SAFETY DATA SHEET

Preparation Date: 02/09/2015  Revision Date: 10/22/2018  Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: PA115
Product Name: PANCREATIN, POWDER, USP

Other means of identification

Synonyms: No information available
CAS #: 8049-47-6
RTECS #: RT9033000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: No information available.
Uses advised against: No information available

Supplier:
Spectrum Chemical Mfg. Corp
14422 South San Pedro St.
Gardena, CA  90248
(310) 516-8000

Order Online At:  https://www.spectrumchemical.com
Emergency telephone number  Chemtrec 1-800-424-9300
Contact Person: Martin LaBenz (West Coast)
Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

<table>
<thead>
<tr>
<th>Skin corrosion/irritation</th>
<th>Category 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious eye damage/eye irritation</td>
<td>Category 2B</td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>Category 1A</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>Category 1B</td>
</tr>
</tbody>
</table>

Label elements

Danger

Hazard statements
Causes skin irritation
Causes eye irritation
May cause allergy or asthma symptoms or breathing difficulties if inhaled
May cause an allergic skin reaction
Hazards not otherwise classified (HNOC)
Not Applicable

Other hazards
Not available

Precautionary Statements - Prevention
Wash face, hands and any exposed skin thoroughly after handling
Wear protective gloves/protective clothing/eye protection/face protection
Avoid breathing dust/fume/gas/mist/vapors/spray
In case of inadequate ventilation wear respiratory protection
Contaminated work clothing must not be allowed out of the workplace

Precautionary Statements - Response
Specific treatment (see .? on this label)
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 advice/attention.
IF ON SKIN: Wash with plenty of water
Take off contaminated clothing and wash it before reuse
If skin irritation or rash occurs: Get medical advice/attention
IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

Precautionary Statements - Disposal
Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatin</td>
<td>8049-47-6</td>
<td>100</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

First aid measures

General Advice: National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention. If skin irritation persists, call a physician.

Eye Contact: Flush eyes with water for 15 minutes. Get medical attention.

Inhalation: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion: Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Obtain medical attention.

Most important symptoms and effects, both acute and delayed
Symptoms
Causes eye irritation
Causes skin irritation
May cause an allergic skin reaction
May cause allergy or asthma symptoms or breathing difficulties if inhaled

Indication of any immediate medical attention and special treatment needed
Notes to Physician: Treat symptomatically.

Protection of first-aiders
First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

5. FIRE-FIGHTING MEASURES

Extinguishing Media
Suitable Extinguishing Media: Dry chemical. Water spray mist or foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical
Hazardous Combustion Products: No information available.
Specific hazards: May be combustible at high temperatures.

Special Protective Actions for Firefighters
Specific Methods: No information available.
Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures
Personal Precautions: Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Keep people away from and upwind of spill/leak. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Remove all sources of ignition.

Environmental precautions: Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up
Methods for containment: Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.
Methods for cleaning up: Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

Product code: PA115  Product name: PANCREATIN, POWDER, USP
Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

**Safe Handling Advice**
Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Do not ingest. Do not breathe dust. Handle in accordance with good industrial hygiene and safety practice.

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

**Technical Measures/Storage Conditions:**
Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container.

**Incompatible Materials:**
No information available

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### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Control parameters**

**National occupational exposure limits**

#### United States

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<th>Components</th>
<th>CAS-No.</th>
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<th>NIOSH</th>
<th>ACGIH</th>
<th>AIHA WEEL</th>
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#### Canada

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<th>Canada - Ontario</th>
<th>Canada - Quebec</th>
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#### Australia and Mexico

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<th>Mexico</th>
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<tr>
<td>Pancreatin</td>
<td>8049-47-6</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

**Appropriate engineering controls**

**Engineering measures to reduce exposure:**
Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

**Individual protection measures, such as personal protective equipment**

**Personal Protective Equipment**

**Eye protection:**
Safety glasses with side-shields. or Goggles

**Skin and body protection:**
Long sleeved clothing
Chemical resistant apron
Gloves
Respiratory protection: Effective dust mask. or. Wear respirator with dust filter. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds), inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.

