

SAFETY DATA SHEET
PRODUCT: Ropivacine Hydrochloride Injection USP

Section 1: PRODUCT AND COMPANY INFORMATION

54/1, Boodhihal village,
 Nelamangala,
 Bangalore, India-562123.
 PRODUCT NAME: Ropivacine Hydrochloride Injection USP

Section 2: HAZARD(S) IDENTIFICATION

EMERGENCY OVERVIEW	
Appearance	A clear colorless solution. Filled in clear tubular glass vial plugged with rubber stopper and sealed with flip off aluminium seal.
Classification of the substance or Mixture	
GHS - Classification	Not classified as hazardous
EU Classification:	EU indication of danger: Not classified
Label Elements: Not classified in accordance with international standards for workplace safety	

Section 3: COMPOSITION AND INFORMATION ON INGREDIENTS

Chemical Name	CAS Number
Ropivacine Hydrochloride	132112-35-7
Sodium Chloride USP*	7647-14-5
Hydrochloric acid NF*	7647-01-0
Sodium Hydroxide NF**	1310-73-2
Water for injection*	7732-18-5

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace

safety. * Proprietary

** to adjust pH

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret

Section 4: FIRST AID MEASURES

Eye Contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Contact:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Inhalation:	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Section 5: FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion - Formation of toxic gases is possible during heating or fire.

Products:

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus

Section 6: ACCIDENTAL RELEASE MEASURES

Small Spill:	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly
Large Spill:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel

Section 7: HANDLING AND STORAGE

Precautions	Minimize generating airborne mists and vapors. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.
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Storage:	Store as directed by product packaging.
Storage Conditions	20°C – 25°C (68°F – 77°F) [see USP Controlled Room Temperature]
Specific End Use	Pharmaceutical drug product

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Pharmaceutical drug product	OEB 3 (control exposure to the range of 10ug/m ³ to < 100ug/m ³)
Engineering Controls	Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.
Personal Protection	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

<p>Appearance Clear colourless liquid</p> <p>Decomposition Temperature (°C): No data available.</p> <p>Evaporation Rate (Gram/s): No data available</p> <p>Vapor Pressure (kPa): No data available</p> <p>Vapor Density (g/ml): No data available</p> <p>Relative Density: No data available</p> <p>Viscosity: No data available</p> <p>Flammability: Autoignition Temperature (Solid) (°C): No data available</p> <p>Flammability (Solids): No data available</p> <p>Flash Point (Liquid) (°C): No data available</p> <p>Upper Explosive Limits (Liquid) (% by Vol.): No data available</p> <p>Lower Explosive Limits (Liquid) (% by Vol.): No data available</p>
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Section 10: STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable at normal conditions.
Decomposition Products	No data available
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	No data available

Section 11: TOXICOLOGY INFORMATION

Short Term:	Anesthetic drug: may cause central nervous system and cardiovascular system effects
Known Clinical Effects:	May cause tingling/itching (paresthesia), allergic reaction, decrease in blood pressure (hypotension), decreased heart rate (bradycardia), respiratory depression.

Section 12: ECOLOGICAL INFORMATION

<p>Ecotoxicity</p> <p>Aquatic: No data available.</p> <p>Terrestrial: No data available.</p> <p>Persistence and Degradability: No data available.</p> <p>Bio accumulative Potential: No data available.</p> <p>Mobility in Soil: No data available.</p> <p>Mobility in Environment: No data available.</p> <p>Other Adverse Effects: No data available.</p>

Section 13: DISPOSAL CONDITIONS

Waste Disposal:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORTATION INFORMATION

<p>UN Number None allocated</p> <p>DG Class None allocated</p> <p>Subsidiary Risk None allocated</p> <p>Packing Group None allocated</p> <p>Hazchem Code None allocated</p> <p>The following refers to all modes of transportation unless specified below. Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.</p>

Section 15: REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Poisons Schedule Number Schedule 4 (S4) – Prescription only medicine

Section 16: OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life

Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects

Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage

Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

Xn - Harmful

C - Corrosive

T - Toxic

R22 - Harmful if swallowed.

R35 - Causes severe burns.

R23 - Toxic by inhalation

Data Sources: Publicly available toxicity information.

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Disclaimer: As of the date of issuance, we are providing available information relevant to the handling of this material. All information contained herein is offered with the good faith belief that it is accurate. In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.