



MATERIAL SAFETY DATA SHEET

Product Name: Morphine Sulfate Injection (with additives)

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address Hospira Inc.
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Lake Forest, Illinois USA
60045

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

Product Name Morphine Sulfate Injection (with additives)

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Morphine Sulfate Pentahydrate

Chemical Formula C₃₄H₃₈N₂O₆ • H₂O₄S • 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.

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Morphine Sulfate Pentahydrate	≤5	6211-15-0	QC8760000

3. HAZARD INFORMATION

Carcinogen List

Substance	IARC	NTP	OSHA
Morphine Sulfate Pentahydrate	Not Listed	Not Listed	Not Listed

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

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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

Component	Type	Exposure limits			Note
		mg/m ³	ppm	µg/m ³	
Morphine Sulfate Pentahydrate	Not Applicable	N/A	N/A	N/A	None Established

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

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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:

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

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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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	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 (> 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.
Target Organ Effects	Based on clinical use, possible target organs include the central 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

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, 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
IMDG STATUS:	Not regulated
ICAO/IATA STATUS:	Not regulated
Transport Comments:	None

15. REGULATORY INFORMATION

USA Regulations

Substance	TSCA Status	CERCLA Status	SARA 302 Status	SARA 313 Status	PROP 65 Status
Morphine Sulfate Pentahydrate	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

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

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