emergency plan and drag added Experts.
- Remove all potential ignition sources in the area.
- Avoid electrostatic charges. See chapter 7.



Areas where the substance occurs in the form of dust in such quantities that the possibility of a dust explosion is considered a nonhazardous.



Protective equipment for emergency responders see chapter 8.

Seite: 5 / 15

# **PANCREATIN**

Created on: 20.07.17
Revised on: 23.10.19
Effective from: 25.10.10

Effective from: 25.10.19

Version: 1.05 Replace Version: 1.04

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### 6.2 Environmental Precautions

- If safe to do so, close the leak.
- Prevent further release.
- Do not allow the substance to enter drains or mix with surface water.
- Beat down the dust with a water spray.

### 6.3 Methods and Material for Containment and Cleaning Up

- Take the substance to mechanically dry.
- To those in tightly closed containers for disposal Run.
- Avoid dust (dust explosion hazard cannot be excluded if dusts with organic substances).
- Ventilate the affected area.
- Clean contaminated objects and surfaces with water.
- · Remove all sources of ignition.

### 6.4 Reference to Other Sections

- Information for safe handling see chapter 7.
- Information on protective equipment see chapter 8.
- Disposal see chapter 13.



# **PANCREATIN**

Created on: 20.07.17
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Effective from: 25.10.19

Version: 1.05 Replace Version: 1.04

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# 7 Handling and Storage

# 7.1 Precautions for Safe Handling

### Measures to Protect Against Fire and Explosions

- Worry for good ventilation of stores and work.
- Handle and open the container with care.
- If the containers are not in use, keep them tightly closed.
- Wear a respirator when decanting larger quantities without extractor.
- Use for the transport in earthen vessels in breakable container.
- Meet usual measures for preventive fire protection.
- Avoid dust development.
- Do not inhale the dust a.
- Avoid contact with substance.
- Keep the substance away from sources of ignition (for example, open flames, heat sources and sparks).
- Smoking, welding, drilling or not grind around.
- Prevent electrostatic charging.



Areas where the substance occurs in the form of dust in such quantities that the possibility of a dust explosion is considered a nonhazardous.

### **Measures to Prevent Dusts and Aerosols**

- Take work on under the hood.
- Do not inhale the substance.
- Avoid contact with the eyes, the skin and clothing.
- Follow the instructions on the label.
- Do not spill the substance with an open handling.
- Avoid dust development.
- · Record to regularly dust unavoidable.
- Do not whirl the dust unnecessarily when cleaning.



The blow-off for cleaning purposes is not permitted.

### **Measures to Protect the Environment**

- Avoid a release to the environment.
- Prevent penetrating into the ground, water and sewerage

### **General Hygiene Measures**

- Observe the precautions for handling chemicals.
- Avoid contact with the skin and eyes.
- Remove contaminated clothing immediately.
- Wash contaminated clothing before reuse.
- Where a hazard can be expected by contamination of work clothes, make separate storage for street work wear available.
- Eat, drink or do not smoke in the work area.
- Wash before breaks and at the end of the hands.
- Insert before entering eating areas from contaminated work clothing and protective equipment.
- You know about preventing skin care.
- Provide eye wash or eye shower at work.

Seite: 7 / 15

# **PANCREATIN**

 Created on:
 20.07.17

 Revised on:
 23.10.19

 Effective from:
 25.10.19

Version: 1.05 Replace Version: 1.04



# 7.2 Conditions for Safe Storage, Including Any Incompatibilities

### **Information About Storage Conditions**

- Keep the container tightly closed in a cool, dry, well-ventilated place.
- Protect the containers from the sun or light exposure.
- The storage temperature is < 15 ° C.

### **Requirements for Storage Rooms and Containers**

- Resistant containers are made of steel, stainless steel and aluminum.
- Check plastic containers before their use for resistance.
- Store the substance in its original container.
- Keep the substance on the basis of the likelihood of confusion, not in food containers.
- Store the substance dry and cool.

Do not store the substance together with the following equipment or substances:

- Medicines
- Feed, including additives
- Infectious, radioactive materials
- Strong oxidizing substances of storage class 5.1A
- Food

Storage Class: TRGS 510 10 – 13 Other liquids and solids

### 7.3 Specific End Use(s)

### **Industry and Sector Specific Guidance**

Not applicable

### 8 Exposure Controls/Personal Protection

# 8.1 Control Parameters

### Occupational Exposure Limits in the Workplace and/or Biological Limits,

Occupational Exposure Limits (OEL) Germany

For valid lists the substance contains no substances with under safeguards, workplace limit values.

# 8.2 Exposure Controls

# **Appropriate Engineering Controls**

- Ensure good ventilation of the work area and/or the suction at the workplace (suction of objects).
- Make fire extinguishing equipment ready.
- Look at the workplace before a launderette.
- Provide an eyewash or eye bath.
- Mark the eyewash or eyewash bottle striking.
- · Take measures to prevent electrostatic charging.

Seite: 8 / 15

# **PANCREATIN**

 Created on:
 20.07.17

 Revised on:
 23.10.19

 Effective from:
 25.10.19

Version: 1.05 Replace Version: 1.04



### **Individual Protection Measures - Personal Protective Equipment**

 Insert the personal protective equipment determined according to the amount and concentration of hazardous substances in the workplace.

### Recommendation:

- Protective clothing
- General safety and hygiene measures see chapter 7.1

### **Eye/Face Protection**

• Use glasses with side shields conforming to EN 166th.

### Skin Protection

### **Pair of Gloves**

• Use protective gloves according to EN 374.

The following glove material is suitable for full contact and splash contact:

- Nitrile rubber Layer thickness ≥ 0.11 mm
- Breakthrough time (maximum wearing time) > 480 min
- Check the gloves for leaks before use.
- The penetration time varies depending on the design and application conditions.
- Observe the instructions of the manufacturer of the protective gloves for permeability and breakthrough times.

### **Other Skin Protection**

Use a Cat. III SIR chemical protection coverall; EN 1149.

### **Inhalation Protection**

Continuously respected workplace exposure limits and other limits a respiratory protection is normally not required.

- If dust situations, use the equipment with filter type P1 (EN 147).
- Remove more about application requirements and maximum concentrations of the "Rules for the use of respiratory protection equipment" (BGR 190).
- Ensure that maintenance, cleaning and testing are carried out of respirators according to the instructions of the manufacturer and documented.

### **Heat / Cold Protection**

 The storage and natural conditions for the handling of the substance require no heat or cold protection.

# **Delimitation and Monitoring of the Environmental Exposition**

Do not allow the substance to enter drains, surface water or soil.

Seite: 9 / 15

# **PANCREATIN**

 Created on:
 20.07.17

 Revised on:
 23.10.19

 Effective from:
 25.10.19

Version: 1.05 Replace Version: 1.04



# 9 Physical and Chemical Properties

### 9.1 Information on Basic Physical and Chemical Properties

Appearance

Aggregate state
 Color
 Aroma
 Fixed
 Light yellow
 Characteristic

Odor -

pH-Value Appr. 5 to 6 for 10 g/L; 20 °C

Dripping/freezing point Initial boiling point/range Flashing point Evaporation rate Flammability Upper/lower flammability or -

explosion range Reid vapor Vapor

relative volume mass -

Solubility (20 °C) Partially soluble in water

Partition coefficient

n-octane/water

Spontaneous ignition temperature - Decomposition temperature -

Viscosity Not applicable

Explosive properties -

Oxygenize properties -

Bulk density Appr. 400 kg/m<sup>3</sup>

## 9.2 Other Information

Not applicable

# 10 Stability and Reactivity

# Reactivity

**10.1** Generally applies to solid, combustible organic substances and mixtures:

If the substance is finely dispersed in the fluidized state, a dust explosion potential is generally to be assumed.

# 10.2 Chemical Stability

The substance is chemically stable under normal ambient conditions (room temperature).

### 10.3 Possibility of Hazardous Reactions

Strong oxidizing agents

### 10.4 Conditions to Avoid

heating up

### 10.5 Incompatible Materials

Strong oxidizing agents

# 10.6 Hazardous Decomposition Products

See chapter 5.2

Seite: 10 / 15

# **PANCREATIN**

Created on: 20.07.17 Revised on: 23.10.19

Effective from: 25.10.19

Version: 1.05 **Replace Version:** 1.04

### 11 **Toxicological Information**

# 11.1 Information on Toxicological Effects

Acute toxicity LD50 orally (Rat)

Value > 10 000 mg/kg

Skin corrosion / irritation

Causes skin irritation After skin contact

Serious eye damage / irritation

After eye contact Causes serious eye irritation

Respiratory or skin sensitization

After inhalation Irritation of the respiratory tract. Causes allergies,

asthma symptoms or difficulty breathing.

Causes allergic skin reactions.

Germ cell mutagenicity

Genotoxicity in vitro Ames Test Result negative (Lit.)

Carcinogenicity Not specified

Reproductive toxicity

Not specified

Specific target organ toxicity - single exposure

Irritating to the respiratory tract

Specific target organ toxicity - repeated exposure

Not specified

Aspiration hazard

Not specified

Symptoms and Effects (Delayed and Chronic) With Data on the Exposure Routes, also:

Information on Toxicokinetics, Metabolism and Distribution

Under physiological conditions in the body occurring substance.

Observe the usual precautionary measures when handling chemicals.

- 12 **Ecological Information**
- 12.1 Toxicity
- 12.2 Persistence and Degradability
- 12.3 Bioaccumulative Potential
- 12.4 Mobility in Soil

Seite: 11 / 15

# **PANCREATIN**

Created on: 20.07.17
Revised on: 23.10.19
Effective from: 25.10.19

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Version: 1.05 Replace Version: 1.04



### 12.5 Results of PBT and vPvB Assessment

### 12.6 Other Adverse Effects

Water hazard class (WHC) see chapter 15

### 13 Disposal Considerations

### 13.1 Waste Treatment Methods

### Treatment of contaminated packaging

Hand over the original containers to the responsible disposal company.

### Recommendation:

Special waste incineration with official approval.



Never mix contaminated containers / packaging with other waste or household waste!

### Waste code according to the Waste Catalog Ordinance (AVV)

The waste producer is responsible for the correct encryption and designation of his waste.

### Special precautions

See chapter 8.2

### Relevant EU or other provisions

Waste Directive 2008/98 / EC

### 14 Transport Information

### 14.1 UN number

The substance is not subject to the transport regulations.

### 14.2 UN Proper Shipping Name

### ADR/RID

The substance is not subject to the transport regulations.

# IMDG-Code/ICAO-TI/IATA-DGR

The substance is not subject to the transport regulations.

# 14.3 Transport Hazard Class(es)

The substance is not subject to the transport regulations.

### 14.4 Packing Group

The substance is not subject to the transport regulations.

### 14.5 Environmental Hazards

L	abe	l env	ironm	entall	y hazaro	lous su	bstan	ces		
Α	DR/	RID/I	MDG-	Code/	ICAO-TI	/IATA-D	GR: 🗌	yes	/	nc nc

Marine Pollutant: ☐ yes / ☐ no

Seite: 12 / 15

# PANCREATIN

Created on: 20.07.17 Revised on: 23.10.19

**Effective from:** 25.10.19

Version: 1.05 **Replace Version:** 1.04



# 14.6 Special Precautions for User

### 14.7 Transport in Bulk According to Annex II of MARPOL73/78 and the IBC Code

The substance is not subject to the transport regulations.

