

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Pankreas Pulver reinst, Ph.Eur

Revision date: 14.12.2023

Product code: 24687

Page 1 of 9

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

1.1. Product identifier

Pankreas Pulver reinst, Ph.Eur

Substance name: Pancreatin
CAS No: 8049-47-6
EC No: 232-468-9

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

Laboratory chemicals

Industrial uses: Uses of substances as such or in preparations at industrial sites

Professional uses: Public domain (administration, education, entertainment, services, craftsmen)

Uses advised against

Do not use for private purposes (household).

1.3. Details of the supplier of the safety data sheet

Company name: AnalytiChem GmbH
Street: Stempelstraße 6
Place: D-47167 Duisburg
Telephone: 0203/5194-0
E-mail: info@analytichem.de
Contact person: Abteilung Produktsicherheit
E-mail: produktsicherheit@analytichem.de
Internet: www.analytichem.de
Responsible Department: Abteilung Produktsicherheit

Telefax: 0203/5194-290

Telephone: 0203/5194-107/117

1.4. Emergency telephone number:

For Hazardous Materials [or Dangerous Goods] Incidents Spill, Leak, Fire, Exposure, or Accident Call CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 Outside USA and Canada: +1 703-741-5970 (collect calls accepted)

Further Information

A registration number is not available for this substance as the substance or its use are exempted from registration according to Article 2 REACH Regulation (EC) No 1907/2006, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Skin Irrit. 2; H315
Eye Irrit. 2; H319
Resp. Sens. 1; H334
Skin Sens. 1; H317
STOT SE 3; H335

Full text of hazard statements: see SECTION 16.

2.2. Label elements

Regulation (EC) No 1272/2008

Signal word: Danger

Safety Data Sheet

according to Regulation (EC) No 1907/2006

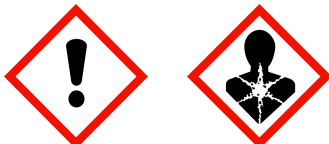
Pankreas Pulver reinst, Ph.Eur

Revision date: 14.12.2023

Product code: 24687

Page 2 of 9

Pictograms:



Hazard statements

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

Precautionary statements

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

2.3. Other hazards

No data available

SECTION 3: Composition/information on ingredients

3.1. Substances

Relevant ingredients

CAS No	Chemical name	Quantity
	EC No	
	Index No	
	REACH No	
	Classification (Regulation (EC) No 1272/2008)	
8049-47-6	Pancreatin	100 %
	232-468-9	
	Skin Irrit. 2, Eye Irrit. 2, Resp. Sens. 1, Skin Sens. 1, STOT SE 3; H315 H319 H334 H317 H335	

Full text of H and EUH statements: see section 16.

Further Information

This product does not contain substances of very high concern according to Regulation (EC) No 1907/2006 (REACH), Article 57 above the respective regulatory concentration limit of = 0.1 % (w/w).

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

Self-protection of the first aider

After inhalation

Provide fresh air.
Call a physician immediately.

After contact with skin

After contact with skin, wash immediately with plenty of water and soap.
Take off immediately all contaminated clothing and wash it before reuse.
Call a physician immediately.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Pankreas Pulver reinst, Ph.Eur

Revision date: 14.12.2023

Product code: 24687

Page 3 of 9

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.
Remove contact lenses, if present and easy to do. Continue rinsing.
Consult an ophthalmologist.

After ingestion

Rinse mouth immediately and drink plenty of water.
Call a physician immediately.

4.2. Most important symptoms and effects, both acute and delayed

Irritant
Allergic reactions
Cough
Dyspnoea

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

No data available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Water
Carbon dioxide (CO₂)
Foam
Extinguishing powder

Unsuitable extinguishing media

no restriction

5.2. Special hazards arising from the substance or mixture

Combustible solids
Hazardous combustion products
Danger of dust explosion.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.
In case of fire and/or explosion do not breathe fumes.
Avoid contact with skin, eyes and clothes.

Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.
Move undamaged containers from immediate hazard area if it can be done safely.
Use water spray jet to protect personnel and to cool endangered containers.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Provide adequate ventilation.
Use personal protection equipment.
Avoid contact with skin, eyes and clothes.
Remove persons to safety.
Emergency procedures
Do not breathe dust/fume/gas/mist/vapours/spray.

For emergency responders

Precautionary statements For emergency responders : Personal protection equipment: see section 8

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Pankreas Pulver reinst, Ph.Eur

Revision date: 14.12.2023

Product code: 24687

Page 4 of 9

6.3. Methods and material for containment and cleaning up

For containment

- Cover drains.
- Prevent spread over a wide area (e.g. by containment or oil barriers).
- Collect in closed and suitable containers for disposal.
- Take up carefully when dry. Take up dust-free and set down dust-free.

For cleaning up

- Clean contaminated articles and floor according to the environmental legislation.

Other information

- Provide adequate ventilation.
- Do not breathe dust/fume/gas/mist/vapours/spray.
- Wear breathing apparatus if exposed to vapours/dusts/aerosols.

6.4. Reference to other sections

- Safe handling: see section 7
- Personal protection equipment: see section 8
- Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

- Read label before use. Handle and open container with care.
- When using do not eat, drink, smoke, sniff. Keep container tightly closed.
- Use personal protection equipment. Use extractor hood (laboratory).
- Avoid dust formation. Do not breathe dust.
- Provide adequate ventilation.

Advice on protection against fire and explosion

- Usual measures for fire prevention.

Advice on general occupational hygiene

- Keep away from food, drink and animal feedingstuffs.
- Wash hands and face before breaks and after work and take a shower if necessary.
- When using do not eat or drink.
- Avoid dust formation. Do not breathe dust.

Further information on handling

- Take off immediately all contaminated clothing and wash it before reuse.
- Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary. If handled uncovered, arrangements with local exhaust ventilation have to be used.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

- Keep container tightly closed and dry.
- Store in a place accessible by authorized persons only.

Hints on joint storage

- No data available

Further information on storage conditions

- storage temperature: < +15°C

7.3. Specific end use(s)

- Laboratory chemicals

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Pankreas Pulver reinst, Ph.Eur

Revision date: 14.12.2023

Product code: 24687

Page 5 of 9

8.2. Exposure controls

Appropriate engineering controls

Technical measures and the application of suitable work processes have priority over personal protection equipment.

If handled uncovered, arrangements with local exhaust ventilation have to be used.

Individual protection measures, such as personal protective equipment

Eye/face protection

goggles

Face protection umbrella

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Protective gloves are recommended Company KCL GmbH, D-36124 Eichenzell, email: vertrieb@kcl.de With specification (test according to EN374):

By long-term hand contact

Trade name/designation: KCL 741 Dermatril® L

Recommended material: NBR (Nitrile rubber) 0,11 mm

Wearing time with permanent contact: > 480 min

By short-term hand contact

Trade name/designation: KCL 741 Dermatril® L

Recommended material: NBR (Nitrile rubber) 0,11 mm

Wearing time with occasional contact (splashes): > 480 min

The breakthrough times stated above were determined by KCL in laboratory tests acc. to EN374 with samples of the recommended glove types. This recommendation applies only to the product stated in the safety data sheet (>, <) supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Skin protection

Take off immediately all contaminated clothing and wash it before reuse.

Wear suitable protective clothing. Take off immediately all contaminated clothing.

Wash hands and face before breaks and after work and take a shower if necessary.

