



Scientific Documentation

B1391, Bupivacaine Hydrochloride,
Monohydrate, USP

Not appropriate for regulatory submission.
Please visit 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

B1391, Bupivacaine Hydrochloride, Monohydrate, USP

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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 ₂ O•HCl•H ₂ O
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

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

Item Number	B1391	Lot Number	4IK0006
Item	Bupivacaine Hydrochloride, Monohydrate, USP	Manufacturer Lot	18G56N03
CAS Number	73360-54-0	Manufacturer Code	14527
Molecular Formula	C ₁₈ H ₂₈ N ₂ O•HCl•H ₂ O	Molecular Weight	342.90

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (ANHYDROUS BASIS)	98.5	101.5 %	99.9 %
pH OF A 1 IN 100 SOLUTION	4.5	6.0	5.12
WATER DETERMINATION	4.0	6.0 %	5.3631 %
CHROMATOGRAPHIC PURITY:			.
INDIVIDUAL IMPURITY		0.5 %	<0.5 %
TOTAL IMPURITIES		2.0 %	<2.0 %
RESIDUE ON IGNITION		0.1 %	0.05 %
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION B (UV)		3.0 %	0.16 %
IDENTIFICATION (C)	POSITIVE FOR CHLORIDE		POSITIVE FOR CHLORIDE
EXPIRATION DATE			30-JUN-2023
DATE OF MANUFACTURE			01-JUL-2018
APPEARANCE			WHITE CRYSTALLINE POWDER
RESIDUAL SOLVENTS	AS REPORTED		.
CLASS 3 (solvent) / 2-PROPANOL			<5000 ppm

Certificate of Analysis Results Entered By:

MPEREZ
Melchor Perez
21-NOV-19 07:31:28

Spectrum Chemical Mfg Corp
777 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

MPEREZ
Melchor Perez
21-NOV-19 07:31:34

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. 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.

Eye contact	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.
Skin contact	Get immediate medical advice/attention. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
Ingestion	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.
Self-protection of the first aider	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

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the 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.
Hazardous combustion products	Carbon monoxide. Carbon dioxide (CO ₂). Nitrogen oxides (NO _x). hydrogen chloride gas.
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. 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.
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. 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.

Skin contact Specific test data for the substance or mixture is not available. Fatal in contact with skin. (based on components).

Ingestion 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

Symptoms 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

Skin corrosion/irritation No information available.
Serious eye damage/eye irritation No information available.
Respiratory or skin sensitization No information available.
Germ cell mutagenicity No information available.

Reproductive toxicity No information available.

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

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

Persistence and degradability No information available.
Bioaccumulation 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
UN/ID no UN1544

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

TDG

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

MEX

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

ICAO (air)

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

IATA

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

IMDG

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

RID

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

ADR

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

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

ADN

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

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 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) (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 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

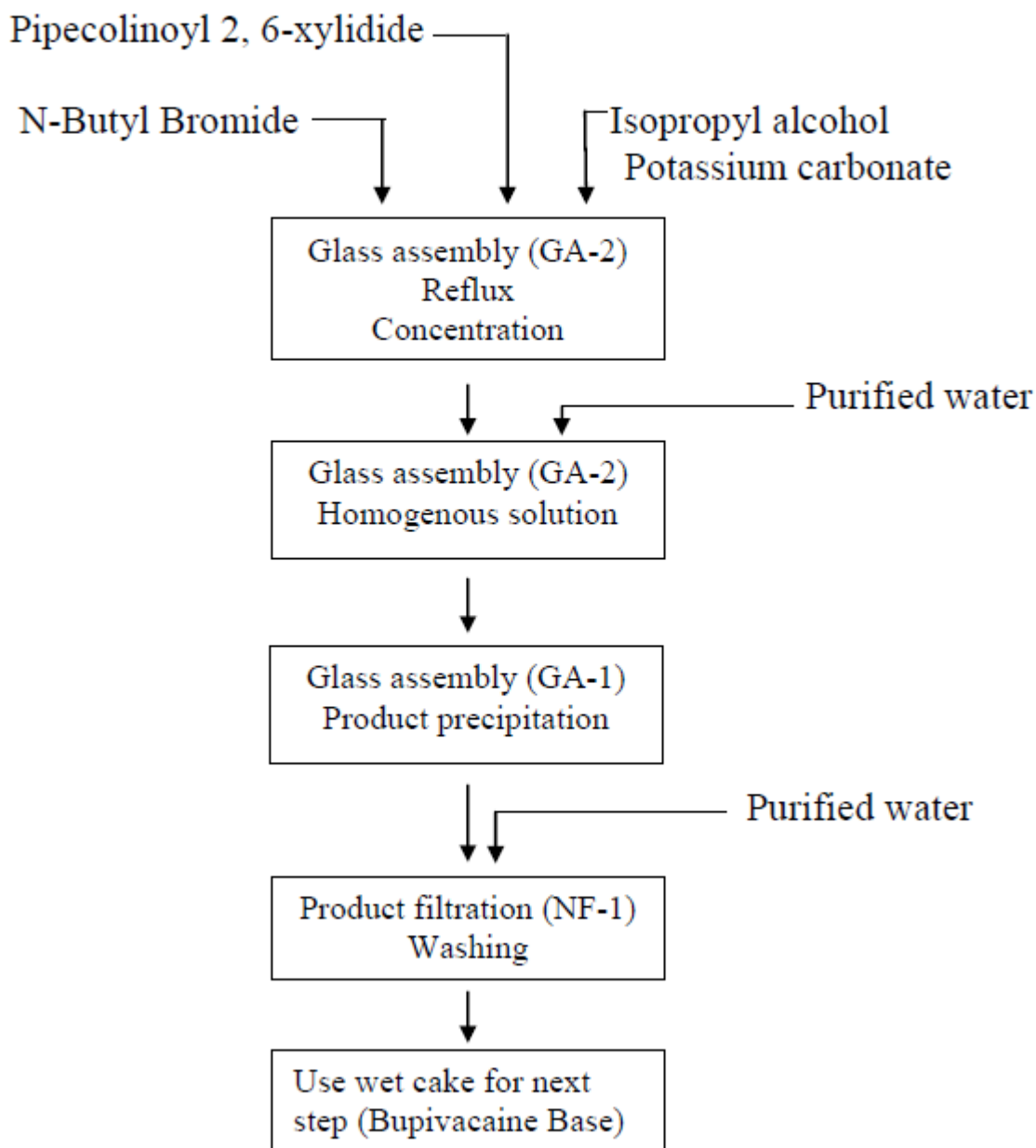
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

