SAFETY DATA SHEET

Issuing Date: 13-Sep-2019 **Revision date:** 27-Oct-2023

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

SDS Number: BXU542372
Product Name: Ropivacaine Hydrochloride Injection USP

Other means of identification

Product Code(s): 4306601501, 4306601510, 4306602301, 4306602310, 4306601901, 4306601910, 4306602701, 4306602710 7257270701, GLRVC200BUS, GLRVC400BUS
Synonyms: None

Recommended use of the chemical and restrictions on use

Product Use: Pharmaceutical.
Product Type: Regulated Prescription Drug
Uses advised against: No information available

Details of the supplier of the safety data sheet

BAXTER HEALTHCARE CORPORATION
1 BAXTER PARKWAY
DEERFIELD, ILLINOIS 60015
US: (800) 933-0303
Canada: (855)-584-1368

Emergency telephone number

Verisk 3E Global Incident Response Hotline +1 760 476 3962; Access Code 335625

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Serious eye damage/eye irritation	Category 2A

Label Elements

Emergency Overview

Warning

Hazard Statements

Causes serious eye irritation.



The product contains no substances which at their given concentration, are considered to be hazardous to health

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling
Wear eye/face protection

Precautionary Statements -
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 advice/attention

Hazards not otherwise classified (HNOC)
Other Information
• Causes mild skin irritation
Unknown Acute Toxicity 1 % of the mixture consists of ingredient(s) of unknown toxicity

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Weight-%
Ropivacaine hydrochloride	132112-35-7	0.2-1
Sodium Chloride	7647-14-5	<1
Water	7732-18-5	>98

4. FIRST AID MEASURES

Description of first aid measures

General Advice 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. 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. Get medical attention if symptoms occur.

Ingestion: Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

Most important symptoms and effects, both acute and delayed
Causes skin irritation.

Indication of any immediate medical attention and special treatment needed
Treat symptomatically. See patient package insert in shipping carton for complete information.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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.

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
See Section 12 for environmental precautions.

Methods and material 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.

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.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

Exposure Limits: This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Chemical name	OSHA- Time Weighted Average:	OSHA- Ceiling Limits	OSHA- Short Term Exposure Limit:	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Ropivacaine hydrochloride 132112-35-7	None	None	None	None	None	None
Sodium Chloride 7647-14-5	None	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None	None

Appropriate engineering 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).
Respiratory protection	No personal respiratory protective equipment normally required.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state:	Liquid
Appearance:	Aqueous solution.
Color:	Clear, Colorless.
Odor:	No information available
Odor threshold	No information available
pH	4.0-6.0
Melting point / melting range:	No information available
Boiling point / boiling range:	No information available
Flash point:	No information available
Evaporation rate:	No information available
Flammability	No data available
Flammable limits in air-upper (%):	No information available
Flammable limits in air-lower (%):	No information available
Vapor pressure:	No information available
Relative vapor density	No information available
Density:	No information available
Solubility:	Soluble in water.
Partition coefficient (n-octanol/water):	No information available
Autoignition temperature:	No information available
Decomposition temperature	No information available
Viscosity:	No information available
Explosive Properties:	No information available
Oxidizing Properties:	No information available

Other information

10. STABILITY AND REACTIVITY

Reactivity
No data available

Chemical stability
Stable under recommended storage conditions

Possibility of hazardous reactions
None under normal use conditions

Conditions to Avoid
Do not freeze.

Incompatible materials
None known

Hazardous decomposition products

No data available

11. TOXICOLOGICAL INFORMATION

Chemical name	Inhalation LC50	Dermal LD50	Oral LD50
Ropivacaine hydrochloride 132112-35-7	-	-	-
Sodium Chloride 7647-14-5	42 g/m³ 1 h (Rat)	> 10 g/kg (Rabbit)	= 3 g/kg (Rat)
Water 7732-18-5	-	-	> 90 mL/kg (Rat)

Information on likely routes of exposure

Inhalation: Inhalation not likely under normal use conditions.

