

**Product Name:**  
**Issued:**

**Pancreatin**  
**Apr-15-2015**

**abbvie**  
**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; Pancreatin 4X  
**Drug Code Number:** 55143; 20032570

**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:** Manufactured for:  
AbbVie Inc.  
1 North Waukegan Road  
North Chicago, IL 60064  
USA  
+1-847-932-7900  
**E-mail Address:** AbbVie.SDS@abbvie.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**

**2.2 Label elements**



**Signal Word:** Danger

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**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  
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician  
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
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  
P501 - Dispose of contents/container to an approved waste disposal plant

### **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.

**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:** None known from occupational exposure.

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**Medical Conditions** None known from occupational exposure.  
**Aggravated by Exposure:**

**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:** Not determined

**Explosivity:** Fine dust clouds may form explosive mixtures with air.

**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:** For personal protection see section 8.

**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.

**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.

**7.2. Conditions for safe storage, including any incompatibilities**

Store according to label instructions.

**7.3. Specific end use(s)**

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**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 <sup>3</sup>	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.

**Gloves:** Impervious gloves.

**Other PPE Data:** Wear appropriate body coverings if contact may 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 to tan Powder

**Odor:** Characteristic

**Odor Threshold:** Not determined

**pH:** 6

**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<sup>3</sup>

**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):** Not determined.

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**Viscosity (centipoise):** Not determined.  
**Explosion Severity:** Not determined.  
**Oxidizer Properties:** Not determined.

## **9.2. Other information**

Not determined  
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**Maximum Pressure Rise (bar):** 6.9  
**Max. rate of pressure rise** 575  
**(bar/sec):**  
**Kst Value (bar.m/s):** 156  
**Min. Ignition Energy-Cloud** 100-300  
**(mJ):**  
**Min. Explosive Conc. (g/m<sup>3</sup>):** 75

## **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.

### **10.5 Incompatible materials**

Oxidizing agents, Acids

### **10.6 Hazardous decomposition products**

Carbon oxides, Nitrogen oxides (NO<sub>x</sub>)

## **Section 11. Toxicological information**

### **11.1. Information on toxicological effects**

#### **Routes of Exposure:**

**Oral:** Clinical Route  
**Dermal:** Unlikely  
**Inhalation:** Unlikely

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

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

**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.

**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

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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**

### **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** Not applicable  
according to Annex II of  
MARPOL 73/78 and the IBC  
**Code:**

## **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

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DSL/NDL - 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  
**Delayed Health:** No  
**Fire:** No  
**Sudden Pressure:** No  
**Reactivity:** No

**RCRA Status:** Not determined.

**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  
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**

**Full text of H-Statements referred to under sections 2 and 3**

H317 - May cause an allergic skin reaction

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

**Document Authored By:** Occupational and Environmental Toxicology

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**Supersedes the SDS dated:** Jan-29-2013



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