

# Scientific Documentation

## Lidocaine 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



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# Specification for Lidocaine Hydrochloride, Monohydrate, USP (LI103)

Item Number	LI103
Item	Lidocaine Hydrochloride, Monohydrate, USP
CAS Number	6108-05-0
Molecular Formula	$C_{14}H_{22}N_2O \cdot HCl \cdot H_2O$
Molecular Weight	288.81
MDL Number	
Synonyms	Lignocaine Hydrochloride

Test	Specification	
	Min	Max
APPEARANCE		
ASSAY (ANHYDROUS BASIS)	97.5	102.5%
WATER DETERMINATION	5.0	7.0%
RESIDUE AFTER IGNITION		0.1%
SULFATE		0.1 %
ORGANIC IMPURITIES:		
LIDOCAINE RELATED COMPOUND H		0.10 %
ROPIVACAINE RELATED COMPOUND A		0.01 %
ANY INDIVIDUAL IMPURITY		0.10 %
TOTAL IMPURITIES		0.5 %
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION A) FTIR	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD	
IDENTIFICATION (C)	POSITIVE FOR CHLORIDE	
EXPIRATION DATE		
DATE OF MANUFACTURE		
MONOGRAPH EDITION		

Test	Specification	
	Min	Max
RESIDUAL SOLVENTS	AS REPORTED	

***Spectrum Chemical Mfg Corp***

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<i><b>Corporate Headquarters:</b></i>	<i><b>West Coast Facility:</b></i>
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	LI103	Lot Number	4NE0027
Item	Lidocaine Hydrochloride, Monohydrate, USP	Manufacturer Lot	LDH/724001
CAS Number	6108-05-0	Manufacturer Code	7068
Molecular Formula	C <sub>14</sub> H <sub>22</sub> N <sub>2</sub> O•HCl•H <sub>2</sub> O	Molecular Weight	288.81

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE			WHITE CRYSTALLINE POWDER
ASSAY (ANHYDROUS BASIS)	97.5	102.5%	99.9 %
WATER DETERMINATION	5.0	7.0%	6.56 %
RESIDUE AFTER IGNITION		0.1%	0.1 %
SULFATE		0.1 %	<0.1 %
ORGANIC IMPURITIES:			<0.10 %
LIDOCAINE RELATED COMPOUND H		0.10 %	<0.10 %
ROPIVACAINE RELATED COMPOUND A		0.01 %	<0.01 %
ANY INDIVIDUAL IMPURITY		0.10 %	<0.10 %
TOTAL IMPURITIES		0.5 %	<0.5 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
IDENTIFICATION A) FTIR	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD
IDENTIFICATION (C)	POSITIVE FOR CHLORIDE		POSITIVE FOR CHLORIDE
EXPIRATION DATE			31-DEC-2028
DATE OF MANUFACTURE			01-JAN-2024
MONOGRAPH EDITION			USP 2024
RESIDUAL SOLVENTS	AS REPORTED		.
CLASS 2 (solvent) TOLUENE			<890 ppm
CLASS 3 (solvent) / ACETONE			<5000 ppm

Certificate of Analysis Results Entered By:

MCAMACHO  
Matheu Camacho  
06-AUG-24 06:31:58

Spectrum Chemical Mfg Corp  
777 Jersey Avenue  
New Brunswick NJ 08901

Certificate of Analysis Results Approved By:

MTHUKU  
Marieta Thuku  
06-AUG-24 06:33:38



**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, repackaging 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 Swati Spentose Private Limited at A-1/2102,2103, Phase III, GIDC-Vapi, Gujarat 396195, 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

This safety data sheet was created pursuant to the requirements of: US OSHA Hazard Communication Standard (29 CFR 1910.1200)



# spectrum®

Revision date 02-February-2025

Revision Number 4

## 1. Identification

### Product identifier

**Product Name** LIDOCAINE HYDROCHLORIDE, MONOHYDRATE, USP

### Other means of identification

**Product Code(s)** LI103

**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 4
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### Hazards not otherwise classified (HNOC)

Not applicable.

