MATERIAL SAFETY DATA SHEET

Product Name: Demerol Meperidine Hydrochloride Injection, Solution

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 Demerol Meperidine Hydrochloride Injection, Solution

Synonyms Ethyl 1-methyl-4-phenylisonipecotate hydrochloride. * Demerol is a registered trademark of Sanofi Pharmaceuticals Inc.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Meperidine Hydrochloride

Chemical Formula C_{15}H_{21}NO_{2} • HCl

Preparation Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% may include sodium hydroxide and/or hydrochloric acid which are added for pH adjustment. In some preparations, sodium acetate (anhydrous) and glacial acetic acid are added as buffers. Multiple dose vials may contain metacresol 0.1 percent as preservative.

<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>Meperidine Hydrochloride</td>
<td>≤ 10</td>
<td>50-13-5</td>
<td>NS5950000</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>Meperidine Hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview Demerol (Meperidine Hydrochloride) Injection, Solution contains meperidine hydrochloride, a narcotic analgesic which produces analgesia and sedation. In the US, meperidine hydrochloride is a Schedule II controlled substance. Clinically, it is indicated for the relief of moderate to severe pain, for preoperative medication, for support of anesthesia, and for obstetrical analgesia. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the central nervous system, respiratory system and cardiovascular 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 No signs or symptoms from occupational exposure are known. In clinical use, adverse effects
may include euphoria, lightheadedness, dizziness, facial flushing, sedation, nausea, sweating, vomiting, dry mouth, constipation, pinpoint pupils, muscle rigidity and/or twitching, and respiratory depression. Other effects on the heart and circulatory system can include change in heart rate (fast or slow), palpitations, decreased blood pressure, and fainting. Rarely, allergic reactions have occurred. Shock and cardiac arrest have been reported following overdose.

Medical Conditions Aggravated by Exposure
Hypersensitivity to this or similar materials; pre-existing central nervous system, cardiovascular system, or respiratory system ailments; concurrent therapy with monoamine oxidase (MAO) inhibitors; pre-existing asthma, chronic obstructive pulmonary disease or cor pulmonale, or substantially decreased respiratory reserve.

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. In the US, meperidine hydrochloride is a Schedule II controlled substance. Additional training may be required for proper handling of this product.

Storage
No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary
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container label, or the product insert. In the US, meperidine hydrochloride is a Schedule II controlled substance. Additional training may be required for proper storage of this product.

**Special Precautions**
No special precautions required for hazard control.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Exposure Guidelines</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component</td>
<td>Type</td>
</tr>
<tr>
<td>Meperidine Hydrochloride</td>
<td>Not Applicable</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>Appearance/Physical State</th>
<th>Liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>Clear and Colorless Solution</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
<tr>
<td>pH:</td>
<td>Between 3.5 and 6.0</td>
</tr>
<tr>
<td>Melting point/Freezing point:</td>
<td>NA</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point Range:</td>
<td>NA</td>
</tr>
<tr>
<td>Evaporation Rate:</td>
<td>NA</td>
</tr>
<tr>
<td>Flammability (solid, gas):</td>
<td>NA</td>
</tr>
<tr>
<td>Upper/Lower Flammability or Explosive Limits:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Pressure:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Density:</td>
<td>NA</td>
</tr>
<tr>
<td>Specific Gravity:</td>
<td>5% solution at 20C = 1.086; 10% solution at 20C = 1.0165</td>
</tr>
<tr>
<td>Solubility:</td>
<td>Meperidine hydrochloride is readily soluble in water</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water:</td>
<td>NA</td>
</tr>
<tr>
<td>Auto-ignition temperature:</td>
<td>NA</td>
</tr>
</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>Meperidine Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>170</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>178</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>500</td>
<td>mg/kg</td>
<td>Rabbit</td>
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<tr>
<td>Meperidine Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>30</td>
<td>mg/kg</td>
<td>Rat</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>32</td>
<td>mg/kg</td>
<td>Mouse</td>
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<tr>
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<td>20</td>
<td>mg/kg</td>
<td>Rabbit</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>68</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. Occasionally, during clinical use pruritus, urticaria, other skin rashes, and wheal and flare following intravenous injection have been reported in patients.

Reproductive Effects Studies to assess the reproductive effects of meperidine have not been conducted.

Mutagenicity Studies to assess the mutagenic potential of meperidine have not been conducted.
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**Carcinogenicity**
Studies to assess the carcinogenic potential of meperidine have not been conducted.

**Target Organ Effects**
Based on clinical use, possible target organs include the central nervous system, respiratory system and cardiovascular 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. Disposal should be performed in accordance with the federal, state or local regulatory requirements. In the US, meperidine hydrochloride is a Schedule II controlled substance. Additional requirements may be necessary for proper disposal of this material.

**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>Meperidine Hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**RCRA Status**
Not Listed

**U.S. OSHA Classification**
Possibly Toxic by Ingestion

**Target Organ Toxin**
Possible Irritant

**GHS**
*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as
Product Name: Demerol Meperidine Hydrochloride Injection, Solution

**Classification**
medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

**Hazard Class** Not Applicable

**Hazard Category** Not Applicable

**Signal Word** Not Applicable

**Symbol** Not Applicable

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

**Hazard Statement** 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 Meperidine 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 - Avoid contact with skin.
  S25 - Avoid contact with 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 law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT US Department of Transportation Regulations
EC50 Concentration in water that produces 50% inhibition of growth in algae
EEL Employee Exposure Limit
IATA International Air Transport Association
LC50 Concentration in water that produces 50% mortality in fish
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
Product Name: Demerol Meperidine Hydrochloride Injection, Solution

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

MSDS Coordinator: Hospira GEHS
Date Prepared: 10/17/2011
Obsolete Date: 04/14/2008

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