

SAFETY DATA SHEET

Benztropine Mesylate Tablets, USP

1. IDENTIFICATION

Manufacturer:

InvaGen Pharmaceuticals Inc.
7, Oser Avenue
Hauppauge, NY 11788

Emergency Phone:

1-631-231-3233

Common Name: Benzotropine Mesylate Tablets, USP

Chemical Family: Tropane derivative; tertiary amine

Synonym(s): 3-Diphenylmethoxytropane Mesylate

Chemical Name: 8-Azabicyclo [3.2.1] octane, 3-(diphenylmethoxy)- endo, methanesulfonate

Trade Name(s): Benzotropine Mesylate Tablets, USP 0.5 mg, 1 mg and 2 mg

Therapeutic Category: Antiparkinsonian

Molecular formula: C₂₂H₂₉NO₄S **Molecular Weight:** 403.54

2. HAZARDS IDENTIFICATION

Not considered hazardous when handled under normal conditions.

EMERGENCY OVERVIEW

Caution Statement: Each Benzotropine Mesylate Tablets intended for oral administration contains Benzotropine Mesylate, USP and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Routes of Entry: Oral

Effects of Overexposure: Tablets are intended for human consumption under guidance of a physician. Intact tablets are not considered hazardous under normal handling procedures.

Medical conditions Aggravated by Long Term Exposure:

Hypersensitivity to material, active alcoholism, cardiovascular instability, tardive dyskinesia, glaucoma, impaired liver or kidney function, hypertension, intestinal obstruction, myasthenia gravis, dementia, and enlarged prostate gland or urinary retention.

Carcinogenicity: Benztropine Mesylate - Not listed by IARC, NTP and OSHA.

3.COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS #</u>	<u>Concentration %</u>		
		0.5 mg	1 mg	2 mg
Benzotropine Mesylate, USP	132-17-2	≈ 0.625 %	≈ 1.250 %	≈ 2.500 %
Excipients	NA	≈ 99.375 %	≈ 98.750 %	≈ 97.500 %

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.

* All Concentrations are percent by weight.

4. FIRST AID MEASURES

Inhalation: Move in to fresh air and keep at rest. For breathing difficulties, Oxygen may be necessary. Get medical attention. If breathing stops, provide artificial respiration.

Skin Contact: Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes.

Eye Contact: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: Do not induce vomiting unless directed to do so by medical personnel. Never give liquid to an unconscious person. Get medical attention.

Notes to the Physician:

Benzotropine Mesylate possesses both anticholinergic and antihistaminic effects, although only the former have been established as therapeutically significant in the management of Parkinsonism.

Overdose Treatment:

Physostigmine salicylate, 1 to 2 mg, SC or IV, reportedly will reverse symptoms of anticholinergic intoxication. A second injection may be given after 2 hours if required. Otherwise treatment is symptomatic and supportive. Induce emesis or perform gastric lavage (contraindicated in precomatose convulsive or psychotic states). Maintain respiration. A short-acting barbiturate may be used for CNS excitement, but with caution to avoid subsequent depression; supportive care for depression (avoid convulsant stimulants such as picrotoxin, pentylenetetrazol, or bemegride); artificial respiration for severe respiratory depression; a local miotic for mydriasis and cycloplegia; ice bags or other cold applications and alcohol sponges for hyperpyrexia, a vasopressor and fluids for circulatory collapse. Darken room for photophobia.

5.FIRE-FIGHTING MEASURES

Extinguishing Media: Water spray, CO₂, dry chemical or alcohol resistant foam.

Unusual Fire & Explosion Hazards: Emits toxic fumes under fire conditions.

Special Fire Fighting Procedures: Self-Contained breathing apparatus and full protective clothing must be worn in case of fire.

Protective Measures: Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

6.ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all firefighting procedures.

Environmental precautions: Do not release in to the environment.

Spill Cleanup methods: Use a vacuum cleaner. If not possible, moisten dust with water before it is collected with shovel, broom or the like. Collect in containers and seal securely. For waste disposal, see section 13 of the SDS.

7.HANDLING AND STORAGE

Handling: Do not breathe dust. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.

Storage: Keep container tightly closed in a cool, well-ventilated place. Keep away from heat and direct sun light.

8.EXPOSURE CONTROLS / PERSONAL PROTECTION

Compressed tablets are not considered hazardous under normal handling procedures and protective equipment is not required. The following are recommended for manufacturing or other situations where exposure to the powder may occur.

Protective Measures: Minimize open handling. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas.

Respiratory Protection: Use a NIOSH approved respirator or an alternate approved dust mask should be used.

Hand Protection: Chemical resistant gloves.

