

Scientific Documentation

Meclizine Hydrochloride, 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



Table of Contents

Product Specification
Certificate of Analysis
Safety Data Sheet (SDS)
Certification of Current Good Manufacturing Practices (cGMP)
Technical Statements
Elemental Impurities Statement
Residual Solvents Statement
General Label Information – Sample Label

Specification for Meclizine Hydrochloride, USP (M3985)

Item Number	M3985
Item	Meclizine Hydrochloride, USP
CAS Number	1104-22-9
Molecular Formula	$C_{25}H_{27}ClN_2 \cdot 2HCl$
Molecular Weight	463.88
MDL Number	
Synonyms	1-([4-Chlorophenyl]phenylmethyl)-4-([3-methylphenyl]methyl)piperazine

Test	Specification	
	Min	Max
ASSAY (ANHYDROUS BASIS)	97.0 - 102.0 %	
WATER		5.0 %
RESIDUE ON IGNITION		0.1 %
ELEMENTAL IMPURITIES		AS REPORTED
ORGANIC IMPURITIES	.	
3-METHYLBENZYL ALCOHOL		0.10 %
1,4-BIS (3-METHYLBENZYL) PIPERAZINE		0.10 %
4-CHLOROBENYLHYDROL		0.15 %
MECLIZINEO-CHLORO ISOMER		0.10 %
ISOMECLIZINE (MECLIZINEO-METHYL ISOMER)		0.15 %
ANY INDIVIDUAL, UNSPECIFIED IMPURITY		0.10 %
TOTAL IMPURITIES		1.0 %
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	POSITIVE FOR CHLORIDE	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS		AS REPORTED

<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	M3985	Lot Number	1MD0343
Item	Meclizine Hydrochloride, USP	Manufacturer Lot	2MCH1021122
CAS Number	1104-22-9	Manufacturer Code	13524
Molecular Formula	C ₂₅ H ₂₇ ClN ₂ •2HCl	Molecular Weight	463.88

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (ANHYDROUS BASIS)	97.0 - 102.0 %		99.1 %
WATER		5.0 %	3.9 %
RESIDUE ON IGNITION		0.1 %	0.0 %
ELEMENTAL IMPURITIES		AS REPORTED	COMPLIES WITH STANDARD
ORGANIC IMPURITIES	.		.
3-METHYLBENZYL ALCOHOL		0.10 %	0.00 %
1,4-BIS (3-METHYLBENZYL) PIPERAZINE		0.10 %	0.00 %
4-CHLOROBENYLHYDROL		0.15 %	0.00 %
MECLIZINEO-CHLORO ISOMER		0.10 %	0.00 %
ISOMECLIZINE (MECLIZINEO-METHYL ISOMER)		0.15 %	0.00 %
ANY INDIVIDUAL, UNSPECIFIED IMPURITY		0.10 %	0.00 %
TOTAL IMPURITIES		1.0 %	<1.0 %
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	POSITIVE FOR CHLORIDE		POSITIVE FOR CHLORIDE
EXPIRATION DATE			31-OCT-2027
DATE OF MANUFACTURE			01-NOV-2022
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS		AS REPORTED	.
CLASS 1 (solvent) / BENZENE			<2 ppm (M)
CLASS 2 (solvent) / TOLUENE			<890 ppm (M)
CLASS 3 (solvent) / ETHANOL			<5000 ppm (M)

TEST	SPECIFICATION		RESULT
	MIN	MAX	
MONOGRAPH EDITION			(USP) 2023
NOTE: All results reported with (M) are from manufacturer certificate of analysis			.

Certificate of Analysis Results Entered By:

HBERMUDEZ
Hernan Bermudez
20-JUN-23 18:22:55

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



Certificate of Analysis Results Approved By:

JAMAYA
Javier Amaya
21-JUN-23 07:50:12

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 Symed Labs Limited at UNIT-II, Plot No. 25/B, Phase-III, IDA, Jeedimetla (Village), Quthbullapur (Mandal), Medchal-Malkajgiri, Telangana 500055, 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: 10/4/2018

Revision date 8/8/2019

Revision Number: G1

1. IDENTIFICATION

Product identifier

Product code: M3985
Product Name: MECLIZINE DIHYDROCHLORIDE, USP

Other means of identification

Synonyms: 1-p-Chlorbenzhydryl-m-methylbenzylpiperazine dihydrochloride
 Parachloramine dihydrochloride
 Meclozine dihydrochloride
 Piperazine, 1-((4-chlorophenyl)phenylmethyl)-4-((3-methylphenyl)methyl)-, dihydrochloride
CAS #: 1104-22-9
RTECS # TL2005000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Medication.
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
Reproductive toxicity	Category 2

Label elements

Warning

Hazard statements

Harmful if swallowed
 Suspected of damaging fertility or the unborn child

**Hazards not otherwise classified (HNOC)**

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Wear protective gloves/protective clothing/eye protection/face protection

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

Precautionary Statements - Response

IF exposed or concerned: Get medical attention

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

Rinse mouth

Precautionary Statements - Storage

Store locked up

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-%
Meclizine Dihydrochloride	1104-22-9	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. Never give anything by mouth to an unconscious person. Obtain medical attention.

Most important symptoms and effects, both acute and delayed

Product code: M3985

Product name: MECLIZINE
DIHYDROCHLORIDE, USP

Page 2 / 12

Symptoms	May cause eye/skin irritation Dry throat Dryness of mouth Blurred vision Central nervous system effects May cause drowsiness or dizziness Sleepiness tiredness Weakness
-----------------	---

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). hydrogen chloride gas.

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. Do not let product enter 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. 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.

