

1. Identification

Product identifier	Oxymetazoline Hydrochloride	
Other means of identification		
Catalog number	1486004	
Chemical name	Phenol, 3-[(4,5-dihydro-1H-imidazol-2-yl)methyl]-6-(1,1-dimethylethyl)-2,4-dimethyl-, monohydrochloride	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 1
	Acute toxicity, inhalation	Category 1
	Serious eye damage/eye irritation	Category 1
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	Fatal if swallowed or if inhaled. Causes serious eye damage.
Precautionary statement	
Prevention	Use only outdoors or in a well-ventilated area. Do not breathe dust/fume. In case of inadequate ventilation wear respiratory protection. Wash thoroughly after handling. Wear eye/face protection.
Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth. If inhaled: Remove person to fresh air and keep comfortable for breathing. Immediately call a poison center/doctor. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Storage	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	Not classified.
Other hazards which do not result in classification	None known.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Oxymetazoline Hydrochloride		2315-02-8	100

4. First-aid measures

Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Call a physician or poison control center immediately.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician or poison control center immediately.
Ingestion	Call a physician or poison control center immediately. Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.
Most important symptoms/effects, acute and delayed	Irritation of eyes and mucous membranes.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically.
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials. Foam. Dry chemical or CO2.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

7. Handling and storage

Precautions for safe handling	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	No exposure standards allocated.

Appropriate engineering controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Avoid any open handling of this material, particularly for grinding, crushing, weighing, or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection	
Hand protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.
Other	For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.
Respiratory protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	White to practically white, fine crystalline powder.
Physical state	Solid.
Form	Powder.
Odor	Slight odor.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	572 - 577.4 °F (300 - 303 °C) (decomposes)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	< 0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Freely soluble.
Partition coefficient (n-octanol/water)	0.97
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Imidazoline.

Molecular formula	C16H24N2O . HCl
Molecular weight	296.84
pH in aqueous solution	4 - 6.5 (50 grams/liter)
Solubility (other)	Soluble in ethanol; slightly soluble in chloroform; practically insoluble in benzene and in ether.

10. Stability and reactivity

Reactivity	Not available.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	Acids. Bases. Oxidizers.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx, HCl.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Fatal if swallowed.
Inhalation	Fatal if inhaled.
Skin contact	Based on available data, the classification criteria are not met.
Eye contact	Causes serious eye damage.

Symptoms related to the physical, chemical, and toxicological characteristics Nervousness. Headache. Lightheadedness. Trembling. Dizziness. Sneezing. Trouble sleeping. Irregular heartbeat. Stinging, burning, or drying of the nasal mucosa.

Cross sensitivity Persons sensitive to other sympathomimetics (e.g., nasal decongestants) may be sensitive to this material also.

Medical conditions aggravated by exposure Porphyria. High blood pressure.

Acute toxicity Fatal if swallowed. Fatal if inhaled.

Product	Species	Test Results
Oxymetazoline Hydrochloride (CAS 2315-02-8)		
Oral LD50	Mouse	10 mg/kg
	Rat	1.3 mg/kg
Acute Inhalation LC50	Rat	0.2 mg/l

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Causes serious eye damage.

Local effects

HET-CAM in vitro irritation test
Result: Irritant.
Organ: Eye
Severity: Severe.
Irritation test
Result: Non-irritant.
Species: Rabbit
Organ: Skin

Respiratory or skin sensitization

Respiratory sensitization Due to lack of data the classification is not possible.

Skin sensitization Due to lack of data the classification is not possible.

Germ cell mutagenicity Due to lack of data the classification is not possible.

Carcinogenicity Due to lack of data the classification is not possible.
This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

Reproductive toxicity Based on available data, the classification criteria are not met.
Epidemiological studies have not shown an association between the use of this material during pregnancy and birth defects.

Specific target organ toxicity - single exposure	Due to lack of data the classification is not possible.
Specific target organ toxicity - repeated exposure	Due to lack of data the classification is not possible.
Aspiration hazard	Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity	No ecotoxicity data noted for the ingredient(s).
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Not available.
Mobility in soil	Not available.
Other adverse effects	Not available.

13. Disposal considerations

Disposal instructions	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations	Not available.
Hazardous waste code	Not regulated.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

UN number	UN2811
UN proper shipping name	Toxic solid, organic, n.o.s. (Oxymetazoline Hydrochloride)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	I

IATA

UN number	UN2811
UN proper shipping name	Toxic solid, organic, n.o.s. (Oxymetazoline Hydrochloride)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	I
Other information	
Passenger and cargo aircraft	Allowed.
Cargo aircraft only	Allowed.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not available.

DOT; IATA



15. Regulatory information

US federal regulations	CERCLA/SARA Hazardous Substances - Not applicable.
	One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

US. California Proposition 65

Not Listed.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 10-22-2010

Revision date 04-26-2016

Version # 04

Further information Not available.

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Revision Information Hazard(s) identification: Prevention
Hazard(s) identification: Response
Physical & Chemical Properties: Multiple Properties
Transport Information: Material Transportation Information
GHS: Classification