SAFETY DATA SHEET
Pancreatin 1X

Section 1. Identification

GHS product identifier : Pancreatin 1X
Code : 19880
Other means of identification :
Supplier/Manufacturer : 3420 Central Expressway, Santa Clara CA 95051
In case of emergency : Chemtrec: 1 800 424 9300
Outside USA & Canada: +1 703 527 3887

Section 2. Hazards identification

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).
Classification of the substance or mixture :
- SKIN CORROSION/IRRITATION - Category 2
- SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2A
- RESPIRATORY SENSITIZATION - Category 1B
- SKIN SENSITIZATION - Category 1B

GHS label elements
Hazard pictograms :

Signal word : Danger
Hazard statements :
- Causes serious eye irritation.
- Causes skin irritation.
- May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- May cause an allergic skin reaction.

Precautionary statements
Prevention :
Wear protective gloves. Wear eye or face protection. In case of inadequate ventilation wear respiratory protection. Avoid breathing dust. Wash hands thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace.

Response :
IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or physician. IF ON SKIN: Wash with plenty of soap and water. Take off contaminated clothing. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical attention. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention.

Storage : Not applicable.
Disposal : Dispose of contents and container in accordance with all local, regional, national and international regulations.
Hazard not otherwise classified : None known.

Section 3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Ingredient name</th>
<th>%</th>
<th>CAS number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatin</td>
<td>99.99 - 100</td>
<td>8049-47-6</td>
</tr>
</tbody>
</table>

Any concentration shown as a range is to protect confidentiality or is due to batch variation.
Section 3. Composition/information on ingredients

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

**Eye contact**
- Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.

**Inhalation**
- Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If necessary, call a poison center or physician. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In the event of any complaints or symptoms, avoid further exposure.

**Skin contact**
- Wash with plenty of soap and water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.

**Ingestion**
- Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

**Potential acute health effects**

- **Eye contact**: Causes serious eye irritation.
- **Inhalation**: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- **Skin contact**: Causes skin irritation. May cause an allergic skin reaction.
- **Ingestion**: Irritating to mouth, throat and stomach.

**Over-exposure signs/symptoms**

- **Eye contact**: Adverse symptoms may include the following:
  - pain or irritation
  - watering
  - redness
- **Inhalation**: Adverse symptoms may include the following:
  - wheezing and breathing difficulties
  - asthma
- **Skin contact**: Adverse symptoms may include the following:
  - irritation
  - redness
- **Ingestion**: No specific data.

**Indication of immediate medical attention and special treatment needed, if necessary**

- **Notes to physician**: Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
Section 4. First aid measures

Protection of first-aiders: No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media
Suitable extinguishing media: Use an extinguishing agent suitable for the surrounding fire.
Unsuitable extinguishing media: None known.

Specific hazards arising from the chemical
Hazardous thermal decomposition products: No specific data.

Special protective actions for fire-fighters: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
For non-emergency personnel: No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
For emergency responders: If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions: Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up
Small spill: Move containers from spill area. Avoid dust generation. Using a vacuum with HEPA filter will reduce dust dispersal. Place spilled material in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.
Large spill: Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.
Section 7. Handling and storage

Precautions for safe handling

Protective measures: Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems or asthma, allergies or chronic or recurrent respiratory disease should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene: Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities: Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

None.

Appropriate engineering controls: Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

Environmental exposure controls: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Hygiene measures: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.

Skin protection

Hand protection: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Section 8. Exposure controls/personal protection

- **Other skin protection**: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

- **Respiratory protection**: Use a properly fitted, particulate filter respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Section 9. Physical and chemical properties

- **Physical state**: Solid.
- **Flash point**: Not available.
- **Auto-ignition temperature**: Not available.
- **Flammable limits**: Not available.
- **Molecular weight**: Not available.
- **Molecular formula**: Not available.
- **pH**: Not available.
- **Boiling/condensation point**: Not available.
- **Melting/freezing point**: Not available.
- **Relative density**: Not available.
- **Vapor pressure**: Not available.
- **Vapor density**: Not available.
- **Volvility**: Not available.
- **Evaporation rate**: Not available.
- **Viscosity**: Not available.
- **Solubility**: Not available.

Section 10. Stability and reactivity

- **Reactivity**: No specific test data related to reactivity available for this product or its ingredients.
- **Chemical stability**: The product is stable.
- **Possibility of hazardous reactions**: Under normal conditions of storage and use, hazardous reactions will not occur.
- **Conditions to avoid**: No specific data.
- **Incompatible materials**: No specific data.
- **Hazardous decomposition products**: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

### Acute toxicity

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>Result</th>
<th>Species</th>
<th>Dose</th>
<th>Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatin</td>
<td>LD50 Oral</td>
<td>Rat</td>
<td>&gt;10000 mg/kg</td>
<td>-</td>
</tr>
</tbody>
</table>

### Irritation/Corrosion

Not available.

### Sensitization

Not available.
Section 11. Toxicological information

Mutagenicity
Not available.

Carcinogenicity
Not available.

Reproductive toxicity
Not available.

Teratogenicity
Not available.

Specific target organ toxicity (single exposure)
Not available.

Specific target organ toxicity (repeated exposure)
Not available.

Aspiration hazard
Not available.

Information on the likely routes of exposure
Not available.

Potential acute health effects
Eye contact : Causes serious eye irritation.
Inhalation : May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin contact : Causes skin irritation. May cause an allergic skin reaction.
Ingestion : Irritating to mouth, throat and stomach.

Symptoms related to the physical, chemical and toxicological characteristics
Eye contact : Adverse symptoms may include the following:
  pain or irritation
  watering
  redness
Inhalation : Adverse symptoms may include the following:
  wheezing and breathing difficulties
  asthma
Skin contact : Adverse symptoms may include the following:
  irritation
  redness
Ingestion : No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure
Potential immediate effects : Not available.
Potential delayed effects : Not available.

Long term exposure
Potential immediate effects : Not available.
Potential delayed effects : Not available.

Potential chronic health effects
Not available.

General : Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.
Section 11. Toxicological information

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carcinogenicity</td>
<td>No known significant effects or critical hazards.</td>
</tr>
<tr>
<td>Mutagenicity</td>
<td>No known significant effects or critical hazards.</td>
</tr>
<tr>
<td>Teratogenicity</td>
<td>No known significant effects or critical hazards.</td>
</tr>
<tr>
<td>Developmental effects</td>
<td>No known significant effects or critical hazards.</td>
</tr>
<tr>
<td>Fertility effects</td>
<td>No known significant effects or critical hazards.</td>
</tr>
</tbody>
</table>

Numerical measures of toxicity

Acute toxicity estimates
Not available.

Section 12. Ecological information

Toxicity
Not available.

Persistence and degradability
Not available.

Bioaccumulative potential
Not available.

Mobility in soil

<table>
<thead>
<tr>
<th>Soil/water partition coefficient (K_{oc})</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not available.</td>
</tr>
</tbody>
</table>

Other adverse effects
Not available.

Section 13. Disposal considerations

Disposal methods
The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

<table>
<thead>
<tr>
<th>DOT Classification</th>
<th>TDG Classification</th>
<th>Mexico Classification</th>
<th>ADR/RID Classification</th>
<th>IMDG Classification</th>
<th>IATA Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN proper shipping name</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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</tr>
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</table>
## Section 14. Transport information

<table>
<thead>
<tr>
<th>Transport hazard class(es)</th>
<th>-</th>
<th>-</th>
<th>-</th>
<th>-</th>
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<th>-</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Additional information</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<td>-</td>
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</tr>
</tbody>
</table>

**Special precautions for user**: Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**: Not available.

## Section 15. Regulatory information

**U.S. Federal regulations**

- **Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs)**: Not listed
- **Clean Air Act Section 602 Class I Substances**: Not listed
- **Clean Air Act Section 602 Class II Substances**: Not listed
- **DEA List I Chemicals (Precursor Chemicals)**: Not listed
- **DEA List II Chemicals (Essential Chemicals)**: Not listed
- **SARA 302/304 Composition/information on ingredients**: No products were found.
- **SARA 304 RQ**: Not applicable.
- **SARA 311/312 Classification**: Immediate (acute) health hazard
- **Composition/information on ingredients**:

<table>
<thead>
<tr>
<th>Name</th>
<th>%</th>
<th>Fire hazard</th>
<th>Sudden release of pressure</th>
<th>Reactive</th>
<th>Immediate (acute) health hazard</th>
<th>Delayed (chronic) health hazard</th>
</tr>
</thead>
</table>

**State regulations**

- **Massachusetts**: This material is not listed.
- **New York**: This material is not listed.
- **New Jersey**: This material is not listed.
- **Pennsylvania**: This material is not listed.
Section 15. Regulatory information

International regulations
Chemical Weapon Convention List Schedules I, II & III Chemicals
Not listed.

Montreal Protocol (Annexes A, B, C, E)
Not listed.

Stockholm Convention on Persistent Organic Pollutants
Not listed.

Rotterdam Convention on Prior Inform Consent (PIC)
Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals
Not listed.

Canada
WHMIS (Canada) : Class D-2A: Material causing other toxic effects (Very toxic).

Canadian lists
Canadian NPRI : This material is not listed.
CEPA Toxic substances : This material is not listed.
Canada inventory : Not determined.

Section 16. Other information

Hazardous Material Information System (U.S.A.)

<table>
<thead>
<tr>
<th>Health</th>
<th>Flammability</th>
<th>Physical hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

The customer is responsible for determining the PPE code for this material.

National Fire Protection Association (U.S.A.)

Health 0 0 0
Flammability
Instability/Reactivity
Special

History
Date of issue/Date of revision : 04/29/2015.
Date of previous issue : No previous validation.
Version : 1
Key to abbreviations : ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
UN = United Nations

Indicates information that has changed from previously issued version.

Notice to reader
Section 16. Other information

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.