



# Scientific Documentation

L1010, 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  
Phone 732.214.1300

Ver4.06 16.September.2021

**L1010**, Lactic Acid, Racemic, USP

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## 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:**  
 769 Jersey Ave.  
 New Brunswick, NJ 08901  
 732.214.1300

**West Coast Facility:**  
 14422 S. San Pedro St.  
 Gardena, CA 90248  
 310.516.8000

Item Number	L1010	Lot Number	2KH0059
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 OR YELLOWISH SYRUPY 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%	88.5 %
SPECIFIC ROTATION	-0.05° to +0.05°		+0.00°
RESIDUE ON IGNITION		0.05%	< 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		COMPLIES WITH STANDARD
CERTIFIED KOSHER			CERTIFIED KOSHER
CERTIFIED HALAL			CERTIFIED HALAL
RESIDUAL SOLVENTS:	AS REPORTED		.
CLASS 2 (SOLVENT) / METHANOL	.		< 3000 ppm
MONOGRAPH EDITION			(USP) 2021
EXPIRATION DATE			10-APR-2026
DATE OF MANUFACTURE			10-APR-2021

Spectrum Chemical Mfg Corp  
755 Jersey Avenue  
New Brunswick 08901 NJ



Certificate of Analysis Results Certified By:

*Jigisha Patel*

Jigisha Patel  
VP Regulatory Compliance & Technical Services,  
Regulatory

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 30-April-2020

Revision Number 2

## 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  
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-%	Trade secret
Lactic Acid Racemic	50-21-5	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** 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.

**Skin contact**

Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Get immediate medical advice/attention.

**Ingestion**

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.

**Self-protection of the first aider**

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**

**Symptoms**

Burning sensation.

**Indication of any immediate medical attention and special treatment needed**

**Note to physicians**

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.

**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**

The product causes burns of eyes, skin and mucous membranes. Thermal decomposition can lead to release of irritating gases and vapors.

**Hazardous combustion products**

Carbon monoxide. Carbon dioxide (CO<sub>2</sub>).

**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. Attention! Corrosive material. Evacuate personnel to safe areas. 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. 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 Acid

**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	None known
Water solubility	No data available	None known
Solubility(ies)	no data available	None known
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

#### Other information

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

<b>Reactivity</b>	No information available.
<b>Chemical stability</b>	Stable under normal conditions.
<b>Possibility of hazardous reactions</b>	None under normal processing.
<b>Conditions to avoid</b>	Exposure to air or moisture over prolonged periods.
<b>Incompatible materials</b>	Oxidizing agent. Acids. Bases.
<b>Hazardous decomposition products</b>	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.

##### Eye contact

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.

**Skin contact**

Specific test data for the substance or mixture is not available. Corrosive. (based on components). Causes burns.

**Ingestion**

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>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<b>Aspiration hazard</b>	No information available.
<b>Other adverse effects</b>	No information available.
<b>Interactive effects</b>	No information available.

**12. Ecological information**

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

**13. Disposal considerations**

**Waste treatment methods**

**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.(lactic acid)  
**Hazard class** 8  
**Packing group:** III  
**Special Provisions** IB3, T7, TP1, TP28  
**Description:** UN3265, Corrosive liquid, acidic, organic, n.o.s., 8, III  
**Emergency Response Guide Number** 153

### TDG

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

### ICAO (air)

**UN-No:** UN3265  
**Proper Shipping Name:** Corrosive liquid, acidic, organic, n.o.s.(lactic acid)  
**Hazard class** 8  
**Packing Group:** III  
**Special Provisions** A3  
**Description:** UN3265, Corrosive liquid, acidic, organic, n.o.s., 8, III

### IATA

**UN number** UN3265  
**Proper Shipping Name:** Corrosive liquid, acidic, organic, n.o.s.(lactic acid)  
**Transport hazard class(es)** 8  
**Packing group** III  
**Description:** UN3265, Corrosive liquid, acidic, organic, n.o.s., 8, III

### IMDG

**UN number** UN3265  
**Proper shipping name** Corrosive liquid, acidic, organic, n.o.s.(lactic acid)  
**Transport hazard class(es)** 8  
**Packing group** III  
**EmS-No** F-A, S-B  
**Special Provisions** 223, 274  
**Marine pollutant** NP1  
**Description** UN3265, Corrosive liquid, acidic, organic, n.o.s. (LACTIC ACID RACEMIC), 8, III

### RID

**UN number** UN3265  
**Proper Shipping Name:** Corrosive liquid, acidic, organic, n.o.s.(lactic acid)  
**Transport hazard class(es)** 8  
**Packing group** III  
**Classification code** C3  
**Special Provisions** 274  
**Description:** UN3265, Corrosive liquid, acidic, organic, n.o.s., 8, III

**ADR**

UN number	UN3265
Proper Shipping Name:	Corrosive liquid, acidic, organic, n.o.s.(lactic acid)
Transport hazard class(es)	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
Labels	8

**ADN**

UN/ID No	UN3265
Proper shipping name	Corrosive liquid, acidic, organic, n.o.s.(lactic acid)
Transport hazard class(es)	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

<b>15. Regulatory information</b>
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**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 30-April-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
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

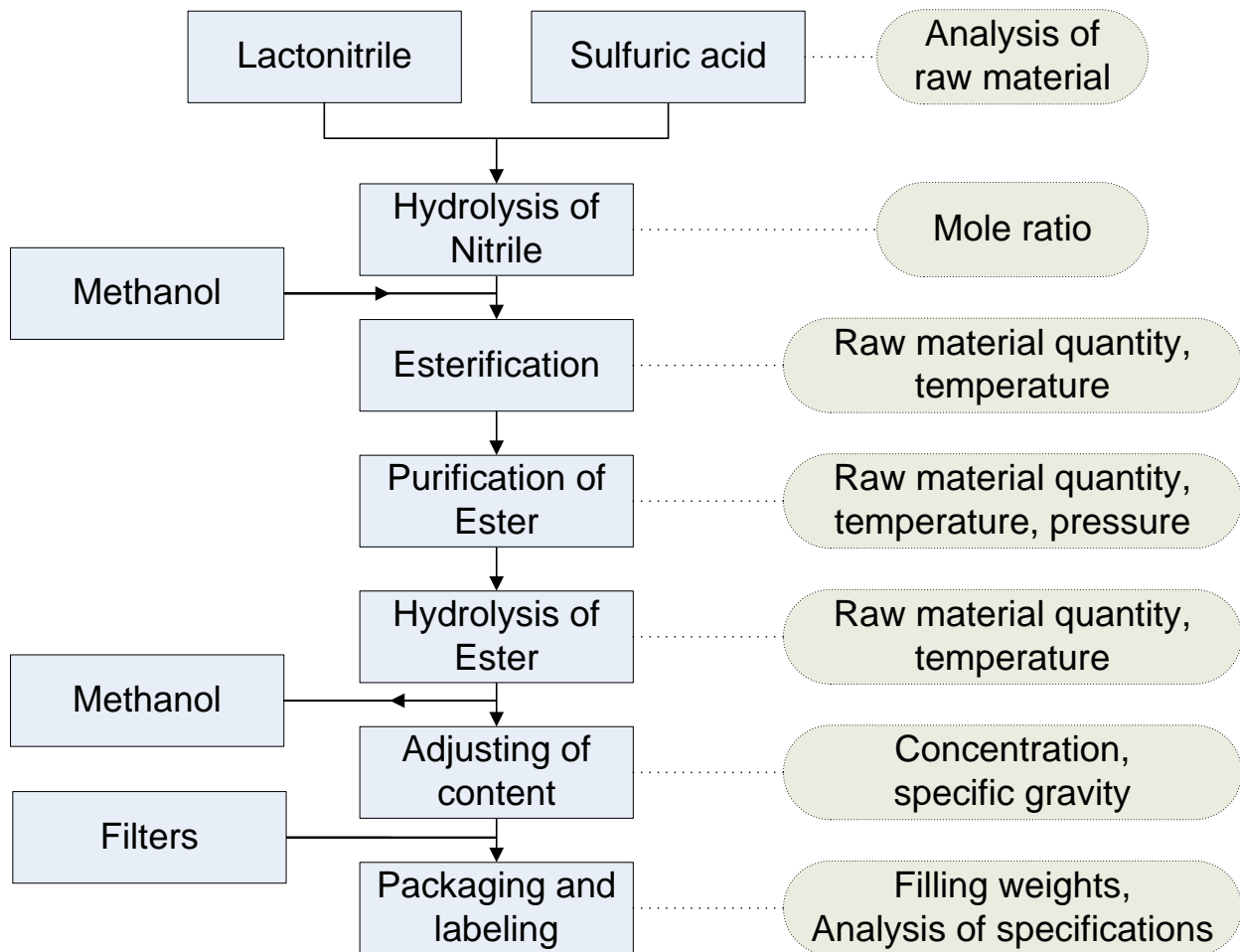
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com)

Sincerely,

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).

Sincerely,

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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.

**B**

**C** • 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.

**D** L1010 **E** **Lactic Acid**  
 (2-Hydroxypropionic Acid)  
 Racemic U.S.P.  
**F** 4 L

**G** CAS 50-21-5

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

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

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

**K**  $C_3H_6O_3$  F.W. 90.10

Lactic Acid is a mixture of Lactic Acid ( $C_3H_6O_3$ ) and Lactic Acid Lactate ( $C_6H_{10}O_5$ ).

Assay ( $C_3H_6O_3$ ) .....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

**L** Exp. Date: 03-31-2025

**M** **IFANCA CERTIFIED**  
**HALAL**

**N** **KOSHER**

**O** **HYGROSCOPIC:** Keep tightly closed.

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

**Q** W 13/G10GHS **A** **Lot No. 062233**

**SPECTRUM CHEMICAL MFG. CORP.** Gardena, CA 90248 • New Brunswick, NJ 08901

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

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:**  
 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 928<sup>th</sup> 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 706<sup>th</sup> 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](mailto:quality_assurance@spectrumchemical.com) if we may be of further assistance.

Sincerely,

Oralia Chavez,  
Quality Assurance Specialist

CORPORATE HEADQUARTERS

769 Jersey Avenue  
New Brunswick, NJ 08901  
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المجلس الإسلامي الأمريكي للغذاء و التغذية  
THE ISLAMIC FOOD AND NUTRITION COUNCIL OF AMERICA

IFANCA HALAL PRODUCT CERTIFICATE شهادة حلال

This is to certify that the following product(s) have been produced under the supervision of the Islamic Food and Nutrition Council of America(IFANCA). The production facility as well as component ingredients have been reviewed and approved. The product(s) are in compliance with the halal requirements under Islamic laws.


Date: July 16, 2020

Document #: 11205.11209.II201286

Company Name & Address: **Spectrum Laboratory Products, Inc.** 755-769 Jersey Ave New Brunswick, New Jersey 08901 USA

Plant Name & Address: **Spectrum Laboratory Products, Inc.** 14422 South San Pedro Street Gardena, California 90248 USA

ProductName	Product Code	Halal-ID	Product Certificate #
1. Lactic Acid, Racemic, USP	L1010	B94010	HC-20SPQQ28

  
Muhammad Munir Chaudry, Ph.D.  
President



This Certificate is valid until **August 31, 2021** and subject to renewal at that time.



Page 1 of 1



KOSHER SUPERVISION OF AMERICA

בס"ד  
Jan 28, 2021

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

**Spectrum Laboratory Products, Inc.**

S-0032

14422 S. San Pedro Street  
Gardena CA 90248  
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, 2022**

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.