



In accordance with 29 CFR 1910.1200(b)(6)(vii), a Material Safety Data Sheet (MSDS) is not required for this product. This Product Information Sheet has been created to address information requests on the product.

PANCRELIPASE™ (pancrelipase) Delayed-Release Capsules

Product Information Sheet

COMPANY NAME AND INFORMATION

Company Name:	X-Gen Pharmaceutical, Inc.	Emergency	
Manufactured by:	Eurand SPA	Telephone No.	800.716.6507
Address	300 Daniel Zenker Drive Horseheads, NY 14845	Other Information Calls	800.716.6507
		Date Prepared	11/19/09
		Last Revision Date	NA

SECTION 1 - IDENTITY

- 1.1 **Product Name:** PANCRELIPASE™ (pancrelipase) Delayed-Release Capsules
 1.2 **Use:** Finished pharmaceutical product
 1.3 **CAS Number:** ---
 1.4 **Synonyms:** PANCRELIPASE™ delayed release capsules
 1.5 **Trade Names:** NA

SECTION 2 – COMPOSITION/INFORMATION ON INGREDIENTS

Principal Hazardous Component(s)	CAS Number	% Weight	Threshold Limit Value (units)
Pancrelipase	53608-75-6	Trade Secret	***
Hypromellose Phthalate	9050-31-1	Trade Secret	***
Talc	14807-96-6	Trade Secret	***
Triethyl Citrate	77-93-0	Trade Secret	***
Croscarmellose Sodium	74811-65-7	Trade Secret	***
Microcrystalline Cellulose	9004-34-6	Trade Secret	***
Hydrogenated Castor Oil	8001-78-3	Trade Secret	***
Colloidal Silicon Dioxide	99439-28-8	Trade Secret	***
Magnesium Stearate	557-04-0	Trade Secret	***
Hypromellose	9004-65-3	Trade Secret	***

*** = Exposure limits have not been established for the product. However, the Occupational Safety and Health Administration (OSHA) and the American Conference of Governmental Industrial Hygienists (ACGIH) have developed the following exposure limits for particulates (dusts) not otherwise classified (PNOC), cellulose and talc:

<u>Ingredient Name</u>	<u>OSHA PEL/STEL</u>	<u>ACGIH TLV/STEL</u>
Particulates Not Otherwise Classified (PNOC)	5 mg/m ³ (PEL, particulates respirable fraction)/ 15 mg/m ³ (PEL particulates, total dust)	10 mg/m ³ (TLV, particulates)
Cellulose	5 mg/m ³ (TWA, respirable fraction)/ 15 mg/m ³ (TWA, total dust)	10 mg/m ³ (TWA)
Talc	NA	2 mg/m ³ (TWA)

SECTION 3 – HAZARD IDENTIFICATION

EMERGENCY OVERVIEW

This product is a capsule in solid final dosage form; normal use will not generate dust. Abusive handling, crushing or opening capsule may generate dust. This product is a tan to creamy colored granule. Avoid breathing dusts; inhalation will irritate the respiratory tract. Eye exposure can cause redness, irritation and tearing.

As with all dusts, care should be taken when creating an atmosphere of airborne dust or increasing the risk of fire/explosion through the use of flammable materials in combination with dusts. This product may present an explosion risk when suspended in air in sufficient concentration in the presence of an ignition source such as heat, sparks, or open flames.

3.1 POTENTIAL HEALTH EFFECTS

This product is a mixture for which no health effects data exist. The information provided below is a comprehensive overview of the effects of the product's hazardous ingredients. The health effects described primarily represent the hazards associated with the pancrelipase. The other materials are non active materials that, according to their MSDS, pose little to no health risks.

3.1.1 ACUTE EFFECTS:

INHALATION: Inhalation of dusts may cause dryness of the nose, throat and sinuses, and may cause irritation of the upper respiratory tract. This product may also produce asthma-like allergic reactions in sensitized individuals. Once an allergy develops, even low exposure levels may trigger symptoms.