Eye contact: May cause eye irritation.

Skin contact: May cause mild irritation with direct contact. Contact will cause numbing of the area.

Ingestion: Hypersensitivity (may include drug fever, rash, itching, anaphylaxis). Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Nervous system effects (headache, dizziness, light headedness). Cardiovascular effects (may include fluctuations in heart rate, changes in blood pressure, chest pain). Back pain.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms: No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation: Causes eye irritation. Mild skin irritation.

Corrosivity: Not classified.

Sensitization: Not classified.

Mutagenic effects: Not classified.

Carcinogenic effects: Not classified.

Chemical name	ACGIH	IARC	NTP	OSHA
Ropivacaine hydrochloride 132112-35-7	-	-	-	-
Sodium Chloride 7647-14-5	-	-	-	-
Water 7732-18-5	-	-	-	-

Reproductive toxicity: No impairment to fertility based on animal data. Not considered fetotoxic 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

Unknown Acute Toxicity 1 % of the mixture consists of ingredient(s) of unknown toxicity

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

ATEmix (oral) 50000 mg/kg

12. ECOLOGICAL INFORMATION

Chemical name	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data
Ropivacaine hydrochloride 132112-35-7	None.	None.	None.	None.
Sodium Chloride 7647-14-5	1000 mg/L EC50 48 h 340.7 - 469.2 mg/L EC50 48 h	5560 - 6080 mg/L LC50 Lepomis macrochirus 96 h 12946 mg/L LC50 Lepomis macrochirus 96 h 6020 - 7070 mg/L LC50 Pimephales promelas 96 h 7050 mg/L LC50 Pimephales promelas 96 h 6420 - 6700 mg/L LC50 Pimephales promelas 96 h 4747 - 7824 mg/L LC50 Oncorhynchus mykiss 96 h	None.	None.
Water 7732-18-5	None.	None.	None.	None.

Ecotoxicity

No information available

0 % of the mixture consists of components(s) of unknown hazards to the aquatic environment

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

Bioaccumulative potential

12.4. Mobility in soil

No information available

Other adverse effects

No information available

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.

14. TRANSPORT INFORMATION

DOT

UN-No: Not regulated
DOT shipping name: Not regulated
DOT Hazard class: Not regulated
Subsidiary risk (hazard class): Not regulated
14.4 Packing group Not regulated

IMDG

UN number or ID number Not regulated
14.3 Transport hazard class(es) Not regulated
14.5 Marine Pollutant Not applicable
14.6 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available

RID

UN number or ID number Not regulated
14.2 UN proper shipping name Not regulated
14.3 Transport hazard class(es) Not regulated
14.4 Packing group Not regulated
14.5 Environmental hazards Not applicable
14.6

ADR

UN number or ID number Not regulated
14.2 UN proper shipping name Not regulated
14.3
Transport hazard class(es) Not regulated
14.5 Environmental hazards Not applicable
14.6

IATA

UN number or ID number Not regulated
14.2 UN proper shipping name Not regulated
14.3 Transport hazard class(es) Not regulated
Packing group Not regulated
14.5 Environmental hazards Not applicable
14.6

15. REGULATORY INFORMATION

U.S. Regulations:

TSCA Inventory List - The product is exempt from TSCA, it is FDA Regulated

OTHER REGULATIONS:

Chemical name	Weight-%	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:

Ropivacaine hydrochloride 132112-35-7	0.2-1	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Chloride 7647-14-5	<1	Not Listed	Not Listed	Not Listed	Not Listed
Water 7732-18-5	>98	Not Listed	Not Listed	Not Listed	Not Listed

STATE REGULATIONS:

Chemical name	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:
Ropivacaine hydrochloride 132112-35-7	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Chloride 7647-14-5	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Water 7732-18-5	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

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s):
Additional product codes.

Additional information:
Not Available.

Prepared by: Baxter Research & Development
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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 Safety Data Sheet