



WEST-WARD

Material Safety Data Sheet

Revision date: 01/18/2012

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1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

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 vials
Product Use: Pharmaceutical.

Supplier:
WEST-WARD PHARMACEUTICALS
EATONTOWN, NJ 07724

Emergency telephone number: CHEMTREC: USA & Canada (800) 424-9300 OUTSIDE USA +1 703-527-3887

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.

Product name: Diphenhydramine Hydrochloride Injection, USP

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.
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/Storage 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.

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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.

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10. STABILITY AND REACTIVITY

Polymerization:	Not applicable
Hazardous decomposition products:	Not available.
Materials to avoid:	Acids. Bases. Oxidizing agents.

11. TOXICOLOGICAL INFORMATION

Component	LD50s and LC50s
Diphenhydramine hydrochloride 147-24-0	Oral LD50 Rat = 500 mg/kg Oral LD50 Mouse = 164 mg/kg Intravenous LD50 Rat = 35 mg/kg Intravenous LD50 Mouse = 20 mg/kg Intravenous LD50 Dog = 24 mg/kg Intravenous LD50 Rabbit = 10 mg/kg
Benzethonium chloride 121-54-0	Oral LD50 Mouse = 338 mg/kg Oral LD50 Rat = 368 mg/kg
Water 7732-18-5	Oral LD50 Rat: >50000 mg/kg

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.

Product name: Diphenhydramine Hydrochloride Injection, USP

12. ECOLOGICAL INFORMATION

Water 7732-18-5	None.	None.	None.	None.
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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 - The product is exempt from TSCA, it is FDA Regulated

OTHER REGULATIONS:

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15. REGULATORY INFORMATION

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	5	Not Listed	Not Listed	Not Listed	Not Listed
Benzethonium chloride	<0.05	Not Listed	Not Listed	Not Listed	Not Listed
Water	>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	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Benzethonium chloride	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Water	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

CANADIAN REGULATIONS:

Canada DSL Inventory List -

This product does not comply with DSL

EU EINECS List -

This product complies with EINECS

Risk Phrases:

Not determined

Safety Phrases:

Not Determined

16. OTHER INFORMATION

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

Updated company name from Baxter to West-Ward. Updated NDC codes

Additional information:

Not Available.

Prepared by:

West-Ward Pharmaceuticals

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

End of safety data sheet

Product name: Diphenhydramine Hydrochloride Injection, USP