

# Scientific Documentation

## Pyrilamine Maleate, USP

Not appropriate for regulatory submission.

Please visit [www.spectrumchemical.com](http://www.spectrumchemical.com) or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp  
769 Jersey Avenue  
New Brunswick, NJ 08901  
Phone 732.214.1300



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## Specification for Pyrilamine Maleate, USP (PY105)

Item Number	PY105
Item	Pyrilamine Maleate, USP
CAS Number	59-33-6
Molecular Formula	$C_{17}H_{23}N_3O \cdot C_4H_4O_4$
Molecular Weight	401.47
MDL Number	
Synonyms	Mepyramine Hydrogen Maleate ; Pyranisamine Maleate ; Midol ; Mepyramine Maleate

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.0	100.5 %
MELTING RANGE	99°	103°C
LOSS ON DRYING		0.5 %
RESIDUE AFTER IGNITION		0.1 %
RELATED COMPOUNDS		AS REPORTED
INDIVIDUAL	INDIVIDUAL IMPURITIES	
TOTAL	TOTAL IMPURITIES	
ELEMENTAL IMPURITIES		AS REPORTED
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	ABSORBTIVITY MATCHES STANDARD	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS		AS REPORTED

### *Spectrum Chemical Mfg Corp*

<b>Corporate Headquarters:</b>	<b>West Coast Facility:</b>
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

## Certificate Of Analysis

Item Number	PY105	Lot Number	4LB0004
Item	Pyrilamine Maleate, USP	Manufacturer Lot	SLL/M/1221037
CAS Number	59-33-6	Manufacturer Code	14154
Molecular Formula	C <sub>17</sub> H <sub>23</sub> N <sub>3</sub> O•C <sub>4</sub> H <sub>4</sub> O <sub>4</sub>	Molecular Weight	401.47

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS)	98.0	100.5 %	100.0%
MELTING RANGE	99°	103°C	101-102°C
LOSS ON DRYING		0.5 %	0.005%
RESIDUE AFTER IGNITION		0.1 %	0.05%
RELATED COMPOUNDS		AS REPORTED	COMPLIES WITH STANDARD
INDIVIDUAL	INDIVIDUAL IMPURITIES		0.0%
TOTAL	TOTAL IMPURITIES		0.0%
ELEMENTAL IMPURITIES		AS REPORTED	COMPLIES WITH STANDARD
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	ABSORBTIVITY MATCHES STANDARD		ABSORBTIVITY MATCHES STANDARD
EXPIRATION DATE			30-NOV-2026
DATE OF MANUFACTURE			01-DEC-2021
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS		AS REPORTED	RESIDUAL SOLVENTS ARE PRESENT
CLASS 2 (SOLVENT) / METHANOL			<3000 PPM
CLASS 2 (solvent) / XYLENE			<2170 PPM
CLASS 3 (solvent) / 2-PROPANOL			<5000 PPM

Certificate of Analysis Results Entered By:

GHERRERA  
Genaro Herrera  
17-MAR-22 06:30:30

Certificate of Analysis Results Approved By:

GHERRERA  
Genaro Herrera  
17-MAR-22 06:30:54

Spectrum Chemical Mfg Corp  
777 Jersey Avenue  
New Brunswick 08901 NJ



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

**Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.**

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Supriya Lifescience Limited at A - 5 / 2, Lote Parshuram Industrial Area, Ratnagiri, Maharashtra 415722, India (IND). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

## SAFETY DATA SHEET

Preparation Date: 7/28/15

Revision date 03/27/2019

Revision Number: G2

### 1. IDENTIFICATION

#### Product identifier

**Product code:** PY105  
**Product Name:** PYRILAMINE MALEATE, USP

#### Other means of identification

**Synonyms:** Anisopyradamine  
 Anthisan maleate  
 Antihist  
 Diaminide maleate  
 N-Dimethylaminoethyl-N-p-methoxy-alpha-aminopyridine maleate  
 Pyridine, 2-((2-(dimethylamino)ethyl)(p-methoxybenzyl)amino)-, maleate (1:1)  
 N,N-Dimethyl-N'-(4-methoxybenzyl)-N'-(2-pyridyl)ethylenediamine maleate  
 1,2-Ethanediamine,  
 N-((4-methoxyphenyl)methyl)-N,N'-dimethyl-N-2-pyridinyl-, (Z)-2-butenedioate  
 Mepyramine maleate  
 N-p-Methoxybenzyl-N'-N'-dimethyl-N-alpha-pyridylethylenediamine maleate  
 Minihist  
 Neo-Antergan maleate  
 Paraminyl maleate  
 Pyra maleate  
 Pyranilamine maleate  
 Pyranisamine maleate  
 Stangen maleate  
 Statomin maleate  
 Thylogen maleate  
**CAS #:** 59-33-6  
**RTECS #** UT122500  
**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:** Tom Tyner (USA - West Coast)  
**Contact Person:** Ibad Tirmiz (USA - East Coast)

### 2. HAZARDS IDENTIFICATION

#### Classification

**Product code:** PY105

**Product name:** PYRILAMINE  
 MALEATE, USP

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

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

Acute toxicity - Oral	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Specific target organ toxicity (single exposure)	Category 3

#### **Label elements**

<p><b>Warning</b></p> <p><b>Hazard statements</b> Harmful if swallowed Causes skin irritation Causes serious eye irritation May cause respiratory irritation</p> 
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#### **Hazards not otherwise classified (HNOC)**

Not Applicable

#### **Other hazards**

Not available

#### **Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling  
Do not eat, drink or smoke when using this product  
Avoid breathing dust/fume/gas/mist/vapors/spray  
Use only outdoors or in a well-ventilated area  
Wear protective gloves

#### **Precautionary Statements - Response**

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  
If skin irritation occurs: Get medical advice/attention  
Take off contaminated clothing and wash it before reuse  
IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.  
IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell  
Rinse mouth

#### **Precautionary Statements - Storage**

Store in a well-ventilated place. Keep container tightly closed  
Store locked up

#### **Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

### **3. COMPOSITION/INFORMATION ON INGREDIENTS**

Component	CAS No	Weight-%
Pyrilamine Maleate	59-33-6	100

#### 4. FIRST AID MEASURES

##### First aid measures

<b>General Advice:</b>	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.
<b>Skin Contact:</b>	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.
<b>Eye Contact:</b>	Flush eyes with water for 15 minutes. Get medical attention.
<b>Inhalation:</b>	Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
<b>Ingestion:</b>	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

<b>Symptoms</b>	Harmful if swallowed Causes serious eye irritation Causes skin irritation May cause respiratory irritation May cause hypermotility, diarrhea Convulsions Excitement Ataxia
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##### Indication of any immediate medical attention and special treatment needed

<b>Notes to Physician:</b>	Treat symptomatically.
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##### 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

<b>Suitable Extinguishing Media:</b>	Dry chemical. Carbon dioxide (CO <sub>2</sub> ). Water spray mist or foam.
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<b>Unsuitable Extinguishing Media:</b>	No information available.
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##### Specific hazards arising from the chemical

<b>Hazardous combustion products</b>	Carbon monoxide. Carbon dioxide (CO <sub>2</sub> ). Nitrogen oxides (NO <sub>x</sub> ).
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<b>Specific hazards</b>	May be combustible at high temperatures.
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##### 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. Avoid contact with skin, eyes and clothing. Remove all sources of ignition. Avoid dust formation. Use personal protective equipment.

**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. Avoid dust formation. Keep away from incompatible materials.

**Safe Handling Advice**

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

**Conditions for safe storage, including any incompatibilities****Technical Measures/Storage Conditions:**

Sensitive to light. Store in light-resistant containers. Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials.

**Incompatible Materials:**

Oxidizing agents  
Bases

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Control parameters****National occupational exposure limits****United States**

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Pyrimamine Maleate	59-33-6	None	None	None	None

## Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Pyrilamine Maleate	59-33-6	None	None	None	None

## Australia and Mexico

Component	CAS No	Australia	Mexico
Pyrilamine Maleate	59-33-6	None	None

### 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

<b>Eye protection:</b>	Goggles or Safety glasses with side-shields.
<b>Skin and body protection:</b>	Long sleeved clothing Gloves Chemical resistant apron
<b>Respiratory protection:</b>	Effective dust mask. 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.
<b>Hygiene measures:</b>	Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical state:</b> Solid	<b>Appearance:</b> Crystalline powder.	<b>Color:</b> White.
<b>Odor:</b> No information available.	<b>Taste</b> No information available.	<b>Formula</b> C <sub>17</sub> H <sub>23</sub> N <sub>3</sub> O.C <sub>4</sub> H <sub>4</sub> O <sub>4</sub>
<b>Molecular/Formula weight (g/mole):</b> 401.47 g/mole	<b>Flammability (solid, gas)</b> no data available	<b>Flashpoint (°C/°F):</b> >187.78°C (>370 °F)
<b>Flash Point Tested according to:</b> Closed cup	<b>Autoignition Temperature (°C/°F):</b> >360°C (>680°F)	<b>Lower Explosion Limit (%):</b> No information available
<b>Upper Explosion Limit (%):</b> No information available	<b>Melting point/range(°C/°F):</b> 99-103°C (210.2-217.4°F)	<b>Decomposition temperature(°C/°F):</b> No information available
<b>Boiling point/range(°C/°F):</b>		

No information available

**Bulk density:**  
No information available

**Density (g/cm<sup>3</sup>):**  
No information available

**Specific gravity:**  
No information available

**pH**  
5.1

**Vapor pressure @ 20°C (kPa):**  
No information available

**Evaporation rate:**  
No information available

**Vapor density:**  
No information available

**VOC content (g/L):**  
No information available

**Odor threshold (ppm):**  
No information available

**Partition coefficient  
(n-octanol/water):**  
No information available

**Viscosity:**  
No information available

**Miscibility:**  
No information available

**Solubility:**  
Slightly soluble in Benzene  
Slightly soluble in Ether  
Freely soluble in alcohol  
Freely soluble in Chloroform

## 10. STABILITY AND REACTIVITY

### Reactivity

Reactive with oxidizing agents

### Chemical stability

**Stability:** Sensitive to light. Stable under recommended storage conditions.

**Possibility of Hazardous Reactions:** Hazardous polymerization does not occur

**Conditions to avoid:** Heat. Exposure to light. Ignition sources. Incompatible materials.

**Incompatible Materials:** Oxidizing agents  
Bases

**Hazardous decomposition products:** Carbon monoxide. Carbon dioxide. Nitrogen oxides (NO<sub>x</sub>).

### 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:**  
Skin. Eyes. Inhalation. Ingestion.

### Acute Toxicity

### Component Information

Pyrilamine Maleate	
CAS No	59-33-6
LD50/oral/rat = 513 mg/kg Oral LD50 Rat	

**Product code:** PY105

**Product name:** PYRILAMINE  
MALEATE, USP

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LD50/oral/mouse = 220 mg/kg Oral LD50 Mouse  
 LD50/dermal/rabbit = No information available  
 LD50/dermal/rat = No information available  
 LC50/inhalation/rat = No information available  
 LC50/inhalation/mouse = No information available  
 Other LD50 or LC50information = No information available

## Product Information

LD50/oral/rat =  
 Value - Acute Tox = 513 mg/kg

LD50/oral/mouse =  
 Value - Acute Tox Oral = 220 mg/kg

LD50/dermal/rabbit  
 Value - Acute Tox = 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.  
**Eye Contact:** Causes serious eye irritation.  
**Inhalation** May cause respiratory irritation.  
**Ingestion** Harmful if swallowed. May cause digestive (gastrointestinal) tract irritation.  
**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:** No information available.  
**Mutagenic Effects:** No information available

**Carcinogenic effects:** Not considered carcinogenic.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic	Australia - Prohibited Carcinogenic
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						<b>Substances</b>	<b>Substances</b>
Pyrilamine Maleate	59-33-6	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

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**

**STOT - single exposure** respiratory system.

**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 in soil** No information available

**Other adverse effects** 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

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Pyrilamine Maleate	59-33-6	None	None	None	None

## **14. TRANSPORT INFORMATION**

### **DOT**

**UN-No:** Not Regulated

**Proper Shipping Name:** No information available

**Hazard Class** No information available

**Product code:** PY105

**Product name:** PYRILAMINE  
MALEATE, USP

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<b>Subsidiary Class</b>	No information available
<b>Packing group:</b>	No information available
<b>Emergency Response Guide Number</b>	No information available
<b>Marine Pollutant</b>	No data available
<b>DOT RQ (lbs):</b>	No information available
<b>Special Provisions</b>	No Information available
<b>Symbol(s):</b>	No information available
<b>Description:</b>	No information available

#### **TDG (Canada)**

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

#### **ADR**

<b>UN Number</b>	Not regulated
<b>Proper Shipping Name:</b>	No information available
<b>Transport hazard class(es)</b>	No information available
<b>Packing group</b>	No information available
<b>Subsidiary Risk:</b>	No information available

#### **IMDG**

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

#### **RID**

<b>UN Number</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Transport hazard class(es)</b>	No information available
<b>Subsidiary Risk:</b>	No information available
<b>Packing group</b>	No information available

#### **ICAO (air)**

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

#### **IATA**

<b>UN Number</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Transport hazard class(es)</b>	No information available
<b>Subsidiary Risk:</b>	No information available
<b>Packing group</b>	No information available
<b>Precautionary Statements - Response</b>	No information available
<b>Special Provisions</b>	No information available

## 15. REGULATORY INFORMATION

### International Inventories

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia (AICS)	EINECS-No.
<i>Pyrilamine Maleate</i>	59-33-6	PresentACTIVE	Not present	Not present	Not present	Present	Present	Present 200-422-7

### U.S. Regulations

#### 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)

Component	CAS No	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
<i>Pyrilamine Maleate</i>	59-33-6	Not Listed	Not Listed	Not Listed	Not Listed

### CERCLA/SARA

Component	CAS No	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
<i>Pyrilamine Maleate</i>	59-33-6	None	None	None	None	None

### U.S. TSCA

Component	CAS No	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
<i>Pyrilamine Maleate</i>	59-33-6	Not Applicable	Not Applicable

### Canada

#### WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

The WHMIS 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

### DSL/NDSL

Component	CAS No	Canada (DSL)	Canada (NDSL)
<i>Pyrilamine Maleate</i>	59-33-6	Present	Not Listed

<b>Component</b>	<b>CAS No</b>	<b>CEPA Schedule I - Toxic Substances</b>
Pyrilamine Maleate	59-33-6	Not listed
<b>Component</b>	<b>CAS No</b>	<b>CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting</b>
Pyrilamine Maleate	59-33-6	Not listed

## EU Classification

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

<b>Component</b>	<b>CAS No</b>	<b>EU GHS - SV - CLP (1272/2008)</b>
Pyrilamine Maleate	59-33-6	

### EU - CLP (1272/2008)

#### **R-phrases(s)**

R22 - Harmful if swallowed

R36/37/38 - Irritating to eyes, respiratory system and skin

#### **S -phrase(s)**

S22 - Do not breathe dust

S36 - Wear suitable protective clothing

S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Pyrilamine Maleate	59-33-6		No information	

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

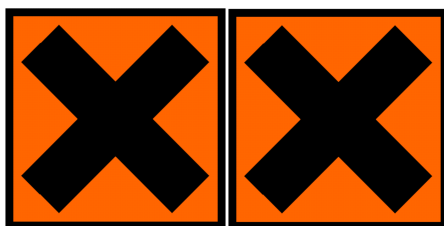
#### Indication of danger:

Xn - Harmful

Xi - Irritant

**Xn**

**Xi**



## 16. OTHER INFORMATION

Preparation Date: 7/28/15  
Revision date: 03/27/2019  
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



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**End of Safety Data Sheet**



**Certification of Compliance with current Good Manufacturing Practices**

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies 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.

