SAFETY DATA SHEET



1. Identification

Product identifier Brimonidine Tartrate

Other means of identification

Catalog number 1076400 70359-46-5 **CAS** number

Synonyms 5-Bromo-6-(2-imidazolidinylideneamino) quinoxaline L-tartrate

Chemical name 6-Quinoxalinamine, 5-bromo-N-(4,5-dihydro-1H-imidazol-2-yl)-, (2R,3R)-2,3-dihydroxybutanedioate

(1:1)

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

U. S. Pharmacopeia Company name **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

CHEMTREC within US & 1-800-424-9300 **Emergency phone number**

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Not classified. Physical hazards

Category 3 **Health hazards** Acute toxicity, oral

Serious eye damage/eye irritation Category 2B

Environmental hazards Not classified. **OSHA** defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement Toxic if swallowed. Causes eye irritation.

Precautionary statement

Prevention Wash thoroughly after handling.

Response If swallowed: Immediately call a poison center/doctor. Rinse mouth. 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.

Store locked up. **Storage**

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise

classified (HNOC)

None known.

Supplemental information Pharmacologically active material.

Material name: Brimonidine Tartrate USP SDS US 1/7

3. Composition/information on ingredients

Substance

Ingestion

Chemical name	Common name and synonyms	CAS number	%
Brimonidine Tartrate	5-Bromo-6-(2-imidazolidinylideneamino)	70359-46-5	100
	quinoxaline L-tartrate		

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Wash off with soap and water. Get medical attention if irritation develops and persists.

Rinse with water. Get medical attention if irritation develops and persists. Eve contact

If swallowed: Immediately call a poison center or doctor/physician. Do not use mouth-to-mouth method if substance is ingested. 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. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper

Pharmacologically active material. Occupational exposure may cause physiological effects.

respiratory medical device.

Most important symptoms/effects, acute and

delayed

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Administer activated charcoal as a slurry. Protect airway and support ventilation if needed. For hypotension, infuse 10-20 mL/kg isotonic fluid. Administer dopamine or norepinephrine if hypotension persists. For bradycardia, administer atropine intravenously.

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

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.

Use standard firefighting procedures and consider the hazards of other involved materials. Specific methods

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. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

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. 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.

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8. Exposure controls/personal protection

Occupational exposure limits

Exposure limit values

Industrial Use

MaterialTypeValueBrimonidine Tartrate (CAS
70359-46-5)TWA12.5
micrograms/m3

Biological limit values

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

Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. 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 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 lab coat. 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 Respirators are generally not required for laboratory operations. Use a tight-fitting full-face

respirator with HEPA filters 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

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. Light yellow.

Odor Not available.
Odor threshold Not available.
pH Not available.

Melting point/freezing point 395.6 - 410 °F (202 - 210 °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 pressureNot available.Vapor densityNot available.Relative densityNot available.

Material name: Brimonidine Tartrate

Solubility(ies)

Solubility (water) Soluble.

Solubility (other) Dimethylsulfoxide: Freely soluble.

> Methanol: Freely soluble. Acetone: Freely soluble.

Auto-ignition temperature Not available. Not available. **Decomposition temperature** Not available. **Viscosity**

Other information

C11H10BrN5 . C4H6O6 Molecular formula

Molecular weight 442.24

3 - 4.5 (1% solution) pH in aqueous solution

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 Oxidizing agents.

Hazardous decomposition

products

NOx. Br-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Knowledge about health hazard is incomplete. Inhalation Skin contact Knowledge about health hazard is incomplete.

Causes eye irritation. Eve contact Toxic if swallowed. Ingestion

Symptoms related to the

physical, chemical, and

toxicological characteristics Alpha-2 adrenergic agonists: Changes in blood pressure, heart rhythm, or heart rate. Dry mouth.

Sedation.

Information on toxicological effects

Acute toxicity Toxic if swallowed.

Test Results Product Species

Brimonidine Tartrate (CAS 70359-46-5)

Acute Oral

LD50 Rat 100 mg/kg

Skin corrosion/irritation Knowledge about health hazard is incomplete.

Serious eye damage/eye

irritation

Causes eye irritation.

Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete. Skin sensitization Knowledge about health hazard is incomplete.

Based on available data, the classification criteria are not met. Germ cell mutagenicity

Mutagenicity

Ames test Result: Negative.

Chromosome aberration: Chinese hamster ovary cells

Result: Negative. Dominant lethal test Result: Negative. Species: Mouse

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Mutagenicity

Mutagenicity, Host mediated assay

Result: Negative. Species: Mouse

Carcinogenicity

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

1 mg/kg/day Carcinogenicity, administered in diet.

Result: Negative. Species: Rat

Test Duration: 24 months

2.5 mg/kg/day Carcinogenicity, administered in diet.

Result: Negative. Species: Mouse

Test Duration: 21 months

IARC Monographs. Overall Evaluation of Carcinogenicity

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

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

Reproductivity

0.66 mg/kg Reproductivity / Developmental

Result: No evidence of impaired fertility or fetal harm.

Species: Rat

Specific target organ toxicity -

Knowledge about health hazard is incomplete.

single exposure

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 Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information

Ecotoxicity

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability

No data is available on the degradability of this substance.

Bioaccumulative potential Mobility in soil

No data available. 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

Class

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. (Brimonidine Tartrate)

Transport hazard class(es)

6.1 Subsidiary risk Packing group Ш

Material name: Brimonidine Tartrate 1076400 Version #: 04 Revision date: 06-21-2019 Issue date: 06-21-2019

IATA

UN number UN2811

UN proper shipping name Toxic solid, organic, n.o.s. (Brimonidine Tartrate)

Transport hazard class(es)

Class 6.1 Subsidiary risk -Packing group III

Other information

Passenger and cargo

Cargo aircraft only

aircraft

Allowed with restrictions.

Allowed with restrictions.

Transport in bulk according to

Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

the IBC Code
DOT; IATA



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

15. Regulatory information

US federal regulationsThis product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

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 Yes

chemical

Classified hazard Acute toxicity (any route of exposure) categories 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

Not regulated.

(SDWA)

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US state regulations

Taiwan

California Proposition 65

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)	No
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	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

Toxic Substances Control Act (TSCA) Inventory United States & Puerto Rico 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 06-21-2019 **Revision date** 06-21-2019

Version # 04

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Taiwan Chemical Substance Inventory (TCSI)

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herein.

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Yes