

Scientific Documentation

Oxymetazoline 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



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Specification for Oxymetazoline Hydrochloride, USP (O1359)

Item Number	O1359
Item	Oxymetazoline Hydrochloride, USP
CAS Number	2315-02-8
Molecular Formula	C ₁₆ H ₂₄ N ₂ O•HCl
Molecular Weight	296.84
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.5	101.5 %
pH	4.0	6.5
LOSS ON DRYING		1.0 %
RESIDUE ON IGNITION		0.1 %
ORGANIC IMPURITIES	TO PASS TEST	
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION	TO PASS TEST	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	TO PASS TEST	

Spectrum Chemical Mfg Corp

Corporate Headquarters:	West Coast Facility:
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	O1359	Lot Number	4MK0034
Item	Oxymetazoline Hydrochloride, USP	Manufacturer Lot	23OM000171
CAS Number	2315-02-8	Manufacturer Code	7068
Molecular Formula	C ₁₆ H ₂₄ N ₂ O•HCl	Molecular Weight	296.84

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS)	98.5	101.5 %	99.8 %
pH	4.0	6.5	5.6
LOSS ON DRYING		1.0 %	0.1 %
RESIDUE ON IGNITION		0.1 %	0.1 %
ORGANIC IMPURITIES	TO PASS TEST		PASSES TEST
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
IDENTIFICATION	TO PASS TEST		PASSES TEST
EXPIRATION DATE			01-AUG-2028
DATE OF MANUFACTURE			01-SEP-2023
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS	TO PASS TEST		.
CLASS 1 (solvent) / BENZENE			2.0 ppm
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm
CLASS 2 (solvent) TOLUENE			<890 ppm
CLASS 3 (solvent) / ACETONE			<5000 ppm
CLASS 3 (solvent) / DIMETHYL SULFOXIDE			<5000 ppm
CLASS 3 (solvent) / ETHYL ACETATE			<5000 ppm
CLASS 3 (solvent) / 2-PROPANOL			<5000 ppm

Certificate of Analysis Results Entered By:

GHERRERA
Genaro Herrera
26-DEC-23 12:52:35

Spectrum Chemical Mfg Corp
777 Jersey Avenue
New Brunswick NJ 08901

Certificate of Analysis Results Approved By:

MCAMACHO
Matheu Camacho
27-DEC-23 05:18:00



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, repackaging 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 CTX Lifesciences Pvt. Ltd. at 251-252, Sachin Magdalla Road, GIDC Sachin,, Surat, Gujarat 394230, 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

spectrum®



Revision date 21-July-2022

Revision Number 2

1. Identification

Product identifier

Product Name OXYMETAZOLINE HYDROCHLORIDE, USP

Other means of identification

Product Code(s) O1359

UN/ID no UN2811

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use No information available

Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Address

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

Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification

Acute toxicity - Oral	Category 1
Acute toxicity - Inhalation (Dusts/Mists)	Category 2
Serious eye damage/eye irritation	Category 2A

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

Fatal if swallowed
Fatal if inhaled
Causes serious eye irritation



Appearance Powder

Physical state Solid

Odor No information available

Precautionary Statements - Prevention

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

Precautionary Statements - Response

Specific treatment (see .? on this label)
Specific treatment is urgent (see .? on this label)
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
If eye irritation persists: Get medical advice/attention
IF INHALED: Remove person to fresh air and keep comfortable for breathing
Immediately call a POISON CENTER or doctor
IF SWALLOWED: Immediately call a POISON CENTER or doctor
Rinse mouth

Precautionary Statements - Storage

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

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Oxymetazoline Hydrochloride	2315-02-8	100	*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures

Description of first aid measures

General advice

Immediate medical attention is required. Show this safety data sheet to the doctor in attendance.

Inhalation

If breathing has stopped, give artificial respiration. Get medical attention immediately. Remove to fresh air. Do not breathe dust. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If breathing is difficult, (trained personnel should) give oxygen.

Eye contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.

Skin contact	Wash skin with soap and water.
Ingestion	Get immediate medical advice/attention. Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person.
Self-protection of the first aider	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Do not breathe dust. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Use personal protective equipment as required. See section 8 for more information. Avoid contact with skin, eyes or clothing.

Most important symptoms and effects, both acute and delayed

Symptoms	Coughing and/ or wheezing. Difficulty in breathing. May cause redness and tearing of the eyes. Burning sensation.
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Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.
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5. Fire-fighting measures

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
Specific hazards arising from the chemical	No information available.
Hazardous combustion products	Carbon dioxide (CO ₂). Hydrocarbons. Produce flammable and toxic gases on contact with water.
Explosion data	
Sensitivity to mechanical impact	none.
Sensitivity to static discharge	none.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions	Ensure adequate ventilation. Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not breathe dust. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.
Other information	Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling

Advice on safe handling

Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not breathe dust. Avoid generation of dust. In case of insufficient ventilation, wear suitable respiratory equipment. Handle product only in closed system or provide appropriate exhaust ventilation. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse.

Conditions for safe storage, including any incompatibilities

Storage Conditions

Store locked up. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children.

8. Exposure controls/personal protection

Control parameters

Exposure Limits

The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

Appropriate engineering controls

Engineering controls

Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection

If splashes are likely to occur, wear safety glasses with side-shields.

Hand protection

Wear suitable gloves.

Skin and body protection

Wear suitable protective clothing.

Respiratory protection

When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

General hygiene considerations

Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Do not breathe dust. Wear suitable gloves and eye/face protection. Take off contaminated clothing and wash before reuse. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state

Solid

Appearance

Powder

Color

White

Odor

No information available

Odor threshold No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	no data available	None known Slightly acidic
Melting point / freezing point	300 °C / 572 °F	None known
Boiling point / boiling range	no data available	None known
Flash point	no data available	None known
Evaporation rate	no data available	None known
Flammability (solid, gas)	no data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	no data available	None known
Water solubility	Soluble in water	None known
Solubility(ies)	Soluble in Ethanol Soluble in Dimethyl Sulfoxide soluble in dimethylformamide	None known
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known
<u>Other information</u>		
Explosive properties	No information available	
Oxidizing properties	No information available	
Softening point	No information available	
Molecular weight	No information available	
VOC Content (%)	No information available	
Liquid Density	No information available	
Bulk density	No information available	

10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	Excessive heat.
Incompatible materials	None known based on information supplied.
Hazardous decomposition products	None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Product Information

Inhalation	Specific test data for the substance or mixture is not available. Fatal if inhaled. (based on components). May cause irritation of respiratory tract.
Eye contact	Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.
Skin contact	Specific test data for the substance or mixture is not available. May cause irritation.

Prolonged contact may cause redness and irritation.

Ingestion

Specific test data for the substance or mixture is not available. Fatal if swallowed. (based on components). Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Coughing and/ or wheezing. Difficulty in breathing. May cause redness and tearing of the eyes.

Acute toxicity

Numerical measures of toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Oxymetazoline Hydrochloride 2315-02-8	= 0.68 mg/kg (Rat) = 680 µg/kg (Rat)	-	-

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

Skin corrosion/irritation May cause skin irritation.
Serious eye damage/eye irritation Classification based on data available for ingredients. Causes serious eye irritation.
Respiratory or skin sensitization No information available.
Germ cell mutagenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure No information available.
STOT - repeated exposure No information available.
Aspiration hazard No information available.

Other adverse effects No information available.

Interactive effects No information available.

12. Ecological information

Ecotoxicity The environmental impact of this product has not been fully investigated.

Persistence and degradability No information available.
Bioaccumulation Inherently biodegradable.

Other adverse effects No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

14. Transport information

DOT

UN/ID no	UN2811
Proper Shipping Name:	Toxic solids, organic, n.o.s.
Hazard class	6.1
Packing group:	I
Special Provisions	IB7, T6, TP33
Marine Pollutant	Severe Marine Pollutant
Description:	UN2811, Toxic solids, organic, n.o.s., 6.1, I
Emergency Response Guide Number	154

TDG

UN-No:	UN2811
Proper Shipping Name:	Toxic solid, organic, n.o.s.
Hazard class	6.1
Packing Group:	I
Special Provisions	16
Description:	UN2811, Toxic solid, organic, n.o.s., 6.1, I

MEX

UN-No	UN2811
Proper Shipping Name	Toxic solid, organic, n.o.s.
Hazard class	6.1
Special Provisions	274
Packing Group	I
Description	UN2811, Toxic solid, organic, n.o.s., 6.1, I

ICAO (air)

UN-No:	UN2811
Proper Shipping Name:	Toxic solid, organic, n.o.s.
Hazard class	6.1
Packing Group:	I
Special Provisions	A3, A5
Description:	UN2811, Toxic solid, organic, n.o.s., 6.1, I

