

# Scientific Documentation

## Ropivacaine Hydrochloride, USP, bioCERTIFIED (TM)

Not appropriate for regulatory submission.

Please visit [www.spectrumchemical.com](http://www.spectrumchemical.com) or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp  
769 Jersey Avenue  
New Brunswick, NJ 08901  
Phone 732.214.1300



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## Specification for Ropivacaine Hydrochloride, USP, bioCERTIFIED (TM) (RO902)

Item Number	RO902
Item	Ropivacaine Hydrochloride, USP, bioCERTIFIED (TM)
CAS Number	132112-35-7
Molecular Formula	C <sub>17</sub> H <sub>26</sub> N <sub>2</sub> O•HCl•H <sub>2</sub> O
Molecular Weight	328.89
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
ASSAY (ANHYDROUS BASIS)	98.5	101.0 %
pH OF A 10 mg/mL SOLUTION @ 25°C	4.5	6.0
WATER DETERMINATION	5.0	6.0 %
COLOR:		
@405nm		0.030
@436nm		0.025
CLARITY		TO PASS TEST
ORGANIC IMPURITIES (PROCEDURE 1):		
BUPIVACAINE		0.2 %
ANY OTHER INDIVIDUAL IMPURITY		0.1 %
TOTAL IMPURITIES		0.5 %
ELEMENTAL IMPURITIES		AS REPORTED
MICROBIAL LIMITS:		
TOTAL AEROBIC MICROBIAL COUNT		10 <sup>3</sup> cfu/g
TOTAL COMBINED YEASTS AND MOLDS COUNT		10 <sup>2</sup> cfu/g
BACTERIAL ENDOTOXINS		60 EU/mg
IDENTIFICATION		TO PASS TEST
APPEARANCE		
EXPIRATION DATE		

Test	Specification	
	Min	Max
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS		TO PASS TEST

***Spectrum Chemical Mfg Corp***

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***Corporate Headquarters:***    ***West Coast Facility:***  
769 Jersey Ave.                      14422 S. San Pedro St.  
New Brunswick, NJ 08901    Gardena, CA 90248  
732.214.1300                              310.516.8000

# Certificate Of Analysis

Item Number	RO902	Lot Number	4LD0023
Item	Ropivacaine Hydrochloride, USP, bioCERTIFIED (TM)	Manufacturer Lot	S124A621011
CAS Number	132112-35-7	Manufacturer Code	14951
Molecular Formula	C <sub>17</sub> H <sub>26</sub> N <sub>2</sub> O•HCl•H <sub>2</sub> O	Molecular Weight	328.89

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (ANHYDROUS BASIS)	98.5	101.0 %	100.1%
pH OF A 10 mg/mL SOLUTION @ 25°C	4.5	6.0	5.13
WATER DETERMINATION	5.0	6.0 %	5.6%
COLOR:			.
@405nm		0.030	0.000
@436nm		0.025	0.000
CLARITY		TO PASS TEST	PASSES TEST
ORGANIC IMPURITIES (PROCEDURE 1):			.
BUPIVACAINE		0.2 %	0.0%
ANY OTHER INDIVIDUAL IMPURITY		0.1 %	0.0%
TOTAL IMPURITIES		0.5 %	0.0%
ELEMENTAL IMPURITIES		AS REPORTED	COMPLIES WITH STANDARD
MICROBIAL LIMITS:			.
TOTAL AEROBIC MICROBIAL COUNT		10 <sup>3</sup> cfu/g	<10 <sup>3</sup> cfu/g
TOTAL COMBINED YEASTS AND MOLDS COUNT		10 <sup>2</sup> cfu/g	<10 <sup>2</sup> cfu/g
BACTERIAL ENDOTOXINS		60 EU/mg	<60 EU/mg
IDENTIFICATION		TO PASS TEST	PASSES TEST
APPEARANCE			WHITE POWDER
EXPIRATION DATE			01-DEC-2025
DATE OF MANUFACTURE			01-JAN-2022
RESIDUAL SOLVENTS		TO PASS TEST	PASSES TEST
CLASS 2 (solvent) / TOLUENE			<890 PPM
CLASS 2 (solvent) / HEXANE			<290 PPM

TEST	SPECIFICATION		RESULT
	MIN	MAX	
CLASS 3 (solvent) / ACETONE			<5000 PPM
CLASS 3 (solvent) / ETHYL ACETATE			<5000 PPM
CLASS 3 (solvent) / 2-PROPANOL			< 5000 PPM

Certificate of Analysis Results Entered By:

BPATEL  
Bhargavi Patel  
01-JUL-22 11:39:10

Certificate of Analysis Results Approved By:

GHERRERA  
Genaro Herrera  
05-JUL-22 01:36:01

Spectrum Chemical Mfg Corp  
777 Jersey Avenue  
New Brunswick 08901 NJ



**All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.**

**Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.**

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by APOTHECON PHARMACEUTICALS PRIVATE LIMITED at Plot No.1134 to 1137,1138 A&B, 1143 A&B,1144 A&B, Padra-Jambusar Highway, At & Post:-Dabhasa, Taluka Padra,, Vadodara, GJ 391440, India (IND). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

# 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
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### 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 - Prevention**

Wear 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**

**Note to physicians**

Treat symptomatically.

## 5. Fire-fighting measures

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Large Fire</b>	CAUTION: Use of water spray when fighting fire may be inefficient.
<b>Unsuitable extinguishing media</b>	Do not scatter spilled material with high pressure water streams.
<b>Specific hazards arising from the chemical</b>	No information available.
<b>Explosion data</b>	
<b>Sensitivity to mechanical impact</b>	none.
<b>Sensitivity to static discharge</b>	none.
<b>Special protective equipment for fire-fighters</b>	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

<b>Personal precautions</b>	Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.
<b>Other information</b>	Refer to protective measures listed in Sections 7 and 8.

### Methods and material for containment and cleaning up

<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
<b>Methods for cleaning up</b>	Pick up and transfer to properly labeled containers.

## 7. Handling and storage

### Precautions for safe handling

<b>Advice on safe handling</b>	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.
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### Conditions for safe storage, including any incompatibilities

<b>Storage Conditions</b>	Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up. Keep out of the reach of children.
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## 8. Exposure controls/personal protection

### Control parameters

<b>Exposure Limits</b>	The 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.
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### Appropriate engineering controls





<b>Chemical stability</b>	Stable under normal conditions.
<b>Possibility of hazardous reactions</b>	None under normal processing.
<b>Conditions to avoid</b>	None known based on information supplied.
<b>Incompatible materials</b>	Strong acids. Strong bases. Strong oxidizing agents.
<b>Hazardous decomposition products</b>	None known based on information supplied.

## 11. Toxicological information

### Information on likely routes of exposure

#### Product Information

<b>Inhalation</b>	Specific test data for the substance or mixture is not available.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available. Causes serious eye damage. May cause irreversible damage to eyes.
<b>Skin contact</b>	Specific test data for the substance or mixture is not available. May cause irritation.
<b>Ingestion</b>	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

<b>Symptoms</b>	Redness. Burning. May cause blindness.
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### Acute toxicity

#### Numerical measures of toxicity

No information available

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

<b>Skin corrosion/irritation</b>	May cause skin irritation.
<b>Serious eye damage/eye irritation</b>	Classification based on data available for ingredients. Causes burns. Risk of serious damage to eyes.
<b>Respiratory or skin sensitization</b>	No information available.
<b>Germ cell mutagenicity</b>	No information available.
<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<b>Aspiration hazard</b>	No information available.
<b>Other adverse effects</b>	No information available.
<b>Interactive effects</b>	No information available.

## 12. Ecological information

<b>Ecotoxicity</b>	The environmental impact of this product has not been fully investigated.
<b>Persistence and degradability</b>	No information available.
<b>Bioaccumulation</b>	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

**ADN** 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/NDSL** Does not Comply  
**EINECS/ELINCS** Does 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 Note** No 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**



**Certification of Compliance with current Good Manufacturing Practices**

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
RO902	Ropivacaine Hydrochloride, USP, bioCERTIFIED™

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632  
Spectrum-New Brunswick, NJ: 2246824

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com)

Sincerely,

Oralia Chavez  
Quality Assurance Specialist

## RO902, Ropivacaine Hydrochloride, USP, bioCERTIFIED™

### Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

### BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

### Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

### EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

### GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

### Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

### **Nitrosamine Statement**

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

### **Animal Testing Statement**

The above mentioned catalog item has not been tested on animals.

### **Organic Compliance Statement**

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

### **Shelf Life Statement**

The above mentioned catalog item is typically assigned a shelf life of 48 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

### **Other Chemicals Statement**


Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- Aflatoxins
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances
- Parabens
- Pesticides
- Phthalates
- Preservatives



## Label Information


The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.



**DANGER**  
 • Causes serious eye damage • Harmful if swallowed.  
 • Do not eat, drink or smoke when using this product • Wear eye protection, face protection • Wash face, hands, and any exposed skin thoroughly after handling.  
**FIRST AID:** Immediately call a POISON CENTER or physician. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF SWALLOWED: Rinse mouth.


**KEEP FROM CHILDREN**

**WARNING:**  
 Cancer and Reproductive Harm-  
[www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)



**R0902**                      **SIZ SY**

### Ropivacaine Hydrochloride

USP, bioCERTIFIED™   
 CAS 132112-35-7

**CAUTION:** For manufacturing, processing or repacking. Rx only. Further processing and testing required for use in parenteral applications.  
**Read and understand the label and Safety Data Sheet (SDS) prior to use.**

**Chemical Emergency: (800)424-9300**

[www.SpectrumChemical.com](http://www.SpectrumChemical.com)

$C_{17}H_{26}N_2O \cdot HCl \cdot H_2O$     F.W. 328.89

Not sterile.

Manufacturer/Supplier Code ..... ?  
 Manufacturer Lot Number ..... ?

Assay (Anhydrous basis) ..... 98.5-101.0%  
 pH of a 10 mg/mL Solution @ 25°C ..... 4.5-6.0  
 Water Determination ..... 5.0-6.0%

MAXIMUM LIMITS

Color:  
 @ 405nm ..... 0.030  
 @ 436nm ..... 0.025

Clarity ..... To pass test

Organic Impurities (Procedure 1):  
 Bupivacaine ..... 0.2%  
 Any Other Individual Impurity ..... 0.1%  
 Total Impurities ..... 0.5%

Elemental Impurities ..... As reported  
 Residual Solvents ..... To pass test

Microbial Limits:  
 Total Aerobic Microbial Count ..... 10<sup>3</sup> cfu/g  
 Total Combined Yeasts and Mold Count ..... 10<sup>2</sup> cfu/g  
 Bacterial Endotoxins ..... 60 EU/mg

Repackaged by Spectrum as:  
 G 3/K6GHS-A    ?    Lot No. XQ####

### Spectrum Chemical Mfg Corp

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