Not appropriate for regulatory submission. Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.
Dear Customer,

Thank you for your interest in Spectrum’s quality products and services.

Spectrum has been proudly serving our scientific community for over 45 years. It is our mission to manufacture and distribute fine chemicals and laboratory products with Quality and delivery you can count on every time.

To accomplish our mission, Spectrum utilizes our sourcing leverage and supplier qualification expertise in offering one of the industry’s most comprehensive line of fine chemical products under one brand, in packaging configurations designed to meet your research and production requirements. Our product grades include: USP, NF, BP, EP, JP, FCC, ACS, KSA, Reagent grade, as well as DEA controlled substances. We operate facilities in the United States on the East Coast, West Coast, as well as in Shanghai, China in order to provide the best logistical support for our customers.

At Spectrum, Quality is priority number one. Suppliers with the best qualifications are preferred and we employ full-functioning in-house analytical laboratories at each of our facilities. Our facilities and systems are USFDA registered and ISO certified. We frequently host customer audits and cherish opportunities for improvements. Quality is engrained into our culture. Quality is priority number one.

In the following pages, we have designed and prepared documented scientific information to aid you in your initial qualification or your continual use of our products. Please do not hesitate to contact us if further information or the most up-to-date documentation is desired from any of the covered areas.

We appreciate your business and we look forward to hearing from you.

Sincerely,

Alan Wang, MSQA, ASQ CQA
Senior Manager of Technical Services
techservices@spectrumchemical.com

PA115, Pancreatin, Powder, USP

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● Product Specification
● Safety Data Sheet (SDS)
● Manufacturer
● Certification of Quality Management System (QMS)
● Certification of current Good Manufacturing Practices (cGMP)
● Product BSE/TSE Statement
● Product Allergen Statement
● Product Aflatoxin Statement
● General Label Information – Sample Label
● Product Certificate of Analysis Sample(s)
● General Lot Numbering System Guidance
● Stability – Shelf Life Guidance
<table>
<thead>
<tr>
<th>Item Number</th>
<th>PA115</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>Pancreatin, Powder, USP</td>
</tr>
<tr>
<td>CAS Number</td>
<td>8049-47-6</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td></td>
</tr>
<tr>
<td>Molecular Weight</td>
<td></td>
</tr>
<tr>
<td>MDL Number</td>
<td></td>
</tr>
<tr>
<td>Synonyms</td>
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</table>

<table>
<thead>
<tr>
<th>Test</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASSAY</strong></td>
<td></td>
</tr>
<tr>
<td>AMYLASE ACTIVITY</td>
<td>Min 25 USP U/mg</td>
</tr>
<tr>
<td>LIPASE ACTIVITY</td>
<td>Min 2.0 USP U/mg</td>
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<tr>
<td>PROTEASE ACTIVITY</td>
<td>Min 25 USP U/mg</td>
</tr>
<tr>
<td>LOSS ON DRYING</td>
<td>Max 5.0%</td>
</tr>
<tr>
<td><strong>MICROBIAL LIMITS</strong></td>
<td></td>
</tr>
<tr>
<td>SALMONELLA</td>
<td>TO PASS TEST</td>
</tr>
<tr>
<td>E.COLI</td>
<td>TO PASS TEST</td>
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<tr>
<td>FAT</td>
<td>Min 3.0%</td>
</tr>
<tr>
<td><strong>IDENTIFICATION</strong></td>
<td>TO PASS TEST</td>
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<tr>
<td><strong>RETEST DATE</strong></td>
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</tr>
<tr>
<td><strong>RESIDUAL SOLVENTS</strong></td>
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</tbody>
</table>

*Spectrum Chemical Mfg Corp*

**Corporate Headquarters**: 769 Jersey Ave. New Brunswick, NJ 08901
**West Coast Facility**: 14422 S. San Pedro St. Gardena, CA 90248
**Phone Numbers**: 732.214.1300 310.516.8000
SAFETY DATA SHEET

Preparation Date: No data available  Revision Date: 02/09/2015  Revision Number: G1

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 by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

<table>
<thead>
<tr>
<th>Hazard Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin corrosion/irritation</td>
<td>Category 2</td>
</tr>
<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
**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

**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 should 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 soap and water
Take off contaminated clothing and wash before reuse
If skin irritation or rash occurs: Get medical advice/attention
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 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>
<th>Trade Secret</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatin</td>
<td>8049-47-6</td>
<td>100</td>
<td>*</td>
</tr>
</tbody>
</table>

### 4. FIRST AID MEASURES

**First aid measures**

**General Advice:**
Poison information centers in each State capital city can provide additional assistance for scheduled poisons (13 1126)

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

**Product code:** PA115
**Product name:** PANCREATEIN, POWDER, USP
Eye Contact: Flush eye 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 allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Indication of any immediate medical attention and special treatment needed**
Treat symptomatically

**Notes to Physician:**

**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:**
Provide sufficient air exchange and/or exhaust in work rooms.

**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 vapours/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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

**United States**

<table>
<thead>
<tr>
<th>Components</th>
<th>OSHA</th>
<th>NIOSH</th>
<th>ACGIH</th>
<th>AIHA WHEEL</th>
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**Canada**

<table>
<thead>
<tr>
<th>Components</th>
<th>Alberta</th>
<th>British Columbia</th>
<th>Ontario</th>
<th>Quebec</th>
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<tbody>
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**Australia and Mexico**

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</thead>
<tbody>
<tr>
<td>Pancreatin 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 Safety glasses with side-shields
- **Skin and body protection:** Long sleeved clothing. Chemical resistant apron. Gloves.
- **Respiratory protection:** Effective dust mask Wear respirator with dust filter.
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

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<th>Property</th>
<th>Value</th>
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<tbody>
<tr>
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<tr>
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<td>Appearance:</td>
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<tr>
<td>Flammability:</td>
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<tr>
<td>Flash Point Tested according to:</td>
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<td>Upper Explosion Limit (%):</td>
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<tr>
<td>Decomposition temperature (°C/°F):</td>
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<tr>
<td>Specific gravity:</td>
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<tr>
<td>Evaporation rate:</td>
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<tr>
<td>Odor threshold (ppm):</td>
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<tr>
<td>Miscibility:</td>
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<td>Solubility:</td>
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<td>Flash point (°C):</td>
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<tr>
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<tr>
<td>Physical state:</td>
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<td>Odor:</td>
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</tr>
<tr>
<td>Molecular/Formula weight:</td>
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</tbody>
</table>

### 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. Ignition sources.
- **Incompatible Materials:** No information available
- **Hazardous decomposition products:** No information available

**Other Information**

- **Corrosivity:** No information available
- **Special Remarks on Corrosivity:** No information available
11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:
Inhalation. Ingestion. Skin.

Acute Toxicity

Component Information

Pancreatin - 8049-47-6
LD50/oral/rat = > 10 g/kg Oral LD50 Rat
LD50/oral/mouse = > 10 g/kg Oral LD50 Mouse
LD50/dermal/rat = No information available
LD50/dermal/rabbit = No information available
LC50/inhalation/rat = No information available
LC50/inhalation/mouse = No information available
Other LD50 or LC50 information = 2100 mg/kg Intraperitoneal LD50 Mouse;
2550 mg/kg Intraperitoneal LD50 Rat;
3870 mg/kg Subcutaneous LD50 Mouse;
>5 g/kg Subcutaneous LD50 Rat

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = >10g/kg

LD50/oral/mouse =
Value - Acute Tox Oral = >10g/kg

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat
VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat
VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse
VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: Causes skin irritation. May cause allergic skin reaction.

Eye Contact: Causes eye irritation.

Inhalation 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.