Hygiene measures: Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid
Odor: Characteristic. Enzyme.
Molecular/Formula weight (g/mole): No information available
Flash Point Tested according to: Not available
Upper Explosion Limit (%): No information available
Boiling point/range(°C/°F): No information available
Specific gravity: No information available
Evaporation rate: No information available
Odor threshold (ppm): No information available
Miscibility: No information available

Appearance: No information available.
Taste: No information available.
Flammability: No information available
Autoignition Temperature (°C/°F): Decomposes
Melting point/range(°C/°F): No information available
Bulk density: No information available
pH: 5.0-8.0
Vapor density: No information available
Partition coefficient (n-octanol/water): No information available
Solubility: No information available

Color: Off-white.
Formula: No information available
Flashpoint (°C/°F): No information available
Lower Explosion Limit (%): No information available
Decomposition temperature(°C/°F): No information available
Density (g/cm3): No information available
Vapor pressure @ 20°C (kPa): No information available
VOC content (g/L): No information available
Viscosity: No information available

10. STABILITY AND REACTIVITY

Reactivity: No information available

Chemical stability
Stability: Stable under recommended storage conditions.
Possibility of Hazardous Reactions: Hazardous polymerization does not occur
Conditions to avoid: Heat.
Incompatible Materials: No information available
Hazardous decomposition products: No information available.

Product code: PA115 Product name: PANCREATIN, POWDER, USP
11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:
Inhalation. Ingestion. Skin.

Acute Toxicity

Component Information

<table>
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<tr>
<th>Component</th>
<th>CAS-No.</th>
<th>LD50/oral/rat</th>
<th>LD50/oral/mouse</th>
<th>LD50/dermal/rabbit</th>
<th>LD50/dermal/rat</th>
<th>LC50/inhalation/rat</th>
<th>LC50/inhalation/mouse</th>
<th>Other LD50 or LC50 information</th>
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<td>8049-47-6</td>
<td>&gt; 10 g/kg Oral LD50 Rat</td>
<td>&gt;10 g/kg Oral LD50 Mouse</td>
<td>No information available</td>
<td>No information available</td>
<td>No information available</td>
<td>No information available</td>
<td>2100 mg/kg Intraperitoneal LD50 Mouse; 2550 mg/kg Intraperitoneal LD50 Rat; 3870 mg/kg Subcutaneous LD50 Mouse; &gt;5 g/kg Subcutaneous LD50 Rat</td>
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Product Information

<table>
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<tr>
<th>LD50/oral/rat</th>
<th>VALUE- Acute Tox Oral =</th>
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<tbody>
<tr>
<td>LD50/oral/mouse</td>
<td>Value - Acute Tox Oral =</td>
<td>&gt;10 g/kg</td>
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<tr>
<td>LD50/dermal/rabbit</td>
<td>VALUE-Acute Tox Dermal =</td>
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<tr>
<td>LD50/dermal/rat</td>
<td>VALUE - Acute Tox Dermal =</td>
<td>No information available</td>
</tr>
</tbody>
</table>

Symptoms
Skin Contact: Causes skin irritation. Moderately irritating to the skin. May cause allergic skin
reaction.

**Eye Contact:**
Causes eye irritation. Mild eye irritation.

**Inhalation**
May cause irritation of respiratory tract. May cause allergic respiratory reaction due to allergic sensitization of the respiratory tract. May cause asthmatic responses.

**Ingestion**
Health injuries are not known or expected under normal use.

**Aspiration hazard**
No information available.

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**Chronic Toxicity**
Prolonged or repeated skin contact may cause allergic reaction. Prolonged or repeated inhalation may cause allergic reaction.

**Sensitization:**
May cause sensitization by inhalation and skin contact.

**Mutagenic Effects:**
No information available

**Carcinogenic effects:**
Not considered carcinogenic.

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>IARC</th>
<th>ACGIH - Carcinogens</th>
<th>NTP</th>
<th>OSHA HCS - Carcinogens</th>
<th>Australia - Notifiable Carcinogenic Substances</th>
<th>Australia - Prohibited Carcinogenic Substances</th>
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<tr>
<td>Pancreatin</td>
<td>8049-47-6</td>
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<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
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</tbody>
</table>

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

**Reproductive toxicity**
No data is available

**Reproductive Effects:**
No information available

**Developmental Effects:**
No information available

**Teratogenic Effects:**
No information available

**Specific Target Organ Toxicity**

<table>
<thead>
<tr>
<th>STOT - single exposure</th>
<th>No information available.</th>
</tr>
</thead>
<tbody>
<tr>
<td>STOT - repeated exposure</td>
<td>No information available.</td>
</tr>
<tr>
<td>Target Organs:</td>
<td>No information available.</td>
</tr>
</tbody>
</table>

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Ecotoxicity effects:**
No data available.

**Persistence and degradability:**
No information available

**Bioaccumulative potential:**
No information available.
13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:
Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:
Empty containers should be taken for local recycling, recovery or waste disposal

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<thead>
<tr>
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<tr>
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<td>None</td>
<td>None</td>
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</tbody>
</table>

14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Class: No information available
Packing group: No information available
Emergency Response Guide Number: No information available
Marine Pollutant: No data available
DOT RQ (lbs): No information available
Special Provisions: No Information available
Symbol(s): No information available
Description: No information available

TDG (Canada)

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant: No Information available
Description: No information available

ADR

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Packing Group: No information available
Subsidiary Risk: No information available

IMO / IMDG

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant: No information available

RID

Product code: PA115  Product name: PANCREATIN, POWDER, USP
15. REGULATORY INFORMATION

International Inventories

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>U.S. TSCA</th>
<th>KOREA KECL</th>
<th>Philippines (PICCS)</th>
<th>Japan ENCS</th>
<th>CHINA</th>
<th>Australia (AICS)</th>
<th>EINECS-No.</th>
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<tbody>
<tr>
<td>Pancreatin</td>
<td>8049-47-6</td>
<td>Present</td>
<td>Present KE-27762</td>
<td>Present</td>
<td>Not present</td>
<td>Present</td>
<td>Present</td>
<td>Present 232-468-9</td>
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</table>

U.S. Regulations

Pancreatin

FDA - Food Additives Generally Recognized as Safe (GRAS): 21 CFR 184.1583
FDA - 21 CFR - Total Food Additives 184.1583
- List Sourced from EAFUS


Chemicals Known to the State of California to Cause Cancer:
This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:
This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Carcinogen</th>
<th>Developmental Toxicity</th>
<th>Male Reproductive Toxicity</th>
<th>Female Reproductive Toxicity</th>
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<td>Not Listed</td>
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CERCLA/SARA

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>CERCLA - Hazardous Substances and their Reportable Quantities</th>
<th>Section 302 Extremely Hazardous Substances and TPQs</th>
<th>Section 302 Extremely Hazardous Substances and RQs</th>
<th>Section 313 - Chemical Category</th>
<th>Section 313 - Reporting de minimis</th>
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<td>None</td>
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U.S. TSCA

Product code: PA115
Product name: Pancreatin, Powder, USP
### Components

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)</th>
<th>TSCA 8(d) - Health and Safety Reporting</th>
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<tr>
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<td>8049-47-6</td>
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<td>Not Applicable</td>
</tr>
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</table>

### Canada

#### WHIMIS 2015 - GHS Classifications

**WHIMIS 2015 Hazard Classification Information:**
The WHIMIS 2015 classification of this product has not been validated or reviewed yet.

**Canada Hazardous Products Regulation:**
This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR.

### Inventory

<table>
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<tr>
<th>Components</th>
<th>CAS-No.</th>
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<th>CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting</th>
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### EU Classification

#### EU GHS - SV - CLP 1272/2008

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<th>CAS-No.</th>
<th>EU GHS - SV - CLP (1272/2008)</th>
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#### EU - CLP (1272/2008)

**R-phrase(s)**
Not determined

**S-phrase(s)**
none

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<th>Concentration Limits:</th>
<th>Safety Phrases</th>
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The product is classified in accordance with Annex VI to Directive 67/548/EEC.

**Indication of danger:**
not determined

### 16. OTHER INFORMATION

**Preparation Date:** 02/09/2015

**Revision Date:** 10/22/2018

**Product code:** PA115

**Product name:** PANCREATIN, POWDER, USP
Prepared by: Sonia Owen

Disclaimer:
All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user’s responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet