

# Scientific Documentation

## Bupivacaine Hydrochloride, Monohydrate, USP

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



## **Table of Contents**

Product Specification  
Certificate of Analysis  
Safety Data Sheet (SDS)  
Certification of Current Good Manufacturing Practices (cGMP)  
Manufacturing Process Flowchart  
Technical Statements  
Elemental Impurities Statement  
Residual Solvents Statement  
General Label Information – Sample Label

# Specification for Bupivacaine Hydrochloride, Monohydrate, USP (B1391)

Item Number	B1391
Item	Bupivacaine Hydrochloride, Monohydrate, USP
CAS Number	73360-54-0
Molecular Formula	$C_{18}H_{28}N_2O \cdot HCl \cdot H_2O$
Molecular Weight	342.90
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
ASSAY (ANHYDROUS BASIS)	98.5	101.5 %
pH OF A 1 IN 100 SOLUTION	4.5	6.0
WATER DETERMINATION	4.0	6.0 %
CHROMATOGRAPHIC PURITY:		
INDIVIDUAL IMPURITY		0.5 %
TOTAL IMPURITIES		2.0 %
RESIDUE ON IGNITION		0.1 %
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION A ( FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION B ( UV )		3.0 %
IDENTIFICATION (C)	POSITIVE FOR CHLORIDE	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	AS REPORTED	

## *Spectrum Chemical Mfg Corp*

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

***Spectrum Chemical Mfg Corp***

---

***Corporate Headquarters:    West Coast Facility:***

732.214.1300

310.516.8000

## Certificate Of Analysis

Item Number	B1391	Lot Number	4LJ0018
Item	Bupivacaine Hydrochloride, Monohydrate, USP	Manufacturer Lot	22H56N07
CAS Number	73360-54-0	Manufacturer Code	14527
Molecular Formula	C <sub>18</sub> H <sub>28</sub> N <sub>2</sub> O•HCl•H <sub>2</sub> O	Molecular Weight	342.90

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (ANHYDROUS BASIS)	98.5	101.5 %	99.06 %
pH OF A 1 IN 100 SOLUTION	4.5	6.0	5.0
WATER DETERMINATION	4.0	6.0 %	5.2 %
CHROMATOGRAPHIC PURITY:			.
INDIVIDUAL IMPURITY		0.5 %	<0.5 %
TOTAL IMPURITIES		2.0 %	<2.0 %
RESIDUE ON IGNITION		0.1 %	0.099 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
IDENTIFICATION A ( FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION B ( UV )		3.0 %	<3.0 %
IDENTIFICATION (C)	POSITIVE FOR CHLORIDE		POSITIVE FOR CHLORIDE
EXPIRATION DATE			31-JUL-2027
DATE OF MANUFACTURE			01-AUG-2022
APPEARANCE			WHITE CRYSTALLINE POWDER
RESIDUAL SOLVENTS	AS REPORTED		.
CLASS 3 (solvent) / 2-PROPANOL			<5000 ppm

Certificate of Analysis Results Entered By:

SVANGOOR  
Swetha Vangoor  
05-DEC-22 15:17:22

Spectrum Chemical Mfg Corp  
777 Jersey Avenue  
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS  
Allison Williams  
05-DEC-22 15:17:38

**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.**

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

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 ABHILASHA PHARMA PVT. LTD. at Plot 1408,1409,GIDC, Ankleshwar, Dist. Bharuch, Gujarat 393002, 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 05-June-2020

Revision Number 2

## 1. Identification

### Product identifier

**Product Name** BUPIVACAINE HYDROCHLORIDE, MONOHYDRATE, USP

### Other means of identification

**Product Code(s)** B1391

**UN/ID no** UN1544

**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

Acute toxicity - Oral	Category 1
Acute toxicity - Dermal	Category 1
Acute toxicity - Inhalation (Dusts/Mists)	Category 1

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

**Danger**

#### Hazard statements

Fatal if swallowed  
Fatal in contact with skin  
Fatal if inhaled



**Appearance** Crystalline powder

**Physical state** Solid

**Odor** Odorless

**Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling  
Do not eat, drink or smoke when using this product  
Do not get in eyes, on skin, or on clothing  
Wear protective gloves/protective clothing  
Do not breathe dust/fume/gas/mist/vapors/spray  
Use only outdoors or in a well-ventilated area  
Wear respiratory protection

**Precautionary Statements - Response**

IF ON SKIN: Wash with plenty of water and soap  
Immediately call a POISON CENTER or doctor  
Take off immediately all contaminated clothing and wash it before reuse  
IF INHALED: Remove person to fresh air and keep comfortable for breathing  
Immediately call a POISON CENTER or doctor  
IF SWALLOWED: Immediately call a POISON CENTER or doctor  
Rinse mouth

**Precautionary Statements - Storage**

Store locked up  
Store in a well-ventilated place. Keep container tightly closed

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

**Unknown acute toxicity**

**Other information**

No information available.

### 3. Composition/information on ingredients

**Substance**

Chemical name	CAS No	Weight-%	Trade secret
Bupivacaine Hydrochloride, Monohydrate	73360-54-0	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**

If breathing has stopped, give artificial respiration. Get medical attention immediately. Remove to fresh air. Do not breathe dust. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If breathing is difficult, (trained personnel should) give oxygen.



<b>Eye contact</b>	Get immediate medical advice/attention. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing.
<b>Skin contact</b>	Get immediate medical advice/attention. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
<b>Ingestion</b>	Get immediate medical advice/attention. Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person.
<b>Self-protection of the first aider</b>	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Do not breathe dust. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Use personal protective equipment as required. See section 8 for more information.

#### **Most important symptoms and effects, both acute and delayed**

**Symptoms** Coughing and/ or wheezing. Difficulty in breathing.

#### **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>Hazardous combustion products</b>	Carbon monoxide. Carbon dioxide (CO <sub>2</sub> ). Nitrogen oxides (NO <sub>x</sub> ). hydrogen chloride gas.
<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. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid generation of dust. Do not breathe dust. Keep people away from and upwind of spill/leak.
<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

#### **Advice on safe handling**

Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Take off contaminated clothing and wash before reuse. Do not breathe dust. Avoid generation of dust. In case of insufficient ventilation, wear suitable respiratory equipment. Handle product only in closed system or provide appropriate exhaust ventilation. Do not eat, drink or smoke when using this product.

### Conditions for safe storage, including any incompatibilities

#### **Storage Conditions**

Store locked up. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children.

## 8. Exposure controls/personal protection

### Control parameters

#### **Exposure Limits**

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.

### Appropriate engineering controls

#### **Engineering controls**

Showers  
Eyewash stations  
Ventilation systems.

### Individual protection measures, such as personal protective equipment

#### **Eye/face protection**

Wear safety glasses with side shields (or goggles).

#### **Hand protection**

Wear suitable gloves. Impervious gloves.

#### **Skin and body protection**

Impervious clothing. Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron.

#### **Respiratory protection**

When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

#### **General hygiene considerations**

Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Regular cleaning of equipment, work area and clothing is recommended. Do not breathe dust. Take off contaminated clothing and wash before reuse. Contaminated work clothing should not be allowed out of the workplace.

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

#### **Physical state**

Solid

#### **Appearance**

Crystalline powder

#### **Color**

white

Odor	Odorless
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	no data available	None known
Melting point / freezing point	255 - 258 °C / 491 - 496.4 °F	None known
Boiling point / boiling range	no data available	None known
Flash point	no data available	None known
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 limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	no data available	None known
Water solubility	Soluble in water	None known
Solubility(ies)	Partially soluble in acetone Soluble in Methanol Soluble in Methanol Insoluble in Ether Insoluble in Chloroform	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
Dynamic viscosity	No data available	None known
<u>Other information</u>		
Explosive properties	No information available	
Oxidizing properties	No information available	
Softening point	No information available	
Molecular weight	342.90	
VOC Content (%)	No information available	
Liquid Density	No information available	
Bulk density	No information available	

## 10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	Excessive heat.
Incompatible materials	None known based on information supplied.
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. Fatal if inhaled. (based on components).
Eye contact	Specific test data for the substance or mixture is not available.

<b>Skin contact</b>	Specific test data for the substance or mixture is not available. Fatal in contact with skin. (based on components).
<b>Ingestion</b>	Specific test data for the substance or mixture is not available. Fatal if swallowed. (based on components).

#### Symptoms related to the physical, chemical and toxicological characteristics

<b>Symptoms</b>	Coughing and/ or wheezing. Difficulty in breathing.
-----------------	---

#### Acute toxicity

**Numerical measures of toxicity**  
No information available

**Unknown acute toxicity**

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

<b>Skin corrosion/irritation</b>	No information available.
<b>Serious eye damage/eye irritation</b>	No information available.
<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.
<b>Other adverse effects</b>	No information available.

## **13. Disposal considerations**

#### Waste treatment methods

<b>Waste from residues/unused products</b>	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
<b>Contaminated packaging</b>	Do not reuse empty containers.

## **14. Transport information**

DOT  
UN/ID no UN1544

<b>Proper Shipping Name:</b>	Alkaloids, solid, n.o.s.
<b>Hazard class</b>	6.1
<b>Packing group:</b>	II
<b>Special Provisions</b>	IB8, IP2, IP4, T3, TP33
<b>Marine Pollutant</b>	Severe Marine Pollutant
<b>Description:</b>	UN1544, Alkaloids, solid, n.o.s. (Bupivacaine Hydrochloride, Monohydrate), 6.1, II
<b>Emergency Response Guide Number</b>	151

#### **TDG**

<b>UN-No:</b>	UN1544
<b>Proper Shipping Name:</b>	Alkaloid salts, solid, n.o.s.
<b>Hazard class</b>	6.1
<b>Packing Group:</b>	II
<b>Description:</b>	UN1544, Alkaloid salts, solid, n.o.s. (Bupivacaine Hydrochloride, Monohydrate), 6.1, II

#### **MEX**

<b>UN-No</b>	UN1544
<b>Proper Shipping Name</b>	Alkaloids, solid, n.o.s.
<b>Hazard class</b>	6.1
<b>Special Provisions</b>	43, 274
<b>Packing Group</b>	II
<b>Description</b>	UN1544, Alkaloids, solid, n.o.s. (Bupivacaine Hydrochloride, Monohydrate), 6.1, II

#### **ICAO (air)**

<b>UN-No:</b>	UN1544
<b>Proper Shipping Name:</b>	Alkaloid salts, solid, n.o.s.
<b>Hazard class</b>	6.1
<b>Packing Group:</b>	II
<b>Special Provisions</b>	A3, A5, A6
<b>Description:</b>	UN1544, Alkaloid salts, solid, n.o.s. (Bupivacaine Hydrochloride, Monohydrate), 6.1, II

#### **IATA**

<b>UN number</b>	UN1544
<b>Proper Shipping Name:</b>	Alkaloid salts, solid, n.o.s.
<b>Transport hazard class(es)</b>	6.1
<b>Packing group</b>	II
<b>Description:</b>	UN1544, Alkaloid salts, solid, n.o.s. (Bupivacaine Hydrochloride, Monohydrate), 6.1, II

#### **IMDG**

<b>UN number</b>	UN1544
<b>Proper shipping name</b>	Alkaloids, solid, n.o.s.
<b>Transport hazard class(es)</b>	6.1
<b>Packing group</b>	II
<b>EmS-No</b>	F-A, S-A
<b>Special Provisions</b>	43, 274
<b>Marine pollutant</b>	NP1
<b>Description</b>	UN1544, Alkaloids, solid, n.o.s. (Bupivacaine Hydrochloride, Monohydrate), 6.1, II

#### **RID**

<b>UN number</b>	UN1544
<b>Proper Shipping Name:</b>	Alkaloids, solid, n.o.s.
<b>Transport hazard class(es)</b>	6.1
<b>Packing group</b>	II
<b>Classification code</b>	T2
<b>Special Provisions</b>	43, 274
<b>Description:</b>	UN1544, Alkaloids, solid, n.o.s. (Bupivacaine Hydrochloride, Monohydrate), 6.1, II
<b>Labels</b>	6.1