Product code: PA115  Product name: PANCREATIN, POWDER, USP
Aspiration hazard: No information available

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

Chronic Toxicity: No information available

Sensitization: May cause sensitization by inhalation and skin contact

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic

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<thead>
<tr>
<th>Components</th>
<th>ACGIH - Carcinogens</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA HCS - Carcinogens</th>
<th>Australia - Prohibited Carcinogenic Substances</th>
<th>Australia - Notifiable Carcinogenic Substances</th>
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<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
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</table>

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:

STOT - single exposure: No information available
STOT - repeated exposure: No information available
Target Organs: No information available

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available
Bioaccumulative potential: No information available
Mobility: 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
--- | --- | --- | --- | ---
Pancreatin | None | None | None | None

14. TRANSPORT INFORMATION

**DOT**
- UN-No: Not Regulated
- Proper Shipping Name: No information available
- Hazard Class: No information available
- Subsidiary Risk: No information available
- Packing Group: None
- ERG No: No information available
- Marine Pollutant: No data available
- DOT RQ (lbs): 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
- 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
- Classification Code: No information available
- Description: No information available
- CEFIC Tremcard No: 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
- Description: No information available
- IMDG Page: No information available
- Marine Pollutant: No information available
- MFAG: No information available
- Maximum Quantity: No information available

**RID**
- 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
- Classification Code: No information available
- Description: No information available

Product code: PA115  
Product name: PANCREATIN, POWDER, USP
14. TRANSPORT INFORMATION

**ICAO**
- **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
- **Description:** No information available

**IATA**
- **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
- **Description:** No information available

15. REGULATORY INFORMATION

**International Inventories**

<table>
<thead>
<tr>
<th>Components</th>
<th>U.S. TSCA</th>
<th>KOREA KECL (PICCS)</th>
<th>Philippines (KECL)</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>Present XU</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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</tbody>
</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
- **California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.**
- **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>Carcinogen</th>
<th>Developmental Toxicity Male Reproductive Toxicity</th>
<th>Female Reproductive Toxicity</th>
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<tbody>
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<td>Pancreatin</td>
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**CERCLA/SARA**

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

**U.S. TSCA**

<table>
<thead>
<tr>
<th>Components</th>
<th>TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)</th>
<th>TSCA 8(d) - Health and Safety Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatin</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

**Canada**

**Product code:** PA115  **Product name:** PANCREATIN, POWDER, USP
WHMIS hazard class:
Non-controlled

Pancreatin
D2A

Canada Controlled Products Regulation:
This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Inventory

<table>
<thead>
<tr>
<th>Components</th>
<th>Canada (DSL)</th>
<th>Canada (NDISL)</th>
</tr>
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<tbody>
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<table>
<thead>
<tr>
<th>Components</th>
<th>CEPA Schedule I - Toxic Substances</th>
<th>CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting</th>
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</thead>
<tbody>
<tr>
<td>Pancreatin</td>
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EU Classification

R-phrase(s)
not determined (not applicable)

S-phrase(s)
none

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<tbody>
<tr>
<td>Pancreatin</td>
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</table>

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:
None.

16. OTHER INFORMATION

Product code: PA115
Product name: PANCREATIN, POWDER, USP
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
Manufacturer

Product Covered: PA115, Pancreatin, Powder, USP

Spectrum takes ownership as the manufacturer for the Spectrum product listed above and provides full quality assurance, customer service, and technical product support.

While information concerning the raw material manufacturer of our starting materials is considered proprietary, such information can be made available upon request contingent on demonstration of business volume justification and successful execution of confidential disclosure agreement (CDA).

Requests for disclosure of proprietary raw material manufacturer information may be submitted to the assigned account representative for consideration.

Sincerely,

Alan Wang, MSQA, ASQ CQA
Senior Manager of Technical Services
techservices@spectrumchemical.com

Certificate of Registration

Intertek

This is to certify that the quality management system of

Spectrum Chemicals and Laboratory Products, Inc
Main Site: 14422 South San Pedro Street, Gardena, California, 90248, USA
Additional Sites: 13915 South Main Street, Los Angeles, California, 90061, USA
755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA
769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA
7400 North Oracle Road, Suite 221, Tucson, Arizona, 85704, USA

has been assessed and registered by Intertek as conforming to the requirements of

ISO 9001:2008

The quality management system is applicable to

California and New Jersey sites: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.

Arizona site: Supporting Spectrum’s two manufacturing facilitates by: selecting and qualifying distributors of Laboratory and Safety Equipment; processing bids and quotes to generate new sales opportunities; sourcing bulk chemicals in support of bulk bids and quotes; assisting production operations through order expediting and IT infrastructure support.

Certificate Number: 94-316m-01
Initial Certification Date: 27 December 1994
Certificate Issue Date: 29 January 2016
Certificate Expiry Date: 14 September 2018

Calin Moldovean, President
Intertek Testing Services NA, Inc.
900 Chelmsford Street, Suite 301-3, Lowell, MA, USA

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate’s validity is subject to the organization maintaining their system in accordance with Intertek’s requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

The certificate remains the property of Intertek, to whom it must be returned upon request.

CT-ISO 9001-2008-ANAB-EN-LT-L-26.jun.15
This is to certify that the quality management system of

**Spectrum China Ltd.**

Building A20, No. 3802, Shengang Road, Songjiang District, Shanghai, China

has been assessed and registered by Intertek as conforming to the requirements of

**ISO 9001: 2008**

The quality management system is applicable to:

*Provision of service of purchase, testing and sales for chemical products, repacking of non-hazardous chemical products.*

Organization Code: 77762704-8
Certificate Number: 111310001-01
Certificate Issue Date: 17 November 2015
Certificate Expiry Date: 14 September 2018

Authorized Signature: Calin Moldovean – President, Business Assurance
Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom

Intertek Certification Limited is a UKAS accredited body under schedule of accreditation no. 014.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek’s requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The annual validity of the certificate can also be checked through the website http://www.cnca.gov.cn of CNCA in China.

The certificate remains the property of Intertek, to whom it must be returned upon request.
March 28, 2016

Certificate of cGMP

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify that our USP, NF, FCC, EP, BP, JP, and food grade products are produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Spectrum is an FDA registered and inspected drug establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824
Spectrum -Shanghai, China: 3006174778

Thank you for your interest with Spectrum products. Please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Michelle Weston
Quality Assurance Specialist
April 25, 2016

Certificate of cGMP

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Product Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>PA115</td>
<td>Pancreatin, Powder, USP</td>
</tr>
</tbody>
</table>

Spectrum is an FDA registered and inspected drug establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824
Spectrum-Shanghai, China: 3006174778

Thank you for your interest with Spectrum products. Please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Michelle Weston
Quality Assurance Specialist
May 11, 2016

Re: Pancreatin, Powder, USP-PA115

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding Bovine Spongiform Encephalopathy (BSE). Please be assured that the chemical Pancreatin, Powder, USP-PA115 is BSE/TSE free.

Porcine raw materials are sourced from USDA/Ag Canada inspected facilities. Porcine animals are not known to possess the BSE/TSE disease causing agents. Bovine lactose is processed using milk sourced from healthy animals under the same conditions as milk collected for human consumption. Bovine lactose has never been shown to possess the BSE/TSE disease causing agents.

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

Darlene Dagdag-Lyudmirskiy
Technical Services
Spectrum Chemical Mfr. Corp.

This document has been produced electronically and is valid without a signature
May 19, 2016

Re: Pancreatin, Powder, USP- PA115

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding the presence of allergens in raw materials. Please be assured that the following chemical does not contain (Egg; Fish; Shellfish; Sulfur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO2; Lupin; Tree nuts; Wheat; Peanuts; Soy; Cereals containing Gluten; Celery; Mustard; Sesame Seed).

Milk derived lactose is used as a diluent, but the manufacturer of this diluent has indicated that the manufacturing process employed removes all measurable traces of allergenic milk proteins from their end lactose product.

Pancreatin, Powder, USP- PA115

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

Darlene Dagdag-Lyudmirskiy
Technical Services
Spectrum Chemical Mfr. Corp.

This document has been produced electronically and is valid without a signature
May 19, 2016

Re: Pancreatin, Powder, USP- PA115

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfg. Corp. understand the concern regarding Aflatoxins in raw materials.

The manufacturing site does not perform any analytical testing to verify the presence or absence of Aflatoxins in this product. The manufacturing site cannot state that this product is Aflatoxin free.

Pancreatin, Powder, USP- PA115

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

Darlene Dagdag- Lyudmirskiy
Technical Services
Spectrum Chemical Mfr. Corp.

This document has been produced electronically and is valid without a signature
Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication.

**DANGER**
- Causes skin and eye irritation • May cause an allergic skin reaction • May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- Wear respiratory protection, protective gloves • Avoid breathing dust • Wash hands, face and any exposed skin thoroughly after handling • Contaminated work clothing must not be allowed out of the workplace.

**FIRST AID:**
- 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.
- 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 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 physician.

**KEEP FROM CHILDREN**

**Source:** Porcine.

**Assay:**
- Amylase Activity ....Min. 25 U.S.P. units/mg
- Lipase Activity .......Min. 2.0 U.S.P. units/mg
- Protease Activity ....Min. 25 U.S.P. units/mg

**MAXIMUM LIMITS**
- Loss on Drying ........................................ 5.0%
- Microbial Limits:
  - Salmonella ................................To pass test
  - Escherichia Coli .........................To pass test
- Fat ........................................................... 3.0%
- Residual Solvents  .........................To pass test

**FLUSHED WITH NITROGEN**

**Product Catalog Number**

**Item Name, Form, Grade**

**Size/Quantity**

**Chemical Abstracts Service (CAS) Registry Number**

**Caution Information**

**DOT Shipping Information**

**Toll-Free 24-Hour Chemical Emergency Telephone Number**

**Empirical Formula, Formula Weight and Technical Specifications Panel**

**Expiration Information**

**Lot Number**

**Kosher Certified by Kosher Supervision of America (KSA).**

**Storage Color Band**

This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

---

**Spectrum Chemical Mfg Corp**

**Corporate Headquarters:**
769 Jersey Ave.
New Brunswick, NJ 08901
732.214.1300

**West Coast Facility:**
14422 S. San Pedro St.
Gardena, CA 90248
310.516.8000
# Certificate Of Analysis

| Item Number | PA115                        | Lot Number | 1EA0937
|-------------|------------------------------|------------|--------
| Item        | Pancreatin, Powder, USP      |            |        
| CAS Number  | 8049-47-6                   |            |        
| Molecular Formula |                       |            |        

<table>
<thead>
<tr>
<th>Test</th>
<th>Specification</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASSAY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMYLASE ACTIVITY</td>
<td>25 USP U/mg</td>
<td>35 USP U/mg</td>
</tr>
<tr>
<td>LIPASE ACTIVITY</td>
<td>2.0 USP U/mg</td>
<td>3.6 USP U/mg</td>
</tr>
<tr>
<td>PROTEASE ACTIVITY</td>
<td>25 USP U/mg</td>
<td>30 USP U/mg</td>
</tr>
<tr>
<td>LOSS ON DRYING</td>
<td>5.0 %</td>
<td>0.5 %</td>
</tr>
<tr>
<td>MICROBIAL LIMITS:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SALMONELLA</td>
<td>TO PASS TEST</td>
<td>PASSES TEST</td>
</tr>
<tr>
<td>E.COLI</td>
<td>TO PASS TEST</td>
<td>PASSES TEST</td>
</tr>
<tr>
<td>FAT</td>
<td>3.0 %</td>
<td>0.6 %</td>
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<tr>
<td>IDENTIFICATION</td>
<td>TO PASS TEST</td>
<td>PASSES TEST</td>
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<tr>
<td>RETEST DATE</td>
<td></td>
<td>22-JUN-2016</td>
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<tr>
<td>RESIDUAL SOLVENTS</td>
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</tr>
<tr>
<td>CLASS 3 (solvent) / ACETONE</td>
<td></td>
<td>&lt;5000 ppm</td>
</tr>
<tr>
<td>APPEARANCE</td>
<td>CREAM POWDER</td>
<td></td>
</tr>
<tr>
<td>MANUFACTURE DATE</td>
<td></td>
<td>23-JUN-2014</td>
</tr>
</tbody>
</table>