IATA

UN number	UN2811
Proper Shipping Name:	Toxic solid, organic, n.o.s.
Transport hazard class(es)	6.1
Packing group	I
ERG Code	6L
Special Provisions	A3, A5
Description:	UN2811, Toxic solid, organic, n.o.s., 6.1, I

IMDG

UN number	UN2811
Proper shipping name	Toxic solid, organic, n.o.s.
Transport hazard class(es)	6.1
Packing group	I
EmS-No	F-A, S-A
Special Provisions	274
Marine pollutant	NP1
Description	UN2811, Toxic solid, organic, n.o.s., 6.1, I

RID

UN number	UN2811
Proper Shipping Name:	TOXIC SOLID, ORGANIC, N.O.S.
Transport hazard class(es)	6.1
Packing group	I
Classification code	T2
Special Provisions	274, 614
Description:	UN2811, TOXIC SOLID, ORGANIC, N.O.S., 6.1, I
Labels	6.1

ADR

UN number	UN2811
Proper Shipping Name:	Toxic solid, organic, n.o.s.
Transport hazard class(es)	6.1
Packing group	I
Classification code	T2
Tunnel restriction code	(C/E)
Special Provisions	274, 614
Description:	UN2811, Toxic solid, organic, n.o.s., 6.1, I, (C/E)
Labels	6.1

ADN

UN/ID No	UN2811
Proper shipping name	Toxic solid, organic, n.o.s.
Transport hazard class(es)	6.1
Packing Group	I
Classification code	T2
Special Provisions	274, 614, 802
Description	UN2811, Toxic solid, organic, n.o.s., 6.1, I
Hazard label(s)	6.1
Limited quantity (LQ)	0
Equipment Requirements	PP, EP

15. Regulatory information

International Inventories

TSCA Not listed

Note *Contact supplier for details. One or more substances in this product are either not listed on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise exempted from inventory listing requirements

DSL/NDSL	Complies
EINECS/ELINCS	Complies
ENCS	This product complies with ENCS:
IECSC	This product does not comply with china:
KECL	Does not Comply
PICCS	Does not Comply
AICS	All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40

CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA

Health hazards 4

Flammability 0

Instability 0

Physical and chemical properties -

HMIS

Health hazards 4

Flammability 0

Physical hazards 0

Personal protection X

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value		

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AEGl(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
World Health Organization

Revision date 21-July-2022
Revision Note No information available.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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
O1359	Oxymetazoline 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