#### **ADR**

<b>UN number</b>	1544
<b>Proper Shipping Name:</b>	Alkaloids, solid, n.o.s.
<b>Transport hazard class(es)</b>	6.1
<b>Packing group</b>	II
<b>Classification code</b>	T2
<b>Tunnel restriction code</b>	(D/E)

<b>Special Provisions</b>	43, 274
<b>Description:</b>	1544, Alkaloids, solid, n.o.s. (Bupivacaine Hydrochloride, Monohydrate), 6.1, II, (D/E)
<b>Labels</b>	6.1

#### **ADN**

<b>UN/ID No</b>	UN1544
<b>Proper shipping name</b>	Alkaloids, solid, n.o.s.
<b>Transport hazard class(es)</b>	6.1
<b>Packing Group</b>	II
<b>Classification code</b>	T2
<b>Special Provisions</b>	43, 274, 802
<b>Description</b>	UN1544, Alkaloids, solid, n.o.s. (Bupivacaine Hydrochloride, Monohydrate), 6.1, II
<b>Hazard label(s)</b>	6.1
<b>Limited quantity (LQ)</b>	500 g
<b>Equipment Requirements</b>	PP, EP

## **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

<b>DSL/NDSL</b>	Does not Comply
<b>EINECS/ELINCS</b>	Does not Comply
<b>ENCS</b>	This product complies with ENCS:
<b>IECSC</b>	This product does not comply with china:
<b>KECL</b>	Does not Comply
<b>PICCS</b>	Does not Comply
<b>AICS</b>	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** 4

**Flammability** 0

**Instability** 0

**Physical and chemical properties** -

#### **HMIS**

**Health hazards** 4

**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) (AEGLe(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** 05-June-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
B1391	Bupivacaine Hydrochloride, Monohydrate, USP

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)

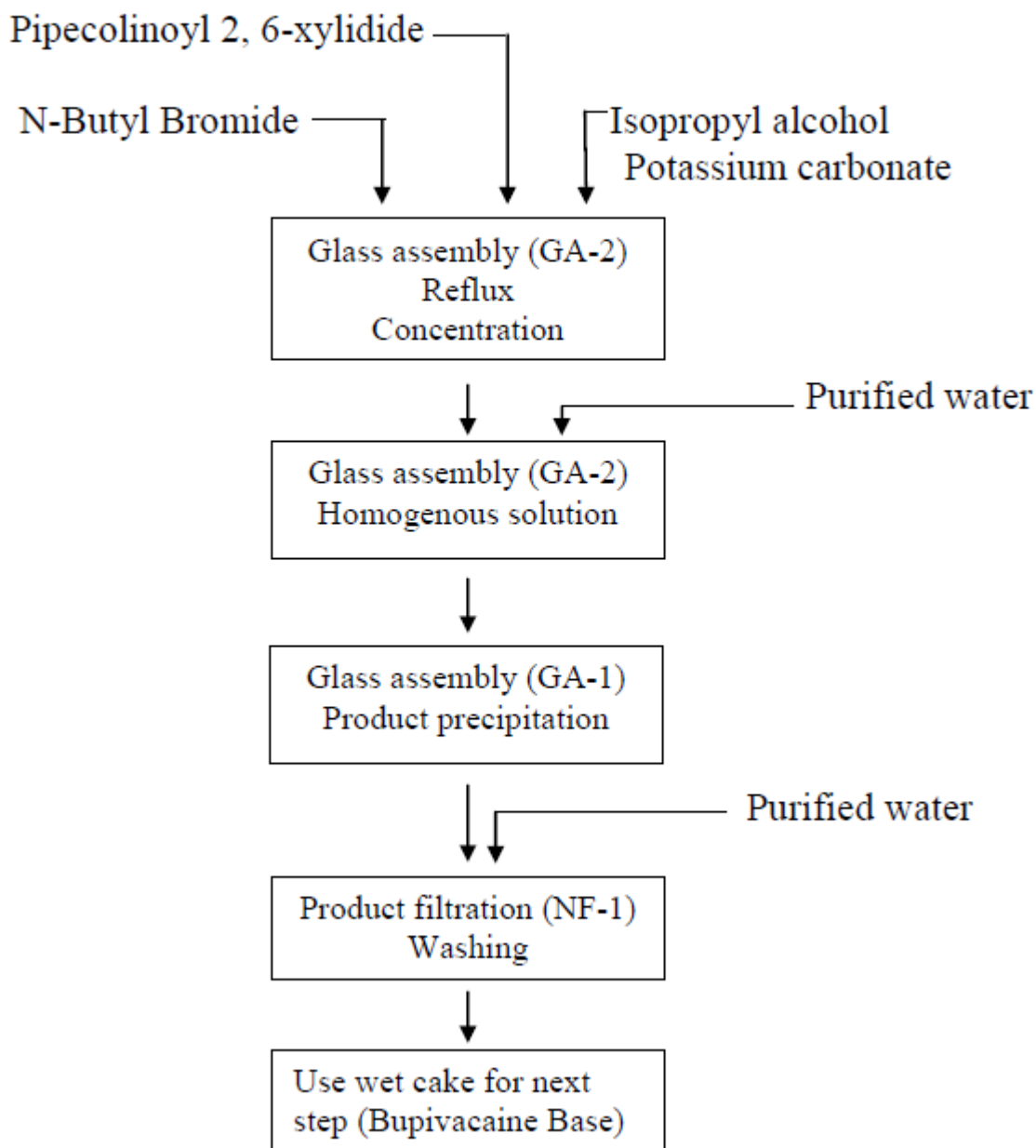
Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez  
Quality Assurance Specialist

