



Material Safety Data Sheet

MSDS Number: 1102387
Revision date: 09/07/2012
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1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MSDS Number: 1102387
Product name: Diphenhydramine Hydrochloride Injection, USP
Product Codes: NDC 0641-0376-25, NDC 0641-0376-21
Synonyms: None
Chemical Family: Antihistaminic Agent.
Product Type: Regulated Prescription Drug
Container Information: 1 ml dosette® vials
Product Use: Pharmaceutical.

Supplier

BAXTER HEALTHCARE CORPORATION
DEERFIELD, ILLINOIS 60015
(800) 422-9837 or (224) 948-4770

Emergency telephone number PROSAR: USA (888) 990-0996 OUTSIDE USA (651)917-6114
CHEMTREC: USA (800) 424-9300 OUTSIDE USA (743)741-6089

2. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Weight %	UN Number:	Classification:
Diphenhydramine hydrochloride 147-24-0	5	None	Xn
Benzethonium chloride 121-54-0	<0.05	None	None
Water 7732-18-5	>94	None	None

3. HAZARDS IDENTIFICATION

Emergency overview: WARNING! HARMFUL IF SWALLOWED. Do not ingest. Central Nervous System depression.

Principle routes of exposure: Absorbed through skin. Eye contact. Ingestion.

Inhalation: Inhalation not likely under normal use conditions.

Ingestion: Harmful if swallowed. Gastrointestinal effects. Nervous system effects (may include drowsiness, confusion, hallucinations, convulsions, visual disturbances, headache, coma).

Skin contact: No known effect according to our database.

Eye contact: No known effect according to our database.

4. FIRST AID MEASURES

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

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Product name: Diphenhydramine Hydrochloride
Injection, USP

Skin contact: Wash contaminated skin with soap and water. Get medical attention if irritation develops.

Ingestion: Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

Eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.

Notes to physician: See patient package insert in shipping carton for complete information.

5. FIRE FIGHTING MEASURES

Suitable extinguishing media: Use foam or all purpose dry chemicals to extinguish.

Special protective equipment for firefighters: Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

Specific methods: No information available.

Flash point: Not determined

Autoignition temperature: Not available.

Flammable limits in air-lower (%): Not available.

Flammable limits in air-upper (%): Not available.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).

Environmental precautions: No information available.

Methods for cleaning up: If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

7. HANDLING AND STORAGE

Handling:

Technical measures/precautions: Wash thoroughly after handling.

Storage:

Technical measures/conditions: Keep containers tightly closed in a cool, well-ventilated place. Store at room temperature between 20°C and 25°C (68°F and 77°F).

Incompatible products: No special restrictions on storage with other products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

Component	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Diphenhydramine hydrochloride 147-24-0	None	None	None	None	None	None
Benzethonium chloride 121-54-0	None	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None	None

Engineering measures: No special containment is required. Good general ventilation should be sufficient to control airborne levels.

Personal protective equipment:

Respiratory protection: No personal respiratory protective equipment normally required.

Hand protection: Use chemical resistant, impervious gloves.

Skin and body protection: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

Eye protection: Eye protection not required for normal final product use. Safety glasses with side-shields are recommended for laboratory and manufacturing use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid
Appearance: Aqueous solution
Color: Colorless
Odor: Not available.
pH: 4.0 - 6.5
Molecular weight: Not applicable.
Boiling point/range: Not available.
Melting point/range: Not available.
Density: Not available.
Vapor pressure: Not available.
Evaporation rate: Not available.
Solubility: Not available.
Partition coefficient (n-octanol/water): Not available.
Viscosity: Not available.
% Volatile by Volume: Not available.

10. STABILITY AND REACTIVITY

Stability: Stable under recommended storage conditions.

Polymerization: Not applicable

Hazardous decomposition products: Not available.

Materials to avoid: Acids. Bases. Oxidizing agents.

11. TOXICOLOGICAL INFORMATION

Component	LD50 Dermal	LC50 Inhalation	LD50 Oral
Diphenhydramine hydrochloride 147-24-0	-	-	500 mg/kg (rat)
Benzethonium chloride 121-54-0	-	-	368 mg/kg (rat)
Water 7732-18-5	-	-	90 mL/kg (rat)

Acute toxicity:	Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Nervous system effects (may include drowsiness, confusion, hallucinations, convulsions, visual disturbances, headache, coma). See patient package insert for additional information.
Chronic toxicity:	Target Organs: Nervous system.
Carcinogenic effects:	No data is available on the product itself.
Mutagenic effects:	No data is available on the product itself.
Reproductive toxicity:	No impairment to fertility based on animal data. Not considered fetotoxic based on animal data.
FDA Pregnancy Category	B

12. ECOLOGICAL INFORMATION

Environmental properties:

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data
Diphenhydramine hydrochloride 147-24-0	None.	None.	None.	None.
Benzethonium chloride 121-54-0	None.	None.	None.	None.
Water 7732-18-5	None.	None.	None.	None.

Ecotoxicity effects: No data available

Bioaccumulation: No data available

13. DISPOSAL CONSIDERATIONS

Waste Classification: Not regulated.

Waste from residues / unused products: Waste disposal must be in accordance with appropriate Federal, State, and local regulations.

14. TRANSPORT INFORMATION

DOT:

DOT shipping name: None
UN Number: None

DOT Packing Group: None
 DOT Hazard class: None

TDG (Canada):

TDG Proper shipping name: None
 TDG UN/NA Number: None
 TDG Packing Group: None
 TDG Hazard class: None

ADR/RID:

ADR Official Transport Name: None
 ADR Proper shipping name: None
 ADR UN/NA number: None
 ADR Hazard Class: None

ICAO / IATA:

IATA Proper shipping name: None
 IATA UN Number: None
 IATA Primary Hazard: None
 IATA Packing group: None
 ICAO ERG Code: None

IMO / IMDG:

IMDG Proper Shipping Name: None
 IMDG Hazard Class and Division: None
 IMDG Packing Group: None
 IMDG Subsidiary Risks: None

15. REGULATORY INFORMATION

U.S. Regulations:

TSCA Inventory List - OTHER REGULATIONS: The product is exempt from TSCA, it is FDA Regulated

Japanese Inventory (ENCS) This product complies with JPENCS

Component	Weight %	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Diphenhydramine hydrochloride 147-24-0	5	Not Listed	Not Listed	Not Listed	Not Listed
Benzethonium chloride 121-54-0	<0.05	Not Listed	Not Listed	Not Listed	Not Listed
Water 7732-18-5	>94	Not Listed	Not Listed	Not Listed	Not Listed

STATE REGULATIONS:

Component	California Prop. 65	Minnesota Right-To -Know:	Florida Right-to-Know Reporting List:	Rhode Island Right-to-Know List:	Massachusetts Right-to-Know List:	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:
Diphenhydramine hydrochloride 147-24-0	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Benzethonium chloride 121-54-0	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Water 7732-18-5	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

CANADIAN REGULATIONS:

Product id: 1102387

Product name: Diphenhydramine Hydrochloride Injection, USP

Canada DSL Inventory List - This product complies with DSL

EU EINECS List - This product complies with EINECS

Risk Phrases:
NONE

Safety Phrases:
NONE

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s)?:

Additional product codes. Changes to Section 8. Changes to Section 7. Changes to Section 1.

Additional information:
Not Available.

Prepared by: Technology Resources, Baxter Healthcare Corporation

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End of safety data sheet: