

SAFETY DATA SHEET
Milrinone Lactate Injection, USP 1 mg/ml



Caplin Steriles Limited

SECTION 1: IDENTIFICATION

| | | |
|--------------------------------------|---|---|
| GHS Product Identifier | : | Milrinone Lactate Injection, USP 1 mg/ml |
| Chemical Name | : | 1,6-dihydro-2-methyl-6-oxo-[3,4'-bipyridine]-5-carbonitrile lactate |
| Other means of identification | : | Not Available |
| Product Code | : | Not Available |
| Product Type | : | Regulated prescription drug |
| Container Information | : | Glass Vial |

Relevant identified uses of the substance or mixture and uses advised against

| | | |
|-----------------------------------|---|--|
| Identified Uses | : | Short term intravenous infusion treatment of patients with acute decompensate heart failure. |
| Supplier Details | : | Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai, Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District), Pin Code: 601 201, Tamil Nadu (State), INDIA. |
| Emergency Telephone Number | : | +91-4467901901/02/03 |

SECTION 2: HAZARDS IDENTIFICATION

| | | |
|---|---|-------------------------------|
| OSHA/HCS Status | : | Not listed. |
| Classification of the substance or mixture | : | Controlled - Class: D2B Toxic |
| BVL Hazard category | : | 2 |

GHS Label Elements

| | | |
|---------------------------|---|---|
| Signal Word | : | Warning |
| Emergency overview | : | Overexposure may result in cardiovascular effects including hypotension |

This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.

Precautionary Statements

| | | |
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| Prevention | : | P201 - Obtain special instructions before use P202 - Do not handle until all safety precautions have been read and understood P280 - Wear protective gloves/protective clothing/eye protection/face protection |
| Response | : | P308 + P313 - IF exposed or concerned: Get medical attention/advice. |
| Storage | : | P405 - Store locked up |
| Disposal | : | P501 - Dispose of contents/container in accordance with all local and national regulations |

SAFETY DATA SHEET
Milrinone Lactate Injection, USP 1 mg/ml



Caplin Steriles Limited

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| Health Hazard (Acute & Chronic) | : Milrinone is an inotropic/vasodilator drug used for the treatment of Acute congestive heart failure. It affects the heart and circulatory systems and smooth muscle and digestive system. It is not carcinogenic, mutagenic or a reproductive hazard. Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace. |
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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

| | |
|---|---|
| Substance/Mixture | : Mixture |
| Chemical Name | : 1,6-dihydro-2-methyl-6-oxo-[3,4'-bipyridine]-5-carbonitrile lactate |
| Other means of identification | : Not Available. |
| CAS Number/Other Identifiers | |
| Product Code | : Not Available. |
| Ingredients | % CAS Number |
| Milrinone Lactate | 0.1 78415-72-2 |
| Dextrose Anhydrous, USP | 4.7 50-99-7 |
| Lactic Acid | 0.1 50-21-5 |
| Water for Injection, USP | Q.S. 7732-18-5 |
| Occupational exposure limits, if available, are listed in Section 8. | |
| See Package Insert for further information. | |

Sodium Hydroxide added for pH adjustment (if necessary)

SECTION 4: FIRST AID MEASURES

| | |
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| Description of necessary first aid measures | |
| Eye Contact | : If irritation or redness develops, move victim away from exposure and into fresh air. Flush eyes with clean water for at least 15 minutes and seek medical attention. |
| Inhalation | : If respiratory symptoms develop, move victim away from source of exposure and into fresh air. If symptoms persist, seek medical attention. If victim is not breathing, clear airway and immediately begin artificial respiration. If breathing difficulties develop, oxygen should be administered by qualified personnel. Seek immediate medical attention |
| Skin Contact | : Remove contaminated shoes and clothing and cleanse affected area(s) thoroughly by washing with mild soap and water. If irritation or redness develops and persists, seek medical attention |
| Ingestion | : If swallowed, seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. If not vomiting and professional advice is not available, DO NOT induce vomiting. If possible, do not leave victim unattended and observe closely for adequacy of breathing. |