## Manufacturing Process Flowchart Bupivacaine Hydrochloride, Monohydrate, USP (Cat# B1391)

### Stage – I: Preparation of Bupivacaine base



#### CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

#### WEST COAST FACILITY

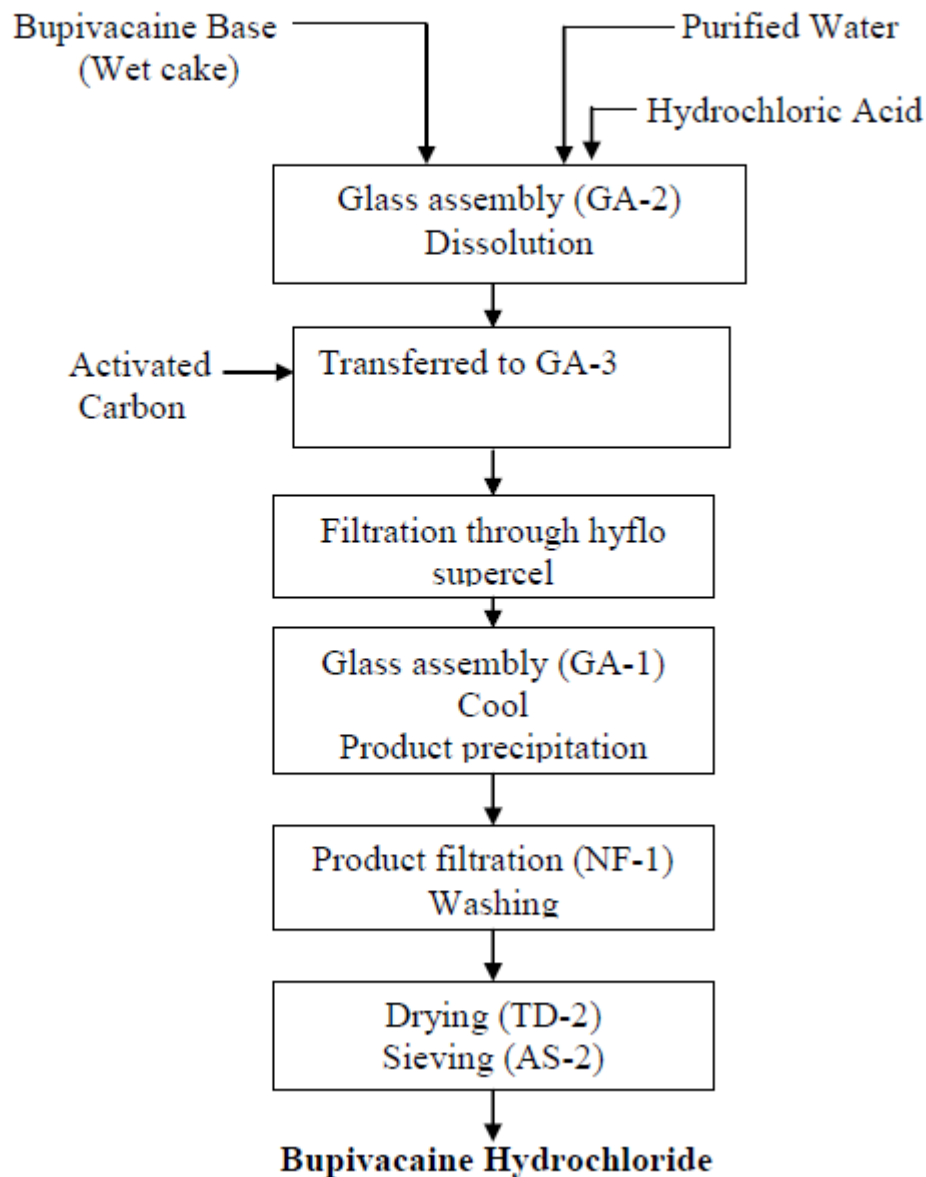
14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

**Stage – II: Bupivacaine hydrochloride preparation and purification.**



**CORPORATE HEADQUARTERS**

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

**WEST COAST FACILITY**

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

## **B1391, Bupivacaine Hydrochloride, Monohydrate, USP**

### **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 60 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        | • Parabens      |
| • Antibiotics       | • Pesticides    |
| • Bisphenol A (BPA) | • Phthalates    |
| • CMR Substances    | • Preservatives |



**RE: Elemental Impurities - Bupivacaine Hydrochloride, Monohydrate, USP  
(Cat# B1391)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue  
New Brunswick, NJ 08901  
PHONE 732.214.1300  
FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street  
Gardena, California 90248  
PHONE 310.516.8000  
FAX 310.516.9843



**RE: Residual Solvents - Bupivacaine Hydrochloride, Monohydrate, USP  
(Cat# B1391)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
2-Propanol	3	< 5000 ppm

No Class 1, Class 2 or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

## 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**

- Fatal if swallowed, in contact with skin or if inhaled.
- Do not eat, drink or smoke when using this product • Wear respiratory protection, protective gloves, protective clothing • Do not get in eyes, on skin, or on clothing • Do not breathe dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling.

**FIRST AID:** Immediately call a POISON CENTER or physician. IF ON SKIN: Wash with plenty of water. Take off immediately all contaminated clothing and wash it before reuse. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth.

**KEEP FROM CHILDREN**



**B1391**

**SIZ SY**

**Bupivacaine Hydrochloride**

Monohydrate, USP

CAS 73360-54-0

**CAUTION:** For manufacturing, processing, repacking, or for prescription compounding. Rx only.  
**Read and understand the label and Safety Data Sheet (SDS) prior to use.**

DOT: UN1544, Alkaloid salt, solid, n.o.s. (bupivacaine hydrochloride), 6.1, PG II

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

www.SpectrumChemical.com

$C_{18}H_{28}N_2O \cdot HCl \cdot H_2O$  F.W. 342.90

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

Assay (Anhydrous Basis) ..... 98.5-101.5%  
pH of a 1 in 100 Solution ..... 4.5-6.0  
Water Determination ..... 4.0-6.0%  
Chromatographic Purity ..... To pass test


MAXIMUM LIMITS

Residue on Ignition ..... 0.1%  
Elemental Impurities ..... As reported  
Residual Solvents ..... To pass test

**WARNING:** Cancer and Reproductive Harm-  
www.P65Warnings.ca.gov

Repackaged by Spectrum as:  
Lot No. XQ####

Exp. Date: 00-00-0000



### Spectrum Chemical Mfg Corp

#### Corporate Headquarters:

769 Jersey Ave.  
New Brunswick, NJ 08901  
732.214.1300

#### West Coast Facility:

14422 S. San Pedro St.  
Gardena, CA 90248  
310.516.8000