

Safety Data Sheet
 acc. to OSHA HCS

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Printing date 10/06/2016

Reviewed on 10/06/2016

Version number: 2

1 Identification

- **Product identifier**
- **Trade name:** Pancreatin
- **Article number:** A0585
- **CAS Number:**
8049-47-6
- **EC number:**
232-468-9
- **Application of the substance / the mixture**
Biochemistry
Laboratory chemical
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
AppliChem GmbH
Ottoweg 4
D-64291 Darmstadt
- **Information department:** Dept. Compliance
- **Emergency telephone number:** +49(0)6151 93570 (Inside normal business hours)

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2 Hazard(s) identification

- **Classification of the substance or mixture**
 Skin Irrit. 2 H315 Causes skin irritation.
 Eye Irrit. 2A H319 Causes serious eye irritation.
 Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 Skin Sens. 1 H317 May cause an allergic skin reaction.
 STOT SE 3 H335 May cause respiratory irritation.

· Label elements

· GHS label elements

The substance is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms



GHS07 GHS08

· Signal word Danger

· Hazard-determining components of labeling:

Pancreatin

· Hazard statements

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

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· **Precautionary statements**

- P280 Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
P304+P341 If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
P302+P352 IF ON SKIN: Wash with plenty of water.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



· **HMIS-ratings (scale 0 - 4)**



· **Other hazards**

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
· **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Substances**
· **CAS No. Description**
8049-47-6 Pancreatin
· **Identification number(s)**
· **EC number:** 232-468-9

4 First-aid measures

- **Description of first aid measures**
· **After inhalation:** Supply fresh air; consult doctor in case of complaints.
· **After skin contact:**
Wash off with plenty of water.
Immediately remove any clothing soiled by the product.
If skin irritation continues, consult a doctor.
· **After eye contact:**
Rinse opened eye for several minutes under running water.
Call a doctor immediately.
· **After swallowing:**
make victim drink water (maximum of 2 drinking glasses)
Seek medical treatment.
· **Information for doctor:**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

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5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture**
Combustible.
Development of hazardous combustion gases or vapours possible in the event of fire.
- **Advice for firefighters**
- **Protective equipment:** *Wear self-contained respiratory protective device.*
- **Additional information**
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Avoid formation of dust.
Do not inhale dust.
Avoid substance contact.
Ensure adequate ventilation
- **Environmental precautions:** *Do not allow to enter sewers/ surface or ground water.*
- **Methods and material for containment and cleaning up:**
Pick up mechanically.
Avoid generation of dusts.
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
Clean up affected area.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of dust.
Any deposit of dust which cannot be avoided must be regularly removed.
- **Information about protection against explosions and fires:** *No special measures required.*
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** *No special requirements.*
- **Information about storage in one common storage facility:** *Not required.*
- **Further information about storage conditions:**
Keep receptacle tightly sealed.
Open receptacle only under localized extractor facilities.
Store under lock and key and with access restricted to technical experts or their assistants only.
- **Recommended storage temperature:** *2-8 °C*
- **Storage class:** *13*
- **Specific end use(s)** *No further relevant information available.*

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** *No further data; see item 7.*

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- **Control parameters**
- **Components with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
 - Keep away from foodstuffs, beverages and feed.
 - Immediately remove all soiled and contaminated clothing.
 - Wash hands before breaks and at the end of work.
 - Vacuum clean contaminated clothing. Do not blow or brush off contamination.
 - Avoid contact with the eyes and skin.
- **Breathing equipment:**
 - In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
 - Filter P1
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**
 - 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.
- **Penetration time of glove material**
 - The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **For the permanent contact gloves made of the following materials are suitable:**
 - Nitrile rubber, NBR
 - Recommended thickness of the material: ≥ 0.11 mm
 - Value for the permeation: Level ≥ 480 min
- **As protection from splashes gloves made of the following materials are suitable:**
 - Nitrile rubber, NBR
 - Recommended thickness of the material: ≥ 0.11 mm
 - Value for the permeation: Level ≥ 480 min
- **Eye protection:**



Tightly sealed goggles

- **Body protection:**
 - Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled.

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Solid
Color:	Light yellow
Odor:	Characteristic
Odor threshold:	Not determined.

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· pH-value at 20 °C (68 °F):	5-6
· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Product is not flammable.
· Ignition temperature:	>360 °C (>680 °F)
· Decomposition temperature:	Not determined.
· Auto igniting:	Not determined.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not applicable.
· Density:	Not determined.
· Bulk density at 20 °C (68 °F):	~400 kg/m ³
· Relative density	Not determined.
· Vapor density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with Water:	Partly soluble. Insoluble.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content:	
Organic solvents:	0.0 %
VOC content:	0.0 g/l / 0.00 lb/gl
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
 - **Chemical stability**
 - **Thermal decomposition / conditions to be avoided:** Heating
 - **Possibility of hazardous reactions**
- Violent reactions possible with:
strong oxidants
- **Conditions to avoid** No further relevant information available.
 - **Incompatible materials:** No further relevant information available.
 - **Hazardous decomposition products:** No dangerous decomposition products known.

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11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **LD/LC50 values that are relevant for classification:**

Components	Type	Value	Species
8049-47-6 Pancreatin			
Oral	LD50	10000 mg/kg (rat)	

- **Primary irritant effect:**
 - **on the skin:** Irritant to skin and mucous membranes.
 - **on the eye:** Irritating effect.
- **Sensitization:**
 - Sensitization possible through inhalation.
 - Sensitization possible through skin contact.
- **Additional toxicological information:**
- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

Substance is not listed.

- **NTP (National Toxicology Program)**

Substance is not listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

Substance is not listed.

12 Ecological information

- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
 - Water hazard class 1 (Assessment by list): slightly hazardous for water
 - Do not allow to enter waters, waste water, or soil.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
 - Chemicals must be disposed of in compliance with the respective national regulations.
 - Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:**
 - Disposal must be made according to official regulations.
 - Packagings that cannot be cleansed are to be disposed of in the same manner as the product.

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14 Transport information

· UN-Number	
· DOT, ADR, ADN, IMDG, IATA	Void
· UN proper shipping name	
· DOT, ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· DOT, ADR, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· DOT, ADR, IMDG, IATA	Void
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	Not dangerous according to the above specifications.
· UN "Model Regulation":	Void

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

- **Section 355 (extremely hazardous substances):**

Substance is not listed.

- **Section 313 (Specific toxic chemical listings):**

Substance is not listed.

- **TSCA (Toxic Substances Control Act):**

Substance is listed.

- **Proposition 65**

- **Chemicals known to cause cancer:**

Substance is not listed.

- **Chemicals known to cause reproductive toxicity for females:**

Substance is not listed.

- **Chemicals known to cause reproductive toxicity for males:**

Substance is not listed.

- **Chemicals known to cause developmental toxicity:**

Substance is not listed.

- **Carcinogenicity categories**

- **EPA (Environmental Protection Agency)**

Substance is not listed.

- **TLV (Threshold Limit Value established by ACGIH)**

Substance is not listed.

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

Substance is not listed.

- **GHS label elements**

The substance is classified and labeled according to the Globally Harmonized System (GHS).

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· **Hazard pictograms**



GHS07 GHS08

· **Signal word** *Danger*

· **Hazard-determining components of labeling:**

Pancreatin

· **Hazard statements**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

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

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

· **Precautionary statements**

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

P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

P304+P341 If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.

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

· **Chemical safety assessment:** *A Chemical Safety Assessment has not been carried out.*

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** *Dept. Compliance*

· **Contact:** *Mr. Th. Stöckle*

· **Date of preparation / last revision** *10/06/2016 / 1*

· **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

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

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

Resp. Sens. 1: Respiratory sensitisation – Category 1

Skin Sens. 1: Skin sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· *** Data compared to the previous version altered.**