INGESTION: Not an ingestion hazard under normal conditions of use. However, ingestion of large amounts may cause nausea and vomiting. Allergic reactions have been reported in hypersensitive individuals and can include skin rashes and irritations of the mouth and gastrointestinal tract.

SKIN: Contains an enzyme which may cause skin irritation and damage or skin allergies.

EYE: May cause irritation, redness, tearing and possible tissue damage.

3.1.2 TARGET ORGAN EFFECTS:

Prolonged inhalation of dusts may cause chronic asthma and other respiratory problems. Hypersensitive individuals may develop sensitivity including asthma and other allergic respiratory conditions.

3.1.3 CARCINOGENIC EFFECTS:

No human carcinogenicity data are available for the product or its hazardous ingredients

3.1.4 REPRODUCTIVE/TERATOGENIC EFFECTS:

No reproductive or teratogenic effects are available for the product or its hazardous ingredients

3.2 CARCINOGENICITY STATUS:

The product and its ingredients are not listed as carcinogenic by NTP, IARC, or OSHA.

3.3 MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:

Breathing dust may aggravate acute or chronic asthma and chronic pulmonary disease such as emphysema and bronchitis.

Individuals with hypersensitivity to pancreatin or pork products may be more likely to develop allergic reactions to this product.

SECTION 4 – FIRST AID MEASURES

INHALATION: Remove exposed subject to fresh air. If not breathing, perform artificial respiration. If breathing is difficult, administer oxygen (by trained personnel only). Get medical attention.

INGESTION: If swallowed, give 1-2 glasses of water. If vomiting occurs, keep head lower than hips to prevent aspiration. Get medical attention. Only induce vomiting at the instruction of a physician.

Never give anything by mouth to an unconscious person. If the victim is unconscious, keep airway open and lay the victim on his or her side with the head lower than the body (to prevent choking in case vomiting occurs). Get immediate medical attention.

SKIN: Remove and isolate contaminated clothing. Wash skin with soap and flush thoroughly with plenty of water. Obtain medical attention if irritation develops or other symptoms occur. Clean contaminated clothing before reuse, or dispose of properly.

EYE: First, check the victim for contact lenses and remove if present. Immediately flush eyes with plenty of water or normal saline for at least 15 minutes while holding eyelids open. If symptoms such as redness or irritation develop or persist, get immediate medical attention. Do not put any medication in the victim's eyes unless instructed by a physician.

SECTION 5 – FIRE FIGHTING MEASURES

5.1 FLASH POINT: Not applicable **METHOD:** ---

5.2 AUTO IGNITION TEMPERATURE: No data available

5.2 FLAMMABILITY LIMITS:

LOWER LIMIT: Not applicable

UPPER LIMIT: Not applicable

5.3 UNUSUAL FIRE AND EXPLOSION HAZARDS:

This product does not generate dust under normal conditions. However, if dust is generated, the product may present an explosion risk when suspended in air in sufficient concentration in the presence of an ignition source such as heat sparks, or open flame.

5.4 EXTINGUISHING METHODS:

For fires involving this material or its packaging materials, use an agent which is appropriate for combustibles and surrounding class(es) of fires.

5.5 FIRE FIGHTING PROCEDURES:

Keep unnecessary people away; isolate hazard area and deny entry. Remove containers exposed to fire if possible, otherwise cool them from the side with water spray. Emergency equipment including self-contained breathing apparatus (SCBA) and full fire fighting turnout gear should be worn by fire fighters.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Follow facility –specific procedures for spill response. Isolate the spill area. Avoid dust generation, and eliminate all heat and ignition sources; use non sparking tools for clean-up. When cleaning spills, wear appropriate personal protective equipment including safety goggles and chemical resistant gloves (See Section 8). Practice contamination avoidance.

For small spills, collect by carefully scooping or shoveling into a pan or paper towel, or by moistening with water and wiping. For large spills, vacuum or wet mop. As much as is possible, avoid spreading the compound. Avoid dust generation.

Decontaminate the spill area. Place contaminated sorbent or other contaminated material into an approved waste container and dispose of all material in accordance with the applicable regulations on waste disposal. In addition, comply with all applicable regulations on spill reporting. (See Section 13)

SECTION 7 – HANDLING AND STORAGE

Keep containers closed when not in use. Store in a cool, dry, well-ventilated area, away from incompatible materials (See Section 10).

Minimize dust generation and accumulation. Avoid breathing dust. Avoid skin and eye contact.

Dry powders can build static electricity charges from friction caused by conveying, mixing, or sliding. To prevent ignition, provide adequate precautions such as electrical grounding and/or inert atmospheres when material is handled or in the presence of flammable materials.

SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 VENTILATION:

Adequate local exhaust ventilation or other engineering controls to minimize dust generation and to keep airborne concentrations below exposure limits (See Section 2)

8.2 RESPIRATORY PROTECTION:

Wear an approved (NIOSH/MSHA) respirator when general and local ventilation are not adequate to keep airborne concentrations below exposure limits listed in Section 2. Typically, the following rules apply:

- To control airborne concentrations up to 5 times the exposure limit, a disposable dust/mist respirator may be appropriate.
- For levels up to 10 times the exposure limit, wear a tight fitting half mask or full facepiece respirator equipped with particulate filters.
- For levels exceeding 10 times the recommended exposure limit, supplied air respirators should be required.

For specific guidance on respirator selection, refer to the OSHA accepted NIOSH Respirator Selection Criteria. It is the employer's responsibility to insure that correct selection occurs. Use these criteria as guidance only.

8.3 PROTECTIVE GLOVES:

Wear impervious gloves to prevent skin contact. Selection of the appropriate gloves for a particular use depends upon the properties of the compound, additional chemicals being handled, and the specific conditions of use. Information to be considered in decisionmaking would include: the level of dexterity and durability needed, and the severity and duration of the chemical contact. In general, rubber, neoprene or nitrile gloves are recommended.

8.4 EYE PROTECTION:

Either safety glasses with side shields or goggles should be worn when handling this material.

8.5 OTHER:

Depending upon the operation, a labcoat, apron or other impermeable clothing may be appropriate.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

9.1 APPEARANCE AND ODOR:	tan to cream colored granule
9.2 MELTING POINT:	No data available
9.3 BOILING POINT:	No data available
9.4 SPECIFIC GRAVITY/ DENSITY:	No data available
9.5 VAPOR DENSITY:	Not applicable
9.6 VAPOR PRESSURE:	Not applicable
9.7 SOLUBILITY:	
• WATER:	No data available
• OTHER SOLVENTS:	No data available
9.8 DECOMPOSITION TEMPERATURE:	No data available
9.9 VISCOSITY:	Not applicable
9.10 PH:	Data not available

SECTION 10 – STABILITY AND REACTIVITY

10.1 STABILITY:

Product is stable under normal conditions of use.

10.2 HAZARDOUS DECOMPOSITION PRODUCTS:

Not determined for product. Hazardous decomposition products of components include toxic fumes of carbon dioxide and carbon monoxide.

10.3 CONDITIONS TO AVOID:

Avoid dust generation or other conditions that might result in a hazardous situation.

10.4 MATERIALS AND SUBSTANCES TO AVOID (INCOMPATIBILITY):

There are no known materials which are incompatible with this product. However, at least one of the hazardous ingredients is incompatible with strong oxidizing agents and reacts violently with bromine trifluoride and lithium.

SECTION 11 – TOXICOLOGICAL INFORMATION

This product is a mixture for which no toxicological data exists. When available, toxicological data for the product's components are provided below. Refer to Section 3.2 for health effects information.