Incompatible Materials:

Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Meclizine Dihydrochloride	1104-22-9	None	None	None	None

Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Meclizine Dihydrochloride	1104-22-9	None	None	None	None

Australia and Mexico

Component	CAS No	Australia	Mexico
Meclizine Dihydrochloride	1104-22-9	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 Safety glasses with side-shields.
Skin and body protection:	Long sleeved clothing Chemical resistant apron Gloves
Respiratory protection:	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.
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: Crystalline powder.	Color: White. Slightly yellow.
Odor: Slight.	Taste Tasteless.	Formula C25H27ClN2.2HCl
Molecular/Formula weight (g/mole): 463.88	Flammability (solid, gas) no data available	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): 212-224 °C/413.6-435.2 °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:
Practically insoluble in water
Insoluble in Ether
Very soluble in chloroform
Very soluble in pyridine

10. STABILITY AND REACTIVITY

Reactivity

Reactive with oxidizing agents

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Avoid dust formation. Dust may form explosive mixture in air. Incompatible materials.

Incompatible Materials: Strong oxidizing agents

Hazardous decomposition products: Carbon monoxide. Nitrogen oxides (NOx). Hydrogen chloride gas.

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

Meclizine Dihydrochloride

CAS No 1104-22-9

LD50/oral/rat = No information available

LD50/oral/mouse = 1600 mg/kg Oral LD50 Mouse

LD50/dermal/rabbit = No information available

LD50/dermal/rat = 1600 mg/kg Oral LD50

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 = No information available

LD50/oral/mouse =

Value - Acute Tox = 1600 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

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 cause upset stomach. May cause gastrointestinal discomfort. May cause vomiting. May cause dry mouth. May cause blurred or foggy vision. May cause headache. May affect behavior/central nervous system (dizziness, drowsiness). May affect behavior/central nervous system (tiredness). May cause weakness.

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 Substances	Australia - Prohibited Carcinogenic Substances

Meclizine Dihydrochloride	1104-22-9	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

Suspected of damaging fertility or the unborn child

Reproductive Effects:

No information available

Developmental Effects:

No information available

Teratogenic Effects:

May cause birth defects (teratogenic effects) based on animal test data

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 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
Meclizine Dihydrochloride	1104-22-9	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

Product code: M3985

Product name: MECLIZINE
DIHYDROCHLORIDE, USP

Page 8 / 12

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.
Meclizine Dihydrochloride	1104-22-9	Present(INACTIVE)	Not present	Not present	Not present	Not listed	Present	Present 214-164-8

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:
Meclizine Dihydrochloride	1104-22-9	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
Meclizine Dihydrochloride	1104-22-9	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
Meclizine Dihydrochloride	1104-22-9	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)
Meclizine Dihydrochloride	1104-22-9	Not Listed	Present

Component	CAS No	CEPA Schedule I - Toxic Substances
Meclizine Dihydrochloride	1104-22-9	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Meclizine Dihydrochloride	1104-22-9	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Meclizine Dihydrochloride	1104-22-9	No information

EU - CLP (1272/2008)

R-phrases(s)

R22 - Harmful if swallowed

S -phrase(s)

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

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Meclizine Dihydrochloride	1104-22-9		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: 10/4/2018
Revision date 8/8/2019
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
M3985	Meclizine Hydrochloride, 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,
Quality Assurance
Spectrum Chemical Mfg. Corp.

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

M3985, Meclizine Hydrochloride, 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 | ▪ Cereals containing Gluten |
| ▪ Egg | ▪ Celery |
| ▪ Fish | ▪ Mustard |
| ▪ Shellfish | ▪ Sesame Seed |
| ▪ Tree Nuts | ▪ Corn |
| ▪ Wheat | ▪ Latex |
| ▪ Peanuts | ▪ Sulfites > 10 ppm |
| ▪ Soy | |

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 the above-mentioned 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 |

Elemental Impurities - Meclizine Hydrochloride, USP (Catalog No. M3985)

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. 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 the 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.

Residual Solvents - Meclizine Hydrochloride, USP (Catalog No. M3985)

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
Benzene	1	< 2 ppm
Toluene	2	< 890 ppm
Ethanol	3	< 5000 ppm

No 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,
Technical Services
Spectrum Chemical Mfg. 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. Below you will find a typical label example for this catalog item.

WARNING

• Harmful if swallowed • Suspected of damaging fertility or the unborn child.

• Obtain special instructions before use • Do not handle until all safety precautions have been read and understood • Do not eat, drink or smoke when using this product • Wear protective gloves, protective clothing, eye protection, face protection • 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. If exposed or concerned: Get medical attention.

KEEP FROM CHILDREN

M3985

SIZ SY

Meclizine Hydrochloride

USP

CAS 1104-22-9

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

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

$C_{25}H_{27}ClN_2 \cdot 2HCl$ F.W. 463.88

Manufacturer/Supplier Code.....?

Manufacturer Lot Number.....?

Assay (Anhydrous Basis).....97.0-102.0%

MAXIMUM LIMITS

Water Determination.....5.0%

Residue on Ignition.....0.1%

Organic Impurities, Procedure 2:

3-Methylbenzyl Alcohol.....	0.10%
1,4-Bis(3-Methylbenzyl) Piperazine.....	0.10%
4-Chlorobenzhydrol.....	0.15%
Meclizine o-Chloro Isomer.....	0.10%
Isomeclizine.....	0.15%
Any Individual Unspecified Impurity.....	0.10%
Total Impurities.....	1.0%
Elemental Impurities.....	As reported
Residual Solvents.....	To pass test

Store at Room Temperature: Keep tightly closed.

Repackaged by Spectrum as:

G 8/J2GHS-A ? Lot No. XQ####

Exp. Date: 00-00-0000

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