MATERIAL SAFETY DATA SHEET

Product Name: Morphine Sulfate Injection (with additives)

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 - 61-290372994; UK - 44-870-8200418

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

Product Name
Morphine Sulfate Injection (with additives)

Synonyms
7, 8-didehydro-4, 5α-epoxy-17-methylmorphinan-3, 6α-diol sulfate (2:1) (salt), pentahydrate

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Morphine Sulfate Pentahydrate

Chemical Formula
C₃₄H₃₈N₂O₆ • H₂O • S • 5H₂O

Preparation
Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% may include sodium chloride, edetate disodium, sodium biphosphate, sodium metabisulfite, sodium formaldehyde sulfoxylate, and phenol. Sulfuric acid, hydrochloric acid, and/or sodium hydroxide 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>Morphine Sulfate Pentahydrate</td>
<td>≤5</td>
<td>6211-15-0</td>
<td>QC8760000</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>Morphine Sulfate Pentahydrate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Morphine Sulfate Injection (with additives) is a solution containing morphine sulfate, a narcotic analgesic used for the management of pain not responsive to non-narcotic analgesics. In the US, morphine sulfate is a Schedule II controlled substance with abuse potential. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract and a potent drug. Based on clinical use, possible target organs include the central nervous system, eyes, respiratory system, gastrointestinal system and cardiovascular system.

Occupational Exposure Potential
Information on the absorption of this product via inhalation is not available. There is evidence to suggest that morphine has some potential for absorption through the skin. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms
In the workplace, hypersensitivity reactions, including asthma, have been reported following
Product Name: Morphine Sulfate Injection (with additives)

occupational exposures to narcotic dusts during the processing of raw opiates. In clinical use, the most common adverse effects are nausea, vomiting, lightheadedness, dizziness, sedation, constipation, urinary retention and sweating. Morphine sulfate can produce physical and psychological dependence. Morphine, like other narcotic analgesics, can cause respiratory depression at high doses. Circulatory depression, respiratory arrest, shock and cardiac arrest have also been reported. Morphine sulfate can cause physical and psychological dependence to develop in some patients. The probable lethal oral dose is between 120 and 250 mg; parenteral doses of less than 30 mg have produced serious toxicity. Respiratory failure is the most common cause of death. Naloxone is the antagonist of choice for morphine poisoning.

Medical Conditions Aggravated by Exposure

Pre-existing hypersensitivity to this material or similar materials; pre-existing ocular, central nervous system, respiratory system, gastrointestinal system or cardiovascular system ailments; pre-existing chemical dependency concerns.

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. Overdosage is characterized by respiratory depression with or without concomitant CNS depression. Since respiratory arrest may result either through direct depression of the respiratory center or as the result of hypoxia, primary attention should be given to the establishment of adequate respiratory exchange through provision of a patent airway and institution of assisted or controlled ventilation. The narcotic antagonist, naloxone, is a specific antidote. Naloxone hydrochloride should be administered intravenously, simultaneously with respiratory resuscitation. As the duration of effect of naloxone is considerably shorter than that of morphine, repeated administration may be necessary. Patients should be closely observed for evidence of renarcotization.

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 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 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 for hazard control under conditions of normal product use. In the US, morphine sulfate is a Schedule II controlled substance. Additional training may be required for handling this material.

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>Morphine Sulfate Pentahydrate</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

Appearance/Physical State  Liquid

Color  Clear to pale yellow solution

Odor  NA

Odor Threshold:  NA

pH:  2.5 to 6.5
Product Name: Morphine Sulfate Injection (with additives)

Melting point/Freezing point: NA
Initial Boiling Point/Boiling Point Range: NA
Evaporation Rate: NA
Flammability (solid, gas): NA
Upper/Lower Flammability or Explosive Limits: NA
Vapor Pressure: NA
Vapor Density: NA
Specific Gravity: NA
Solubility: Morphine sulfate pentahydrate is a white crystalline powder, soluble in water
Partition coefficient: n-octanol/water: NA
Auto-ignition temperature: NA
Decomposition temperature: NA

10. STABILITY AND REACTIVITY

Reactivity Not determined.
Chemical Stability Stable under standard use and storage conditions.
Hazardous Reactions Stable under standard use and storage conditions.
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), sulfur oxides (SOx), and hydrogen sulfide.
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>Morphine Sulfate Pentahydrate</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>973</td>
<td>mg/kg</td>
<td>Rat Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1125</td>
<td>mg/kg</td>
<td></td>
</tr>
<tr>
<td>Morphine Sulfate</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>461</td>
<td>mg/kg</td>
<td>Rat Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>600</td>
<td>mg/kg</td>
<td></td>
</tr>
<tr>
<td>Morphine Sulfate</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>70</td>
<td>mg/kg</td>
<td>Rat Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>156</td>
<td>mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>316</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.
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<table>
<thead>
<tr>
<th>Ocular Irritation/Corrosion</th>
<th>None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with redness and tearing.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermal or Respiratory Sensitization</td>
<td>None anticipated from normal handling of this product. In the workplace, hypersensitivity reactions, including asthma, have been reported following occupational exposures to narcotic dusts during the processing of raw opiates.</td>
</tr>
<tr>
<td>Reproductive Effects</td>
<td>Studies of morphine sulfate in animals to evaluate the effect on fertility have not been conducted. Morphine sulfate was not teratogenic in rats at 35 mg/kg/day, but did result in increased pup mortality and growth retardation at doses that narcotize the animal (&gt; 10 mg/kg/day, ten times the usual human dose). Morphine has also been shown to be teratogenic in hamsters when given in doses several hundred times the human dose.</td>
</tr>
<tr>
<td>Mutagenicity</td>
<td>Studies to evaluate the mutagenic potential of morphine sulfate have not been conducted.</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Studies to evaluate the carcinogenic potential of morphine sulfate have not been conducted.</td>
</tr>
<tr>
<td>Target Organ Effects</td>
<td>Based on clinical use, possible target organs include the central nervous system, eyes, respiratory system, gastrointestinal system and cardiovascular system.</td>
</tr>
</tbody>
</table>

### 12. ECOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Aquatic Toxicity</th>
<th>Not determined for product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persistence/Biodegradability</td>
<td>Not determined for product</td>
</tr>
<tr>
<td>Bioaccumulation</td>
<td>Not determined for product</td>
</tr>
<tr>
<td>Mobility in Soil</td>
<td>Not determined for product</td>
</tr>
</tbody>
</table>

### 13. DISPOSAL CONSIDERATIONS

<table>
<thead>
<tr>
<th>Waste Disposal</th>
<th>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, morphine sulfate is a Schedule II controlled substance and may have additional requirements for proper disposal.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Container Handling and Disposal</td>
<td>Dispose of container and unused contents in accordance with federal, state and local regulations.</td>
</tr>
</tbody>
</table>

### 14. TRANSPORTATION INFORMATION

<table>
<thead>
<tr>
<th>ADR/ADG/ DOT STATUS:</th>
<th>Not regulated</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMDG STATUS:</td>
<td>Not regulated</td>
</tr>
<tr>
<td>ICAO/IATA STATUS:</td>
<td>Not regulated</td>
</tr>
<tr>
<td>Transport Comments:</td>
<td>None</td>
</tr>
</tbody>
</table>
**Product Name:** Morphine Sulfate Injection (with additives)

### 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>Morphine Sulfate Pentahydrate</td>
<td>Not Listed</td>
<td>Not Listed</td>
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</tr>
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</table>

**RCRA Status** Not Listed

**U.S. OSHA Classification**

- Target Organ Toxin
- Possible Irritant

**GHS 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:

**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 Morphine Sulfate Pentahydrate.*

**Classification(s):** Not Applicable

**Symbol:** Not Applicable

**Indication of Danger:** Not Applicable

**Risk Phrases:** R00 - 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 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
- TSCA: Toxic Substance Control Act
- TWA: 8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: 10/19/2012
Obsolete Date: 10/27/2011

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