Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MSDS Number: 1102387
Revision date: 11/12/2003
Print date: 11/13/2003

Product name: Diphenhydramine Hydrochloride Injection, USP
Product code: 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

<table>
<thead>
<tr>
<th>Component</th>
<th>Weight %</th>
<th>UN Number</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphenhydramine hydrochloride</td>
<td>5</td>
<td>None</td>
<td>T</td>
</tr>
<tr>
<td>147-24-0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzethonium chloride</td>
<td>&lt;0.05</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>121-54-0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water</td>
<td>&gt;94</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>7732-18-5</td>
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</tbody>
</table>

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.

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 applicable

Flammable limits in air-lower (%): Not applicable

Flammable limits in air-upper (%): Not applicable

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. Keep at temperatures between 15 and 30 °C (59 to 86°F).

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

Product id: 1102387  Product name: Diphenhydramine Hydrochloride Injection, USP
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Component</th>
<th>OSHA- Time Weighted Average:</th>
<th>OSHA- Short Term Exposure Limit:</th>
<th>OSHA- Ceiling Limits</th>
<th>ACGIH- Time Weighted Average:</th>
<th>ACGIH- Short Term Exposure Limit:</th>
<th>ACGIH- Ceiling Limit Value:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphenhydramine hydrochloride</td>
<td>None</td>
<td>None</td>
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<td>None</td>
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Engineering measures: No special containment is required. Good general ventilation should be sufficient to control airborne levels.

Personal protective equipment:

**Respiratory protection:** Perform exposure monitoring for this product and its components to ensure that employees are not exposed to levels greater than applicable regulatory limits. If exposure levels exceed regulatory limits, implement a respiratory protection program including respiratory protection that is in compliance with OSHA 29 CFR1910.134 (in the US) or equivalent regulation in other regions. Fire fighting requires the use of a self-contained breathing apparatus with full face piece and positive pressure mode.

**Hand protection:** Use chemical resistant, impervious gloves.

**Skin and body protection:** Work uniform or laboratory coat.

**Eye protection:** Safety glasses. Goggles, face shield, or other full-face protection if potential exists for direct exposure to aerosols or splashes.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state:</td>
<td>Liquid</td>
</tr>
<tr>
<td>Appearance:</td>
<td>Aqueous solution</td>
</tr>
<tr>
<td>Color:</td>
<td>Colorless</td>
</tr>
<tr>
<td>Odor:</td>
<td>Not available.</td>
</tr>
<tr>
<td>pH:</td>
<td>4.0 - 6.5</td>
</tr>
<tr>
<td>Molecular weight:</td>
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</tr>
<tr>
<td>Boiling point/range:</td>
<td>Not available.</td>
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<tr>
<td>Melting point/range:</td>
<td>Not available.</td>
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<tr>
<td>Density:</td>
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<tr>
<td>Vapor pressure:</td>
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<tr>
<td>Evaporation rate:</td>
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</tr>
<tr>
<td>Solubility:</td>
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<tr>
<td>Partition coefficient (n-octanol/water):</td>
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</tr>
<tr>
<td>Viscosity:</td>
<td>Not available.</td>
</tr>
<tr>
<td>% Volatile by Volume:</td>
<td>Not available.</td>
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</table>

Product id: 1102387  Product name: Diphenhydramine Hydrochloride Injection, USP
10. STABILITY AND REACTIVITY

Stability: Stable under recommended storage conditions.
Polymerization: Not applicable
Hazardous decomposition products: Not available.

11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Component</th>
<th>LD50s and LC50s</th>
</tr>
</thead>
</table>
| 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:
<table>
<thead>
<tr>
<th>Component</th>
<th>Ecotoxicity - Water Flea Data</th>
<th>FishSpecies Ecotoxicity</th>
<th>Ecotoxicity - Freshwater Algae Data</th>
<th>Microtox Etoxicity Data</th>
</tr>
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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

Product id: 1102387
Product name: Diphenhydramine Hydrochloride Injection, USP
15. REGULATORY INFORMATION

U.S. Regulations:
TSCA Inventory List - The product is exempt from TSCA, it is FDA Regulated
OTHER REGULATIONS:
Japanese Inventory (ENCS) This product complies with JPENCS

<table>
<thead>
<tr>
<th>Component</th>
<th>Weight %</th>
<th>RCRA Status:</th>
<th>CERCLA Reportable Quantity:</th>
<th>CERCLA/SARA - 302 Ext. haz. substances:</th>
<th>Listed as Sara 313 title III:</th>
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STATE REGULATIONS:

<table>
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<tr>
<th>Component</th>
<th>California Prop 65:</th>
<th>Minnesota Right-To-Know Reporting List:</th>
<th>Florida Right-To-Know Reporting List:</th>
<th>Rhode Island Right-to-Know List:</th>
<th>Massachusetts Right-to-Know List:</th>
<th>Pennsylvania Right-to-Know:</th>
<th>New Jersey Right-to-Know:</th>
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CANADIAN REGULATIONS:

Canada DSL Inventory List - This product does not comply 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.

Additional information: Not Available.

Prepared by: Technology Resources, Baxter Healthcare Corporation
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End of safety data sheet: