SAFETY DATA SHEET SPECTRUM®



Revision date 09-March-2020

Revision Number 1

1. Identification

Product identifier

Product Name Ropivacaine Hydrochloride, USP

Other means of identification

Product Code(s) RO902

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use No information available

Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Address

Spectrum Chemical Mfg. Corp. 14422 South San Pedro St. Gardena, CA 90248 (310) 516-8000

Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification

Serious eye damage/eye irritation Category 1

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

Causes serious eye damage



Appearance No information available Physical state Solid Odor No information available

Precautionary Statements - PreventionWear eye protection/ 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 Immediately call a POISON CENTER or doctor

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Ropivacaine Hydrochloride	132112-35-7	100	*

^{*}The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures

Description of first aid measures

General advice Immediate medical attention is required. Show this safety data sheet to the doctor in

attendance.

Inhalation Remove to fresh air. Get medical attention immediately if symptoms occur.

Eye contact Get immediate medical advice/attention. Rinse immediately with plenty of water, also under

the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do.

Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area.

Skin contact Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical

attention if irritation develops and persists.

Ingestion Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth

to an unconscious person. Do NOT induce vomiting. Call a physician.

Self-protection of the first aider Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Symptoms Burning sensation.

Indication of any immediate medical attention and special treatment needed

5. Fire-fighting measures

surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing media Do not scatter spilled material with high pressure water streams.

Specific hazards arising from the

chemical

No information available.

Explosion data

Sensitivity to mechanical impact none.

Sensitivity to static discharge none.

Special protective equipment for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout

gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

Other information Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with

skin, eyes or clothing. Do not eat, drink or smoke when using this product.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up.

Keep out of the reach of children.

8. Exposure controls/personal protection

Control parameters

Exposure LimitsThe following ingredients are the only ingredients of the product above the cut-off level (or

level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other

recommended limit. At this time, the other relevant constituents have no known exposure

limits from the sources listed here.

Appropriate engineering controls

Engineering controls Showers

Eyewash stations Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Tight sealing safety goggles.

Hand protection Wear suitable gloves.

Skin and body protectionWear suitable protective clothing.

Respiratory protectionNo protective equipment is needed under normal use conditions. If exposure limits are

exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do

not eat, drink or smoke when using this product.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid

AppearanceNo information availableColorNo information availableOdorNo information availableOdor thresholdNo information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

no data available Ha None known Melting point / freezing point no data available None known no data available None known Boiling point / boiling range no data available None known Flash point **Evaporation rate** no data available None known Flammability (solid, gas) no data available None known Flammability Limit in Air None known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Vapor pressure No data available None known no data available Vapor density None known Relative density no data available None known Water solubility No data available None known Solubility(ies) no data available None known Partition coefficient No data available None known **Autoignition temperature** no data available None known **Decomposition temperature** None known

Kinematic viscosity

no data available

None known

None known

None known

None known

Other information

Explosive properties

Oxidizing properties

No information available
No information available
No information available

Molecular weight 328.89

VOC Content (%)

Liquid Density

Bulk density

No information available
No information available
No information available

10. Stability and reactivity

Reactivity No information available.

Chemical stability Stable under normal conditions.

None under normal processing. Possibility of hazardous reactions

Conditions to avoid None known based on information supplied.

Strong acids. Strong bases. Strong oxidizing agents. Incompatible materials

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available. Causes serious eye

damage. May cause irreversible damage to eyes.

Skin contact Specific test data for the substance or mixture is not available. May cause irritation.

Ingestion Specific test data for the substance or mixture is not available. Ingestion may cause

gastrointestinal irritation, nausea, vomiting and diarrhea.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Redness. Burning. May cause blindness.

Acute toxicity

Numerical measures of toxicity

No information available

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

Skin corrosion/irritation May cause skin irritation.

Serious eye damage/eye irritation Classification based on data available for ingredients. Causes burns. Risk of serious

damage to eyes.

Respiratory or skin sensitization

Germ cell mutagenicity

No information available. No information available.

No information available.

Reproductive toxicity STOT - single exposure No information available.

STOT - repeated exposure No information available. **Aspiration hazard** No information available.

Other adverse effects No information available.

Interactive effects No information available.

12. Ecological information

The environmental impact of this product has not been fully investigated. **Ecotoxicity**

Persistence and degradability

Bioaccumulation

No information available. Inherently biodegradable. Other adverse effects

No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

Contaminated packaging Do not reuse empty containers.

14. Transport information

DOT not regulated

TDG not regulated

MEX not regulated

ICAO (air) not regulated

IATA not regulated

IMDG not regulated

RID not regulated

ADR not regulated

<u>ADN</u> not regulated

15. Regulatory information

International Inventories

TSCA Not listed

Note *Contact supplier for details. One or more substances in this product are either not listed

on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise

exempted from inventory listing requirements

DSL/NDSLDoes not ComplyEINECS/ELINCSDoes not Comply

ENCS This product complies with ENCS:

IECSC This product does not comply with china:

KECL Does not Comply **PICCS** Does not Comply

AICS This product does not comply with AICS

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA

Health hazards 3 Flammability 0 Instability 0

Physical and chemical properties -

HMIS

Health hazards 3 Flammability 0 Physical hazards 0 Personal protection X

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database European Food Safety Authority (EFSA) EPA (Environmental Protection Agency) Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

World Health Organization

Revision date 09-March-2020

Revision NoteNo information available.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet