

# Scientific Documentation

## Lactose, Monohydrate, Powder, NF

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 Lactose, Monohydrate, Powder, NF (LA106)

Item Number	LA106
Item	Lactose, Monohydrate, Powder, NF
CAS Number	64044-51-5
Molecular Formula	$C_{12}H_{22}O_{11} \cdot H_2O$
Molecular Weight	360.31
MDL Number	
Synonyms	4-O-Beta-Galactopyranosyl-D-glucose ; Milk Sugar

Test	Specification	
	Min	Max
CLARITY AND COLOR OF SOLUTION		TO PASS TEST
SPECIFIC ROTATION $[\alpha]_D$	+54.4° to +55.9°	
ACIDITY / ALKALINITY		TO PASS TEST
WATER DETERMINATION	4.5	5.5 %
MICROBIAL LIMITS:		
TOTAL AEROBIC MICROBIAL COUNT		10 <sup>2</sup> cfu/g
TOTAL MOLDS AND YEASTS		5x10 <sup>1</sup> cfu/g
TEST FOR E. COLI	NEGATIVE	
LOSS ON DRYING		0.5 %
RESIDUE ON IGNITION		0.1 %
PROTEIN & LIGHT-ABSORBING IMPURITIES		TO PASS TEST
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION		TO PASS TEST
CERTIFIED KOSHER-DAIRY		
CERTIFIED HALAL		
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	AS REPORTED	

Test	Specification	
	Min	Max
MONOGRAPH EDITION		

***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	LA106	Lot Number	2NB0043
Item	Lactose, Monohydrate, Powder, NF	CAS Number	64044-51-5
Molecular Formula	C <sub>12</sub> H <sub>22</sub> O <sub>11</sub> •H <sub>2</sub> O	Molecular Weight	360.31

TEST	SPECIFICATION		RESULT
	MIN	MAX	
CLARITY AND COLOR OF SOLUTION		TO PASS TEST	PASSES TEST
SPECIFIC ROTATION [α] <sub>D</sub>	+54.4° to +55.9°		+55.2°
ACIDITY / ALKALINITY		TO PASS TEST	PASSES TEST
WATER DETERMINATION	4.5	5.5 %	4.7 %
MICROBIAL LIMITS:			.
TOTAL AEROBIC MICROBIAL COUNT		10 <sup>2</sup> cfu/g	1 cfu/g
TOTAL MOLDS AND YEASTS		5x10 <sup>1</sup> cfu/g	1 cfu/g
TEST FOR E. COLI	NEGATIVE		NEGATIVE
LOSS ON DRYING		0.5 %	0.1 %
RESIDUE ON IGNITION		0.1 %	0.0 %
PROTEIN & LIGHT-ABSORBING IMPURITIES		TO PASS TEST	PASSES TEST
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
IDENTIFICATION		TO PASS TEST	PASSES TEST
CERTIFIED KOSHER-DAIRY			CERTIFIED KOSHER-DAIRY
CERTIFIED HALAL			CERTIFIED HALAL
EXPIRATION DATE			31-DEC-2026
DATE OF MANUFACTURE			01-JAN-2024
APPEARANCE			WHITE CRYSTALLINE POWDER
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS PRESENT
MONOGRAPH EDITION			NF 2023

Certificate of Analysis Results Entered By:

GHERRERA  
Genaro Herrera  
08-FEB-24 09:05:17

Certificate of Analysis Results Approved By:

MCAMACHO  
Matheu Camacho  
12-FEB-24 05:56:21

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 28-December-2021

Revision Number 2

## 1. Identification

### Product identifier

**Product Name** LACTOSE, MONOHYDRATE, POWDER, NF

### Other means of identification

**Product Code(s)** LA106

**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

Combustible dust	Yes
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### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

#### Warning

#### Hazard statements

May form combustible dust concentrations in air

**Appearance** Crystalline powder

**Physical state** Solid

**Odor** Odorless

### Precautionary Statements - Prevention

Keep away from all ignition sources including heat, sparks, and flame  
Keep container closed and grounded  
Prevent dust accumulations to minimize explosion hazard

**Other information**

No information available.

### 3. Composition/information on ingredients

**Substance**

Chemical name	CAS No	Weight-%	Trade secret
Lactose, Monohydrate	64044-51-5	100	*

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

### 4. First-aid measures

**Description of first aid measures**

Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash skin with soap and water.
Ingestion	Clean mouth with water and drink afterwards plenty of water.

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

Symptoms	No information available.
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**Indication of any immediate medical attention and special treatment needed**

Note to physicians	Treat symptomatically.
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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>	Avoid generation of dust. Fine dust dispersed in air may ignite.
<b>Explosion data</b>	
<b>Sensitivity to mechanical impact</b>	none.
<b>Sensitivity to static discharge</b>	yes.
<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

**Personal precautions** Ensure adequate ventilation. Avoid generation of dust. Avoid contact with eyes. Use personal protective equipment as required. Do not breathe dust. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Take precautionary measures against static discharges.

**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. Prevent dust cloud.

**Methods for cleaning up** Take up with inert, damp, non-combustible material using clean non-sparking tools and place into loosely covered plastic containers for later disposal. 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. Ensure adequate ventilation. Avoid generation of dust. Do not breathe dust. Avoid contact with eyes. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use spark-proof tools and explosion-proof equipment. Take precautionary measures against static discharges.

### Conditions for safe storage, including any incompatibilities

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

## 8. Exposure controls/personal protection

### Control parameters

**Exposure Limits** The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

### Appropriate engineering controls

**Engineering controls** Showers  
Eyewash stations  
Ventilation systems.

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

**Eye/face protection** Wear safety glasses with side shields (or goggles).

**Skin and body protection** No special protective equipment required.

<b>Respiratory protection</b>	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
<b>General hygiene considerations</b>	Do not breathe dust.

## 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>	Odorless
<b>Odor threshold</b>	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>pH</b>	Slightly acidic	None known
<b>Melting point / freezing point</b>	202 - 214 °C / 395.6 - 417.2 °F	None known
<b>Boiling point / 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 (solid, gas)</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>Vapor density</b>	no data available	None known
<b>Relative density</b>	1.5	None known
<b>Water solubility</b>	Soluble in water	None known
<b>Solubility(ies)</b>	no data available	None known
<b>Partition coefficient</b>	No data available	None known
<b>Autoignition temperature</b>	470 °C / 878 °F	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

### Other information

<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>	360.31
<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 normal conditions.
<b>Possibility of hazardous reactions</b>	None under normal processing.
<b>Conditions to avoid</b>	Excessive heat. Heating in air. dust formation.
<b>Incompatible materials</b>	None known based on information supplied.
<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. May cause irritation of respiratory tract.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

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

Symptoms	No information available.
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### Acute toxicity

**Numerical measures of toxicity**  
No information available

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

Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

## 12. Ecological information

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

## 13. Disposal considerations

### Waste treatment methods

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

## 14. Transport information

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

## 15. Regulatory information

### International Inventories

<b>TSCA</b>	Not listed
Note	*Contact supplier for details. One or more substances in this product are either not listed on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise exempted from inventory listing requirements
<b>DSL/NDSL</b>	Does not Comply
<b>EINECS/ELINCS</b>	Does not Comply
<b>ENCS</b>	This product complies with ENCS:
<b>IECSC</b>	This product complies with China:
<b>KECL</b>	Does not Comply
<b>PICCS</b>	Complies
<b>AICS</b>	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** 0

