SAFETY DATA SHEET

Ropivacaine Hydrochloride Injection, USP

Section 1: IDENTIFICATION

Product Name	:	Ropivacaine Hydrochloride Injection USP
Product code	:	65QCP64
Chemical Family	:	Local anaesthetic
Product type	:	Regulated prescription drug
Container information	:	2 mg/mL (0.2%) , 5 mg/mL (0.5%) and 10 mg/mL (1%)
Details of the Supplier of the Safety Data Sheet	:	Caplin Steriles Limited, Survey No. 895 & 897 Guruvarajakandigai Sirupuzhalpettai (Post) Gummidipoondi (Taluk) Tiruvallur (District) Pin Code: 601 201 Tamil Nadu (State), INDIA
Contact E-mail	:	uday@caplinsteriles.net
Emergency Contact Number (with hours of operation)	:	+91-44-67901901/02/03 Ext: 212

Section 2: HAZARDS IDENTIFICATION

Classification of the substance or mixture :

GHS-US Classification

Eye Irritation.2A - H319

STOT RE 2 - H373

Full text of classification categories and H statements : see section 16

Label elements :

GHS-US labelling

Hazard pictograms (GHS-US) :



Signal word (GHS-US) : H319 - Causes serious eye irritation
H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary statements (GHS-US) : P260 - Do not breathe dust/fume/gas/mist/vapors/spray P264 - Wash thoroughly after handling
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P314 - Get medical advice/attention if you feel unwell
P337+P313 - If eye irritation persists: Get

medical advice/attention
P501 - Dispose of contents/container in accordance with local/ regional/national/international regulations.

Other Hazards : No additional information available

Unknown acute toxicity (GHS US) : Not applicable

Section 3: COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients Name	CAS#	Ingredient Percentage (Quantity per mL)		
		0.2% w/v	0.5% w/v	1 % w/v
Ropivacaine Hydrochloride	132112-35-7	2	5	10.0
Sodium chloride	7647-14-5	8.60	8	7.10
Sodium Hydroxide/ Hydrochloric acid	1310-73-2/7647-01-0	q.s to adjust pH	q.s to adjust pH	q.s to adjust pH
Water for Injection	7732-18-5	Vehicle	Vehicle	Vehicle

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Section 4: FIRST AID MEASURES

Description of first aid measures

First-aid measures after inhalation : Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

First-aid measures after 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.

First-aid measures after 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.

First-aid measures after ingestion : Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary

Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation : None anticipated from normal handling of this product. However, inadvertent contact of this product with the respiratory system may produce irritation and numbness. Rarely, allergic-type reactions

		have been reported during the clinical use of this product.
Symptoms/injuries after skin contact	:	None anticipated from normal handling of this product. However, inadvertent contact with this product may be irritating to broken skin and mucous membranes, and may produce numbness.
Symptoms/injuries after eye contact	:	Causes serious eye irritation. May produce numbness and blurred vision.
Symptoms/injuries after ingestion	:	Ingestion may cause numbness of the tongue and anesthetic effects on the stomach.

Indication of any immediate medical attention and special treatment needed

No additional information available

Section 5: FIRE FIGHTING MEASURES

Extinguishing media

Suitable extinguishing media	:	Use an extinguishing agent suitable for the surrounding fire
Unsuitable extinguishing media	:	None known.

Special hazards arising from the substance or mixture

Fire hazard	:	None Known

Advice for firefighters

Protection during firefighting	:	Do not enter fire area without proper protective equipment, including respiratory protection.

Section 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

General measures	:	No special measures required.

For non-emergency personnel

No additional information available

For emergency responders

No additional information available

Environmental precautions

Prevent entry to sewers and public waters.

Methods and material for containment and cleaning up

For containment	:	Stop the flow of material, if this is without risk.
Methods for cleaning up	:	Absorb any 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

Reference to other sections
No additional information available

Section 7: HANDLING AND STORAGE

Precautions for safe handling

Precautions for safe handling	:	No special handling required for hazard control under conditions of normal product use.

Conditions for safe storage, including any incompatibilities

Storage conditions	:	For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure controls

Appropriate engineering controls	:	Local exhaust and general ventilation must be adequate to meet exposure standards.
Hand Protection	:	If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.
Eye protection	:	Use protective goggles if eye contact is likely.
Skin and body protection	:	Wear suitable working clothes.
Respiratory protection	:	Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, wear NIOSH approved respirator when handling.

Exposure Guidelines
Hydrochloric Acid/Sodium hydroxide

Guideline ACGIH	:	TLV-STEL: 2 ppm(ceiling)
Guideline OSHA	:	OSHA PEL-STEL 5 ppm Ceiling/Peak

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical States	:	Liquid

Appearance	:	Clear
Color	:	Colorless
Odor	:	Odorless
Odor threshold	:	No data available
pH	:	4.5 - 6 (1% solution)
Melting Point	:	No data available
Freezing Point	:	No data available
Boiling Point	:	No data available
Flash Point	:	No data available
Relative evaporation rate (butyl acetate=1)	:	No data available
Flammability (solid, gas)	:	No data available
Vapour Pressure	:	No data available
Relative vapor density at 20 °C	:	No data available
Relative density	:	1.002 - 1.005 (25°C)
Solubility	:	At 25°C Ropivacaine HCl has a solubility of 53.8 mg/mL in water. It is freely soluble in methanol and soluble in isopropanol.
Log $P_{o/w}$	:	No data available
Auto ignition Pt	:	No data available
Decomposition Temperature	:	No data available
Viscosity, kinetic	:	No data available
Viscosity, Dynamic	:	No data available
Explosion limits	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available

Other information
No additional information available

Section 10: STABILITY AND REACTIVITY

Reactivity	:	No additional information available
Chemical Stability	:	The product is stable at normal handling and storage conditions.
Possibility of hazardous reactions	:	Will not occur.

Conditions To Avoid:	:	Not determined.
Incompatibility materials	:	Strongly alkaline conditions.
Hazardous decomposition products	:	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.

Section 11: TOXICOLOGICAL INFORMATION

Information on toxicological effects

Acute toxicity	:	Not classified
Skin corrosion/irritation	:	Not classified. None anticipated from normal handling of this product. However, inadvertent contact with this product may be irritating to broken skin and mucous membranes, and may produce numbness.
Serious eye damage/irritation	:	Causes serious eye irritation.
Respiratory or skin sensitization	:	Not classified. None anticipated from normal handling of this product. However, inadvertent contact of this product with the respiratory system may produce irritation and numbness. Rarely, allergic-type reactions have been reported during the clinical use of this product
Germ cell mutagenicity	:	Not classified. Weak mutagenic activity was seen in the mouse lymphoma test. Mutagenicity was not noted in other assays.
Carcinogenicity	:	Not classified. Long term studies in animals of most local anesthetics, including ropivacaine, to evaluate the carcinogenic potential have not been conducted.
Reproductive toxicity	:	Not classified. Studies conducted with ropivacaine in rats did not demonstrate an effect on fertility or general reproductive performance over 2 generations. Ropivacaine was administered subcutaneously to rabbits on gestation days 6-18 at dosages of 1.3, 4.2, or 13 mg/kg/day. Similarly, ropivacaine was given subcutaneously to rats on gestation days 6-15 at dosages of 5.3, 11 and 26 mg/kg/day. No teratogenic effects were observed in rats or rabbits at the highest dosages tested. In two pre-natal and post-natal studies, female rats were treated daily from day 15 of gestation to day 20 postpartum with subcutaneous dosages of 5.3, 11 and 26 mg/kg/day. There were no treatment-related effects on late fetal development, parturition, lactation, neonatal viability, or growth of the offspring.

		In another study, male rats were dosed daily for 9 weeks before mating and during mating. Females were dosed daily for 2 weeks before mating and then during the mating, pregnancy, and lactation, up to day 42 post coitus. At a dosage of 23 mg/kg/day, an increased loss of pups was observed during the first 3 days postpartum. The finding was considered secondary to impaired maternal care due to maternal toxicity.
Specific target organ toxicity (single exposure)	:	Not classified
Specific target organ toxicity (repeated exposure)	:	May cause damage to organs through prolonged or repeated exposure. Based on clinical use, possible target organs include the nervous system, cardiovascular system, and skin.
Aspiration hazard	:	Not classified

Section 12: ECOLOGICAL INFORMATION

Toxicity

Not determined for product. Information for ropivacaine hydrochloride is as follows:
*LC 50(96 hr) = 38 mg/L in fish.
*EC50(48 hr) = 34 mg/L in Daphnia magna
*EC 50(72 hr) = 59 mg/L in green algae.

Persistence and degradability

Not readily biodegradable.

Bioaccumulative potential

No additional information available

Mobility in soil

No additional information available

Other adverse effects

Effect on the global warming : No known effects from this product.

Section 13: DISPOSAL CONSIDERATIONS

Waste treatment methods		
Waste disposal recommendations	:	Dispose of contents/container in accordance with local/regional/national/international regulations.

Section 14: TRANSPORT INFORMATION

Department of Transportation (DOT)
In accordance with DOT
Not applicable

Section 15: REGULATORY INFORMATION

US Federal regulations

No additional information available

US State regulations

No additional information available

Section 16: OTHER INFORMATION:

Full text of H-phrases

Eye Dam. 1	:	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	:	Serious eye damage/eye irritation Category 2A
STOT RE 2	:	Specific target organ toxicity (repeated exposure) Category 2
H318	:	Causes serious eye damage
H319	:	Causes serious eye irritation
H373	:	May cause damage to organs through prolonged or repeated exposure

The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Caplin Steriles Limited assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.

Issue Date: 28/11/19 (DD/MM/YY)
Revision Date: Nil
Version#00

------End of SDS-------