Catalog Number	Product Name
PY105	Pyrilamine Maleate, USP

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

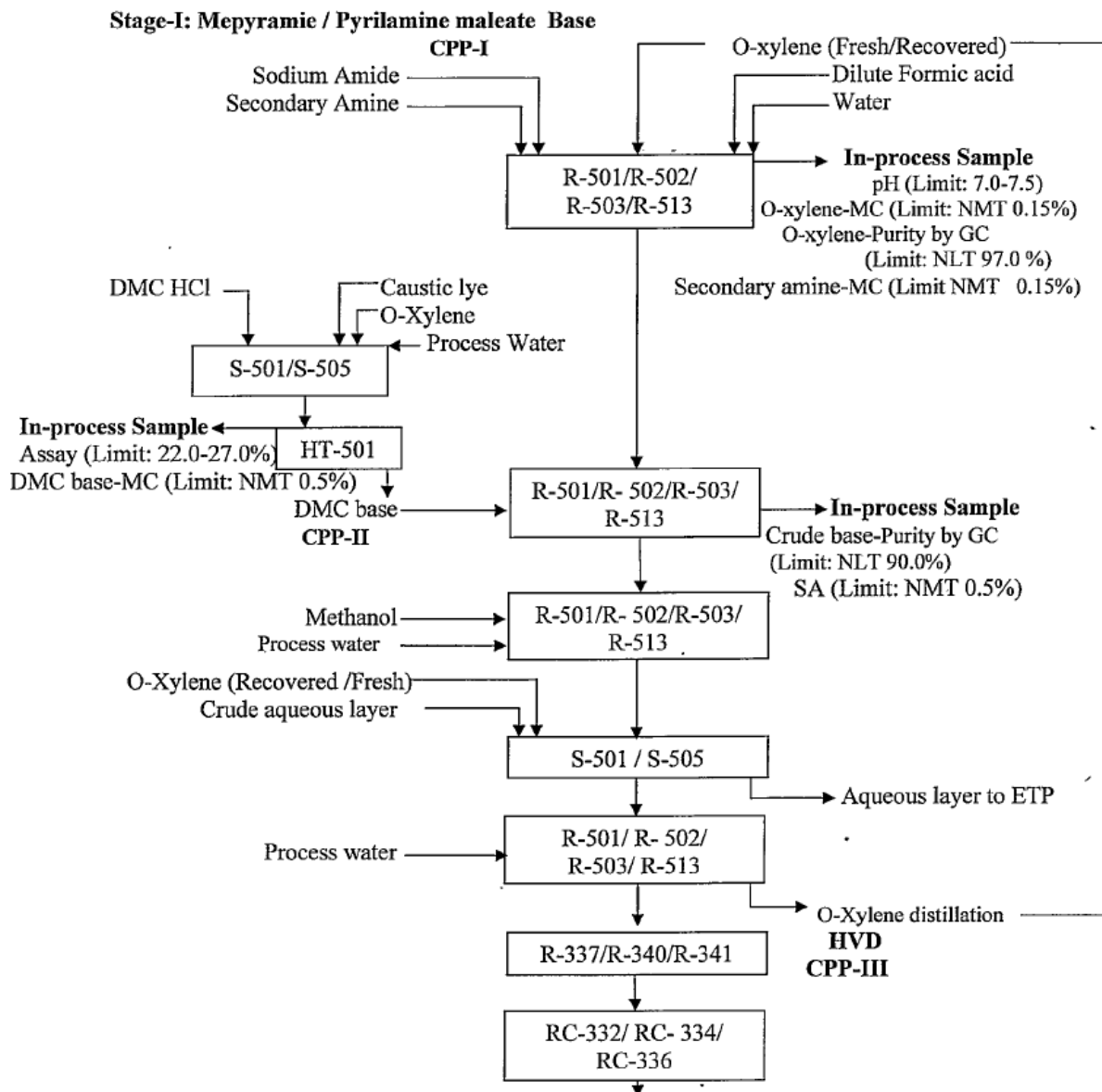
Spectrum-Gardena, CA: 2020632  
Spectrum-New Brunswick, NJ: 2246824

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com)

Sincerely,

Oralia Chavez  
Quality Assurance Specialist

## Manufacturing Process Flowchart Pyrilamine Maleate, USP (Cat# PY105)

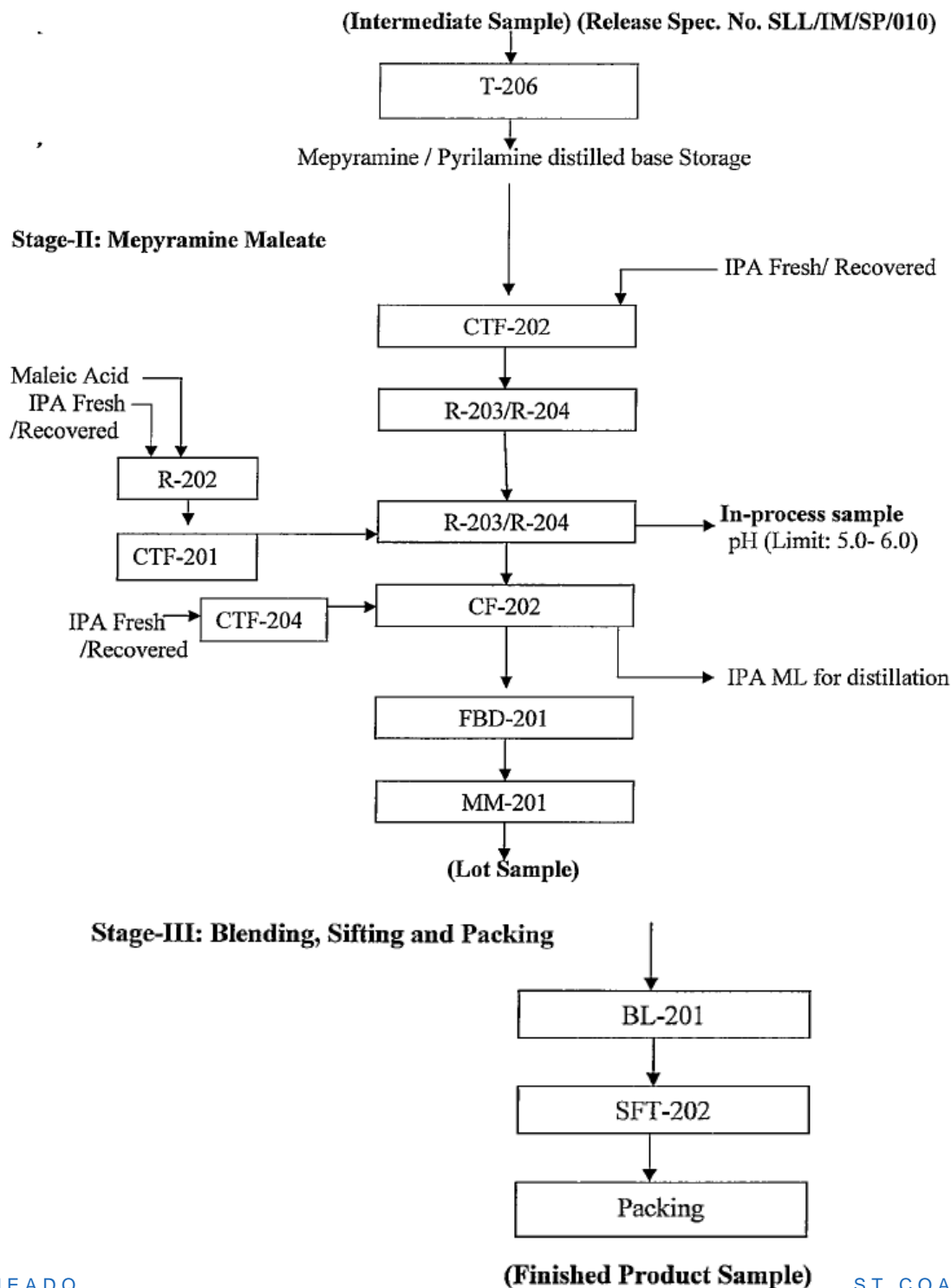


### CORPORATE HEADQUARTERS

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[www.spectrumchemical.com](http://www.spectrumchemical.com)

## PY105, Pyriline Maleate, USP

### Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

### BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

### Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

### EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

### GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

### Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

## **Nitrosamine Statement**

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

## **Animal Testing Statement**

The above mentioned catalog item has not been tested on animals.

## **Organic Compliance Statement**

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

## **Shelf Life Statement**

The above mentioned catalog item is typically assigned a shelf life of 60 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

## **Other Chemicals Statement**

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- |                     |                 |
|---------------------|-----------------|
| • Aflatoxins        | • Parabens      |
| • Antibiotics       | • Pesticides    |
| • Bisphenol A (BPA) | • Phthalates    |
| • CMR Substances    | • Preservatives |



**RE: Elemental Impurities - Pyrilamine Maleate, USP (Cat# PY105)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	< 1 ppm
Lead	Pb	1	< 1 ppm
Arsenic	As	1	< 1 ppm
Mercury	Hg	1	< 0.5 ppm
Cobalt	Co	2A	< 1 ppm
Vanadium	V	2A	< 1 ppm
Nickel	Ni	2A	< 1 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

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**RE: Residual Solvents - Pyriline Maleate, USP (Cat# PY105)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Methanol	2	< 3000 ppm
