MATERIAL SAFETY DATA SHEET

Product Name: Diphenhydramine Hydrochloride Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address
Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Emergency Telephone
CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia (02) 8014 4880

Hospira, Inc., Non-Emergency
224-212-2000

Product Name
Diphenhydramine Hydrochloride Injection

Synonyms
2-(Diphenylmethoxy)-N,N-dimethylethylamine hydrochloride.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Diphenhydramine Hydrochloride

Chemical Formula
C17H21NO•HCl

Preparation
Non-hazardous ingredients include Water for Injection. Sodium hydroxide or hydrochloric acid may be added to adjust the pH.

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphenhydramine Hydrochloride</td>
<td>5</td>
<td>147-24-0</td>
<td>KR7000000</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphenhydramine Hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Diphenhydramine Hydrochloride Injection is a solution containing diphenhydramine hydrochloride, an antihistamine used for relief of symptoms associated with allergies or colds; it is also used for the treatment of symptoms associated with motion sickness. In the workplace, this material should be considered potentially irritating to eyes and the respiratory tract. Based on clinical use, possible target organs include skin, eyes, central nervous system, and gastrointestinal system.

Occupational Exposure Potential
Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms
None known from occupational exposure. In clinical use, adverse effects may include sedation, sleepiness, dyspnea, breathing difficulty, disturbed coordination, gastrointestinal upset and thickened bronchial secretion. Allergic dermatitis is not uncommon in topically applied H1-blockers. Over dosage can result in atropine like signs (dry-mouth, dilated pupils, flushing and gastrointestinal symptoms) and cycles of CNS depression and stimulation (hallucinations, incoordination and convulsions).
Medical Conditions Aggravated by Exposure
Pre-existing hypersensitivity to diphenhydramine base and salts; pre-existing ailments such as narrow-angle glaucoma, peptic ulcers and other gastrointestinal disorders, bladder obstruction, prostatic hypertrophy, asthma, hyperthyroid, cardiovascular disease, and hypertension.

4. FIRST AID MEASURES

Eye contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability
None anticipated for this aqueous product.

Fire & Explosion Hazard
None anticipated for this aqueous product.

Extinguishing media
As with any fire, use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures
No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal
Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling
No special handling required under conditions of normal product use.

Storage
No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions
No special precautions required for hazard control.
## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>mg/m³</th>
<th>ppm</th>
<th>µg/m³</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphenhydramine Hydrochloride</td>
<td>Not Applicable</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>None Established</td>
</tr>
</tbody>
</table>

### Respiratory protection

Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA’s 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

### Skin protection

If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

### Eye protection

Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

### Engineering Controls

Engineering controls are normally not needed during the normal use of this product.

## 9. PHYSICAL/CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance/Physical State</strong></td>
<td>Liquid</td>
</tr>
<tr>
<td><strong>Color</strong></td>
<td>Clear</td>
</tr>
<tr>
<td><strong>Odor</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Odor Threshold:</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>pH:</strong></td>
<td>Between 4 and 6.5</td>
</tr>
<tr>
<td><strong>Melting point/Freezing point:</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Initial Boiling Point/Boiling Point Range:</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Evaporation Rate:</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Flammability (solid, gas):</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Upper/Lower Flammability or Explosive Limits:</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Vapor Pressure:</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Vapor Density:</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Specific Gravity:</strong></td>
<td>1.005</td>
</tr>
<tr>
<td><strong>Solubility:</strong></td>
<td>Freely soluble in water and alcohol</td>
</tr>
<tr>
<td><strong>Partition coefficient: n-octanol/water:</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Auto-ignition temperature:</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Decomposition temperature:</strong></td>
<td>NA</td>
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</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity
Not determined.

Chemical Stability
Stable under standard use and storage conditions.

Hazardous Reactions
Not determined.

Conditions to avoid
Not determined.

Incompatibilities
Not determined.

Hazardous decomposition products
Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and hydrogen chloride.

Hazardous Polymerization
Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity
Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphenhydramine Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>500, 700</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>64, 164</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>280</td>
<td>mg/kg</td>
<td>Guinea Pig</td>
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<tr>
<td>Diphenhydramine Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>35</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>20</td>
<td>mg/kg</td>
<td>Mouse</td>
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<td>10</td>
<td>mg/kg</td>
<td>Rabbit</td>
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<td></td>
<td>18</td>
<td>mg/kg</td>
<td>Hamster</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>24</td>
<td>mg/kg</td>
<td>Dog</td>
</tr>
</tbody>
</table>

Aspiration Hazard
None anticipated from normal handling of this product.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with redness and tearing.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product.

Reproductive Effects
Reproduction studies have been performed in rats and rabbits at doses up to 5 times the human dose and have shown no evidence of impaired fertility or harm to the fetus due to diphenhydramine hydrochloride.

Mutagenicity
Long-term studies in animals to determine mutagenic potential have not been conducted.

Carcinogenicity
Long-term studies in animals to determine the carcinogenic potential have not been conducted.
Product Name: Diphenhydramine Hydrochloride Injection

Target Organ Effects
Possible target organs include skin, eyes, central nervous system and gastrointestinal system.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity
Not determined for product.

Persistence/Biodegradability
Not determined for product.

Bioaccumulation
Not determined for product.

Mobility in Soil
Not determined for product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal
All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal
Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS: Not regulated

IMDG STATUS: Not regulated

ICAO/IATA STATUS: Not regulated

Transport Comments: None

15. REGULATORY INFORMATION

USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphenhydramine Hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
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</tbody>
</table>

RCRA Status: Not Listed

U.S. OSHA Classification: Target Organ Toxin

GHS Classification: Possible Irritant

*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

Hazard Class: Not Applicable
Product Name: Diphenhydramine Hydrochloride Injection

Hazard Category Not Applicable

Signal Word Not Applicable

Symbol Not Applicable

Prevention P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

Hazard Statement H00 - Not Applicable

Response: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

Get medical attention if you feel unwell.

EU Classification*
*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Diphenhydramine Hydrochloride.

Classification(s): Not Applicable

Symbol: Not Applicable

Indication of Danger: Not Applicable

Risk Phrases: Not Applicable

Safety Phrases: S23 - Do not breathe vapor.

S24/25 - Avoid contact with skin and eyes.

S37/39 - Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION:

Notes:

ACGIH TLV American Conference of Governmental Industrial Hygienists – Threshold Limit Value

CAS Chemical Abstracts Service Number

CERCLA US EPA, Comprehensive Environmental Response, Compensation, and Liability Act

DOT US Department of Transportation Regulations

EEL Employee Exposure Limit

IATA International Air Transport Association

LD50 Dosage producing 50% mortality

NA Not applicable/Not available

NE Not established

NIOSH National Institute for Occupational Safety and Health

OSHA PEL US Occupational Safety and Health Administration – Permissible Exposure Limit

Prop 65 California Proposition 65

RCRA US EPA, Resource Conservation and Recovery Act

RTECS Registry of Toxic Effects of Chemical Substances

SARA Superfund Amendments and Reauthorization Act

STEL 15-minute Short Term Exposure Limit

TSCA Toxic Substance Control Act

TWA 8-hour Time Weighted Average
Product Name: Diphenhydramine Hydrochloride Injection

MSDS Coordinator: Hospira GEHS
Date Prepared: 09/15/2011
Obsolete Date: 10/21/2008

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