according to Regulation (EC) No. 1907/2006/EG, Article 31



Product number: \$5239 Product name: Pancreatin from porcine pancreas

1. Identification of the substance/preparation and of the company

Product identifier

Product Name: Pancreatin from porcine pancreas

 Catalogue-No.:
 S5239

 CAS Number:
 8049-47-6

 EC Number:
 232-468-9

REACH Registration Number: A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

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

No further relevant information available.

Application of the substance/the preparation

Laboratory chemical Biochemistry

Details of the supplier of the safety data sheet

Manufacturer /Supplier:

Genaxxon bioscience GmbH, Söflinger Str. 70, 89077 Ulm/Germany.

Tel.: +49 (0)731 3608 123, info@genaxxon.com

Further information available from: General Management

Emergency telephone number: +49 (0)731 3608 123 (Monday till Friday: 7:30 – 18:30 o'clock)

NOTE: If this product is a kit or supplied with more than one material, please refer to the MSDS for each component for hazard information.

Product Use:

This products are for laboratory research use only and are not intended for human or animal diagnostics, therapeutics or other clinical uses.

2. Hazardous identification

Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Skin Irrit. 2 H315 Causes skin irritation. Eye Irrit. 2 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

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labeled according to the CLP regulation.

Hazard pictograms





Ciamal ...and. Daman

Signal word: Danger

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.

P284 [In case of inadequate ventilation] wear respiratory 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.

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

P405 Store locked up

P501 Dispose of contents/container in accordance with local/regional/national/ international regulations.

Other hazards

Result of PBT and vPvB assessment

PBT: not applicable **vPvB:** not applicable

3. Composition/information on ingredients

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Chemical characterisation: 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

General information: No special measures required.

After inhalation:

Do not use mouth to mouth or mouth to nose resuscitation.

Supply fresh air. Consult doctor.

In case of unconsciousness place patient stably in side position for transportation. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel.

After skin contact:

Call a doctor immediately.

Immediately wash with water and rinse thoroughly.

After eye contact:

Call a doctor immediately.

After swallowing:

Rinse out mouth.

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.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing agents:

Carbon Dioxide (CO2). Dry chemical powder, or appropriate foam. Fight larger fires with water spray or alcohol resistant foam.

Special hazards arising from the substance or mixture:

Ambient fire may liberate hazardous vapours.

In case of a fire, the following can be released:

Carbon oxides (CO, CO2)

Nitrogen oxides (NOx)

Hydrogen chloride (HCI)

Non-combustible

Advice for fire fighters:

Protective equipment:

Wear self-contained respiratory protective device

Additional information:

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

Contain escaping vapours with water.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Avoid formation of dust.

Do not inhale dust.

Ensure adequate ventilation.

Use respiratory protective device against the effects of fumes/dust/aerosol.

Environmental precautions: No special measures required.

Methods and materials for containment and cleaning up:

Pick-up mechanically.

Avoid generation of dust.

Ensure adequate ventilation.

Clean up affected area.

Reference to other sections

No dangerous substances are released.

Additional information: None

7. Handling and storage

Precautions for safe handling:

No special precautions are necessary if used correctly.

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Ensure good ventilation/exhaustion at the workplace.

Information about fire - and explosion protection: The product is not flammable.

Conditions for safe storage, including any incompatibilities

Requirements to be met by storerooms and receptacles: Keep receptacles tightly sealed. Information about storage in a common storage facility: Store only in the original receptacle.

Further information about storage conditions:

Keep container tightly sealed.

Protect from exposure to the light.

Store in dry conditions in well closed respectable. Recommended storage temperature: +2°C - +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 facilities: No further data; see item 7 of this data sheet.

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:

The usual precautionary measures are to be adhered to when handling chemicals.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

Avoid contact with eyes and skin.

Store protective clothing separately.

Immediately remove all soiled and contaminated clothing.

Respiratory protection: Respiratory protection required when vapours/aerosols are generated. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Filter P3 (EN 143).



Required when dusts are generated

Protection of hands:



Protective gloves (EN 374)

The glove material has to be impermeable and resist ant 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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

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:

Nitril rubber, NBR

Recommended thickness of the material: ≥0.11mm

Value for permeation: Level: >480 min.

