# SAFETY DATA SHEET



## 1. Identification

**Product identifier Betaxolol Hydrochloride** 

Other means of identification

Catalog number 1069903 **CAS** number 63659-19-8

**Chemical name** (±)-1-[p-[2-(Cyclopropylmethoxy)ethyl]phenoxy]-3-(isopropylamino)-2-propanol hydrochloride

Recommended use For analytical laboratory use only.

Not for use as a drug. Not for administration to humans or animals. **Recommended restrictions** 

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name U. S. Pharmacopeia **Address** 12601 Twinbrook Parkway

> Rockville MD

20852-1790 **United States** 

**Technical Services** 301-816-8129 Telephone

Website www.usp.org E-mail RSTECH@usp.org

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

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.

**Health hazards** Acute toxicity, oral Category 4

> Serious eye damage/eye irritation Category 2A

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

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

Label elements



Signal word

Harmful if swallowed. Causes serious eye irritation. Causes damage to organs (cardiovascular **Hazard statement** 

system).

**Precautionary statement** 

Prevention Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Wear eye

protection/face protection.

If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If in eyes: Rinse Response

> 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 exposed: Call a poison

center/doctor.

Storage Store locked up.

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

Hazard(s) not otherwise

classified (HNOC)

None known.

Material name: Betaxolol Hydrochloride USP SDS US 1/7

## 3. Composition/information on ingredients

#### **Substance**

Ingestion

Chemical name	Common name and synonyms	CAS number	%
Betaxolol Hydrochloride		63659-19-8	100

## 4. First-aid measures

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

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

Immediately flush eves with plenty of water for at least 15 minutes. Remove contact lenses, if Eve contact

present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Rinse mouth. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

Get medical advice/attention if you feel unwell.

Most important

symptoms/effects, acute and

delayed

Cardiovascular effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

Indication of immediate medical attention and special treatment needed

Treat symptomatically. For beta-adrenergic blockers: Treatment may include the following: Do NOT induce vomiting. Administer activated charcoal as a slurry and perform gastric lavage to decrease absorption. Gastric lavage may increase vagal tone. Maintain an open airway and assist ventilation if necessary. Perform an early echocardiographic evaluation. For mild hypotension, administer IV fluids. If severe, administer IV glucagon, calcium, or catecholamines (dopamine, norepinephrine, epinephrine). Concurrent high-dose insulin euglycemia therapy may allow for a decrease in the dose of catecholamine. For bradycardia, administer IV atropine, glucagon, and isoproterenol. Cardiac pacing may also be needed. Sodium bicarbonate may be helpful for dysrhythmias and conduction defects. For bronchospasm, administer nebulized bronchodilators. Systemic corticosteroids may also be beneficial. For seizures, administer a benzodiazepine (diazepam or lorazepam) intravenously. Muscle relaxants and artificial ventilation may also be required. For hypoglycemia, administer glucose or glucagon.

**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.

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. 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.

Material name: Betaxolol Hydrochloride USP SDS US

## 7. Handling and storage

Precautions for safe handling

As a general rule, when handling USP materials, 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. This material should be handled and stored per label instructions to ensure product integrity.

# 8. Exposure controls/personal protection

Occupational exposure limits

No exposure limits noted for ingredient(s).

**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 USP materials.

## 9. Physical and chemical properties

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

Solid. **Physical state** Powder. **Form** 

White. Off-white. Color

Odor Odorless. Not available. **Odor threshold** Not available. pН

235.4 - 242.6 °F (113 - 117 °C) Melting point/freezing point

Initial boiling point and boiling

range

Not available.

Flash point Not available. Not available. **Evaporation rate** 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.

Solubility(ies)

Solubility (water) Freely soluble.

Solubility (other) Chloroform: Freely soluble.

Ethanol: Freely soluble.

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

Chemical family Propanolamine.

Molecular formula C18H29NO3

Molecular weight 343.89

# 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 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

InhalationKnowledge about health hazard is incomplete.Skin contactKnowledge about health hazard is incomplete.

**Eye contact** Causes serious eye irritation.

**Ingestion** Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

Beta-adrenergic blockers: Gastrointestinal disturbances. Headache. Mood or mental changes. Drowsiness. Weakness. Insomnia. Nervousness. Visual disturbances. Swelling of feet or legs. Muscle, joint, or chest paint. Seizures. Coma. Cardiovascular effects. Respiratory depression.

#### Information on toxicological effects

Acute toxicity Harmful if swallowed.

Product Species Test Results

Betaxolol Hydrochloride (CAS 63659-19-8)

Oral

LD50 Mouse 48 mg/kg

Rat 860 - 980 mg/kg

998 mg/kg

**Skin corrosion/irritation** Knowledge about health hazard is incomplete.

Serious eye damage/eye

irritation

Causes serious eye irritation.

## Local effects

Eye irritation Result: Irritant. Species: Rabbit

## Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete.

Skin sensitization Knowledge about health hazard is incomplete.

Germ cell mutagenicity Knowledge about mutagenicity is incomplete.

Material name: Betaxolol Hydrochloride

USP SDS US

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

3 - 48 mg/kg/day Lifetime study

Result: No evidence of carcinogenicity.

Species: Rat

6 - 60 mg/kg/day Lifetime study

Result: No evidence of a carcinogenicity.

Species: Mouse

## IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed

## US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

# Reproductive toxicity Based on available data, the classification criteria are not met. Some beta-adrenergic blocking

agents have been reported to cause fetal and neonatal bradycardia, hypotension, and

hypoglycemia when administered during pregnancy, and may also be associated with fetal growth

retardation. Human epidemiological studies have not identified abnormalities caused by

therapeutic use of this material during pregnancy.

#### Reproductivity

36 mg/kg/day Gestational study

Result: Increased post-implantation loss but no birth defects.

Species: Rabbit

400 mg/kg/day Gestational study

Result: Maternal toxicity, increased post-implantation loss, reduced litter size and weight, and increased skeletal and

visceral abnormalities.

Species: Rat

Specific target organ toxicity -

single exposure

Causes damage to organs (cardiovascular system).

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** 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 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

Not regulated as dangerous goods.

Material name: Betaxolol Hydrochloride usp sds us

#### IATA

Not regulated as dangerous goods.

Transport in bulk according to

Not applicable.

Annex II of MARPOL 73/78 and

the IBC Code

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

shipment.

# 15. Regulatory information

US federal regulations This product is a "Haza

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

#### **Toxic Substances Control Act (TSCA)**

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 1910.1001-1053)

Not listed

#### Superfund Amendments and Reauthorization Act of 1986 (SARA)

Yes

#### SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

chemical

Classified hazard Acute toxicity (any route of exposure) categories Serious eye damage or eye irritation

Specific target organ toxicity (single or repeated exposure)

#### 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)

#### **US** state regulations

## **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. 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)	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)	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	No

Material name: Betaxolol Hydrochloride

On inventory (yes/no)\* Country(s) or region Inventory name

**Philippines** Philippine Inventory of Chemicals and Chemical Substances

(PICCS)

Taiwan Taiwan Chemical Substance Inventory (TCSI) Yes 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 02-16-2011 **Revision date** 03-08-2022

Version # 03

USP materials are sold for analytical laboratory use only, and NOT for human consumption. The Disclaimer

> information contained herein is applicable solely to the chemical substance when used for analytical laboratory use and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP materials are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A

PARTICULAR PURPOSE is made with respect to the information contained herein.

Material name: Betaxolol Hydrochloride USP SDS US