### Label elements



Warning

**Hazard statements**

Harmful if swallowed.

**Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling.

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

**Precautionary Statements - Response**

IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell.

Rinse mouth.

**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-%
Lidocaine Hydrochloride, Monohydrate	6108-05-0	100

### 4. First-aid measures

**Description of first aid measures**

<b>General advice</b>	Show this safety data sheet to the doctor in attendance.
<b>Inhalation</b>	Remove to fresh air.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Wash skin with soap and water.
<b>Ingestion</b>	Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Call a physician.

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



Symptoms No information available.

Effects of Exposure No information available.

**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.

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. Nitrogen oxides (NOx). hydrogen chloride gas.

**Explosion data**

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

Special protective equipment and precautions 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 Ensure adequate ventilation.

**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.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

## 7. Handling and storage

**Precautions for safe handling**

Technical Measures/Precautions: Provide sufficient air exchange and/or exhaust in work rooms Avoid dust formation Keep away from incompatible materials

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

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

**Conditions for safe storage, including any incompatibilities**

**Storage Conditions** Keep container tightly closed. Store at controlled room temperature.

**Incompatible Materials:** Strong oxidizing agents

## **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** Appropriate eye/face protection should be selected and used according to the chemical nature, hazards and use of this product and safety requirements of the local jurisdiction.

**Hand protection** Appropriate hand protection should be selected and used according to the chemical nature, hazards and use of this product and safety requirements of the local jurisdiction.

**Skin and body protection** Appropriate skin and body protection should be selected and used according to the chemical nature, hazards and use of this product and safety requirements of the local jurisdiction.

**Respiratory protection** Appropriate respiratory protection should be selected and used according to the chemical nature, hazards and use of this product and safety requirements of the local jurisdiction. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

## **9. Physical and chemical properties**

### Information on basic physical and chemical properties

<b>Physical state</b>	Solid
<b>Appearance</b>	Crystalline powder
<b>Color</b>	White
<b>Odor</b>	Characteristic
<b>Odor threshold</b>	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>pH</b>	No data available	None known
<b>pH (as aqueous solution)</b>		None known
<b>Melting point / freezing point</b>	74 °C / 165.2 °F	None known
<b>Initial boiling point and boiling range</b>	No data available	None known
<b>Flash point</b>	No data available	None known
<b>Evaporation rate</b>	no data available	None known

<b>Flammability</b>	no data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Vapor pressure</b>	No data available	None known
<b>Relative vapor density</b>	No data available	None known
<b>Relative density</b>	no data available	None known
<b>Water solubility</b>	Soluble in water	None known
<b>Solubility(ies)</b>	Insoluble in diethyl ether Soluble in Benzene Soluble in Ethanol Soluble in Chloroform	None known
<b>Partition coefficient</b>	No data available	None known
<b>Autoignition temperature</b>	No data available	None known
<b>Decomposition temperature</b>		None known
<b>Kinematic viscosity</b>	no data available	None known
<b>Dynamic viscosity</b>	No data available	None known
<b><u>Other information</u></b>		
<b>Explosive properties</b>	No information available	
<b>Oxidizing properties</b>	No information available	
<b>Softening point</b>	No information available	
<b>Molecular weight</b>	288.81	
<b>VOC content</b>	No information available	
<b>Liquid Density</b>	No information available	
<b>Bulk density</b>	No information available	

## 10. Stability and reactivity

<b>Reactivity</b>	No information available.
<b>Chemical stability</b>	Stable under recommended storage 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>	None known based on information supplied.
<b>Hazardous decomposition products</b>	Spontaneous polymerisation.

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

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

**Symptoms** No information available.

**Acute toxicity** No information available.

**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.

**Carcinogenicity** 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** There is no data for this product.

**Other adverse effects** No information available.

### 13. Disposal considerations

#### Disposal 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

<b><u>DOT</u></b>	Not regulated
<b><u>TDG</u></b>	Not regulated
<b><u>MEX</u></b>	Not regulated
<b><u>ICAO (air)</u></b>	Not regulated
<b><u>IATA</u></b>	Not regulated
<b><u>IMDG</u></b>	Not regulated
<b>ADR</b>	Not regulated
<b>RID</b>	Not regulated

### 15. Regulatory information

#### International Inventories

<b>TSCA</b>	Not listed
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\*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>AIIC</b>	All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).
<b>NZIoC</b>	Does not comply
<b>TCSI</b>	Does not comply

#### **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

**NZIoC** - New Zealand Inventory of Chemicals  
**TCSI** - Taiwan Chemical Substance Inventory

**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).

**CAA (Clean Air Act)**

This product does not contain any substances regulated as pollutants pursuant to Clean Air Act (CAA).

**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

**International Inventories**

Chemical name	CAS No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	IECSC	AIIC	EINECS-No.
	6108-05-0	Not Present. Exempt from TSCA 8(b) Inventory listing since it is a hydrate. However, the anhydrous form	Not present	Not present	Not present	Not listed	X	Not present

		(CAS no. 73-78-9) is listed on the TSCA 8(b) Inventory.						
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## U.S. Regulations

### California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

#### Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

#### Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemical name	CAS No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
	6108-05-0	Not Listed	Not Listed	Not Listed	Not Listed

### CERCLA/SARA

CERCLA

TSCA

Chemical name	CAS No.	Hazardous Substances RQs	TPQ	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category
	6108-05-0			None	None

### U.S. TSCA

Chemical name	CAS No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
	6108-05-0	Not Applicable	Not Applicable

### Canada

#### WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

The WHMIS 2015 classification of this product has not been validated or reviewed yet.

**Canada Hazardous Products Regulation** This product has not been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

### DSL/NDSL

Not listed Does not Comply

Chemical name	CAS No.	Canada (DSL)	Canada (NDSL)
	6108-05-0	Not Listed	Not Listed

Chemical name	CAS No.	CEPA Schedule I - Toxic Substances
	6108-05-0	Not listed
Chemical name	CAS No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
	6108-05-0	Not listed

Chemical name	CAS No.	EU GHS - SV - CLP (1272/2008)
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	6108-05-0	
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**S -phrase(s)**

none

Chemical name	CAS No.	Classification according to Directive 67/548/EEC or 1999/45/EC	Concentration Limits:	Safety Phrases
Lidocaine Hydrochloride, Monohydrate	6108-05-0		No information	

**The product is classified in accordance with Annex VI to Directive 67/548/EEC**

**Indication of danger:**

Not dangerous

**16. Other information**

<b>NFPA</b>	<b>Health hazards</b> 2	<b>Flammability</b> 0	<b>Instability</b> 0	<b>Special hazards</b> -
<b>HMIS</b>	<b>Health hazards</b> 2	<b>Flammability</b> 0	<b>Physical hazards</b> 0	<b>Personal protection</b> X

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

**Legend**

SVHC: Substances of Very High Concern for Authorization:  
PBT: Persistent, Bioaccumulative, and Toxic (PBT) Substances  
vPvB: Very Persistent and very Bioaccumulative (vPvB) Substances  
STOT: Specific Target Organ Toxicity  
ATE: Acute Toxicity Estimate  
LC50: 50% Lethal Concentration  
LD50: 50% Lethal Dose

**Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	Sk*	Skin designation
+	Sensitizers		

**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)  
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)  
National Institute of Technology and Evaluation (NITE)  
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)  
U.S. 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** 02-February-2025  
**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
LI103	Lidocaine 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)

