

# Scientific Documentation

## Lactic Acid, Racemic, 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  
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## **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  
Kosher Certification

## Specification for Lactic Acid, Racemic, USP (L1010)

Item Number	L1010
Item	Lactic Acid, Racemic, USP
CAS Number	50-21-5
Molecular Formula	C <sub>3</sub> H <sub>6</sub> O <sub>3</sub>
Molecular Weight	90.10
MDL Number	
Synonyms	2-Hydroxypropionic Acid

Test	Specification	
	Min	Max
APPEARANCE		
IDENTIFICATION	POSITIVE FOR LACTATE	
ASSAY (C <sub>3</sub> H <sub>6</sub> O <sub>3</sub> )	88.0	92.0%
SPECIFIC ROTATION	-0.05° to +0.05°	
RESIDUE ON IGNITION		0.05%
SUGARS	NO RED PRECIPITATE	
CHLORIDE	NO OPALESCENCE	
CITRIC, OXALIC, PHOSPHORIC AND TARTARIC ACID	NO TURBIDITY	
SULFATE	NO TURBIDITY	
READILY CARBONIZABLE SUBSTANCES	NO DARK COLOR AT INTERFACE	
ELEMENTAL IMPURITIES	AS REPORTED	
CERTIFIED KOSHER		
CERTIFIED HALAL		
RESIDUAL SOLVENTS:	AS REPORTED	
CLASS 2 (SOLVENT) / METHANOL	.	
MONOGRAPH EDITION		
EXPIRATION DATE		
DATE OF MANUFACTURE		

*Spectrum Chemical Mfg Corp*

Corporate Headquarters: West Coast Facility:

769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

## Certificate Of Analysis

Item Number	L1010	Lot Number	2NB0227
Item	Lactic Acid, Racemic, USP	CAS Number	50-21-5
Molecular Formula	C <sub>3</sub> H <sub>6</sub> O <sub>3</sub>	Molecular Weight	90.10

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE			COLORLESS LIQUID
IDENTIFICATION	POSITIVE FOR LACTATE		POSITIVE FOR LACTATE
ASSAY (C <sub>3</sub> H <sub>6</sub> O <sub>3</sub> )	88.0	92.0%	88.4 %
SPECIFIC ROTATION	-0.05° to +0.05°		0.00 °
RESIDUE ON IGNITION		0.05%	NMT 0.05%
SUGARS	NO RED PRECIPITATE		NO RED PRECIPITATE
CHLORIDE	NO OPALESCENCE		NO OPALESCENCE
CITRIC, OXALIC, PHOSPHORIC AND TARTARIC ACID	NO TURBIDITY		NO TURBIDITY
SULFATE	NO TURBIDITY		NO TURBIDITY
READILY CARBONIZABLE SUBSTANCES	NO DARK COLOR AT INTERFACE		NO DARK COLOR AT INTERFACE
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES
CERTIFIED KOSHER			CERTIFIED KOSHER
CERTIFIED HALAL			CERTIFIED HALAL
RESIDUAL SOLVENTS:	AS REPORTED		.
CLASS 2 (SOLVENT) / METHANOL	.		< 3000 ppm
MONOGRAPH EDITION			USP 2023
EXPIRATION DATE			21-JUL-2028
DATE OF MANUFACTURE			22-JUL-2023

Certificate of Analysis Results Entered By:

CMARIN  
Catherine Marin  
04-MAR-24 12:11:19

Certificate of Analysis Results Approved By:

GHERRERA  
Genaro Herrera  
05-MAR-24 13:30:12

Spectrum Chemical Mfg Corp  
755 Jersey Avenue  
New Brunswick 08901 NJ



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

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

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.

# SAFETY DATA SHEET

# spectrum®



Revision date 12-February-2024

Revision Number 3

## 1. Identification

### Product identifier

**Product Name** LACTIC ACID, RACEMIC, USP

### Other means of identification

**Product Code(s)** L1010

**UN/ID no** UN3265

**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

Skin corrosion/irritation	Category 1
Serious eye damage/eye irritation	Category 1
Corrosive to metals	Category 1

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

**Danger**

#### Hazard statements

Causes severe skin burns and eye damage  
May be corrosive to metals



**Appearance** viscous

**Physical state** Liquid

**Odor** Slight Acid

#### Precautionary Statements - Prevention

Do not breathe dusts or mists

Wash face, hands and any exposed skin thoroughly after handling

Wear protective gloves/protective clothing/eye protection/face protection

Keep only in original container

#### Precautionary Statements - Response

Immediately call a POISON CENTER or doctor

Specific treatment (see .? on this label)

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

Immediately call a POISON CENTER or doctor

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower

Wash contaminated clothing before reuse

IF INHALED: Remove person to fresh air and keep comfortable for breathing

Immediately call a POISON CENTER or doctor

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting

Absorb spillage to prevent material damage

#### Precautionary Statements - Storage

Store locked up.

Store in corrosive resistant/ .? container with a resistant inner liner

#### Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

#### Other information

May be harmful if swallowed.

### 3. Composition/information on ingredients

#### Substance

Chemical name	CAS No	Weight-%
Lactic Acid Racemic	50-21-5	100

### 4. First-aid measures

#### Description of first aid measures

##### General advice

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

##### Inhalation

Remove to fresh air. If breathing has stopped, give artificial respiration. Get medical attention immediately. 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. Delayed pulmonary edema may occur. Get immediate medical advice/attention.

##### Eye contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open



while rinsing. Do not rub affected area. Get immediate medical advice/attention.

<b>Skin contact</b>	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Get immediate medical advice/attention.
<b>Ingestion</b>	Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Get immediate medical advice/attention.
<b>Self-protection of the first aider</b>	Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8). Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.

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

<b>Symptoms</b>	Burning sensation.
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#### **Indication of any immediate medical attention and special treatment needed**

<b>Note to physicians</b>	Product is a corrosive material. Use of gastric lavage or emesis is contraindicated. Possible perforation of stomach or esophagus should be investigated. Do not give chemical antidotes. Asphyxia from glottal edema may occur. Marked decrease in blood pressure may occur with moist rales, frothy sputum, and high pulse pressure.
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### **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>	The product causes burns of eyes, skin and mucous membranes. Thermal decomposition can lead to release of irritating gases and vapors.
<b>Hazardous combustion products</b>	Carbon monoxide. Carbon dioxide (CO <sub>2</sub> ).
<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. Attention! Corrosive material. Evacuate personnel to safe areas. 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. 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. Take off contaminated clothing and wash before reuse.

### Conditions for safe storage, including any incompatibilities

#### **Storage Conditions**

Keep containers tightly closed in a dry, cool and well-ventilated place. Protect from moisture. Store locked up. Keep out of the reach of children. Store away from other materials.

## 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**

Tight sealing safety goggles. Face protection shield.

#### **Hand protection**

Wear suitable gloves. Impervious gloves.

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

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

#### **Respiratory protection**

No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

#### **General hygiene considerations**

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

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

#### **Physical state**

Liquid

#### **Appearance**

viscous

#### **Color**

Colorless light yellow

#### **Odor**

Slight Acrid

#### **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	16.8 °C / 62.2 °F	None known
Boiling point / boiling range	122 °C / 251.6 °F	None known
Flash point	112.8 °C / 235 °F	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	0 kPa @ 25°C	None known
Vapor density	no data available	None known
Relative density	1.2 @ 20°C	None known
Water solubility	Soluble in cold water	None known
	Soluble in hot water	
Solubility(ies)	Partially soluble in diethyl ether	None known
	Practically insoluble in Chloroform	
	Practically insoluble in Petroleum Ether	
	Soluble in Alcohol	
Partition coefficient	-0.7	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	90.10	
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	Exposure to air or moisture over prolonged periods.
Incompatible materials	Oxidizing agent. Acids. Bases.
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. Corrosive by inhalation. (based on components). Inhalation of corrosive fumes/gases may cause coughing, choking, headache, dizziness, and weakness for several hours. Pulmonary edema may occur with tightness in the chest, shortness of breath, bluish skin, decreased blood pressure, and increased heart rate. Inhaled corrosive substances can lead to a toxic edema of the lungs. Pulmonary edema can be fatal.
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<b>Eye contact</b>	Specific test data for the substance or mixture is not available. Causes serious eye damage. (based on components). Corrosive to the eyes and may cause severe damage including blindness. May cause irreversible damage to eyes.
<b>Skin contact</b>	Specific test data for the substance or mixture is not available. Corrosive. (based on components). Causes burns.
<b>Ingestion</b>	Specific test data for the substance or mixture is not available. Causes burns. (based on components). Ingestion causes burns of the upper digestive and respiratory tracts. May cause severe burning pain in the mouth and stomach with vomiting and diarrhea of dark blood. Blood pressure may decrease. Brownish or yellowish stains may be seen around the mouth. Swelling of the throat may cause shortness of breath and choking. May cause lung damage if swallowed. May be fatal if swallowed and enters airways.

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

**Symptoms** Redness. Burning. May cause blindness. Coughing and/ or wheezing.

**Acute toxicity**

**Numerical measures of toxicity**

Component Information			
Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Lactic Acid Racemic 50-21-5	= 3543 mg/kg ( Rat )	> 2 g/kg ( Rabbit )	>7.940 mg/l (rat, 4 hr)

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

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

**12. Ecological information**

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

Other adverse effects

No information available.

### 13. Disposal considerations

#### Waste treatment methods

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

### 14. Transport information

#### DOT

UN/ID no	UN3265
Proper shipping name	Corrosive liquid, acidic, organic, n.o.s.
Hazard class	8
Special Provisions	III
Special Provisions	386, IB3, T7, TP1, TP28
Marine Pollutant	Severe Marine Pollutant
Description	UN3265, Corrosive liquid, acidic, organic, n.o.s., 8, III
Emergency Response Guide Number	153

#### TDG

UN/ID no.	UN3265
Proper shipping name	Corrosive liquid, acidic, organic, n.o.s.
Hazard class	8
Packing Group	III
Special Provisions	16
Description	UN3265, Corrosive liquid, acidic, organic, n.o.s., 8, III

#### MEX

UN-No	UN3265
Proper Shipping Name	Corrosive liquid, acidic, organic, n.o.s.
Hazard class	8
Special Provisions	223, 274
Packing Group	III
Description	UN3265, Corrosive liquid, acidic, organic, n.o.s., 8, III

#### ICAO (air)

UN/ID no.	UN3265
Hazard class	8
Packing Group	III
Special Provisions	A3

#### IATA

UN number	UN3265
Hazard Class	8
Packing group	III
Emergency Response Guide Number	8L
Special Provisions	A3, A803

#### IMDG

UN number	UN3265
Hazard Class	8
Packing group	III
EmS-No	F-A, S-B
Special Provisions	223, 274

Marine Pollutant NP1

**RID**

UN number	UN3265
Proper shipping name	CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S.
Hazard Class	8
Packing group	III
Classification code	C3
Special Provisions	274
Description	UN3265, CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S., 8, III
Labels	8

**ADR**

UN number	UN3265
Proper shipping name	Corrosive liquid, acidic, organic, n.o.s.
Hazard Class	8
Packing group	III
Classification code	C3
Tunnel restriction code	(E)
Special Provisions	274
Description	UN3265, Corrosive liquid, acidic, organic, n.o.s., 8, III, (E)
Labels	8

**ADN**

UN/ID No	UN3265
Proper shipping name	Corrosive liquid, acidic, organic, n.o.s.
Hazard Class	8
Packing Group	III
Classification code	C3
Special Provisions	274
Description	UN3265, Corrosive liquid, acidic, organic, n.o.s., 8, III
Hazard label(s)	8
Limited quantity (LQ)	5 L
Equipment Requirements	PP, EP

## 15. Regulatory information

**International Inventories**

TSCA Complies

DSL/NDSL	Complies
EINECS/ELINCS	Complies
ENCS	This product complies with ENCS:
IECSC	This product complies with China:
KECL	Complies
PICCS	Complies
AICS	All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).

**Legend:**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing and Evaluated Chemical Substances  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**US Federal Regulations**

**SARA 313**

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

#### **SARA 311/312 Hazard Categories**

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

#### **CWA (Clean Water Act)**

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

#### **CERCLA**

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

#### **US State Regulations**

##### **California Proposition 65**

This product does not contain any Proposition 65 chemicals.

##### **U.S. State Right-to-Know Regulations**

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

##### **U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not applicable

## **16. Other information**

#### **NFPA**

**Health hazards** 3

**Flammability** 1

**Instability** 0

**Physical and chemical properties** -

#### **HMIS**

**Health hazards** 3

**Flammability** 1

**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** 12-February-2024  
**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
L1010	Lactic Acid, Racemic, 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)

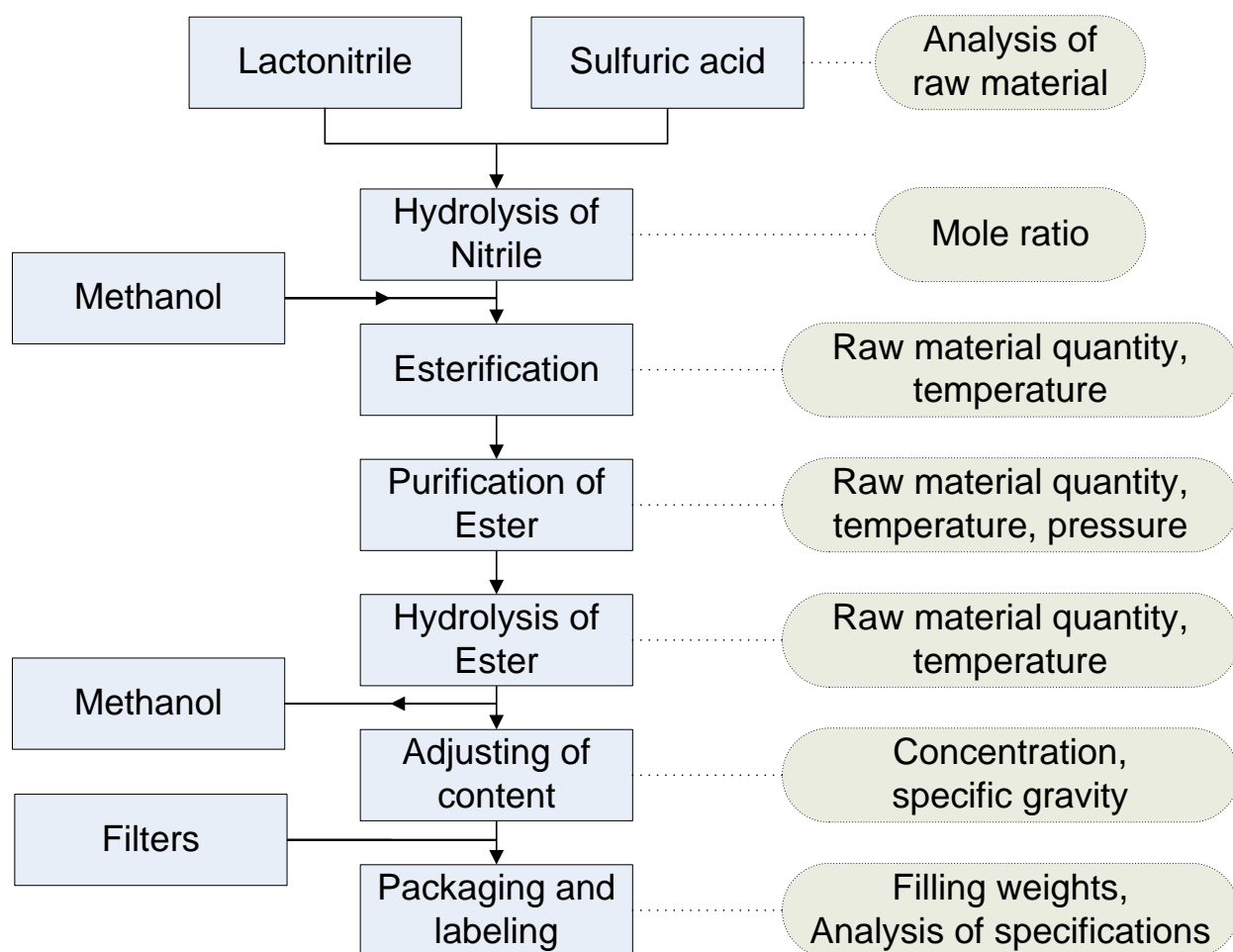
Sincerely,

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

Oralia Chavez  
Quality Assurance Specialist

## Manufacturing Process Flowchart

### Lactic Acid, Racemic, USP - L1010



#### ***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

## **L1010, Lactic Acid, Racemic, 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
- Latex

### **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 after November 2007.

## Organic Compliance Statement

The above mentioned catalog item has not been produced using ethylene oxide (EtO).

## 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
- CMR Substances
- Pesticides
- Phthalates
- Preservatives



**RE: Elemental Impurities - Lactic Acid, Racemic, USP (Cat# L1010)**

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 - Lactic Acid, Racemic, USP (Cat# L1010)**

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
Methanol	2	< 3000 ppm

No Class 1, Class 3 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.

**A** **DANGER**

- Causes severe skin burns and eye damage
- May be corrosive to metals • May be harmful if swallowed.
- Wear protective gloves, protective clothing, eye protection, face protection • Do not breathe mist or vapors • Wash face, hands and any exposed skin thoroughly after handling • Keep only in original container • Absorb spillage to prevent material damage.

**FIRST AID:** Immediately call a POISON CENTER or physician. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. Wash contaminated clothing before reuse. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth. DO NOT induce vomiting.

**L** **KEEP FROM CHILDREN**

**spectrum®**  
CHEMICAL MFG CORP

**L1010** **D**

**E** **Lactic Acid**  
(2-Hydroxypropionic Acid)

Racemic  
U.S.P.

**N** **KSA**  
KOSHER **H**

**G** **CAS 50-21-5**

**I** **DOT:** UN3265, Corrosive liquid, acidic, organic, n.o.s. (lactic acid) 8, PG III

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

**C<sub>3</sub>H<sub>6</sub>O<sub>3</sub>** **K** **F.W. 90.10**

Lactic Acid is a mixture of Lactic Acid (C<sub>3</sub>H<sub>6</sub>O<sub>3</sub>) and Lactic Acid Lactate (C<sub>6</sub>H<sub>10</sub>O<sub>5</sub>).

Assay (C<sub>3</sub>H<sub>6</sub>O<sub>3</sub>) ..... 88.0-92.0%  
Specific Rotation ..... -0.05° to +0.05°

**MAXIMUM LIMITS**

Residue on Ignition ..... 0.05%  
Sugars ..... To pass test  
Chloride ..... To pass test  
Citric, Oxalic, Phosphoric or Tartaric Acid ..... To pass test  
Sulfate ..... To pass test  
Readily Carbonizable Substances ..... To pass test  
Elemental Impurities ..... As reported  
Residual Solvents ..... To pass test

**HYGROSCOPIC:** Keep tightly closed.

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

**W 13/G10GHS** **A** **O** **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>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> <p><b>O</b> Storage Color Band</p> <p><b>P</b> Halal Certified by IFANCA</p> <p><b>Q</b> bioCertified</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.

### 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

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



KOSHER SUPERVISION OF AMERICA

בס"ד  
Jan 18, 2024

The following product(s) prepared by the named company are certified kosher with the stated requirements:

**Spectrum Laboratory Products, Inc.**

S-0032

14422 South San Pedro Street,  
Gardena, CA 90248  
755-769 Jersey Ave.  
New Brunswick NJ 08901  
USA

**Product Name** L1010, Lactic Acid, Racemic, USP

**Brand** Spectrum

**UKD-ID** KSAV3-P8N6N16

**D/P/M** P

**Symbol Required** KSA

**Special Conditions**

This certificate expires on  
**Feb 01, 2025**

Rabbi Binyomin Lisbon  
Kashrus Administrator

Placing the KSA logo on products not listed above constitutes an un-authorized use of the KSA symbol, which is a federally registered trademark.