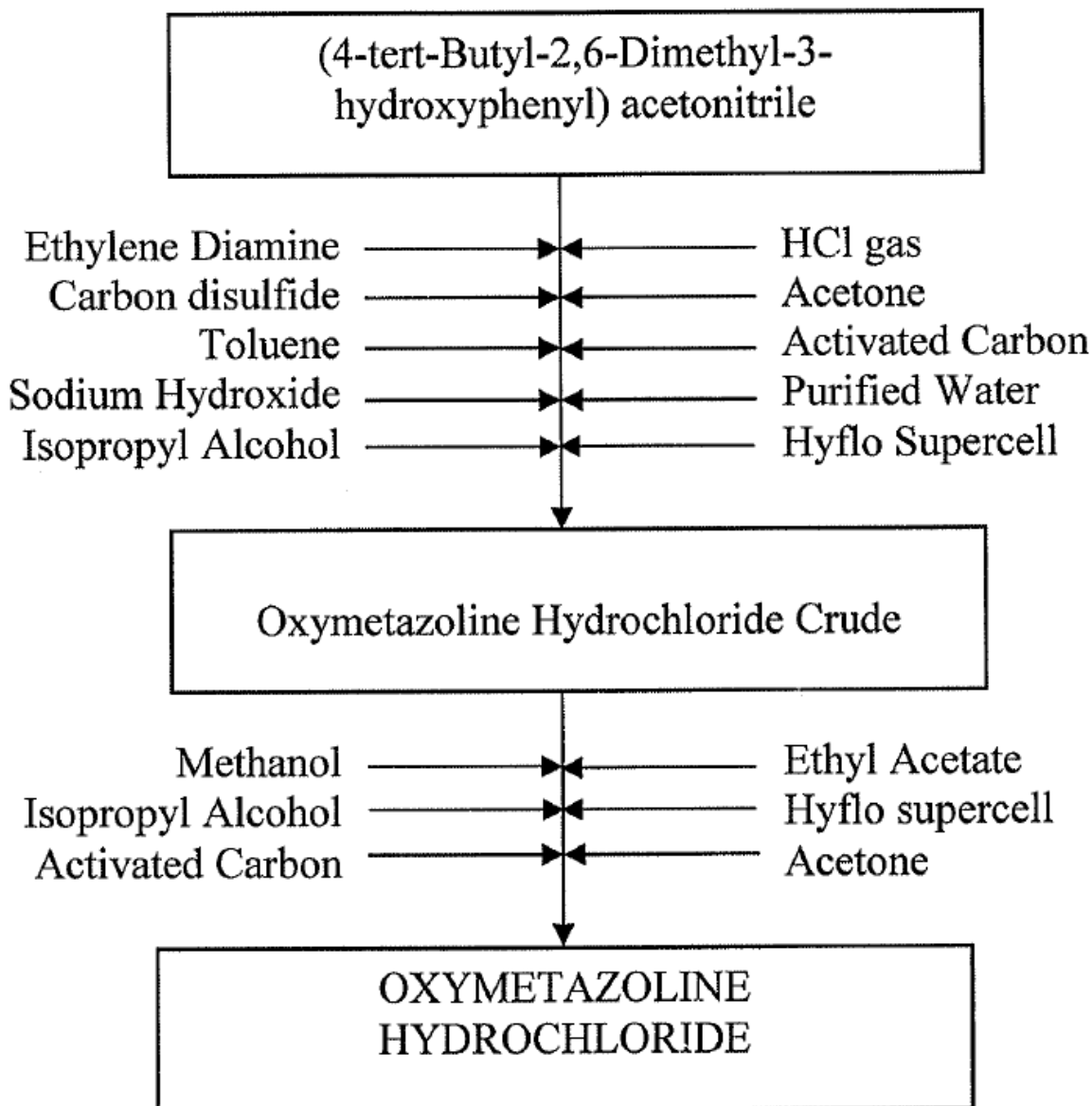
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart Oxymetazoline Hydrochloride, USP (Cat# O1359)



CORPORATE HEADQUARTERS

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PHONE 310.516.8000
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O1359, Oxymetazoline 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
- 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.

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 - Oxymetazoline Hydrochloride, USP (Cat# 01359)

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
Nickel	Ni	2A	< 0.5 ppm
Molybdenum	Mo	3	< 1.0 ppm
Chromium	Cr	3	< 0.3 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.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS

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PHONE 310.516.8000

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RE: Residual Solvents - Oxymetazoline Hydrochloride, USP (Cat# O1359)

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	< 2.0 ppm
Methanol	2	< 3000 ppm
Toluene	2	< 890 ppm
Acetone	3	< 5000 ppm
Ethyl Acetate	3	< 5000 ppm
Isopropyl Alcohol	3	< 5000 ppm
Dimethyl Sulfoxide	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.

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PHONE 310.516.8000
FAX 310.516.9843

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.



DANGER
 • Fatal if swallowed or if inhaled • Causes serious eye irritation.
 • Do not eat, drink or smoke when using this product • Wear respiratory protection, eye protection, face protection • Do not breathe dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling.
FIRST AID: Immediately call a POISON CENTER or physician. 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 INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth.

KEEP FROM CHILDREN



01359 SIZ SY
Oxymetazoline Hydrochloride
 USP
 CAS 2315-02-8

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

DOT: UN2811, Toxic solid, organic, n.o.s. (oxymetazoline hydrochloride), 6.1, PG I

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

$C_{16}H_{24}N_2O \cdot HCl$ F.W. 296.84

Manufacturer/Supplier Code ?
 Manufacturer Lot Number..... ?
 Assay (Dried Basis).....98.5-101.5%
 pH.....4.0-6.5

MAXIMUM LIMITS

Loss on Drying.....1.0%
 Residue on Ignition.....0.1%
 Elemental ImpuritiesAs reported
 Organic Impurities:
 Oxymetazoline Related Compound A.....0.15%
 Any individual Unspecified Impurity.....0.10%
 Total Impurities.....0.5%
 Residual SolventsTo pass test

WARNING: Cancer and Reproductive Harm-
www.P65Warnings.ca.gov

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

B 10/J2GHS-A ?

Spectrum Chemical Mfg Corp

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 732.214.1300

West Coast Facility:

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