SAFETY DATA SHEET



1. Identification

Product identifier Benztropine Mesylate

Other means of identification

Catalog number 1061005 CAS number 132-17-2

Synonyms Benztropine methanesulfonate

Chemical name 8-Azabicyclo[3.2.1]octane, 3-(diphenylmethoxy)-, endo, 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

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 & 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

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Warning

Hazard statement Harmful if swallowed.

Precautionary statement

Prevention Wash thoroughly after handling.

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

Storage Not available.

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

Hazard(s) not otherwise

classified (HNOC)

None known.

Supplemental information Potent pharmacologically active material.

3. Composition/information on ingredients

Substance

Material name: Benztropine Mesylate

CAS number % Chemical name Common name and synonyms Benztropine Mesylate 132-17-2 100 Benztropine methanesulfonate

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.

Eye contact Rinse with water. 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. Ingestion

Get medical advice/attention if you feel unwell.

Most important symptoms/effects, acute and

delayed

Anticholinergic effects. 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. Treatment of anticholinergic overdose may include the following: Do not induce vomiting. Gastric decontamination may be successful, even if delayed. Administer activated charcoal as a slurry. To reverse anticholinergic delirium, administer physostigmine. For tachydysrhythmias with signs of hemodynamic instability, treat with physostigmine or intravenous beta blockers. For QRS widening or ventricular tachycardia, administer sodium bicarbonate. If sodium bicarbonate is unsuccessful, consider lidocaine. 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 imbalances, and hypoxia. For agitation, with and without hypertension and tachycardia, administer intravenous benzodiazepines. For severe hypertension, administer nitroprusside, labetalol, nitroglycerin, or phentolamine. For hyperthermia, treat with external cooling and avoid phenothiazines. For hypotension, administer isotonic fluid. If hypotension persists, consider dopamine or norepinephine. For rhabdomyolysis, administer saline. Monitor input and output, serum electrolytes, CK, and renal function, Diuretics may be necessary to maintain urine output. Urinary alkalinization is NOT recommended.

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

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

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

Specific methods

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.

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.

Avoid discharge into drains, water courses or onto the ground. **Environmental precautions**

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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.

Store in tight container as defined in the USP-NF. This material should be handled and stored per

Conditions for safe storage,

including any incompatibilities 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	Туре	Value
Benztropine Mesylate (CAS	TWA	0.01 mg/m3
132-17-2)		

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.

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 Crystalline powder.

Color White.

Odor Practically odorless.

Odor threshold Not available.
pH Not available.

Melting point/freezing point 285.8 - 298.4 °F (141 - 148 °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.

Not available. Explosive limit - lower (%) Explosive limit - upper (%) Not available.

< 0.0000001 kPa (77 °F (25 °C)) Vapor pressure

Not available. Vapor density Not available. Relative density

Solubility(ies)

Solubility (water) Very soluble.

Solubility (other) Alcohol: Freely soluble. Ether: Very slightly soluble.

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

Other information

Chemical family Tropane derivative: tertiary amine.

Molecular formula C21H25NO . CH4O3S

Molecular weight 403.54

10. Stability and reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport. Reactivity

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. Strong bases.

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

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

Ingestion Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics Antidyskinetics: Blurred vision. Constipation. Decreased sweating. Difficult or painful urination. Drowsiness. Dry mouth, nose or throat. Increased sensitivity of eyes to light. Nausea. Vomiting. False sense of well-being. Headache. Muscle cramps. Nervousness. Numbness or weakness of the extremities. Dizziness. Sore mouth or tongue. Stomach pain. Clumsiness. Unsteadiness. Rapid heartbeat. Troubled breathing. Mood or mental changes. Hallucinations. Seizures.

Information on toxicological effects

Harmful if swallowed. **Acute toxicity**

Product Species Test Results

Benztropine Mesylate (CAS 132-17-2)

Oral

LD50 Rat 940 mg/kg

Skin corrosion/irritation Knowledge about health hazard is incomplete. Serious eye damage/eye

irritation

Knowledge about health hazard is incomplete.

Material name: Benztropine Mesylate 1061005 Version #: 03 Revision date: 06-16-2020 Issue date: 10-17-2007 Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete. Knowledge about health hazard is incomplete. Skin sensitization Germ cell mutagenicity Knowledge about mutagenicity is incomplete. Knowledge about carcinogenicity is incomplete. Carcinogenicity

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Knowledge about health hazard is incomplete. Reproductive toxicity

Specific target organ toxicity -

single exposure

Knowledge about health hazard is incomplete.

Specific target organ toxicity -

repeated exposure

Knowledge about health hazard is incomplete.

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

Further information Potent pharmacologically active material. Occupational exposure to small amounts may cause

physiological effects.

12. Ecological information

The product is not classified as environmentally hazardous. However, this does not exclude the **Ecotoxicity**

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability Readily biodegradable.

No data available. Bioaccumulative potential 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

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the **Disposal instructions**

user of the product to determine, at the time of disposal, whether the product meets RCRA criteria

for hazardous waste.

Dispose in accordance with all applicable regulations. Local disposal 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.

IATA

Not regulated as dangerous goods.

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

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 "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

Material name: Benztropine Mesylate USP SDS US

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)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

Yes

chemical

Classified hazard

Acute toxicity (any route of exposure)

categories

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)	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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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
 10-17-2007

 Revision date
 06-16-2020

Version # 03

Material name: Benztropine Mesylate

USP SDS US

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).

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