

Product Name:
Issued:

Pancreatin
Aug-13-2015



SAFETY DATA SHEET

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier

Product Name: Pancreatin
Synonyms: Pancreatin (T485) IP: Pancreatin SPL; Pancreas Powder, Pancrelipase
Drug Code Number: 86143

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

Recommended use: Pharmaceuticals

1.3 Details of the supplier of the safety data sheet

Supplier: Abbott Products Operations AG
Hegenheimermattweg 127
4123 Allschwil
Switzerland

Manufacturer European: Abbott Products GmbH
Justus-Von-Liebig-Strasse 33
31535 Neustadt
Germany

E-mail Address: Abbott.SDS@abbott.com

1.4 Emergency telephone number

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada)
or +1-703-527-3887 (international)

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008

Respiratory sensitization Category 1
Skin sensitization Category 1

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Risk Phrases: R42 - May cause sensitization by inhalation
R43 - May cause sensitization by skin contact

2.2 Label elements

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Signal Word: Danger

Hazard Statements: H317 - May cause an allergic skin reaction
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary Statements P285 - In case of inadequate ventilation wear respiratory protection
P304 + P341 - IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention

2.3 Other hazards

Not determined

Section 3. Composition/information on ingredients

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Pancreatin 8049-47-6	100	Present	Xn; R42, R43	Resp. Sens. 1 (H334) Skin Sens. 1 (H317)	No data available

For the full text of the R-phrases mentioned in this Section, see Section 16

For the full text of the H-Statements mentioned in this Section, see Section 16

Section 4. First aid measures

4.1 Description of first aid measures

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

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Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Protection of First-aiders: Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms: Allergic reactions, respiratory irritation, skin irritation, breathing difficulty, eye irritation, occupational asthma,

Medical Conditions Aggravated by Exposure: Respiratory conditions.

4.3 Indication of any immediate medical attention and special treatment needed

Notes To Physician: Treat symptomatically

Section 5. Firefighting measures

5.1 Extinguishing Media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not determined

5.2 Special hazards arising from the substance or mixture

Special Exposure Hazards: This material is capable of forming explosive dust clouds in air, therefore, measures must be taken to avoid ignition. This material is particularly sensitive to ignition by electrostatic discharge. Combustible.

Explosivity: dust explosion hazard.

5.3 Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus and full protective gear

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: Avoid contact with skin, eyes and clothing. Use personal protective equipment. Ensure adequate ventilation. Avoid dust formation. All equipment used when handling the product must be grounded.

6.2. Environmental precautions

Environmental Precautions: Contain material and prevent release to waterways or soil.

6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Recover product and place in an appropriate container for disposal.

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6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Avoid contact with skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Wear personal protective equipment. Take precautionary measures against static discharges. Fine dust dispersed in air may ignite. Avoid dust formation.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions.

7.3. Specific end use(s)

Recommended use: Pharmaceuticals

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
Pancreatin 8049-47-6	160 mcg/m ³	None

8.2. Exposure controls

Engineering Controls: Local exhaust ventilation as necessary to maintain exposures to within applicable limits.

Respiratory Protection: An approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

Eyes: Wear eye protection appropriate to handling activities. Face shield.

Gloves: Impervious gloves.

Other PPE Data: Wear impervious clothing if contact will occur.

Environmental Exposure Controls: Do not allow material to contaminate ground water system

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: Light Yellow Gray Powder
Odor: Characteristic
Odor Threshold: Not determined
pH: 6

Product Name:	Pancreatin
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Boiling Pt. @ 760 mm Hg (°C):	Not determined.
Melting/Freezing Point (°C):	Not determined
Flash Point (°C):	Not determined.
Evaporation Rate at 20°C:	Not determined.
Flammability (Solid):	Not determined.
Lower Explosive Limit:	Not determined.
Upper Explosive Limit:	Not determined.
Vapor Pressure (mm Hg):	Not determined.
Vapor Density (Air = 1):	Not determined.
Bulk Density at 20°C:	300-800 kg/m ³
Specific Gravity:	Not determined.
Solubility(ies):	Slightly soluble in: water.
Partition coefficient:	Not determined.
n-octanol/water	
Autoignition Temp. (°C):	Not determined.
Decomposition temperature (°C):	200
Viscosity (centipoise):	Not determined.
Explosion Severity:	Maximum Pressure Pmax=6.9bar
Oxidizer Properties:	Not determined.

