



SAFETY DATA SHEET

1. Identification

Product identifier	Xylometazoline Hydrochloride	
Other means of identification		
Catalog number	1721002	
CAS number	1218-35-5	
Chemical name	1H-Imidazole, 2-[[4-(1,1-dimethylethyl)-2,6-dimethylphenyl]methyl]-4,5-dihydro-, 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 3
	Acute toxicity, dermal	Category 3
	Acute toxicity, inhalation	Category 4
	Skin corrosion/irritation	Category 2
	Serious eye damage/eye irritation	Category 1
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	Toxic if swallowed. Toxic in contact with skin. Causes skin irritation. Causes serious eye damage. Harmful if inhaled.
Precautionary statement	
Prevention	Avoid breathing dust. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. Use only outdoors or in a well-ventilated area.
Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth. If on skin: Wash with plenty of water. If skin irritation occurs, seek medical advice/attention. Take off immediately all contaminated clothing and wash it before reuse. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor.

Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.
Supplemental information	Potent pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Xylometazoline Hydrochloride		1218-35-5	100

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Do not use mouth-to-mouth method if the substance is inhaled. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Skin contact	Take off contaminated clothing and wash before reuse. Rinse skin with water/shower. If skin irritation occurs: Get medical advice/attention.
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	If swallowed: Immediately call a poison center or doctor/physician. Rinse mouth. Do not induce vomiting without advice from poison control center.
Most important symptoms/effects, acute and delayed	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
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	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
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.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Ensure adequate ventilation. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. For personal protection, see section 8 of the SDS. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Methods and materials for containment and cleaning up	Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

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. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

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

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

Industrial Use Material	Type	Value
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Xylometazoline Hydrochloride (CAS 1218-35-5)	TWA	7 micrograms/m3
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Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection

Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance

Appearance descriptions are general information and not specific to any USP lot.

Physical state

Solid.

Form

Powder.

Color

White. Off-white.

Odor

Odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

602.6 - 624.2 °F (317 - 329 °C)

Initial boiling point and boiling range

Not available.

Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
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(ies)	
Solubility (water)	Soluble.
Solubility (other)	Ethanol: Freely soluble. Methanol: Soluble. Chloroform: Sparingly soluble. Benzene: Practically insoluble. Ether: Practically insoluble.
Auto-ignition temperature	806 °F (430 °C)
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Imidazoline.
Dust explosion properties	
Minimum ignition energy (MIE) - dust cloud	3 - 10 mJ
Molecular formula	C16H24N2 . HCl
Molecular weight	280.84

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Acids. Bases. Reducing agents. Strong oxidizing agents.
Hazardous decomposition products	Cl-. NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Harmful if inhaled.
Skin contact	Toxic in contact with skin. Causes skin irritation.
Eye contact	Causes serious eye damage.
Ingestion	Toxic if swallowed.
Symptoms related to the physical, chemical, and toxicological characteristics	Sneezing. Headache. Dizziness. Drowsiness. Lightheadedness. Nervousness. Difficulty sleeping. Sweating. Nausea. Irregular heartbeat.

Information on toxicological effects

Acute toxicity	Toxic in contact with skin. Toxic if swallowed. Harmful if inhaled.
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Product	Species	Test Results
Xylometazoline Hydrochloride (CAS 1218-35-5)		
Dermal		
LD50	Rabbit	267 - 900 mg/kg
Inhalation		
LC50	Rat	0.4 - 1.8 mg/l/4h
Oral		
LD50	Mouse	75 mg/kg
	Rat	230 mg/kg
Skin corrosion/irritation	Causes skin irritation.	
Serious eye damage/eye irritation	Causes serious eye damage.	
Local effects		
Skin irritation		
Result: Negative.		
Species: Rabbit		
Skin irritation: TER test		
Result: Positive.		
Species: Rat		
Respiratory or skin sensitization		
Respiratory sensitization	Knowledge about health hazard is incomplete.	
Skin sensitization	Based on available data, the classification criteria are not met.	
Skin sensitization		
Result: Negative.		
Species: Rabbit		
Germ cell mutagenicity	Knowledge about mutagenicity is incomplete.	
Mutagenicity		
Ames test		
Result: Negative.		
Micronucleus test		
Result: Negative.		
Carcinogenicity	Knowledge about carcinogenicity is incomplete.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Not listed.		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)		
Not regulated.		
US. National Toxicology Program (NTP) Report on Carcinogens		
Not listed.		
Reproductive toxicity	Knowledge about health hazard is incomplete.	
Specific target organ toxicity - single exposure	Knowledge about health hazard is incomplete.	
Specific target organ toxicity - repeated exposure	Knowledge about health hazard is incomplete.	
Aspiration hazard	Based on available data, the classification criteria are not met.	
Further information	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.	

12. Ecological information

Ecotoxicity

Product	Species	Test Results
Xylometazoline Hydrochloride (CAS 1218-35-5)		
Aquatic		
Fish	LC50 Danio rerio	60.61 mg/l, 96 hours
Persistence and degradability	No data is available on the degradability of this product.	
Bioaccumulative potential	No data available.	

Mobility in soil	No data available.
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.
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	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	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	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. (Xylometazoline Hydrochloride)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	III

IATA

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

Other information

Passenger and cargo aircraft Allowed with restrictions.

Cargo aircraft only Allowed with restrictions.

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

DOT; IATA



General information	It is the shipper's responsibility to determine the correct transport classification at the time of shipment.
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15. Regulatory information

US federal regulations	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
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TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**SARA 302 Extremely hazardous substance**

Not listed.

SARA 311/312 Hazardous chemical Yes

Classified hazard categories

Combustible dust
Acute toxicity (any route of exposure)
Skin corrosion or irritation
Serious eye damage or eye irritation

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.**US state regulations****California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

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)	No
Canada	Non-Domestic Substances List (NDSL)	Yes
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)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*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	04-19-2010
Revision date	10-01-2019
Version #	04
Further information	Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

Disclaimer

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