As protection from splashes gloves made of the following materials are suitable:

Nitril rubber, NBR

Recommended thickness of the material: ≥0.11mm

Value for the permeation: Level ≥480 min. Eye/face protection: Safety glasses.



Safety glasses (EN 166)

Body protection:

Use protective suit.

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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: Powder
Colour: Light yellow
Odour: Characteristic
Odour threshold: Not determined

pH value at 20°C: Not determined

Change in conditions

Melting point/Melting range:
Boiling point/Boiling range:
Not determined
Not applicable

Flammability (solid, gaseous): Product is not flammable

 Ignition temperature:
 Not applicable

 Decomposition temperature:
 Not determined

 Self-ignition:
 Not applicable

Danger of explosion: Product does not present an explosion hazard.

Explosion limits:

Lower:
Upper:
Not applicable
Not applicable
Not applicable
Not determined
Relative density:
Not determined
Bulk density:
Vapour density:
Evaporation rate:
Not determined
Not determined
Not determined

Solubility in / Miscibility with

(water): Soluble

Viscosity:

Dynamic: Not determined **Kinematic:** Not determined

Solvent content:

Corrosive to metals

Desensitised explosives

 Organic solvents:
 0.0%

 VOC (EC)
 0.00%

Information with regard to physical hazard classes

Explosives Void Flammable gases Void · Aerosols Void Oxidising gases Void · Gases under pressure Void · Flammable liquids Void · Flammable solids Void · Self-reactive substances and mixtures Void · Pyrophoric liquids Void · Pyrophoric solids Void · Self-heating substances and mixtures Void Substances and mixtures, which emit flammable gases in contact with water Void · Void · Oxidising liquids Oxidising solids Void · Organic peroxides Void ·

Other information: No further relevant information available.

Void ·

Void

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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. Incompatible materials: No further relevant information available.

Hazardous decomposition products: In the event of fire: See chapter 5 of this data sheet.

11. Toxicological information

Information on toxicological effects

Acute toxicity:

LD50/LC50 values relevant for classification

Compon	ents T	Гуре	Value	Species
Oral	L	_D50	>10,000 mg/kg	rat

Primary irritant effect

Skin corrosion/irritation: Causes skin irritation.

Serious eye damage/irritation: Causes serious eye irritation. **After inhalation:** Irritant to skin and mucous membranes.

Respiratory or skin sensitization:

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

May cause an allergic skin reaction.

CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

Germ cell mutagenicity: Based on available data, the classification criteria are not met. Carcinogenicity: Based on available data, the classification criteria are not met. Reproductive toxicity: Based on available data, the classification criteria are not met. STOT-single exposure: Based on available data, the classification criteria are not met. 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 other hazards

Endocrine disrupting properties: Substance is not listed.

Additional toxicological information:

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

The product should be handled with the care usual when dealing with chemicals.

The substance is not subject to classification according to the latest version of the EU lists.

12. Ecological Information

Toxicity

Aquatic toxicity: Quantitative data on the ecological effect of the product are not 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.

Additional ecological information

General notes: Generally not hazardous for water.

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 together with household garbage. Do not allow product to reach sewage system. Contact a licensed professional waste disposal service to dispose of this material. Observe all federal, state, and local environmental regulations.

Uncleaned packaging:

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Recommendation: Disposal must be made according to official regulations. Packagings that may not be cleansed are to be disposed of in the same manner as the product.

Recommended cleaning agents: Water, if necessary, together with cleansing agents.

14. Transport information

UN-Number

ADR, IMDG, IATA Void

UN proper shipping name

ADR, IMDG, IATA Void

Transport hazard class(es)

ADR, IMDG, IATA Void

Packaging group

ADR, IMDG, IATA Void

Special precautions for user Not applicable

Transport in bulk according to Annex II

of MARPOL73/78 and the IBC Code Not applicable

UN "Model Regulation": Void

15. Regulatory information

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

16. Other information

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. Genaxxon bioscience GmbH, shall not be held liable for any damage resulting from handling or from contact with the above product.

Disclaimer

This product is for R&D use only. Not for drug, household or other uses.

Abbreviations and Acronyms:

ACAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)

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

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

EINECS: European Inventory of Existing Commercial Chemical Substances

GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)

GHS: Globally Harmonized System of Classification and labeling of Chemicals

IATA: International Air Transport Association

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organization

IMDG: International Maritime code for Dangerous Goods

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

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

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