# MATERIAL SAFETY DATA SHEET

## Product Name: Naloxone Hydrochloride Injection

## 1. CHEMICAL PRODUCT AND COMPANY INFORMATION

| | |
|---|---|
| **Manufacturer Name And Address** | Hospira Inc.<br>275 North Field Drive<br>Lake Forest, Illinois USA<br>60045 |
| **Emergency Telephone** | CHEMTREC: North America: 800-424-9300;<br>International 1-703-527-3887; Australia (02) 8014 4880 |
| **Hospira, Inc., Non-Emergency** | 224-212-2000 |
| **Product Name** | Naloxone Hydrochloride Injection |
| **Synonyms** | 17-Allyl-4,5 α epoxy-3,14-dihydroxymorphinan-6-one hydrochloride |

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

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|---|---|
| **Active Ingredient Name** | Naloxone Hydrochloride |
| **Chemical Formula** | $C_{19}H_{21}NO_4 \bullet HCl$ |
| **Preparation** | Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% may include sodium chloride. Hydrochloric acid may be use to adjust the pH. Multiple-dose solutions contain methylparaben and propylparaben which are added as preservatives. |

| Component | Approximate Percent by Weight | CAS Number | RTECS Number |
|---|---|---|---|
| Naloxone Hydrochloride | 0.04 | 357-08-4 | QD2275000 |

## 3. HAZARD INFORMATION

**Carcinogen List**

| Substance | IARC | NTP | OSHA |
|---|---|---|---|
| Naloxone Hydrochloride | Not Listed | Not Listed | Not Listed |

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| **Emergency Overview** | Naloxone Hydrochloride Injection is a solution containing naloxone hydrochloride, a competitive antagonist of opioid receptors. Clinically, Naloxone prevents or reverses the effects of opioids including respiratory depression, sedation and hypotension. 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 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** | In the workplace, this material should be considered potentially irritating to eyes. In clinical use, adverse events associated with the use of naloxone hydrochloride injection in postoperative patients include hypotension, hypertension, ventricular tachycardia and fibrillation, dyspnea, pulmonary edema, and cardiac arrest. Death, coma, and encephalopathy have been reported as |

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| | sequelae of these events. When given to normal subjects, cognitive impairment and behavioral symptoms, including irritability, anxiety, tension, suspiciousness, sadness, difficulty concentrating, and lack of appetite were reported. In addition, somatic symptoms, including dizziness, heaviness, sweating, nausea, and stomachaches were also noted. |
| **Medical Conditions Aggravated by Exposure** | Pre-existing hypersensitivity to this material; pre-existing nervous system or cardiovascular system ailments. |

## 4. FIRST AID MEASURES

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| **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

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| **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

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| **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

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| **Handling** | No special handling required for hazard control under conditions of normal product use. |
| **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**

| | Exposure limits | | | | |
|---|---|---|---|---|---|
| **Component** | **Type** | **mg/m3** | **ppm** | **µg/m3** | **Note** |
| Naloxone Hydrochloride | 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

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|---|---|
| **Appearance/Physical State** | Liquid |
| **Color** | Nonpyrogenic solution in water |
| **Odor** | NA |
| **Odor Threshold:** | NA |
| **pH:** | 4.0 (3.0 to 6.5) |
| **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:** | soluble in water, in dilute acids, and in strong alkali; |
| **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** 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:

| Ingredient(s) | Percent | Test Type | Route of Administration | Value | Units | Species |
|---|---|---|---|---|---|---|
| Naloxone Hydrochloride | 100 | LD50 | Oral | >1000<br>>1000 | mg/kg<br>mg/kg | Rat<br>Mouse |
| Naloxone Hydrochloride | 100 | LD50 | Intravenous | 107<br>90 | mg/kg<br>mg/kg | Rat<br>Mouse |

**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. 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.

**Reproductive Effects** Reproduction studies conducted in mice and rats at doses 4-times and 8-times, respectively, the dose of a 50 kg human given 10 mg/day (based on surface area) demonstrated no embryotoxic or teratogenic effects due to naloxone.

**Mutagenicity** Naloxone was weakly positive in the Ames mutagenicity and in the in vitro human lymphocyte chromosome aberration test but was negative in the in vitro Chinese hamster V79 cell HGPRT mutagenicity assay and in the in vivo rat bone marrow chromosome aberration study.

**Carcinogenicity** Studies in animals to assess the carcinogenic potential of naloxone have not been conducted.

**Target Organ Effects** Based on clinical use, possible target organs include the central nervous 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.

**Container Handling and Disposal** Dispose of container and unused contents in accordance with federal, state and local regulations.

## 14. TRANSPORTATION INFORMATION

**DOT STATUS** Not regulated

**IMDG STATUS:** Not regulated

**ICAO/IATA STATUS:** Not regulated

## 15. REGULATORY INFORMATION

**USA Regulations**

| Substance | TSCA Status | CERCLA Status | SARA 302 Status | SARA 313 Status | PROP 65 Status |
|---|---|---|---|---|---|
| Naloxone Hydrochloride | 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 Naloxone Hydrochloride

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**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 - Wear suitable gloves.
S39 - Wear eye / face protection.

## 16. OTHER INFORMATION:

Notes:

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|---|---|
| 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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