9.2. Other information

Not determined
(Bad file name) (Bad file name)

Maximum Pressure Rise (bar):	6.9
Max. rate of pressure rise (bar/sec):	575
Kst Value (bar.m/s):	156
Min. Ignition Energy-Cloud (mJ):	100-300
Min. Ignit. Temp. Dust Cloud (°C):	530
Min. Explosive Conc. (g/m³):	75 g/m ³
Min. Ignition Temp.-Layer (°C):	450

Section 10. Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Hazardous reactions: Not determined.

10.4. Conditions to avoid

Not determined.

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10.5 Incompatible materials

Oxidizing agents, Acids

10.6 Hazardous decomposition products

Carbon oxides, Nitrogen oxides (NOx)

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Yes
Dermal: Yes
Inhalation: Yes

Acute Toxicity - Oral: Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Pancreatin 8049-47-6	LD50 >	15,000	mg/kg	Rats
		15,000		Mice
		15,000		Dogs

Acute Toxicity - Dermal: Not determined.

Acute Toxicity - Inhalation: Not determined.

Other Toxicology Data: Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Pancreatin 8049-47-6	LD50 (ip) =	2,550	mg/kg	Rats	
		2,100		Mice	
	LD 50 (sc) >	5,000		Rats	
		LD50 (sc) =		3,780	

Corrosivity: Not determined.

Dermal Irritation: Not determined.

Eye Irritation: Not determined.

Sensitization: Reported to be sensitizer in humans.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Not determined.

Reproductive Effects: Not determined.

Carcinogenicity: Not determined.

Mutagenicity: Not determined.

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Aspiration hazard: Not determined

Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

Section 12. Ecological information

12.1. Toxicity

Data for component (s) given below.

Chemical Name	Percent	LC 50 (mg/l)	Species	Duration
Pancreatin 8049-47-6	100	422	Brachydanio rerio	48 Hours

12.2. Persistence and degradability

Not determined.

12.3. Bioaccumulative potential

Not determined

12.4. Mobility in soil

Not determined.

12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

Section 13. Disposal considerations

13.1 Waste treatment methods

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local regulations.

Section 14. Transport information

Product Name: Pancreatin
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ADR, DOT, ICAO/IATA, IMDG/IMO

Status: Not regulated

14.1. UN Number: Not applicable
14.2. Proper shipping name: Not applicable
14.3. Hazard class: Not applicable
14.4. Packing group: Not applicable
14.5. Environmental hazard: Not applicable
14.6. Special Provisions: Not applicable
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

Section 15. Regulatory Information

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

International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Pancreatin 8049-47-6	Present	X	-	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Pancreatin 8049-47-6	-	-	X	X	Present	HSR004052

Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
PICCS - Philippines Inventory of Chemicals and Chemical Substances
ENCS - Japan Existing and New Chemical Substances
ISHL - Japan Industrial Safety and Health Law
IECSC - China Inventory of Existing Chemical Substances
AICS - Australian Inventory of Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Pancreatin	100	Not Listed	Not Listed	Not Listed

SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Pancreatin	100	No	Not Applicable	Not applicable

Immediate Health: No Yes
Delayed Health: No
Fire: No
Sudden Pressure: No
Reactivity: No

RCRA Status: Not determined.

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Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

WHMIS Hazard Class: Not determined.

NFPA Rating:
Health: 0 Health: 1
Fire: 1
Reactivity: 0

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

Section 16. Other information

Risk Phrases:

R42 - May cause sensitization by inhalation
R43 - May cause sensitization by skin contact

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Supersedes the SDS dated: Dec-13-2010

Disclaimer:

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