SAFETY DATA SHEET

Product Name: Meperidine Hydrochloride Injection, USP

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

| Manufacturer Name And Address | Hospira, Inc.  
| Address | 275 North Field Drive  
|         | Lake Forest, Illinois 60045  
|         | USA  
| Emergency Telephone | CHEMTREC: North America: 800-424-9300;  
|                     | International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418  
| Hospira, Inc., Non-Emergency | 224 212-2000  
| Product Name | Meperidine Hydrochloride Injection, USP  
| Synonyms | Ethyl 1-methyl-4-phenylisonipecotate hydrochloride  

2. HAZARD(S) IDENTIFICATION

Emergency Overview  Meperidine Hydrochloride Injection, USP is a solution containing 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.

U.S. OSHA GHS Classification

<table>
<thead>
<tr>
<th>Physical Hazards</th>
<th>Hazard Class</th>
<th>Hazard Category</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not Classified</td>
<td>Not Classified</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Health Hazards</th>
<th>Hazard Class</th>
<th>Hazard Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>STOT - RE</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

Label Element(s)

Pictogram

Signal Word  Warning

Hazard Statement(s)  May cause damage to organs through prolonged or repeated exposure

Precautionary Statement(s)

Prevention  Do not breathe vapor or spray  
Wash hands thoroughly after handling

Response  Get medical attention if you feel unwell.  
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.
3. COMPOSITION/INFORMATION ON INGREDIENTS

<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>1</td>
<td>50-13-5</td>
<td>NS5950000</td>
</tr>
</tbody>
</table>

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.

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 such as carbon dioxide, dry chemical extinguishing powder or foam.

**Special Fire Fighting Procedures**
No special provisions required beyond normal firefighting 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 control 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 container label, or the product insert. 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

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>OSHA-PEL</th>
<th>ACGIH-TLV</th>
<th>AIHA WEEL</th>
<th>Hospira EEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meperidine Hydrochloride</td>
<td>8-hr TWA: Not</td>
<td>8-hr TWA: Not</td>
<td>8-hr TWA: Not</td>
<td>8-hr TWA: Not</td>
</tr>
<tr>
<td></td>
<td>Established</td>
<td>Established</td>
<td>Established</td>
<td>Established</td>
</tr>
</tbody>
</table>

Notes:  
OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit  
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value  
AIHA WEEL: Workplace Environmental Exposure Level  
EEL: Employee Exposure Limit  
TWA: 8-hour Time Weighted Average.

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>Appearance/Physical State</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>Flash Point</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 (Air =1)</td>
<td>NA</td>
</tr>
<tr>
<td>Relative Density (Air =1)</td>
<td>A 5 percent solution has a specific gravity of 1.0086 at 20°C and 10 percent solution, a specific gravity of 1.0165 at 20°C</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>
<tr>
<td>Decomposition Temperature</td>
<td>NA</td>
</tr>
<tr>
<td>Viscosity</td>
<td>NA</td>
</tr>
</tbody>
</table>
Product Name: Meperidine Hydrochloride Injection, USP

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 active ingredient 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>
</tr>
<tr>
<td>Meperidine Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>30</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>32</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>20</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>68</td>
<td>mg/kg</td>
<td>Dog</td>
</tr>
</tbody>
</table>

LD 50: Dosage that produces 50% mortality.

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 anticipated from normal handling of this product. 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.

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
None anticipated from normal handling of this product. 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.
11. TOXICOLOGICAL INFORMATION: continued

Carcinogenicity

Studies to assess the carcinogenic potential of meperidine have not been conducted.

Carcinogen Lists

IARC: Not listed  NTP: Not listed  OSHA: Not listed

Specific Target Organ Toxicity

– Single Exposure

NA

– Repeat Exposure

Based on clinical use, possible target organs include the 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.

Notes:

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. 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

Proper Shipping Name

NA

Hazard Class

NA

UN Number

NA

Packing Group

NA

Reportable Quantity

NA

ICAO/IATA STATUS

Not regulated

Proper Shipping Name

NA

Hazard Class

NA

UN Number

NA

Packing Group

NA

Reportable Quantity

NA

IMDG STATUS

Not regulated

Proper Shipping Name

NA

Hazard Class

NA

UN Number

NA

Packing Group

NA

Reportable Quantity

NA

Notes: DOT - US Department of Transportation Regulations
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>US TSCA Status</th>
<th>Exempt</th>
</tr>
</thead>
<tbody>
<tr>
<td>US CERCLA Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>US SARA 302 Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>US SARA 313 Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>US RCRA Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>US PROP 65 (Calif.)</td>
<td>Not listed</td>
</tr>
</tbody>
</table>


**GHS/CLP Classification**

*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.*

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Hazard Category</th>
<th>Pictogram</th>
<th>Signal Word</th>
<th>Hazard Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

**Prevention**

Do not breathe vapor or spray
Wash hands thoroughly after handling

**Response**

Get medical attention if you feel unwell.
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.

**EU Classification**

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.*

<table>
<thead>
<tr>
<th>Classification(s)</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symbol</td>
<td>NA</td>
</tr>
<tr>
<td>Indication of Danger</td>
<td>NA</td>
</tr>
<tr>
<td>Risk Phrases</td>
<td>NA</td>
</tr>
<tr>
<td>Safety Phrases</td>
<td>S23: Do not breathe vapor/spray</td>
</tr>
<tr>
<td></td>
<td>S24: Avoid contact with the skin</td>
</tr>
<tr>
<td></td>
<td>S25: Avoid contact with eyes</td>
</tr>
<tr>
<td></td>
<td>S37/39 Wear suitable gloves and eye/face protection.</td>
</tr>
</tbody>
</table>

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
- 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
- STOT - SE: Specific Target Organ Toxicity – Single Exposure
- STOT - RE: Specific Target Organ Toxicity – Repeated Exposure
- TSCA: Toxic Substance Control Act
- TWA: 8-hour Time Weighted Average
16. OTHER INFORMATION: continued

MSDS Coordinator: Hospira GEHS
Date Prepared: October 18, 2012
Date Revised: June 02, 2014

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