Trichloroethene	2	< 2170 ppm
2-Propanol	3	< 5000 ppm

No Class 1 or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

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## 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. Below you will find a typical label example for this catalog item.

**WARNING**

- Harmful if swallowed • Causes serious eye irritation • Causes skin irritation • May cause respiratory irritation.
- Do not eat, drink or smoke when using this product
- Wear protective gloves, eye protection, face protection • Avoid breathing dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling.

**FIRST AID:** Call a POISON CENTER or physician if you feel unwell. 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 occurs: Get medical attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth.

**KEEP FROM CHILDREN**



**PY105                      SIZ SY**

**Pyrilamine  
Maleate**

USP

CAS 59-33-6

**CAUTION:** For manufacturing, processing or repacking.  
**Read and understand the label and Safety Data Sheet (SDS) prior to use.**

**Chemical Emergency: (800)424-9300**

www.SpectrumChemical.com

$C_{17}H_{23}N_3O \cdot C_4H_4O_4$

F.W. 401.47

Manufacturer/Supplier Code ..... ?  
 Manufacturer Lot Number ..... ?  
 Assay (Dried Basis) ..... 98.0-100.5%  
 Melting Range ..... 99°-103°C


**MAXIMUM LIMITS**

Loss on Drying ..... 0.5%  
 Residue on Ignition ..... 0.1%  
 Related Compounds ..... To pass test  
 Elemental Impurities ..... As reported  
 Residual Solvents ..... To pass test

**LIGHT SENSITIVE:** Keep tightly closed in light-resistant containers.

Repackaged by Spectrum as:  
 Lot No. XQ####

Exp. Date: 00-00-0000



### Spectrum Chemical Mfg Corp

#### Corporate Headquarters:

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#### West Coast Facility:

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