### 15 **Regulatory Information**

### Safety, Health and Environmental Regulations/Legislation Specific for the Substance or 15.1 Mixture

### EU Regulations e.g.

Regulation 1272/2008 / EC (CLP / GHS) and supplements

Regulation 1907/2006 / EC (REACH) and supplements

Supplements:

Regulations 453/2010 / EC (on REACH), 790/2009 / EC and 286/2011 / EC (on GHS / CLP)

Directives RL 67/548 / EEC (substances) and 1999/45 / EC (preparations)

Council Directive 98/24 / EC of 7 April 1998 - Not applicable

Directive 2008/98 / EC of the European Parliament and of the Council of 19 November 2008 on waste

Directive 94/62 / EC on packaging and packaging waste (Waste Directive)

### National Regulations e.g.

### Water Hazard Class

WHC 1 - slightly hazardous to water (classification according to VwVwS) Substance number: 1831

Solvents ordinance (31st BlmSchV)

Accident ordinance (12th BlmSchV)

### **Technical Instructions Air (TI-Air)**

Keeping the air clean; Chapter 5.2.5 Organic substances, class I The following values must not be exceeded in the exhaust gas flow:

Mass flow: 0.10 kg / h

Mass concentration: 20 mg / m<sup>3</sup>

# Other relevant regulations

### 15.2 Chemical Safety Assessment

No chemical safety assessment has been carried out for this substance.

Seite: 13 / 15

# **PANCREATIN**

 Created on:
 20.07.17

 Revised on:
 23.10.19

 Effective from:
 25.10.19

Version: 1.05 Replace Version: 1.04



### 16 Other Information

# Changes compared to the last version

New versions

### **Abbreviations**

PTB Persistent, Toxic, Bioaccumulative

RTECS Registry of Toxic Effects of Chemical Substances

vPvB very persistent, very bioaccumulative

VwVwS General administrative regulation amending the administrative regulation on substances

hazardous to water.

ASR Technical rules for workplaces

### References and data sources

Manufacturer information, UBA, REACH-EU, Hazardous Materials Information Center

# Methods according to Article 9 of Regulation (EC) No 1272/2008 for the evaluation of the information used for classification purposes

The information on the substance described here was found in our laboratory. Another determination was made by the suppliers of pancreatin.

# Wording of the Hazard Statements and / or Precautionary Statements Referred to in Chapter 2 to Chapter 15

P102	Keep out of the reach of children.
P261	Avoid breathing dust / fume / gas / mist / vapor / spray.
P264	Wash thoroughly after use (specify body parts to be washed by the manufacturer).
P271	Use only outdoors or in well-ventilated areas.
P272	Contaminated work clothing should remain in the workplace.
P280	Wear protective gloves / protective clothing / eye protection / face protection.
P285	In case of insufficient ventilation, wear respiratory protection.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P304 + P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for
	breathing.
P304 + P341	IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position
	comfortable for breathing.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if
	possible. Continue rinsing.
P312	Targeted treatment (see notes on the label).
P321	If you feel unwell, call the POISON TIP or doctor.
P332 + P313	If skin irritation occurs: Get medical advice / attention.
P333 + P313	If skin irritation or rash occurs: Get medical advice / attention.
P337 + P313	If eye irritation persists: Get medical advice / attention.
P342 + P311	If experiencing respiratory symptoms: Call POISON or doctor.
P362	Take off contaminated clothing and wash before reuse.
P363	Wash contaminated clothing before reuse.
P403 + P233	Keep container tightly closed in a well-ventilated place
P405	Keep locked up.
P501	Dispose of contents / container to authorized waste disposal company or municipal collection point.
R36/37/38	Irritating to eyes, respiratory system and skin.
R41/42	May cause sensitization by inhalation and skin contact.

Seite: 14 / 15

# **PANCREATIN**

Created on: 20.07.17
Revised on: 23.10.19

Effective from: 25.10.19

Version: 1.05 Replace Version: 1.04

# BeSiTa GmbH

### **Training for Employees**

Regular safety instruction in handling chemical substances.

### **Further Information**

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Seite: 15 / 15