

Section 1. Product and Company Identification

Product Name Pancreatin
CAS Number 8049-47-6

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Section 2. Hazards Identification

Classification of the substance or mixture

According to regulation (EC) No. 286/2011, GHS-regulation (Globally Harmonized System of Classification and Labelling of Chemicals) or CLP (Regulation on Classification, Labelling and Packaging of Substances and Mixtures) The classification is according to current EC-List, but is complete by data from other literatures.

GHS Label Elements

Pictograms:



Signal word: Danger

Hazard and precautionary statements

Hazard statements

Causes skin irritation. (H315)
May cause an allergic skin reaction. (H317)
Causes serious eye irritation. (H319)
May cause allergy or asthma symptoms or breathing difficulties if inhaled. (H334)
May cause respiratory irritation. (H335)

Prevention

Wear protective gloves/protective clothing/eye protection/face protection
Avoid dust inhalation.
After handling wash with sufficient quantities of water.
Handling in area with sufficient ventilation.
Wear suitable protective clothing, gloves and eye-protective glasses.
In case of insufficient ventilation, wear suitable respiratory equipment.



Response

Eye Contact: Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention.

Skin Contact: In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

Serious Skin Contact: Wash with a disinfectant soap and cover the contaminated skin with an antibacterial cream. Seek medical attention.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation: Not available.

Ingestion: Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.

Serious Ingestion: Not available.

Hazards description

Information pertaining to special dangers for human and environment: The product is not dangerous for ecology.

R: 36/37/38-42/43: May cause irritation of eyes respiratory tract and skin. May cause sensitization by inhalation.

Section 3. Composition / Information on Ingredients

Common Name Pancreatin
Synonym(s) Pancreas powder
CAS Number 8049-47-6

COMPONENT	CAS NUMBER	CONCENTRATION
Enzyme: Pancreatin	8049-47-6	10 - 100%
Excipients: Lactose or Maltodextrin	63-42-3/9050-36-6	≤ 90%

Section 4. First Aid Measures

General information: Wear protective clothing.

In case of inhalation: Fresh air

In case of eye and skin contact: Flush eyes carefully with water.

In case of ingestion (big amount): In case of unease seek medical advice.

Section 5. Firefighting Measures

Suitable extinguishing media: Use any media that is appropriate for the surrounding fire.

Extinguishing media which must not be used for safety reasons: Not applicable



Special protective equipment for fire-fighters: Wear positive pressure, self-contained breathing apparatus.

Additional information: Not applicable

Section 6. Accidental Release Measures

Personal precautions: Work dust-free, avoid contact with eyes and skin.

Environmental precautions: Avoid release into storm sewage system.

Methods for cleaning up: Vacuum or moisten with water and collect into a closed container

Additional information: Not applicable

Section 7. Handling and Storage

Advice on safe handling: Handle container carefully.

Precautions against fire and explosion: Explosive mixture of dust and air is not very likely.

Storage

Storage with other Substances: Not applicable

Technical measures and storage conditions: Tightly closed in a cool dry place.

Hints on storage assembly (Storage class): Not applicable.

Section 8. Exposure Controls / Personal Protection

Exposure limit values

Components with occupational exposure limits: Not applicable

Occupational exposure limits: Not applicable

DNEL/DMEL and PNEC-values: Not applicable

Exposure controls

Occupational exposure controls

Technical measures to prevent exposure: General ventilation should be adequate for normal use. For operations where the product may be exceeded, mechanical ventilation such as local exhaust may be needed to maintain exposure levels below applicable limits

Personal protection equipment

Respiratory protection: Wear positive pressure, self-contained breathing apparatus

Hand protection: Wear suitable protective gloves

Eye protection: Wear suitable protective glasses

Body protection: Full protective clothing recommended in case of dust

Environmental exposure controls: Not applicable

Consumer exposure control: Not applicable



Section 9. Physical and Chemical Properties

Appearance: Fine amorphous powder
Color: Cream-colored to slightly brown
Odor: Characteristic, but not offensive odor
Solubility (1%, aqua): Slightly soluble in Water, insoluble in organic solvents.
pH (1%, aqua): 5.0 - 7.0
Bulk density: 0.6 kg/Liter
Flashing point: In closed cup: No Data

Section 10. Stability and Reactivity

Conditions to avoid: Not applicable
Materials to avoid: Not applicable
Hazardous decomposition products: (NO)_x-Gas
Other information: Not applicable

Section 11. Toxicological Information

Acute toxicity

Toxicity of REACH relevant components from capital 3

Pancreatin (EINECS# 232-468-9) oral Rat: LD50 > 10 g/kg
Lactose (EINECS#; E.G.# 200-559-2) oral Rat: LD50 > 10 g/kg
Maltodextrin (EINECS#; E.G.# 232-940-4) LD50 is not defined.

General remarks: May cause irritation of eyes respiratory tract and skin. May cause sensitization by inhalation.

Section 12. Ecological Information

Ecotoxicity (water hazard class, self-classified): WGK 1

Mobility: Not applicable

Persistence and degradability of REACH relevant components from capital 3

Pancreatin (EINECS#232-468-9)

Abiotic Degradation not controlled (OECD 201-202 & 301A-F)
Biodegradation not controlled (OECD 201-202 & 301A-F)
Bioaccumulative potential not controlled (OECD 201-202 & 301A-F)
Bioconcentration factor (BCF) not controlled (OECD 201-202 & 301A-F)
Longterm-Ecotoxicity not controlled (OECD 201-202 & 301A-F)

Lactose (EINECS#; E.G.# 200-559-2)

Abiotic Degradation not controlled (OECD 201-202 & 301A-F)
Biodegradation not controlled (OECD 201-202 & 301A-F)



Bioaccumulative potential not controlled (OECD 201-202 & 301A-F)
Bioconcentration factor (BCF) not controlled (OECD 201-202 & 301A-F)
Longterm-ecotoxicity not controlled (OECD 201-202 & 301A-F)

Maltodextrin (EINECS#; E.G.# 232-940-4)

Abiotic Degradation not controlled (OECD 201-202 & 301A-F)
Biodegradation not controlled (OECD 201-202 & 301A-F)
Bioaccumulative potential not controlled (OECD 201-202 & 301A-F)
Bioconcentration factor (BCF) not controlled (OECD 201-202 & 301A-F)
Longterm-ecotoxicity not controlled (OECD 201-202 & 301A-F)

Other information: Very low accumulative potential

Other adverse effects: Not applicable

Further ecological information: Not applicable

Section 13. Disposal Considerations

Waste Treatment Methods: Dispose of product and contaminated packaging in accordance with all local, state, and federal environmental control regulations.

Section 14. Transport Information

DOT

Proper Shipping Name: None

Non-Hazardous for Transport: This substance is considered to be non-hazardous for transport.

ADR/RID/GGVSE-Class: Not a hazardous material

See Transport IMDG-Code/GGVSee: Not a hazardous material

Air transport (ICAO-IATA/DGR): Not a hazardous material

Section 15. Regulatory Information

Germany regulations

Wassergefährdungsklasse: (Water hazard class WGK 3)

Directive 98/8/EC of biocide Product: There is no information in ESIS for this substance with respect to the BPD

Classification and Labelling Information: This substance is not classified in the Annex I of Directive 67/548/EEC as such, but it may be included in one of the group entries. An example of a group entry is 033-002-00-5 'arsenic compounds with the exception of those specified elsewhere in this Annex'. Substances not listed either individually or in group entries must be self-classified.



Export and Import of Dangerous Chemicals (Regulation (EC) No 689/2008)

Information: This substance is not listed in the Annex I of Regulation (EC) No 689/2008

HPV-LPV (High and Low Production Volume) Information: This substance has not been reported by EU Industry as an HPVC or LPVC.

IUCLID & OECD Chemical Data Sheets and Export Files Information: Not available for this substance.

European Priority Lists and Risk Assessment (Council Regulation (EEC) No 793/93)

Information: This substance is not listed in a priority list (as foreseen under Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances.).

Section 16. Other Information

Disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product.

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