# SAFETY DATA SHEET

## 1. Identification

**Product identifier** **Doxazosin Mesylate**

**Other means of identification**

**Catalog number** 1225419

**Chemical name** Piperazine, 1-(4-amino-6,7-dimethoxy-2-quinazolinyl)-4-[(2,3-dihydro-1,4-benzodioxin-2-yl)carbonyl]-, monomethanesulfonate

**Synonym(s)** Doxazosin methanesulfonate

**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**

**Company name** U. S. Pharmacopeia

**Address** 12601 Twinbrook Parkway
Rockville
MD
20852-1790
US

**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

**Note** 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.

**Physical hazards** Not classified.

**Health hazards** Specific target organ toxicity, single exposure Category 1 (cardiovascular system)

**OSHA hazard(s)** Not classified.

**Label elements**

**Signal word** Danger

**Hazard statement** Causes damage to organs (cardiovascular system).

**Precautionary statement**

**Prevention** Wash thoroughly after handling.

**Response** If exposed: 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)** Not classified.

## 3. Composition/information on ingredients

**Substance**

**Hazardous components**

| Chemical name | Common name and synonyms | CAS number | % |
|---|---|---|---|
| Doxazosin Mesylate | Doxazosin methanesulfonate | 77883-43-3 | 100 |

## 4. First-aid measures

| | |
|---|---|
| **Inhalation** | Move to fresh air. Call a physician if symptoms develop or persist. |
| **Skin contact** | Rinse skin with water/shower. Get medical attention if irritation develops and persists. |
| **Eye contact** | Rinse with water. Get medical attention if irritation develops and persists. |
| **Ingestion** | Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. |
| **Most important symptoms/effects, acute and delayed** | Cardiovascular effects. |
| **Indication of immediate medical attention and special treatment needed** | Treatment of alpha-adrenergic blocker overdose should be symptomatic and supportive and may include the following: Induced vomiting is NOT recommended. Administer activated charcoal as a slurry. Perform gastric lavage soon after ingestion (within one hour). Protect airway by placement in Trendelenburg and left lateral decubitus position or by endotracheal intubation. Control any seizures first. For seizures, administer intravenous diazepam or lorazepam. If seizures recur, consider phenobarbital. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. For circulatory failure, treat by placing patient in supine position and elevating legs. For shock, treat as necessary. Volume expanders may be used, followed by cautious administration of an intravenous vasopressor if needed. For hypotension, infuse isotonic fluid. If hypotension persists, administer norepinephrine. Epinephrine should not be used due to the risk of further hypotension. Priapism is a surgical emergency. Dialysis is unlikely to be of benefit. Monitor fluid and electrolyte status. [Meditext] |
| **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

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|---|---|
| **Suitable extinguishing media** | Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2. |
| **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. |

## 6. Accidental release measures

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| **Personal precautions, protective equipment and emergency procedures** | 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. 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

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|---|---|
| **Precautions for safe handling** | Combustible dust clouds may be created where operations produce fine material (dust). Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. 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

**Exposure limit values**

**Industrial Use**

| Material | Type | Value |
|---|---|---|
| Doxazosin Mesylate (CAS 77883-43-3) | TWA | 30 micrograms/m3 |

**Biological limit values** No biological exposure limits noted for the ingredient(s).

**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. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

**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.

**Other** For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing 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).

**Thermal hazards** Not available.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

**Appearance** White to tan colored powder.

**Physical state** Solid.

**Form** Powder.

**Odor** Essentially odorless.

**Odor threshold** Not available.

**pH** Not available.

**Melting point/freezing point** 523.4 - 530.6 °F (273 - 277 °C)

**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** Very slightly soluble.

**Partition coefficient (n-octanol/water)** Not available.

| | |
|---|---|
| **Auto-ignition temperature** | Not available. |
| **Decomposition temperature** | Not available. |
| **Viscosity** | Not available. |
| **Other information** | |
| **Chemical family** | Piperazinyl quinazoline. |
| **Dust explosion properties** | |
| **Minimum explosible concentration (MEC)** | 2 g/cu. ft |
| **Molecular formula** | C23-H25-N5-O5.C-H4-O3-S |
| **Molecular weight** | 547.59 g/mol |
| **Potential for dust explosion** | Severe dust deflagration hazard. Sensitive to ignition by electrostatic discharge. |
| **Solubility (other)** | Freely soluble in formic acid and dimethylsulfoxide; soluble in dimethylformamide; slightly soluble in ethanol; very slightly soluble in methanol, in acetone, and in methylene chloride. |