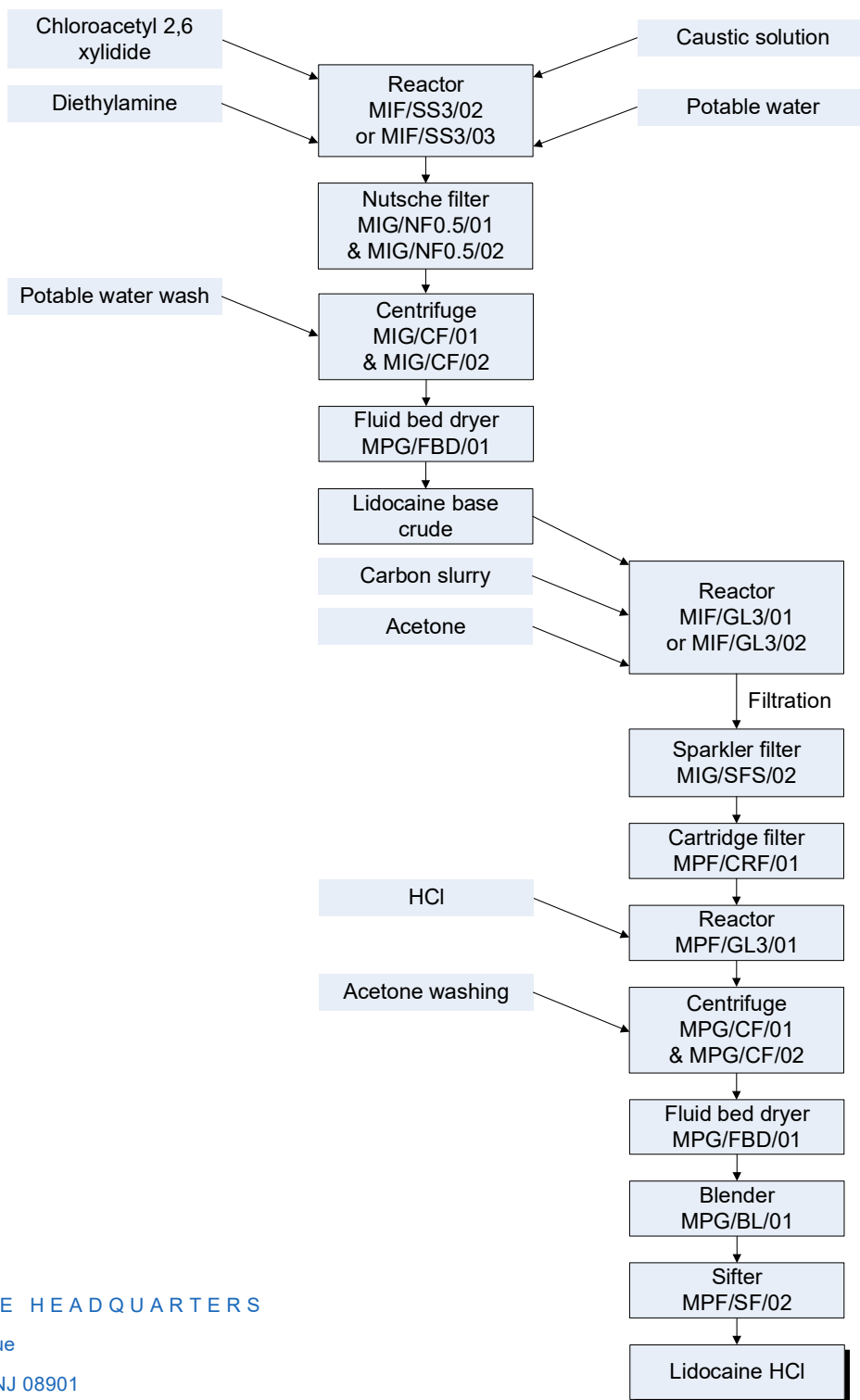
Sincerely,

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

Oralia Chavez  
Quality Assurance Specialist

## Manufacturing Process Flowchart

### Lidocaine Hydrochloride, Monohydrate, USP - LI103



#### 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

## LI103, Lidocaine 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      | • Cereals containing Gluten |
| • Egg       | • Celery                    |
| • Fish      | • Mustard                   |
| • Shellfish | • Sesame Seed               |
| • Tree Nuts | • Corn                      |
| • Wheat     | • Sulfites > 10 ppm         |
| • Peanuts   | • Soy                       |