Respiratory protection

Respiratory protection necessary at: dust formation

Environmental exposure controls

Do not allow to enter into surface water or drains.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	solid	
Colour:	yellow	
Odour:	characteristic	
Odour threshold:	No data available	
Melting point/freezing point:		No data available

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Pankreas Pulver reinst, Ph.Eur

Revision date: 14.12.2023

Product code: 24687

Page 6 of 9

Boiling point or initial boiling point and boiling range:	No data available
Flammability:	No data available
Lower explosion limits:	No data available
Upper explosion limits:	No data available
Flash point:	No data available
Auto-ignition temperature:	>360 °C
Decomposition temperature:	No data available
pH-Value (at 20 °C):	5-6 (10 g/l)
Viscosity / kinematic:	No data available
Water solubility:	No data available
Solubility in other solvents	No data available
Dissolution rate:	No data available
Partition coefficient n-octanol/water:	No data available
Dispersion stability:	No data available
Vapour pressure:	No data available
Vapour pressure:	No data available
Density:	No data available
Relative density:	No data available
Bulk density:	~400 kg/m ³
Relative vapour density:	No data available
Particle characteristics:	No data available

9.2. Other information

Information with regard to physical hazard classes

Explosive properties	
Danger of dust explosion.	
Sustaining combustion:	No data available
Self-ignition temperature	
Solid:	No data available
Gas:	No data available
Oxidizing properties	
No data available	

Other safety characteristics

Evaporation rate:	No data available
Solvent separation test:	No data available
Solvent content:	No data available
Solid content:	100%
Sublimation point:	No data available
Softening point:	No data available
Pour point:	No data available
Viscosity / dynamic:	No data available
Flow time:	No data available

Further Information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

Danger of dust explosion.

10.2. Chemical stability

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Pankreas Pulver reinst, Ph.Eur

Revision date: 14.12.2023

Product code: 24687

Page 7 of 9

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

Oxidising agent

10.4. Conditions to avoid

Heat

10.5. Incompatible materials

No data available

10.6. Hazardous decomposition products

No data available

Further information

No data available

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Toxicokinetics, metabolism and distribution

No data available

Acute toxicity

Based on available data, the classification criteria are not met.

Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

Sensitising effects

May cause allergy or asthma symptoms or breathing difficulties if inhaled. (Pancreatin)

May cause an allergic skin reaction. (Pancreatin)

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

May cause respiratory irritation. (Pancreatin)

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Information on likely routes of exposure

No data available

Specific effects in experiment on an animal

No data available

Additional information on tests

No data available

Practical experience

No data available

11.2. Information on other hazards

Endocrine disrupting properties

No data available

Other information

No data available

Further information

Irritant

Allergic reactions

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Pankreas Pulver reinst, Ph.Eur

Revision date: 14.12.2023

Product code: 24687

Page 8 of 9

Cough
Dyspnoea

SECTION 12: Ecological information

12.1. Toxicity

Based on available data, the classification criteria are not met.

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

12.6. Endocrine disrupting properties

This substance does not have endocrine disrupting properties with respect to non-target organisms.

12.7. Other adverse effects

Avoid release to the environment.

Further information

Do not allow to enter into surface water or drains.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Waste disposal according to directive 2008/98/EC, covering waste and dangerous waste.
Send to a physico-chemical treatment facility under observation of official regulations.
Do not empty into drains.

Contaminated packaging

Handle contaminated packages in the same way as the substance itself.
The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

SECTION 14: Transport information

Land transport (ADR/RID)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Pankreas Pulver reinst, Ph.Eur

Revision date: 14.12.2023

Product code: 24687

Page 9 of 9

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

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

EU regulatory information

Information according to Directive 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

Water hazard class (D): 1 - slightly hazardous to water

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 12.

Abbreviations and acronyms

Skin Irrit: Skin irritation

Eye Irrit: Eye irritation

Resp. Sens: Respiratory sensitisation

Skin Sens: Skin sensitisation

STOT SE: Specific target organ toxicity - single exposure

Relevant H and EUH statements (number and full text)

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

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

H335 May cause respiratory irritation.

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material. The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights.

The receiver of our product is singularly responsible for adhering to existing laws and regulations.