

SAFETY DATA SHEET
Milrinone Lactate in 5% Dextrose Injection



SECTION 1: IDENTIFICATION

Product Identifier

Product Name	:	Milrinone Lactate Injection
Recommended use of the chemical and restrictions on use		
Product Use	:	Pharmaceutical.
Product Type	:	Regulated Prescription Drug
Supplier Details	:	Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai, Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District), Pin Code: 601201, Tamil Nadu (State), INDIA.
Emergency Telephone Number	:	+91- 4467901901/02/03

SECTION 2: HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status	:	This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200). Not a dangerous substance or mixture according to the Globally Harmonized System (GHS).
Label Elements		
Emergency Overview	:	The product contains no substances, which at their given concentration, are considered hazardous to health.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS Number	Weight-%
Milrinone	78415-72-2	0.02-0.1
Dextrose, anhydrous	50-99-7	4-6
Lactic Acid	50-21-5	<0.2
Water for Injection	7732-18-5	>95

SECTION 4: FIRST AID MEASURES

Description of First Aid Measures

General Advise	:	Treat symptomatically and supportively.
Eye Contact	:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.
Skin Contact	:	In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Get medical attention if irritation develops.
Inhalation	:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

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Ingestion	:	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention if symptoms appear.
Most Important Symptoms/Effects, Both Acute and Delayed		
No information available.		
Indication of the Immediate Medical Attention and Special Treatment Needed		
Treat symptomatically. See patient package insert in shipping carton for complete information.		

SECTION 5: FIRE FIGHTING MEASURES

Suitable Extinguishing Media	:	Use foam or all-purpose dry chemicals to extinguish.
Specific Hazards arising from the chemical		
No information available.		
Special protective equipment for firefighters		
Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.		

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures		
Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).		
Environmental Precautions		
No information available.		
Methods and Materials for Containment and Cleaning Up		
Methods for Containment	:	If emergency personnel are unavailable, contain spilled material
Methods for cleaning up	:	For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling		
Technical measures/precautions	:	Wash thoroughly after handling.
Conditions for safe storage, including any incompatibilities		
Technical measures and storage conditions	:	Keep containers tightly closed in a cool, well-ventilated place. Store at room temperature between 20°C and 25°C (68°F and 77°F).
Incompatible materials	:	No special restrictions on storage with other products.

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure Controls	
Engineering Measures	: No special containment is required. Good general ventilation should be sufficient to control airborne levels.
Individual protection measures, such as personal protective equipment	
Eye Protection	: Eye protection not required for normal final product use. Safety glasses with side-shields are recommended for laboratory and manufacturing use.
Hand Protection	: Use chemical resistant, impervious gloves.
Skin and body protection	: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Respiratory protection	: No personal respiratory protective equipment normally required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State	: Liquid.
Appearance	: Aqueous solution.
Color	: Colorless to light yellow.
Odor	: Not available.
Odor Threshold	: No information available.
pH	: 3.2 - 4.0.
Melting point/melting range	: Not available.
Boiling point/boiling range	: Not available.
Flash point	: Not determined.
Evaporation Rate	: Not available.
Flammability (Solid, gas)	: No information available.
Flammable limits	: Not available.
in air-upper (%)	
Flammable limits	: Not available.
in air-lower (%)	
Vapour Pressure	: Not available.
Vapour Density	: No information available
Density	: Not available.
Solubility	: Soluble in water
Partition coefficient (n-octanol/water)	: Not available
Autoignition temperature	: Not available.

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Decomposition temperature	:	No information available
Viscosity	:	No information available
Explosive properties	:	No information available
Oxidising properties	:	No information available

SECTION 10: STABILITY AND REACTIVITY

Reactivity	:	No data Available
Chemical Stability	:	Stable under recommended storage conditions
Possibility of Hazardous Reactions		
Not applicable.		
Conditions to Avoid		
Do not freeze.		
Incompatible Materials		
Not Available.		
Hazardous Decomposition Products		
Not Available.		

SECTION 11: TOXICOLOGICAL INFORMATION

Component	Inhalation LC50	Dermal LD50	Oral LD50
Milrinone	-	-	= 91 mg/kg (Rat)
Dextrose, anhydrous	-	-	= 25800 mg/kg (Rat)
Lactic Acid	11.4 mg/L 4 h (Rat)	> 2 g/kg (Rabbit)	= 3543 mg/kg (Rat)
Water for Injection	-	-	> 90 mL/kg (Rat)

Information On likely routes of exposure		
Inhalation	:	Inhalation not likely under normal use conditions.
Eye Contact	:	Not expected to cause eye irritation.
Skin Contact	:	Not expected to cause skin irritation.
Ingestion	:	Practically non-toxic if swallowed.
Information on Toxicological Effects		
Symptoms	:	No information available
Delayed and immediate effects as well as chronic effects from short and long-term exposure		
Irritation	:	May cause skin and eye irritation.

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Corrosivity	:	Not classified
Sensitization	:	Not classified
Mutagenic Effects	:	May be mutagenic. Data too limited to be conclusive. See patient package insert for additional information.
Carcinogenic Effects	:	Not classified

Chemical Name	ACGIH	IARC	NTP	OSHA
Milrinone	-	-	-	-
Dextrose, anhydrous	-	-	-	-
Lactic Acid	-	-	-	-
Water for Injection	-	-	-	-

Reproductive toxicity	:	No impairment to fertility based on animal data. Not considered teratogenic based on animal data.
STOT - single exposure	:	Not classified
STOT - repeated exposure	:	Not classified
Aspiration Hazard	:	Not classified

Numerical measures of toxicity - Product Information

The following values are calculated based on chapter 3.1 of the GHS document.

ATEmix (oral)	91000 mg/kg
ATEmix (inhalation-vapor)	2326 mg/L

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity	:	No information available.
Persistence and Degradability	:	No information available.
Bioaccumulative Potential	:	No information available.
Mobility In Soil	:	No information available.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Treatment Methods		
Waste from residues/unused products	:	In accordance with local and national regulations
Contaminated Packaging	:	In accordance with local and national regulations

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SECTION 14: TRANSPORT INFORMATION

DOT	:	Not regulated
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SECTION 15: REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible Caplin use. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your city/state/country.

TSCA – The product is exempt from TSCA, it is FDA Regulated

US Regulations

CERCLA-No

SARA 302 – No

SARA 313 – No

Component	California Prop. 65	Minnesota Right-To - Know:	Florida Right-to-Know Reporting List:	Rhode Island Right-to-Know List:	Massachusetts Right-to-Know List:	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:
Milrinone	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed
Dextrose, anhydrous	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed
Lactic Acid	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed
Water for Injection	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

CANADIAN REGULATIONS:

Canada DSL Inventory List - This product does not comply with DSL

SECTION 16: OTHER INFORMATION

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.

History:

Creation Date	:	30.07.24
Revision Date	:	Not Applicable
Version	:	00

----End of SDS---