



SAFETY DATA SHEET

Product Name: Morphine Sulfate Injection (additive free)

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

| | |
|--------------------------------------|---|
| Manufacturer Name And Address | Hospira, Inc. 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 | Morphine Sulfate Injection (additive free) |
| Synonyms | 7, 8-didehydro-4, 5 α -epoxy-17-methylmorphinan-3, 6 α -diol sulfate (2:1) (salt), pentahydrate |

2. HAZARD(S) IDENTIFICATION

Emergency Overview Morphine Sulfate Injection (additive free) 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 nervous system, eyes, respiratory system, gastrointestinal system and cardiovascular system.

U.S. OSHA GHS Classification

| Physical Hazards | Hazard Class | Hazard Category |
|------------------|----------------------|-----------------|
| | Not Classified | Not Classified |
| Health Hazards | Hazard Class | Hazard Category |
| | Sensitization – Skin | 1 |
| | STOT – RE | 2 |

Label Element(s)

Pictogram



Signal Word

Warning

Hazard Statement(s)

May cause an allergic skin reaction
May cause damage to organs through prolonged or repeated exposure

Precautionary Statement(s)

Prevention

Do not breathe vapor or spray
Wear protective gloves
Wash hands thoroughly after handling
Contaminated work clothing must not be allowed out of the workplace

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.

IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical

advice/attention. Wash contaminated clothing before reuse.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Morphine Sulfate Pentahydrate
Chemical Formula $C_{34}H_{38}N_2O_6 \cdot H_2O_4S \cdot 5H_2O$

| Component | Approximate Percent by Weight | CAS Number | RTECS Number |
|-------------------------------|-------------------------------|------------|--------------|
| Morphine Sulfate Pentahydrate | ≤2.5 | 6211-15-0 | QC8760000 |

Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% may include sodium chloride, sodium hydroxide, hydrochloric acid, sulfuric acid, or citric acid anhydrous and sodium citrate may be added to adjust the pH.

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 re-narcotization.

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 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

| Component | Exposure Limits | | | |
|-------------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | OSHA-PEL | ACGIH-TLV | AIHA WEEL | Hospira EEL |
| Morphine Sulfate Pentahydrate | 8-hr TWA: Not Established | 8-hr TWA: Not Established | 8-hr TWA: Not Established | 8-hr TWA: Not Established |

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

| | |
|---|---|
| Appearance/Physical State | Clear to pale yellow solution |
| Odor | NA |
| Odor Threshold | NA |
| pH | 2.5 to 6.5 |
| Melting point/Freezing Point | NA |
| Initial Boiling Point/Boiling Point Range | NA |
| Flash Point | NA |
| Evaporation Rate | NA |
| Flammability (solid, gas) | NA |
| Upper/Lower Flammability or Explosive Limits | NA |
| Vapor Pressure | NA |
| Vapor Density (Air =1) | NA |
| Relative Density | 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 |
| Viscosity | NA |

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), 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 active ingredient is as follows:

| Ingredient(s) | Percent | Test Type | Route of Administration | Value | Units | Species |
|-------------------------------|----------------|------------------|--------------------------------|------------------|-------------------------|---------------------|
| Morphine Sulfate Pentahydrate | 100 | LD50 | Oral | 973 1125 | mg/kg mg/kg | Rat Mouse |
| Morphine Sulfate | 100 | LD50 | Oral | 461 600 | mg/kg mg/kg | Rat Mouse |
| Morphine Sulfate | 100 | LD50 | Intravenous | 70 156 316 | mg/kg mg/kg mg/kg | Rat Mouse Dog |

LD 50: Dosage that produces 50% mortality.

11. TOXICOLOGICAL INFORMATION: continued

| | | | |
|---|--|------------------------|-------------------------|
| 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 | 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. 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. | | |
| 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. In the workplace, hypersensitivity reactions, including asthma, have been reported following occupational exposures to narcotic dusts during the processing of raw opiates. | | |
| Reproductive Effects | None anticipated from normal handling of this product. Studies of morphine sulfate in animals to evaluate the effect on fertility have not been conducted. However, a non-clinical study in the literature in which male rats were administered morphine sulfate (subcutaneously prior to mating (up to 30 mg/kg twice daily) and during mating (20 mg/kg twice daily) with untreated females) reported a number of adverse reproductive effects including reduction in total pregnancies, higher incidence of pseudo-pregnancies, and reduction in implantation sites were seen. Morphine sulfate was not teratogenic in rats at a dosage of 35 mg/kg/day, but did result in increased pup mortality and growth retardation at doses that narcotize the animal (> 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. | | |
| Mutagenicity | Studies to evaluate the mutagenic potential of morphine sulfate have not been conducted. | | |
| Carcinogenicity | Studies to evaluate the carcinogenic potential of morphine sulfate have not been conducted. | | |
| Carcinogen Lists | IARC: Not listed | NTP: Not listed | OSHA: Not listed |
| Specific Target Organ Toxicity – Single Exposure | NA | | |
| Specific Target Organ Toxicity – Repeat Exposure | Based on clinical use, possible target organs include the nervous system, eyes, respiratory system, gastrointestinal 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 U.S., morphine sulfate is a Schedule II controlled substance and may have additional requirements for proper disposal. |
| 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

| | |
|----------------------------|------------|
| US TSCA Status | Exempt. |
| US CERCLA Status | Not listed |
| US SARA 302 Status | Not listed |
| US SARA 313 Status | Not listed |
| US RCRA Status | Not listed |
| US PROP 65 (Calif.) | Not listed |

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

15. REGULATORY INFORMATION: continued

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.

| Hazard Class | Hazard Category | Pictogram | Signal Word | Hazard Statement |
|--------------|-----------------|-----------|-------------|------------------|
| NA | NA | NA | NA | NA |

Prevention

Do not breathe vapor or spray
 Wear protective gloves
 Wash hands thoroughly after handling
 Contaminated work clothing must not be allowed out of the workplace

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.
 IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention.
 Wash contaminated clothing before reuse.

EU Classification*

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

Classification(s)

NA

Symbol

NA

Indication of Danger

NA

Risk Phrases

R43: May cause sensitization by skin contact

Safety Phrases

S23: Do not breathe vapor/spray
 S24: Avoid contact with the 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 |
| EEL | Employee Exposure Limit |
| IATA | International Air Transport Association |
| LD ₅₀ | 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

Product Name: Morphine Sulfate Injection (additive free)



16. OTHER INFORMATION: continued

MSDS Coordinator: Hospira GEHS
Date Prepared: October 28, 2011
Date Revised: June 02, 2014

Disclaimer:

The information and recommendations contained herein are based upon tests believed to be reliable. However, Hospira does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. Hospira assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.