

Scientific Documentation

Chlorpheniramine Maleate, USP

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.

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



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Specification for Chlorpheniramine Maleate, USP (CH133)

Item Number	CH133
Item	Chlorpheniramine Maleate, USP
CAS Number	113-92-8
Molecular Formula	$C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$
Molecular Weight	390.86
MDL Number	
Synonyms	Chlorprophenpyridamine Maleate ; Chlorphenamine Maleate ; (+/-)-3-(4-Chlorophenyl)-N,N-dimethyl-3-(2-pyridyl)propylamine Hydrogen Maleate

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.0	102.0 %
SPECIFIC ROTATION, $[\alpha]_D^{25}$	-0.10° to +0.10°	
LOSS ON DRYING		0.5 %
RESIDUE ON IGNITION		0.2 %
ORGANIC IMPURITIES:		
DIAMINE ANALOG		0.2 %
CHLORPHENIRAMINE RELATED COMPOUND B		0.1 %
CHLORPHENIRAMINE RELATED COMPOUND C		0.1 %
CHLORPHENIRAMINE NITRILE		0.1 %
ANY OTHER UNSPECIFIED IMPURITY		0.10 %
TOTAL IMPURITIES		0.5 %
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD	
APPEARANCE		
EXPIRATION DATE		

Test	Specification	
	Min	Max
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS:	AS REPORTED	

Spectrum Chemical Mfg Corp

<i>Corporate Headquarters:</i>	<i>West Coast Facility:</i>
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	CH133	Lot Number	4KD0020
Item	Chlorpheniramine Maleate, USP	Manufacturer Lot	SLL/C/0221032
CAS Number	113-92-8	Manufacturer Code	14154
Molecular Formula	C ₁₆ H ₁₉ ClN ₂ •C ₄ H ₄ O ₄	Molecular Weight	390.86

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS)	98.0	102.0 %	100.02 %
SPECIFIC ROTATION, [α] _D 25	-0.10° to +0.10°		< 0.10
LOSS ON DRYING		0.5 %	0.16 %
RESIDUE ON IGNITION		0.2 %	0.06 %
ORGANIC IMPURITIES:			.
DIAMINE ANALOG		0.2 %	< 0.2 %
CHLORPHENIRAMINE RELATED COMPOUND B		0.1 %	< 0.1 %
CHLORPHENIRAMINE RELATED COMPOUND C		0.1 %	< 0.1 %
CHLORPHENIRAMINE NITRILE		0.1 %	< 0.1 %
ANY OTHER UNSPECIFIED IMPURITY		0.10 %	< 0.10 %
TOTAL IMPURITIES		0.5 %	< 0.5 %
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME COMPOUNDS TO STANDARD
APPEARANCE			WHITE CRYSTALLINE POWDER
EXPIRATION DATE			31-JAN-2026
DATE OF MANUFACTURE			01-FEB-2021

TEST	SPECIFICATION		RESULT
	MIN	MAX	
RESIDUAL SOLVENTS:	AS REPORTED		.
CLASS 3 (solvent) / 2-PROPANOL			< 5000 PPM
CLASS 2 (SOLVENT) / METHANOL			< 3000 PPM
CLASS 2 (solvent) / XYLENE			< 2170 PPM

Certificate of Analysis Results Entered By:

BDHRUVE
Bijal Dhruve
22-MAY-21 05:59:20

Spectrum Chemical Mfg Corp
777 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

BDHRUVE
Bijal Dhruve
22-MAY-21 05:59:38

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. 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: 06/30/2015

Revision date 7/22/2019

Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: CH133
Product Name: CHLORPHENIRAMINE MALEATE, USP

Other means of identification

Synonyms: 2-(p-chloro-alpha-(2-(dimethylamino)ethyl)benzyl)pyridine maleate
CAS #: 113-92-8
RTECS # US6504000
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

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
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Label elements

Warning

Hazard statements
Harmful if swallowed

**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

IF SWALLOWED: Call a POISON CENTER or physician if you feel unwell
Rinse mouth

Precautionary Statements - Disposal

Dispose of contents and container to an approved waste disposal plant in accordance with local, regional, national and international regulations as applicable

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight-%
Chlorpheniramine Maleate	113-92-8	100

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 irritation develops. Consult a physician if necessary.

Eye Contact: Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.

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. Obtain medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms

- May cause nausea
- May cause stomach pain
- May cause constipation
- Dryness of mouth
- Dry throat
- Blurred vision
- May cause drowsiness or dizziness
- Difficulty with concentration

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Nervousness
Restlessness
Excitement
May affect behavior/central nervous system (tremor, convulsions)

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: Carbon dioxide (CO₂). Dry chemical. Water spray mist or foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous combustion products Carbon Monoxide, Carbon Dioxide. Nitrogen oxides (NO_x).

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. Keep people away from and upwind of spill/leak. Use personal protective equipment. Avoid contact with skin, eyes and clothing. 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.

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. 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. Store away from incompatible materials. Sensitive to light. Store in light-resistant containers.

Incompatible Materials:

Oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Chlorpheniramine Maleate	113-92-8	None	None	None	None

Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Chlorpheniramine Maleate	113-92-8	None	None	None	None

Australia and Mexico

Component	CAS No	Australia	Mexico
Chlorpheniramine Maleate	113-92-8	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

Eye protection:	Safety glasses with side-shields. or Goggles
Skin and body protection:	Chemical resistant apron Gloves Long sleeved clothing
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	Appearance: No information available.	Color: No information available.
Odor: No information available.	Taste No information available.	Formula C16H19ClN2•C4H4O4
Molecular/Formula weight (g/mole): 390.86	Flammability (solid, gas) May be combustible at high temperatures	Flashpoint (°C/°F): No information available
Flash Point Tested according to: Not available	Autoignition Temperature (°C/°F): No information available	Lower Explosion Limit (%): No information available
Upper Explosion Limit (%): No information available	Melting point/range(°C/°F): 132.5°C/270.5°F	Decomposition temperature(°C/°F): No information available
Boiling point/range(°C/°F): No information available	Bulk density: No information available	Density (g/cm3): No information available
Specific gravity: No information available	pH No information available	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: Soluble in cold water	

10. STABILITY AND REACTIVITY

Reactivity
Reactive with oxidizing agents

Chemical stability

Stability: Sensitive to light. Exposure to light accelerates decomposition. Stable at normal conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Exposure to light. Incompatible materials.

Incompatible Materials: Oxidizing agents

Hazardous decomposition products: Carbon oxides. Nitrogen oxides (NOx).

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:

Ingestion. Inhalation.

Acute Toxicity

Component Information

Chlorpheniramine Maleate	
CAS No	113-92-8

LD50/oral/rat = 306 mg/kg Oral LD50 Rat
LD50/oral/mouse = 130 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 LC50 information = No information available

Product Information

LD50/oral/rat =
Value - Acute Toxicity = 306 mg/kg

LD50/oral/mouse =
Value - Acute Tox = 130 mg/kg

LD50/dermal/rabbit
Value - Acute Toxicity = No information available

LD50/dermal/rat
VALUE - Acute Tox = 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

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VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: May cause skin irritation.

Eye Contact: May cause eye irritation.

Inhalation May cause respiratory tract irritation.

Ingestion Harmful if swallowed. May affect behavior/central nervous system (tremor, convulsions). May cause nausea. May cause abdominal pain. May cause constipation. May cause blurred or foggy vision. May cause dry mouth. It may cause twitching or tremors/trembling. It may affect behavior/central nervous system (dizziness, excitement). May affect behavior/central nervous system (somnolence, convulsions/seizures, CNS stimulation, irritability, restlessness). It may affect behavior/central nervous system (drowsiness).

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: Cytogenic analysis - hamster ovary
Sister Chromatid Exchange - Hamster ovary

Carcinogenic effects: Not considered carcinogenic.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Chlorpheniramine Maleate	113-92-8	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 No information available.
STOT - repeated exposure No information available.
Target Organs: No information available.