Eye Protection: Wear safety glasses with side shields (or goggles). If the work environment or activity involves dusty conditions, mist or aerosols, wear the appropriate goggles. Wear a face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and Body Protection: Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene Measures: Wash skin thoroughly with soap and water.

9.PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

Physical State: Solid

Form: Tablets

Appearance:

0.5 mg Tablets	White, Round, flat faced beveled edged tablets de-bossed with 'I' on the left side of bisect and 'G' on the right side of bisect and "318" on the other side.
1 mg Tablets	White, Modified Oval biconvex tablets de-bossed with 'I' on the left side of bisect and 'G' on the right side of bisect on one side and "319" on the other side.
2 mg Tablets	White, Round, flat faced beveled edged tablets de-bossed with 'I' on the left side of bisect and 'G' on the right side of the bisect and "320" on the other side

10. STABILITY AND REACTIVITY

Possibility of hazardous reactions: Stable under ordinary conditions of use and storage.

Conditions to avoid: Excessive heat & Moisture.

Incompatible materials: Strong oxidizers, Strong Bases and Strong Acids.

Hazardous Decomposition products: Thermal decomposition or combustion may liberate irritating gases or vapors.

11. TOXICOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients (Benztropine Mesylate, USP), and not to the mixture(s) or final formulations.

Inhalation: No data available.

Ingestion: Harmful if swallowed. (Benztropine Mesylate, USP)

Skin Corrosion/ irritation: No data available.

Serious eye damage/eye irritation: No data available.

Respiratory sensitizer/Skin sensitizer: No data available.

Carcinogenesis: No data available.

Mutagenesis: No data available.

Impairment of Fertility: No data available.

Other information:

The adverse reactions below, most of which are anticholinergic in nature, have been reported and within each category are listed in order of decreasing severity.

Cardiovascular - Tachycardia. Digestive-Paralytic ileus, constipation, vomiting, nausea, dry mouth. If dry mouth is so severe that there is difficulty in swallowing or speaking, or loss of appetite and weight, reduce dosage, or discontinue the drug temporarily. Slight reduction in dosage may control nausea and still give sufficient relief of symptoms. Vomiting may be controlled by temporary discontinuation, followed by resumption at a lower dosage. Nervous System-Toxic psychosis, including confusion, disorientation, memory impairment, visual hallucinations; exacerbation of preexisting psychotic

symptoms; nervousness; depression; listlessness; numbness of fingers. Special Senses Blurred vision, dilated pupils. Urogenital-Urinary retention, dysuria. Metabolic/Immune or Skin-Occasionally, an allergic reaction, e.g., skin rash, develops. If this cannot be controlled by dosage reduction, the medication should be discontinued. Other-Heat stroke, hyperthermia, fever.

12.ECOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients (Benztropine Mesylate, USP), and not to the mixture(s) or final formulations.

Ecotoxicity Effects:

Acute toxicity to Fish: No data available.

Acute toxicity to Aquatic Invertebrates: No data available.

Toxicity to Aquatic Plants: No data available.

Bioaccumulation: No data available.

Mobility: No data available.

13.DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of waste must be in accordance with all applicable Federal, State and local laws.

Measures for Avoidance and Recovery: Incineration is the most effective method of disposal in most instances. Do not allow runoff to sewer, waterway or ground. Operations that involve the crushing or shredding of waste materials or returned goods should take into account recommended exposure limits where they exist.

14.TRANSPORT INFORMATION

DOT: Not Regulated

IMDG: Not regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

15.REGULATORY INFORMATION

Stated regulatory information chosen primarily for possible usage of InvaGen Pharmaceutical, Inc. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

CERLA Hazardous Substance List (40 CFR 302.4): None

TSCA : None

Revision:01

Effective Date:10-June-2015

SARA Title III
Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): None

Section 313 Toxic Release Inventory (40 CFR 372): None

16.OTHER INFORMATION

SDS Sections Revised:

Revision 01: Sections 1 to 16 contain revisions to comply with 29 CFR 1910.1200(g) and Appendix D.

GLOSSARY:

SDS	Safety Data Sheet
NA	Not Applicable
CAS Number	Chemical Abstract Service Registry Number
NTP	National Toxicology Program
NIOSH	National Institute for Occupational Safety and Health
DOT	Department of Transportation
IMDG	International Maritime Dangerous Goods Code
ICAO	International Civil Aviation Organization
IATA	International Air Transport Association
IMO	International Maritime Organization
TSCA	Toxic Substances Control Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
SARA	Superfund Amendments and Reauthorization Act
OSHA	Occupational Safety and Health Administration

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute or product literature which may accompany the finished product.