### 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 above mentioned catalog item 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 - Lidocaine Hydrochloride, Monohydrate, USP (Cat# LI103)**

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 – Lidocaine Hydrochloride, Monohydrate, USP (Cat# LI103)**

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
Acetone	2	< 890 ppm
Toluene	3	< 5000 ppm

No Class 1 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).

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## 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.

**Retest Date: 03-31-2030**

**WARNING**

- Harmful if swallowed.
- Do not eat, drink or smoke when using this product • Wash face, hands and any exposed skin thoroughly after handling.

**FIRST AID: IF SWALLOWED:** Rinse mouth. Call a POISON CENTER or physician if you feel unwell.

**KEEP FROM CHILDREN**

**spectrum®**  
CHEMICAL MFG CORP

**LI103** **5 KG**

**Lidocaine Hydrochloride**  
(Lignocaine Hydrochloride)  
Monohydrate  
USP

CAS 6108-05-0

**CAUTION:** For manufacturing, processing or repacking. Must be subject to further processing and testing during the preparation of injectable dosage forms.  
**Read and understand the label and Safety Data Sheet (SDS) prior to use.**

**Chemical Emergency: (800)424-9300**  
www.SpectrumChemical.com

$C_{14}H_{22}N_2O \cdot HCl \cdot H_2O$  F.W. 288.81

Not sterile.

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

Assay (Anhydrous Basis) ..... 97.5-102.5%  
Water Determination ..... 5.0-7.0%

**MAXIMUM LIMITS**

Residue After Ignition ..... 0.1%  
Sulfate ..... 0.1%

**Organic Impurities:**

Lidocaine Related Compound H ..... 0.10%  
Ropivacaine Related Compound A ..... 0.01%  
Any Unspecified Impurity ..... 0.10%  
Total Impurities ..... 0.5%

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

Preserve in well-closed containers. Store at controlled room temperature.

Repackaged by Spectrum as: Lot No. 062233

**SPECTRUM CHEMICAL MFG. CORP.**

**Gardena, CA 90248 • New Brunswick, NJ 08901**

- |  |   |   |
|--|---|---|
| <p><b>A</b> Bar Code</p> <p><b>B</b> GHS Hazard Pictograms</p> <p><b>C</b> Warning, Safety Data and Precautionary Information</p> <p><b>D</b> Product Catalog Number</p> <p><b>E</b> Item Name, Form, Grade</p> <p><b>O</b> Storage Color Band</p> | <p><b>F</b> Size/Quantity</p> <p><b>G</b> Chemical Abstracts Service (CAS) Registry Number</p> <p><b>H</b> Caution Information</p> <p><b>I</b> DOT Shipping Information</p> <p><b>J</b> Toll-Free 24-Hour Chemical Emergency Telephone Number</p> | <p><b>K</b> Empirical Formula, Formula Weight and Technical Specifications Panel</p> <p><b>L</b> Expiration Information</p> <p><b>M</b> Lot Number</p> <p><b>N</b> Kosher Certified by Kosher Supervision of America (KSA).</p> |
|--|---|---|

This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

- YELLOW:** Oxidizer
- RED:** Flammable
- GREEN:** General Storage
- BLUE:** Health Hazard
- WHITE:** Corrosive

### Spectrum Chemical Mfg Corp

#### Corporate Headquarters:

769 Jersey Ave.  
New Brunswick, NJ 08901  
732.214.1300

#### West Coast Facility:

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310.516.8000