SAFETY DATA SHEET
Milrinone Lactate Injection, USP 1 mg/ml



Caplin Steriles Limited

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| Other Measures | : | Victims of chemical exposure must be taken for medical attention. Take a copy of the MSDS to the physician or health professional with victim. Physicians should refer to Section XI (Toxicological Information) as well as the Physicians' Desk Reference for additional treatment information. |
| <u>Most important symptoms/effects, acute and delayed</u> | | |
| <u>Potential Acute Health Effects</u> For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information. | | |
| Eye Contact | : | minor irritation to eyes |
| Inhalation | : | minor irritation to respiratory tract |
| Skin Contact | : | minor irritation to Skin |
| Ingestion | : | nausea, vomiting and abdominal pain |
| <u>Over-Exposure Signs/Symptoms</u> | | |
| Eye Contact | : | stinging, watering, and redness of the eyes |
| Inhalation | : | irritation to respiratory tract |
| Skin Contact | : | Burning sensation on the skin |
| Ingestion | : | nausea, vomiting and abdominal pain |
| <u>Indication of immediate medical attention and special treatment needed, if necessary</u> | | |
| Notes to Physician | : | None. |
| Specific Treatments | : | None. |
| Protection of first-aiders | : | None. |
| See toxicological information (Section 11) | | |

SECTION 5: FIRE FIGHTING MEASURES

| | | |
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| Extinguishing Media | | |
| Suitable Extinguishing Media | : | Use water or multi-purpose ABC extinguisher. |
| Unsuitable extinguishing media | : | Not known. |
| Specific hazards arising from the chemical | : | Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion. |
| Hazardous thermal decomposition products | : | No specific data. |
| Special protective actions for fire-fighters | : | For fires beyond the incipient stage, emergency responders in the immediate hazard area should wear bunker gear. When the potential chemical hazard is unknown, in enclosed or confined spaces, or when explicitly required by DOT, a self-contained breathing apparatus should be worn. In addition, wear other appropriate protective equipment as conditions warrant (see Section XVIII). Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Move undamaged containers from immediate hazard area if it can be done with minimal risk. Cool equipment exposed to fire with water, if it can be done with minimal risk. |
| Special protective equipment for fire-fighters | : | |



SECTION 6: ACCIDENTAL RELEASE MEASURES

| <u>Personal precautions, protective equipment and emergency procedures</u> | | |
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| For Non-emergency Personnel | : | Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel. |
| For Emergency Responders | : | Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. |
| Environmental Precautions | : | <p>Release to Land: Absorb Milrinone with absorbent materials (soil may be used in the absence of other suitable materials) and dispose of according to local, state, and federal regulations.</p> <p>Release to Air: If aerosols are generated, wear a disposable dust/mist respirator (N95) to reduce Exposures. Ventilate the area and clean up spill immediately.</p> <p>Release to Water: Refer to local water authority; drain disposal is not recommended.</p> |

Methods and materials for containment and cleaning up

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|------------------------|---|--|
| Small Spill | : | For small releases of this product, wear latex or nitrile gloves and safety glasses. Absorb spilled liquid and rinse area thoroughly with soap and water |
| Large Spill | : | For large or uncontrolled releases, stay away from spill. Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Wear appropriate protective equipment including respiratory protection as conditions warrant (see Section 8). Prevent spilled material from entering sewers, storm drains, other unauthorized treatment drainage systems, and natural waterways. Notify appropriate federal, state, and local agencies. Immediate cleanup of any spill is recommended. |
| Decontamination | : | No specific decontamination or detoxification procedure has been identified for this product. |

SECTION 7: HANDLING AND STORAGE

| <u>Precautions for safe handling</u> | | |
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| Handling Procedures & Equipment | : | See Section VI above. Wear latex or nitrile gloves, safety glasses (protective coveralls and shoe covers for large spills) and a disposable dust/mist respiratory (N95). Wash thoroughly after handling. |
| Waste Disposal Method | : | Incineration in an approved /permitted incinerator is recommended. Refer to local, state, and federal rules. |
| Conditions for safe storage, including any incompatibilities | : | Store at 20° to 25°C (68 ° to 77°F). Avoid Freezing |

SAFETY DATA SHEET
Milrinone Lactate Injection, USP 1 mg/ml



Caplin Steriles Limited

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

| <u>Control Parameters</u> | |
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| Occupational Exposure classification | : Category 2 – Moderate (5 band system) |
| Appropriate Engineering Controls | : Use with adequate ventilation. Follow standard medical product handling procedures. |
| Environmental Exposure Controls | : Not Known |
| <u>Individual Protection Measures</u> | |
| Hygiene Measures | : Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Wash hands following use. No eating, drinking, or smoking while handling this product. |
| Eye/face Protection | : Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.) |
| Skin and Body Protection | : Work uniform or laboratory lab coat. |
| Hand Protection | : Nitrile or latex gloves. |
| Other Skin Protection | : Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.) |
| Respiratory Protection | : Under normal use, respirators are not required. General room ventilation is satisfactory. If aerosols are generated, use a disposable dust/mist respirator (N95). Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134. |