## 10. Stability and reactivity

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|---|---|
| **Reactivity** | No reactivity hazards known. |
| **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** | Strong oxidizers. |
| **Hazardous decomposition products** | NOx, SOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. |

## 11. Toxicological information

**Information on likely routes of exposure**

| | |
|---|---|
| **Ingestion** | Based on available data, the classification criteria are not met. |
| **Inhalation** | Due to lack of data the classification is not possible. |
| **Skin contact** | Due to lack of data the classification is not possible. |
| **Eye contact** | Due to lack of data the classification is not possible. |
| **Symptoms related to the physical, chemical, and toxicological characteristics** | Alpha-adrenergic blockers: Nausea. Vomiting. Headache. Dizziness. Lightheadedness. Fainting. Drowsiness. Sleepiness. Nervousness. Restlessness. Irritability. Tiredness. Weakness. Shortness of breath. Swelling of feet or lower legs. Chest pain. Back pain. Joint pain. Blurred vision. Fast, pounding, or irregular heartbeat. Abnormal ejaculation. Decreased sexual desire. |
| **Delayed and immediate effects of exposure** | Alpha-adrenergic blockers: Upper respiratory tract infection. Low blood pressure. |
| **Cross sensitivity** | Persons sensitive to one quinazoline may be sensitive to this material also. |
| **Medical conditions aggravated by exposure** | Alpha-adrenergic blockers: Active alcoholism. Heart disease. Impaired liver function. |
| **Acute toxicity** | Based on available data, the classification criteria are not met. |

| Product | Species | Test Results |
|---|---|---|
| Doxazosin Mesylate (CAS 77883-43-3) | | |
| *Oral* | | |
| LD50 | Rat | > 5000 mg/kg |

| | |
|---|---|
| **Skin corrosion/irritation** | Due to lack of data the classification is not possible. |
| **Serious eye damage/eye irritation** | Due to lack of data the classification is not possible. |
| **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.<br>Data from germ cell mutagenicity tests were not found. |

**Mutagenicity**

Ames test in S. typhimurium
Result: Negative.
Forward mutation assay in E. coli
Result: Negative.
In vitro cytogenetics assay in human lymphocytes
Result: Negative.

**Mutagenicity**

In vivo cytogenetics assay in mouse bone marrow
Result: Negative.

**Carcinogenicity** Based on available data, the classification criteria are not met.
This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

0 - 120 mg/kg/day Carcinogenicity study in mice
Result: No evidence of carcinogenic potential.
Test Duration: 24 months
0 - 40 mg/kg/day Carcinogenicity study in rats
Result: No evidence of carcinogenic potential.
Test Duration: 24 months

**Reproductive toxicity** Based on available data, the classification criteria are not met.

**Reproductivity**

0 - 20 mg/kg/day Reproductivity study in rats
Result: No evidence of teratogenicity, but fertility was reduced in males.
0 - 41 mg/kg/day Reproductivity study in pregnant rabbits
Result: No evidence of teratogenicity; however, doses of 82 mg/kg reduced fetal survival.

**Specific target organ toxicity - single exposure** Causes damage to organs (cardiovascular system).

**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**

| Product | | Species | Test Results |
|---|---|---|---|
| Doxazosin Mesylate (CAS 77883-43-3) | | | |
| *Acute* | | | |
| Crustacea | LC50 | Daphnia magna | > 5 mg/l, 48 hours |

**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.

**Local disposal regulations** Not available.

**Hazardous waste code** Not available.

**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**

Not regulated as a hazardous material by DOT.

**IATA**

Not regulated as a dangerous good.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** No information available.

## 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 - No<br>Delayed Hazard - No<br>Fire Hazard - Yes<br>Pressure Hazard - No<br>Reactivity Hazard - No |
| **SARA 302 Extremely hazardous substance** | No |
| **SARA 311/312 Hazardous chemical** | No |

**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.

**International Inventories**

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|---|---|---|
| Australia | Australian Inventory of Chemical Substances (AICS) | No |
| Canada | Domestic Substances List (DSL) | No |
| Canada | Non-Domestic Substances List (NDSL) | No |
| China | Inventory of Existing Chemical Substances in China (IECSC) | Yes |
| Europe | European Inventory of Existing Commercial Chemical Substances (EINECS) | No |
| 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)

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

| | |
|---|---|
| **Issue date** | 02-07-2011 |
| **Revision date** | 08-08-2014 |
| **Version #** | 02 |
| **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. |
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| **Revision Information** | This document has undergone significant changes and should be reviewed in its entirety. |