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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
Chlorpheniramine Maleate	113-92-8	None	None	None	None

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

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

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

ICAO (air)

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

IATA

UN Number Not Regulated
Proper Shipping Name: No information available
Transport hazard class(es) No information available
Subsidiary Risk: No information available
Packing group No information available
Precautionary Statements - Response No information available
Special Provisions 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.
Chlorpheniramine Maleate	113-92-8	PresentACTIVE	Present KE-05616	Present	Not present	Not listed	Present	Present 204-037-5

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:

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 CHLORPHENIRAMINE MALEATE,
 USP

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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:
Chlorpheniramine Maleate	113-92-8	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
Chlorpheniramine Maleate	113-92-8	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
Chlorpheniramine Maleate	113-92-8	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)
Chlorpheniramine Maleate	113-92-8	Present	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Chlorpheniramine Maleate	113-92-8	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Chlorpheniramine Maleate	113-92-8	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Chlorpheniramine Maleate	113-92-8	

EU - CLP (1272/2008)

R-phrases(s)

R22 - Harmful if swallowed

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S -phrase(s)

S46 - If swallowed, seek medical advice immediately and show this container or label

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Chlorpheniramine Maleate	113-92-8		No information	

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

Indication of danger:

Xn - Harmful

Xn

**16. OTHER INFORMATION**

Preparation Date: 06/30/2015
Revision date 7/22/2019
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 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



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
CH133	Chlorpheniramine 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

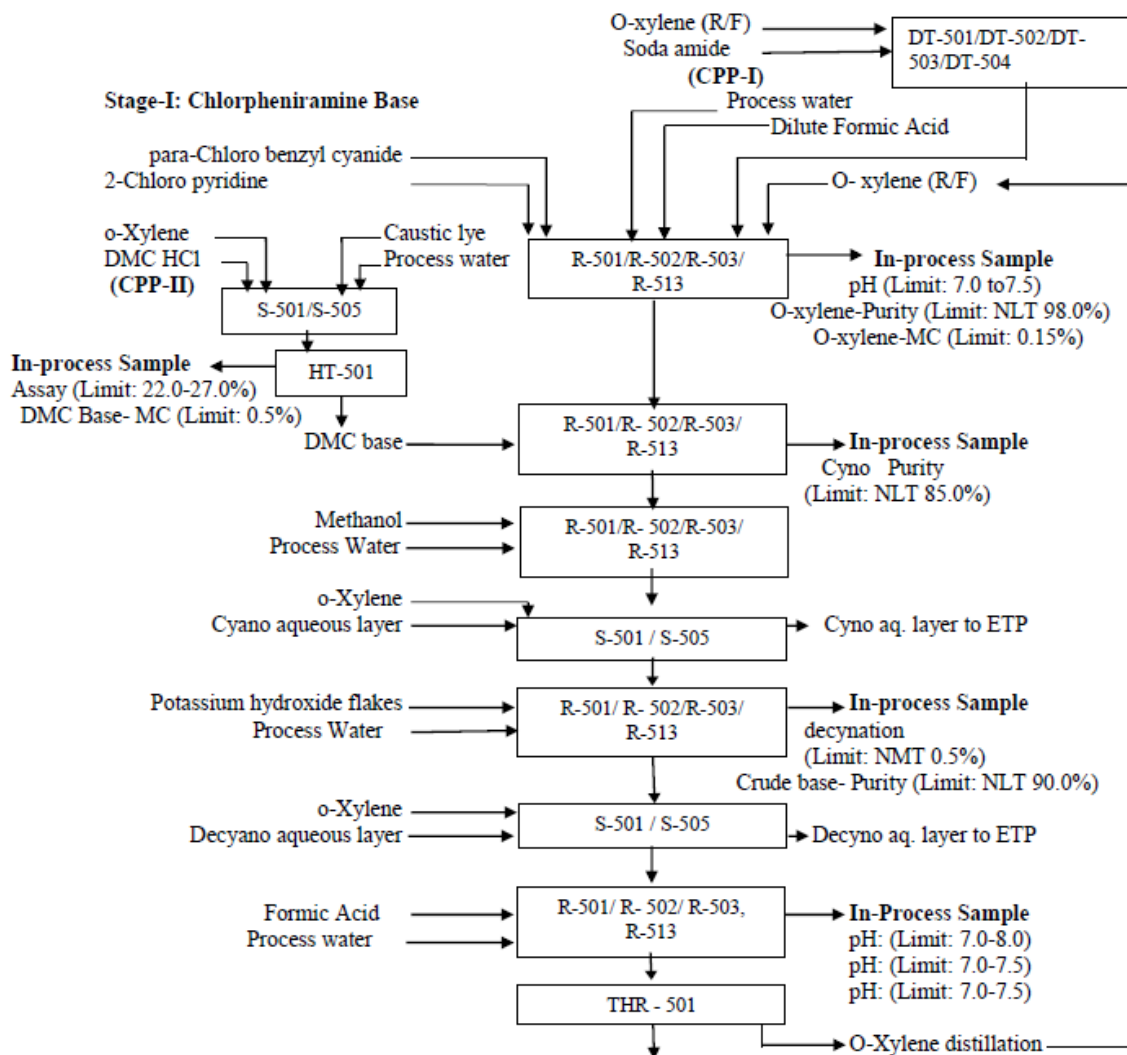
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez".

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart Chlorpheniramine Maleate, USP (Cat# CH133)

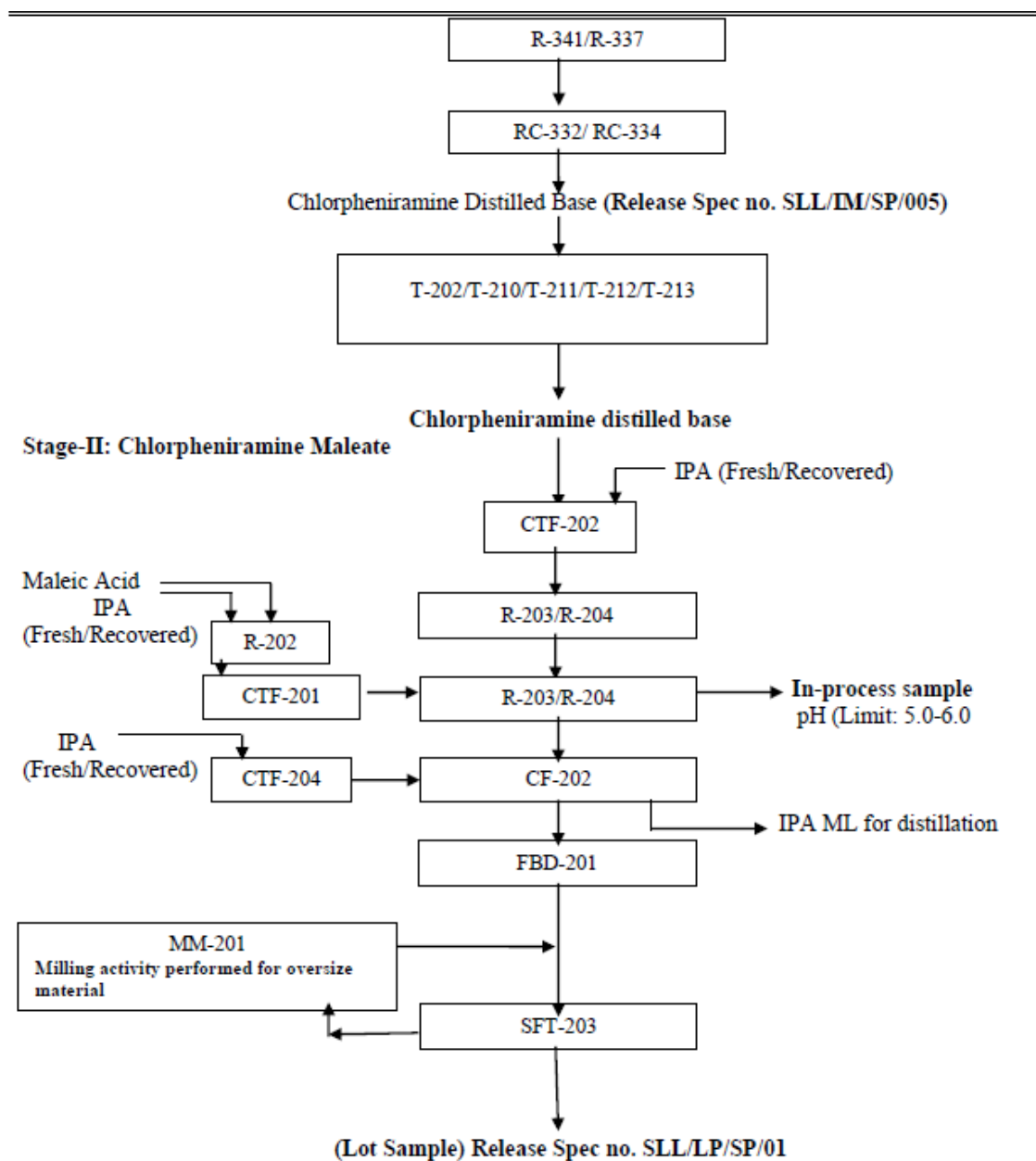


CORPORATE HEADQUARTERS

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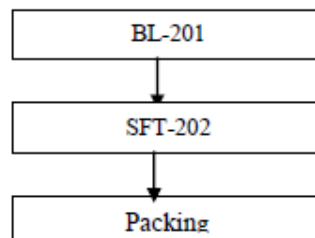
CORPORATE HEADQUARTERS

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WEST COAST FACILITY

14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843

Stage-III: Blending, Sifting and Packing



(Finished product)

FP. Spec no.: SLL/FPSP/C/Ph.Eur.-BP/001

SLL/ FPSP/C/ USP/003

SLL/FPSP/C/IP/005

Note: Recovered solvents are used in the same stage of the next same Chlorpheniramine Maleate batch.

Where *

R-Reactor,

S-Separator,

THR-Thermosyphon System,

HT-Holding Tank,

RC- Receiver,

CF-Centrifuge,

CTF Cartridge Filter,

FBD-Fluid bed Dryer,

MM Multi Mill,

SFT-Sifter,

BL- Blender,

IPA-Isopropyl Alcohol,

DMC HCl- Dimethyl Amino Ethyl Chloride Hydro Chloride,

F- Fresh,

R-Recovered.

CORPORATE HEADQUARTERS

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WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

CH133, Chlorpheniramine 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 - Chlorpheniramine Maleate, USP (Cat# CH133)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are 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.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843



RE: Residual Solvents - Chlorpheniramine Maleate, USP (CH133)

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
Xylene	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.

Sincerely,

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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.

A 

L Exp. Date: 03-31-2030

C **WARNING**
 • Harmful if swallowed.
 • Do not eat, drink or smoke when using this product • Wash face, hands and any exposed skin thoroughly after handling.
FIRST AID: IF SWALLOWED: Call a POISON CENTER or physician if you feel unwell. Rinse mouth.
KEEP FROM CHILDREN

B 

spectrum®
CHEMICAL MFG CORP

D CH133 **F** 1 KG

E **Chlorpheniramine**
Maleate
USP

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

G CAS 113-92-8

J **Chemical Emergency: (800)424-9300**
www.SpectrumChemical.com

K $C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$ F.W. 390.86

Manufacturer/Supplier Code ?
 Manufacturer Lot Number ?

Assay (Dried Basis) 98.0-102.0%
 Specific Rotation, $[\alpha]_D^{25}$ -0.10° to +0.10°

MAXIMUM LIMITS

Loss on Drying 0.5%
 Residue on Ignition 0.2%
 Organic Impurities:
 Diamine Analog 0.2%
 Chlorpheniramine Related Compound B 0.1%
 Chlorpheniramine Related Compound C 0.1%
 Chlorpheniramine Nitrile 0.1%
 Any Other Unspecified Impurity 0.10%
 Total Impurities 0.5%
 Elemental Impurities As reported
 Residual Solvents To pass test

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

Repackaged by Spectrum as: **M** Lot No. 062233

O **Storage Color Band**

SPECTRUM CHEMICAL MFG. CORP. Gardena, CA 90248 • New Brunswick, NJ 08901

- | | | |
|--|---|---|
| <p>A Bar Code</p> <p>B GHS Hazard Pictograms</p> <p>C Warning, Safety Data and Precautionary Information</p> <p>D Product Catalog Number</p> <p>E Item Name, Form, Grade</p> <p>O Storage Color Band</p> | <p>F Size/Quantity</p> <p>G Chemical Abstracts Service (CAS) Registry Number</p> <p>H Caution Information</p> <p>I DOT Shipping Information</p> <p>J Toll-Free 24-Hour Chemical Emergency Telephone Number</p> | <p>K Empirical Formula, Formula Weight and Technical Specifications Panel</p> <p>L Expiration Information</p> <p>M Lot Number</p> <p>N Kosher Certified by Kosher Supervision of America (KSA).</p> |
|--|---|---|

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.

- YELLOW:** Oxidizer
- RED:** Flammable
- GREEN:** General Storage
- BLUE:** Health Hazard
- WHITE:** Corrosive

Spectrum Chemical Mfg Corp

Corporate Headquarters:

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West Coast Facility:

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