Spectrum Chemical Mfg Corp  
14422 South San Pedro Street  
Gardena 90248 CA

Certificate of Analysis Results Certified By:

Adan Hernandez  
Quality Control Manager  
Spectrum Chemicals & Laboratory Products

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.
### Certificate Of Analysis

<table>
<thead>
<tr>
<th>Item Number</th>
<th>PA115</th>
<th>Lot Number</th>
<th>2EG0120</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>Pancreatin, Powder, USP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAS Number</td>
<td>8049-47-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular Formula</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
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<table>
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<td><strong>ASSAY</strong></td>
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</tr>
<tr>
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<td>25 USP U/mg</td>
<td>35 USP U/MG</td>
</tr>
<tr>
<td>LIPASE ACTIVITY</td>
<td>2.0 USP U/mg</td>
<td>4.4 USP U/MG</td>
</tr>
<tr>
<td>PROTEASE ACTIVITY</td>
<td>25 USP U/mg</td>
<td>28 USP U/MG</td>
</tr>
<tr>
<td>LOSS ON DRYING</td>
<td>5.0 %</td>
<td>0.8 %</td>
</tr>
<tr>
<td><strong>MICROBIAL LIMITS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SALMONELLA</td>
<td>TO PASS TEST</td>
<td>PASSES TEST</td>
</tr>
<tr>
<td>E. COLI</td>
<td>TO PASS TEST</td>
<td>PASSES TEST</td>
</tr>
<tr>
<td>FAT</td>
<td>3.0 %</td>
<td>1.1 %</td>
</tr>
<tr>
<td><strong>IDENTIFICATION</strong></td>
<td>TO PASS TEST</td>
<td>PASSES TEST</td>
</tr>
<tr>
<td>RETEST DATE</td>
<td>09-FEB-2017</td>
<td></td>
</tr>
<tr>
<td>RESIDUAL SOLVENTS</td>
<td>TO PASS TEST</td>
<td></td>
</tr>
<tr>
<td>CLASS 3 (solvent) / ACETONE</td>
<td>&lt;5000 ppm</td>
<td></td>
</tr>
<tr>
<td>APPEARANCE</td>
<td>CREAM COLORED POWDER</td>
<td></td>
</tr>
<tr>
<td>DATE OF MANUFACTURE</td>
<td>10-FEB-2015</td>
<td></td>
</tr>
</tbody>
</table>

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Certificate of Analysis Results Certified By:

[Signature]

Mubinah F. Dwanah  
Laboratory Supervisor  
Spectrum Chemicals & Laboratory Products
January 26, 2016

RE: Lot Numbering System

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products' Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of six characters, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum's Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

Example: ZI0928 = The 928th material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of seven characters. The first character, a number, represents the production facility:

1 = Gardena, CA Facility
2 = New Brunswick, NJ Facility
3 = China Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

Example: 2AA0706 = The 706th material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at qualityassurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Michael Dang
Manager, GMP Compliance
Stability – Shelf Life Guidance

Product Covered: PA115, Pancreatin, Powder, USP

Spectrum Chemical’s manufacturing partner has assigned the following shelf life guidance for the product listed above.

The product, PA115, Pancreatin, Powder, USP, is assigned a 24 months shelf life from date of manufacturing. The quality and integrity of the chemical depends on the handling and storage conditions. Please refer to the Safety Data Sheet for proper storage and handling procedures.

Adan R. Hernandez
Quality Control Manager

Corporate Headquarters
769 Jersey Avenue
New Brunswick, NJ 08901-3605