

Safety Data Sheet according to WHS Regulations

Printing date 05.06.2019

Revision: 05.06.2019

1 Identification

- **Product identifier**
- **Trade name:** Pancreatin USP
- **Article number:** 102557
- **CAS Number:**
8049-47-6
- **EC number:**
232-468-9
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Research use only.
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
MP Biomedicals, LLC
29525 Fountain Parkway
Solon, OH 44139
United States
www.mpbio.com
- MP Biomedicals Australia Pty Limited
2/29 Bearing Road
Seven Hills, NSW 2147 Aust.
Telephone Number: (02) 9838 7422
Fax Number: (02) 9838 7390
www.mpbio.com
- **Further information obtainable from:** Quality Control Department
- **Emergency telephone number:**
CHEMTREC: 1-800-424-9300 (1-703-527-3887)
Australia Poison Control Centre: +61 13 11 26

2 Hazard(s) Identification

- **Classification of the substance or mixture**



health hazard

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.



Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2A H319 Causes serious eye irritation.

STOT SE 3 H335 May cause respiratory irritation.

- **Label elements**

- **GHS label elements**

The substance is classified and labelled according to the Globally Harmonised System (GHS).

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· Hazard pictograms



GHS07 GHS08

· Signal word *Danger*

· Hazard-determining components of labelling:

Pancreatin, USP

· Hazard statements

Causes skin irritation.

Causes serious eye irritation.

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

May cause respiratory irritation.

· Precautionary statements

If medical advice is needed, have product container or label at hand.

Keep out of reach of children.

Read label before use.

Avoid breathing dust/fume/gas/mist/vapours/spray.

Wear protective gloves / eye protection / face protection.

In case of inadequate ventilation wear respiratory protection.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· Other hazards

· Results of PBT and vPvB assessment

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition and Information on Ingredients

· Chemical characterisation: Substances

· CAS No. Description

8049-47-6 Pancreatin, USP

· Identification number(s)

· **EC number:** 232-468-9

4 First Aid Measures

· Description of first aid measures

· **General information:** Immediately remove any clothing soiled by the product.

· **After inhalation:** In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

· After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:** If symptoms persist consult doctor.

· Information for doctor:

· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

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- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire Fighting Measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **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.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:** -20°C
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Further information about storage conditions:**
- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making 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.
Avoid contact with the eyes and skin.

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- **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

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.

- **Eye protection:**



Tightly sealed goggles

9 Physical and Chemical Properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form:	Powder
Colour:	Whitish
Odour:	Indeterminate
Odour threshold:	Not determined.

- **pH-value:** Not applicable.

- **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.

- **Flash point:** Not applicable.

- **Flammability (solid, gas):** Product is not flammable.

- **Decomposition temperature:** Not determined.

- **Auto-ignition temperature:** Not determined.

- **Explosive properties:** Product does not present an explosion hazard.

- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

- **Vapour pressure:** Not applicable.

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· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with water:	- Not determined. Insoluble.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
Solids content:	100.0 %
· 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:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid**
No further relevant information available.
No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity:**

· LD/LC50 values relevant for classification:
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8049-47-6 Pancreatin, USP

Oral LD50	10,000 mg/kg (rat)
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- **Primary irritant effect:**
- **Skin corrosion/irritation** Irritant to skin and mucous membranes.
- **Serious eye damage/irritation** Irritating effect.
- **Respiratory or skin sensitisation** Sensitisation possible through inhalation.

12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.

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- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Assessment by list): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **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**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|---|-----------------|
| · UN-Number | |
| · ADG, IMDG, IATA | Not regulated |
| · UN proper shipping name | |
| · ADG, IMDG, IATA | Not regulated |
| · Transport hazard class(es) | |
| · ADG, IMDG, IATA | |
| · Class | Not regulated |
| · Packing group | |
| · ADG, IMDG, IATA | Not regulated |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Not regulated |

15 Regulatory information

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

- **Australian Inventory of Chemical Substances**

Substance is listed.

- **Standard for the Uniform Scheduling of Medicines and Poisons**

Substance is not listed.

- **GHS label elements**

The substance is classified and labelled according to the Globally Harmonised System (GHS).

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· **Hazard pictograms**

GHS07 GHS08

· **Signal word** *Danger*· **Hazard-determining components of labelling:***Pancreatin, USP*· **Hazard statements***Causes skin irritation.**Causes serious eye irritation.**May cause allergy or asthma symptoms or breathing difficulties if inhaled.**May cause respiratory irritation.*· **Precautionary statements***If medical advice is needed, have product container or label at hand.**Keep out of reach of children.**Read label before use.**Avoid breathing dust/fume/gas/mist/vapours/spray.**Wear protective gloves / eye protection / face protection.**In case of inadequate ventilation wear respiratory protection.**IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.**Continue rinsing.**Store locked up.**Dispose of contents/container in accordance with local/regional/national/international regulations.*· **Directive 2012/18/EU**· **Named dangerous substances - ANNEX I** *Substance is not listed.*· **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:** *Quality Control Dept.*· **Abbreviations and acronyms:***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**IATA: International Air Transport Association**EINECS: European Inventory of Existing Commercial Chemical Substances**CAS: Chemical Abstracts Service (division of the American Chemical Society)**LC50: Lethal concentration, 50 percent**LD50: Lethal dose, 50 percent**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**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**STOT SE 3: Specific target organ toxicity (single exposure) – Category 3*