11.1 ACUTE DATA:**INHALATION:**

Croscarmellose Sodium – LC₅₀ > 0.13 mg/l (4h)(rat)

Triethyl Citrate - LC₅₀ = 1,300 ppm (rat – 6h)

INGESTION:

Pancreatin – LD₅₀ > 10,000 mg/kg (rat, mouse)

Croscarmellose Sodium – LD₅₀ > 5,050 mg/kg (rat)

Triethyl Citrate - LD₅₀ = 5,900 mg/kg (rat)
 LD₅₀ = 3,500 mg/kg (cat)
 LD₅₀ > 25 ml/kg (guinea pig)
 LD₅₀ = 7,952 mg/kg (rat)
 LD₅₀ = 3,976 mg/kg (cat)

Hypromellose Phthalate - LD₅₀ > 15,000 mg/kg (rat)

EYES: No data available for the product.

SKIN:

Croscarmellose Sodium – LD₅₀ > 2,000 mg/kg (rabbit)

Triethyl Citrate - LD₅₀ > 5,000 mg/kg (rabbit)

11.2 TARGET ORGAN EFFECTS DATA (CHRONIC):

No data available for the product or its components.

11.3 CARCINOGENIC EFFECTS DATA:

No data available for product. None of this product's components are listed by ACGIH, IARC, OSHA, NIOSH or NTP.

11.4 MUTAGENIC EFFECTS DATA:

No data available for product.

11.5 REPRODUCTIVE/TERATOGENIC EFFECTS DATA:

No data available for product.

SECTION 12 – ECOLOGICAL INFORMATION

12.1 ECOTOXICOLOGICAL INFORMATION:

No data available for the product or its hazardous ingredients.

12.2 CHEMICAL FATE INFORMATION:

No data available for the product or its hazardous ingredients.

12.3 AQUATIC TOXICITY DATA:

No data available for product or its hazardous ingredients.

SECTION 13 – DISPOSAL CONSIDERATIONS

Dispose of in accordance with all applicable Federal, State, and local regulations (See Section 15).

SECTION 14 – TRANSPORT INFORMATION

14.1 UNITED STATES DEPARTMENT OF TRANSPORTATION (USDOT):

This product and its ingredients are not regulated by the US DOT.

14.2 INTERNATIONAL TRANSPORTATION REGULATIONS:

This product is not regulated by international transportation regulations.

SECTION 15 – REGULATORY INFORMATION

15.1 FEDERAL REGULATIONS:

This product is not regulated by the federal government; however, specific regulations exist for the following ingredients:

Microcrystalline Cellulose

EPA TSCA Chemical Inventory

Croscarmellose Sodium (as carboxymethyl cellulose)

EPA TSCA Chemical Inventory

Magnesium Stearate

EPA TSCA Chemical Inventory

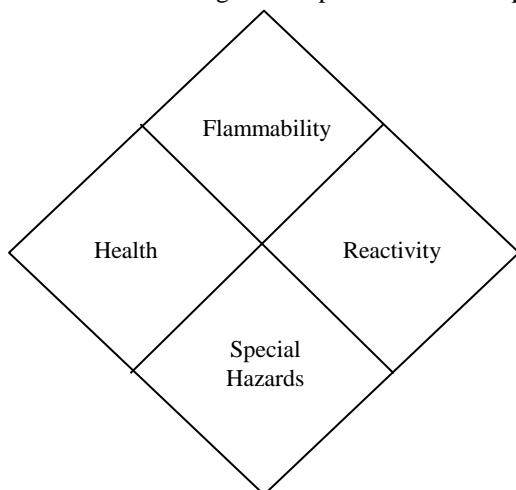
15.2 STATE REGULATIONS:

This product and its ingredients are not regulated by any state government.

SECTION 16 – OTHER INFORMATION

16.1 HAZARD RATINGS*:

*The hazard rating for this product is based upon NFPA criteria, as well as professional judgement.



Health: 2
Flammability: 1
Reactivity: 0
Special Hazards: Sensitizer

16.2 PREPARATION AND REVISION INFORMATION:

Data for this Product Information Sheet was compiled from existing information regarding the raw materials contained in the product.

Revision 0 (11/19/09): Original

The information provided in this Product Information Sheet is based upon sources believed to accurate. However, the Company assumes no responsibility for the accuracy, completeness, or suitability of this information. The product user is responsible to determine the suitability of this information for their particular purpose.