Oralia Chavez
Quality Assurance Specialist

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

Stage – I: Preparation of Bupivacaine base



CORPORATE HEADQUARTERS

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WEST COAST FACILITY

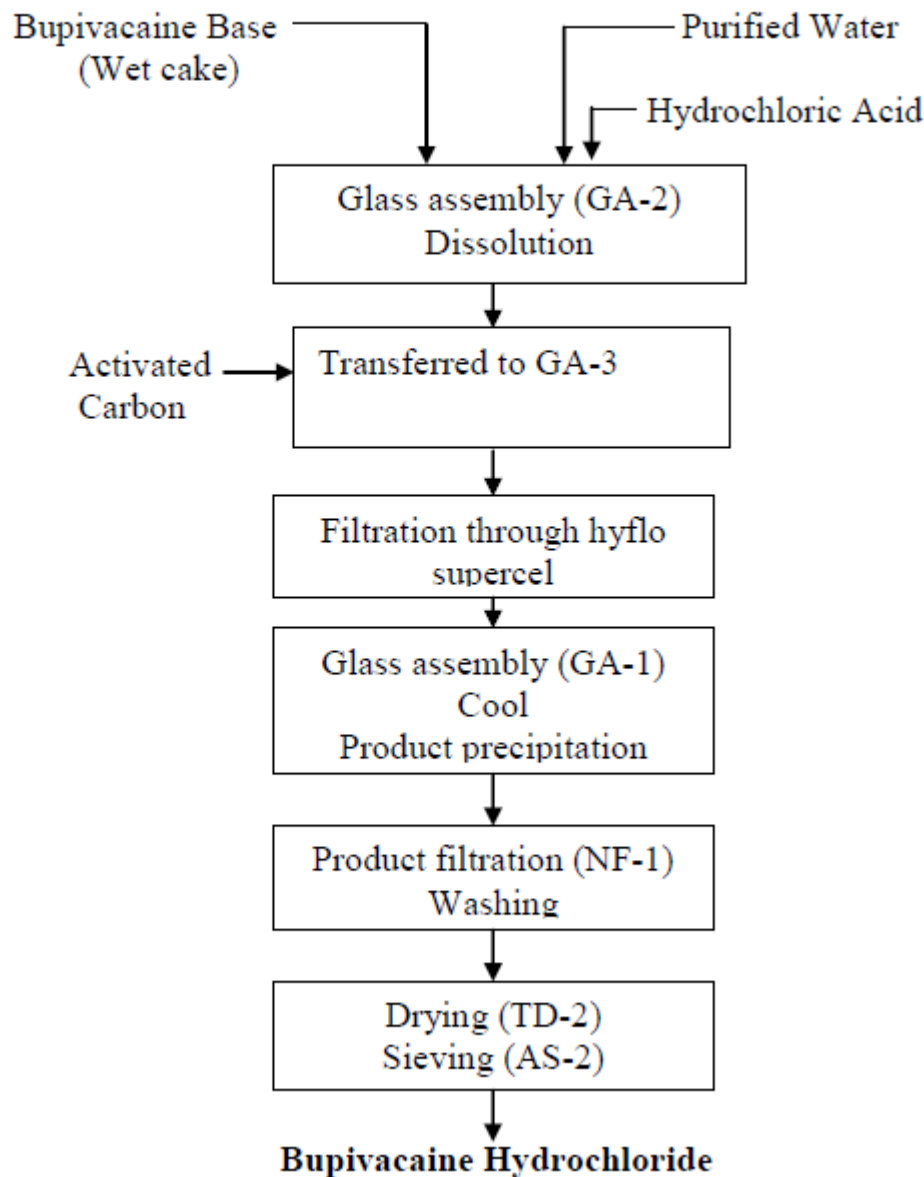
14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

Stage – II: Bupivacaine hydrochloride preparation and purification.



CORPORATE HEADQUARTERS

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

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS

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**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.

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.

Exp. Date: 00-00-0000



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:

B 11/17GHS-A ? Lot No. XQ####

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



RE: Lot Numbering System

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products' Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of **six characters**, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum's Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

Example: ZI0928 = The 928th material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of **seven characters**. The first character, a number, represents the production facility:

- 1 = Gardena, CA Facility
- 2 = New Brunswick, NJ Facility
- 3 = China Facility
- 4 = Pharmacy, NJ Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

Example: 2AA0706 = The 706th material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at quality_assurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Oralia Chavez,
Quality Assurance Specialist

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