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

| <u>Appearance</u> | |
|-----------------------------|---|
| Physical State | : Liquid |
| Color | : Clear, Colorless to pale yellow liquid with no odor |
| Odor | : No odor |
| Odor Threshold | : Odorless |
| pH | : 3.2-4.0 |
| Melting Point | : No data Available |
| Boiling Point | : The lowest known value is 100°C (212°F) (Water) |
| Flash Point | : No data Available |
| Freezing Point (°C.) | : May start to solidify at 0°C (32°F) based on data for water |
| Specific gravity | : ~1 (Water = 1) |

SAFETY DATA SHEET
Milrinone Lactate Injection, USP 1 mg/ml



Caplin Steriles Limited

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|---|---|-------------------|
| Evaporation Rate | : | No data Available |
| Flammability (Solid, gas) | : | No data Available |
| Lower and Upper Explosive (flammable) limits | : | No data Available |
| Vapour Pressure | : | No data Available |
| Vapor Density | : | No data Available |
| Relative Density | : | No data Available |
| Solubility | : | Soluble in water |
| Partition Coefficient: n-octanol/water | : | No data Available |
| Auto Ignition Temperature | : | No data Available |
| Decomposition Temperature | : | No data Available |
| Viscosity | : | No data Available |

SECTION 10: STABILITY AND REACTIVITY

| | | |
|---|---|--|
| Reactivity | : | No data Available |
| Chemical Stability | : | Stable under normal conditions of use. |
| Possibility of Hazardous Reactions | : | None known |
| Conditions to Avoid | : | Store away from acids and oxidizers. |
| Incompatible Materials | : | Acids and strong oxidizers |
| Hazardous Decomposition Products | : | May emit toxic fumes of carbon and nitrogen oxides when burned. As with any burning material, carbon monoxide and carbon dioxide or other toxic gases may be produced. |

SECTION 11: TOXICOLOGICAL INFORMATION

Information on toxicological effects

Effects of acute exposure :

| Chemical Name | LD ₅₀ Oral (mg/kg) | | | LD ₅₀ Subcutaneous (mg/kg) | | LD ₅₀ IV (mg/kg) | | | |
|-------------------|-------------------------------|-------|--------|---------------------------------------|-------|-----------------------------|-------|--------|-----|
| | rat | mouse | rabbit | rat | mouse | rat | mouse | rabbit | dog |
| Milrinone Lactate | 91 | 137 | 40 | 58 | 62 | 73 | 79 | 44.4 | 25 |

Special Remarks on toxicity on animals: Oral and intravenous administration of toxic dosages of milrinone to rats and dogs resulted in myocardial degeneration/fibrosis and endocardial hemorrhage, periarterial edema and inflammation have been observed in dogs only. Doses within the recommended clinical dose range for congestive heart failure patients have not produced significant adverse effects in animals.

SAFETY DATA SHEET
Milrinone Lactate Injection, USP 1 mg/ml



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| Irritancy of Product | : | This product may be mildly irritating to contaminated skin, eyes and other tissues. |
| Skin and Respiratory Sensitization | : | No data to indicate it is a sensitizer. |
| Mutagenicity | : | No mutagenic potential was observed in the ames test, the mouse lymphoma assay, the micronucleus test, and the in vivo rat bone marrow metaphase analysis. However, the Chinese hamster ovary chromosome aberration assay was positive in the presence of a metabolic activation system. |
| <u>Carcinogenicity</u> | : | Not carcinogenic in mice or rats. This product, as well as all components, have NOT been identified as carcinogens by NTP, IARC or OSHA. |
| Reproductive Toxicity | : | Milrinone had no effect on male or female fertility at oral doses up to 32 mg/kg/day in rats. |
| Teratogenicity | : | Oral administration of milrinone to pregnant rats and rabbits during organogenesis produced no evidence of teratogenicity at dose levels up to 40 and 12 mg/kg/day, respectively. Although an increased absorption rate was apparent at both 8 and 12 mg/kg/day (intravenous) in rabbits. |
| Specific Target Organ Toxicity (Single Exposure) | : | There is no data available. |
| Aspiration Hazard | : | There is no data available. |
| Information on the likely Routes of Exposure | : | There is no data available. |
| <u>Potential acute health effects</u> | | |
| Eye Contact | : | There is no data available. |
| Inhalation | : | There is no data available. |
| Skin Contact | : | There is no data available. |
| Ingestion | : | There is no data available. |
| <u>Symptoms related to the physical, chemical and toxicological characteristics</u> | | |
| Eye Contact | : | There is no data available. |
| Inhalation | : | There is no data available. |
| Skin Contact | : | There is no data available. |
| Ingestion | : | There is no data available. |
| <u>Delayed and immediate effects and also chronic effects from short and long term exposure</u> | | |
| <u>Short Term Exposure</u> | | |
| Potential Immediate Effects | : | There is no data available. |
| Potential Delayed Effects | : | There is no data available. |
| <u>Long Term Exposure</u> | | |
| Potential Immediate Effects | : | There is no data available. |
| Potential Delayed Effects | : | There is no data available. |

SAFETY DATA SHEET
Milrinone Lactate Injection, USP 1 mg/ml



Caplin Steriles Limited

Potential Chronic Health Effects

| | | |
|--|---|-----------------------------|
| General | : | There is no data available. |
| Carcinogenicity | : | There is no data available. |
| Mutagenicity | : | There is no data available. |
| Teratogenicity | : | There is no data available. |
| Developmental Effects | : | There is no data available. |
| Fertility Effects | : | There is no data available. |
| <u>Numerical measures of toxicity</u> | | |
| Acute Toxicity Estimates | : | There is no data available. |

SECTION 12: ECOLOGICAL INFORMATION

| | | |
|---|---|--|
| Environmental Stability | : | This product will be relatively stable under ambient environmental conditions |
| Effect of Materials on Plants or Animals | : | No specific information is available on the effect of Milrinone Lactate on plants or animals in the environment. |
| Effect of Chemicals on Aquatic Life | : | No specific information is available on the effect of Milrinone Lactate on plants or animals in the aquatic environment. |

SECTION 13: DISPOSAL CONSIDERATIONS

| | | |
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| Waste Disposal | : | This material, if discarded as produced, is not a RCRA "listed" or "characteristic" hazardous waste. Use resulting in chemical or physical change or contamination may subject it to regulation as a hazardous waste. Waste must be disposed of in accordance with Federal, State and Local Environmental control regulations. |
| Contaminated Packaging | : | Follow any local, state, or federal regulations. |

SECTION 14: TRANSPORT INFORMATION

| | | |
|--|---|--|
| Special Shipping Information (general) | : | Milrin one Lactate Injection is not a DOT Hazardous Material. Milrinone Lactate Injection is not a Marine Pollutant. |
| Specific Local Transport Information or Classifications | : | Not applicable |

SECTION 15: REGULATORY INFORMATION

| | | |
|---|---|---|
| FDA | : | Milrinone Lactate Injection, USP 1 mg/ml is an approved prescription medication. |
| U.S. Federal Regulations | | |
| U.S. SARA Reporting Requirements | : | The components of this product are not subject to the reporting requirements of Sections 302, 304 and 313 of Title II of the Superfund Amendments and Reauthorization Act |

SAFETY DATA SHEET
Milrinone Lactate Injection, USP 1 mg/ml



Caplin Steriles Limited

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| U.S. SARA Threshold Planning Quantity | : | There is no data available. |
| U.S. CERCLA Reportable Quantities (RQ) | : | There is no data available. |
| U.S. TSCA Inventory Status | : | Milrinone Lactate is a "drug" as defined by the Federal Food, Drug and Cosmetic Act and is therefore not a chemical substance under TSCA. |
| <u>California Safe Drinking Water and Toxic Enforcement Act (Proposition 65)</u> | : | This product does not contain chemicals known to the State of California to cause cancer or reproductive effects. |
| Other U.S. Federal Regulations | : | Based on this product's use, the requirements of the OSHA Bloodborne pathogen Standard (29 CFR 1910.1030) are applicable. |

SECTION 16: OTHER INFORMATION

Use of this product should be through or under the direction of a physician. This MSDS does not address the therapeutic use of this material.

Persons administering this drug to patients must be careful to avoid needle sticks from syringes and other sharp objects used in the administration. All needle sticks must be reported to your company management.

History:

| | | |
|----------------------|---|----------|
| Issued Date | : | 25.08.21 |
| Revision Date | : | Nil |
| Version | : | 00 |

Notice to Reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

----End of SDS---