

MERCK HUMAN HEALTH DIVISION, U.S. HUMAN HEALTH
 A Division of Merck and Co., Inc.; P.O. Box 4, West Point, PA 19486

***** MATERIAL SAFETY DATA SHEET *****

LABEL NAME: Cogentin (Injection)

MHHD-005

Emergency Telephone - Professional Information on MHHD-U.S. Marketed Products
 Number (215) 652-7300

SECTION 1 - MATERIAL IDENTIFICATION

Chemical Name----- 3-(Diphenyl methoxy)-8-methyl-8-azacyclo [3.2.1] octane methane sulfonate

Synonyms (Common)----- Congenitol, Tropine benzohydryl ether
 methane sulfonate
 (Chemical)----- Benztropine mesylate

Material Statistical Number--- Not applicable

Material Product Number----- Not applicable

Chemical Classification----- Pharmaceutical

Intended Use----- Anticholinergic management of parkinsonism
 and antihistaminic effects.

SECTION 2 - PRINCIPAL HAZARDOUS COMPONENT(S)

Component	Molecular Formula	Molecular Weight	CAS Number	Percent (%)
Benztropine mesylate	C ₂₁ H ₂₅ NO	403.54	132-17-2	1 mg/ml

SECTION 3 - PHYSICAL PROPERTY DATA

Appearance----- Clear, colorless aqueous solution

Odor/Threshold Level (ppm)---- Not applicable

Boiling Point (oC/oF)----- Not applicable

Freezing Point (oC/oF)----- Not applicable

Melting Range (oC/oF)----- Complex mixture

pH ----- 6.0

Solubility in water----- Freely soluble

Specific Gravity (Water = 1)--- Not applicable

Vapor Density (Air=1)----- Not applicable

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Vapor Pressure (mm Hg @ oC/oF)- Not applicable

Volatile Components (% w/w)--- None

SECTION 4 - FIRE AND EXPLOSION HAZARD DATA

Flash Point (oC/oF)----- Not applicable

Flash Point Test Method----- Not applicable

Autoignition Temperature (oC/oF)- Not applicable

Flammable Limits -LEL (%)---- Not applicable
-UEL (%)---- Not applicable

Combustibility Information--- Not applicable

Dust Explosivity Information-- Not available

Shock Sensitivity Information- Not available

Extinguishing Media----- Small fires: Not available
Large fires: Not available

Special Fire Fighting Procedures- None

Fire/Explosion Hazards----- None known

Hazardous Decomposition Products Resulting From A Fire- None known

SECTION 5 - REACTIVITY DATA

Stability (Normal Storage Conditions)-- Not available

Storage Conditions to Avoid--- Not available

Thermal Stability/Instability Information- None known

Incompatibilities (Chemical Entities)- None known

Incompatibilities (Materials of Construction)- None known

Hazardous Polymerizations--- None known

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SECTION 6 - EMERGENCY AND FIRST AID PROCEDURES

- Eye Contact----- Flush with water; get medical attention if symptoms appear.
- Skin Contact----- Wash with water.
- Inhalation----- Get to fresh air. Get medical attention if symptoms appear.
- Ingestion----- Induce vomiting or perform gastric lavage if a significant quantity has been ingested. These are not recommended in precomatose, convulsive, or psychotic status. Maintain airway.
- Notes to Physician----- Physostigmine salicylate (1-2mg) subcutaneously or intravenously has been shown to reverse CNS symptoms of anticholinergic intoxication.

SECTION 7 - HEALTH HAZARD DATA

Component	OSHA Permissible Exposure Limit (PEL)	ACGIH-1993-94 Threshold Limit Value (TLV)	Merck Exposure Control Limit (ECL)
Benztropine mesylate	Not established	Not established	0.01mg/M3

Carcinogen Designation----- Not listed with IARC, NTP, or OSHA

Effects of Acute Exposure

Eye Contact----- Not established

Skin Contact----- Not established but manufacturing experience has shown that the compound is non irritating to the skin.

Inhalation----- Not established but is not considered a potential route of exposure.

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Ingestion----- Manifestations of overdosage similar to atropine poisoning or antihistamine

overdosage, e.g., CNS depression, hallucinations, anhidrosis, tachycardia, blurred vision, skin rash, hyperthermia, toxic psychosis.

Effects of Chronic Exposure---- Safe use in pregnancy has not been established. Rats tolerated up to 5 mg/kg/day in the diet for 172 days without evidence of effect. Dogs tolerated 0.5 mg/kg/day for 30 weeks without evidence of toxicity or signs of drug effect. At 2 mg/kg/day mydriasis and dryness of nose were seen. At 5 mg/kg/day, ptosis, convulsions, and weight loss were seen.

Quantitative Toxicity Data for Active Ingredient

Test	Species	Route	Results
LD50	Mouse	Intravenous	25.5 mg/kg
LD50	Mouse	Intraperitoneal	65.0 mg/kg
LD50	Cat	Intravenouse	33.0 mg/kg

SECTION 8 - SPILL/LEAK/DISPOSAL PROCEDURE

Steps to be taken in case materials released:

Immediately contact emergency response personnel. Keep unnecessary persons away. If emergency response personnel are unavailable, absorb small spills on vermiculite or other suitable absorbing material and place in a sealed container for disposal. Dike large spills and transfer to an appropriate container for disposal. Use suitable protective equipment (Section 9). Follow all fire prevention procedures (Section 4).

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For additional assistance, CHEMTREC provides a toll-free Hotline for chemical emergencies regarding spills, leaks, exposure or accidents:
1-800-424-9300.

Environmental Data----- Not available

Waste Disposal Information----- Avoid contact of spilled materials and runoff with soil and surface waterways. Dispose of or treat all spill residues

including contaminated soils following all federal, state and local regulations.

SECTION 9 - SPECIAL PROTECTION INFORMATION

Respiratory----- Not required

Hands/Arms----- Not required unless material is spilled then, impervious gloves are recommended.

Eye/Face----- None required

Additional Protective Equipment- Work uniform.

Ventilation----- None required

SECTION 10 - SPECIAL PRECAUTIONS

Special Precautions to be taken when:

Handling----- None recommended at this time.

Storing----- Store under normal environmental conditions.

SECTION 11 - BASIC TRANSPORTATION DESCRIPTION

U.S. DOT----- Not applicable

ICAO/IATA----- Not applicable

IMO----- Not applicable

Hazardous Substance-Reportable Quantity (RQ)--- Not applicable

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SECTION 12 - MSDS PREPARATION - Last revised, April 1994, B. Naumann.

R. W. Shackleford, M.D.

Professional Information-----Date: September 21, 1990

B. Berglund

Corporate Environmental Resources-----Date: September 21, 1990

E. Sargent, Ph.D

Corporate Safety & Industrial Hygiene-----Date: October 18, 1990

SECTION 13 - MERCK DISCLAIMER

While this information and recommendations set forth are believed to be accurate as of the date hereof, MERCK & CO., INC. makes no warranty with respect hereto and disclaims all liability from reliance thereon.