



Material Safety Data Sheet

MSDS Number: 1102387
Revision date: 01/13/2010
Print date: 01/13/2010

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 (847) 948-4770

Emergency telephone number: PROSAR: USA (888) 990-0996 OUTSIDE USA (615)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.

Product id: 1102387

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.

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.

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 id: 1102387

Product name: Diphenhydramine Hydrochloride Injection, USP

12. ECOLOGICAL INFORMATION

| | | | | |
|--------------------|-------|-------|-------|-------|
| 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

Product id: 1102387

Product name: Diphenhydramine Hydrochloride
Injection, USP

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)?:

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

Additional information:

Not Available.

Prepared by:

Technology Resources, Baxter Healthcare Corporation

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.

Product id: 1102387

Product name: Diphenhydramine Hydrochloride Injection, USP

16. OTHER INFORMATION

End of safety data sheet:

Product id: 1102387

**Product name: Diphenhydramine Hydrochloride
Injection, USP**