**Flammability** 1

**Instability** 0

**Physical and chemical properties** -

#### **HMIS**

**Health hazards** 0

**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**

28-December-2021

**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
LA106	Lactose, Monohydrate, Powder, NF

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

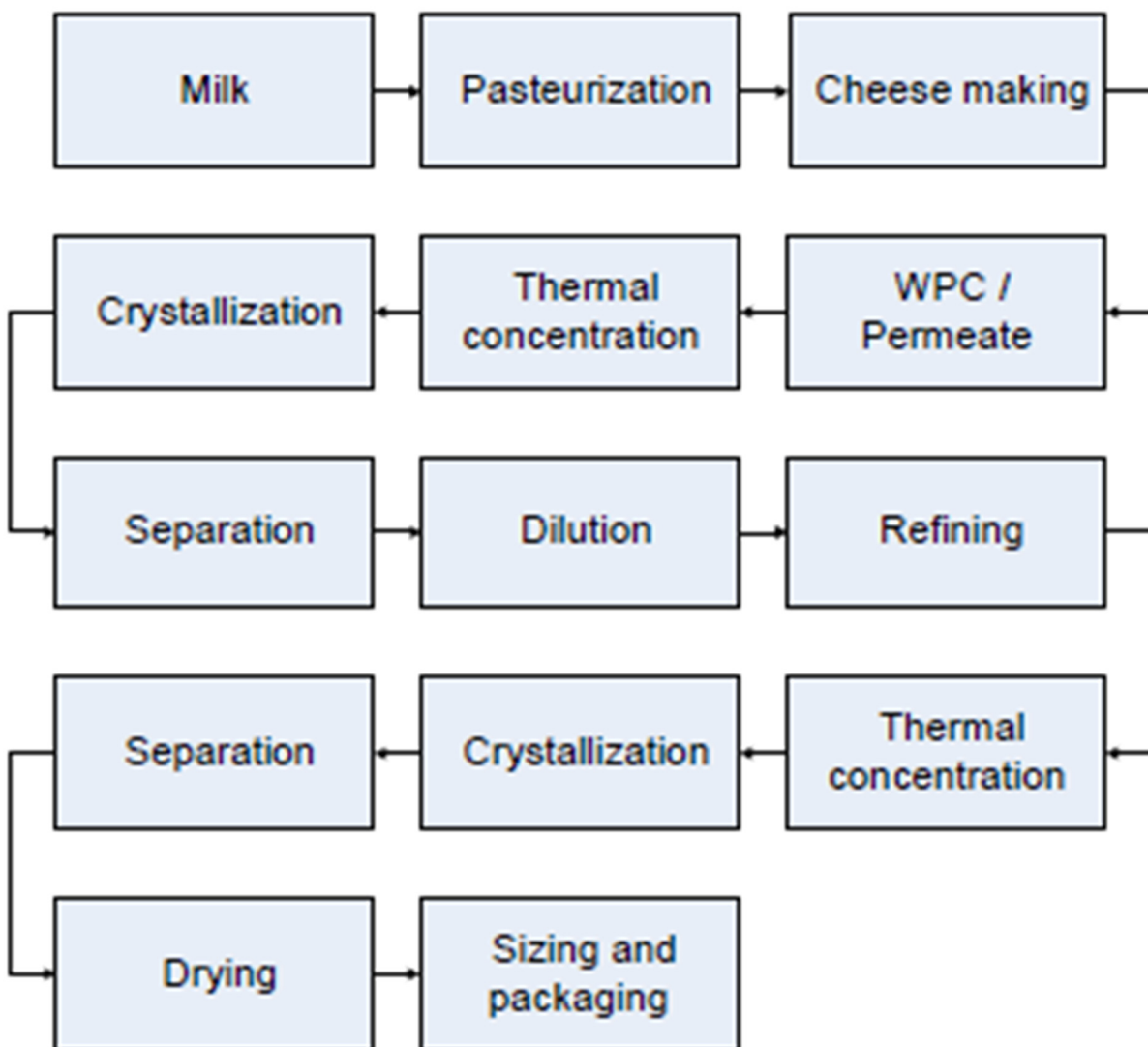
Spectrum-Gardena, CA:	2020632
Spectrum-New Brunswick, NJ:	2246824

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,  
Quality Assurance  
Spectrum Chemical Mfg. Corp.

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

## Manufacturing Process Flowchart - Lactose, Monohydrate, Powder, NF (Catalog No. LA106)





## LA106, Lactose, Monohydrate, Powder, NF

### Source Statement

The above-mentioned catalog item is manufactured by using animal derived material (cow milk). No plant derived products are used in the manufacturing process.

### BSE/TSE Statement

The above-mentioned catalog item is manufactured using animal derived products. Appropriate measures are in place to mitigate BSE/TSE risk and material is considered BSE/TSE free.

### Allergen Statement

The above-mentioned catalog item does not contain any of the following:

- |             |                             |
|-------------|-----------------------------|
| ▪ Soy       | ▪ Cereals containing Gluten |
| ▪ Egg       | ▪ Celery                    |
| ▪ Fish      | ▪ Mustard                   |
| ▪ Shellfish | ▪ Sesame Seed               |
| ▪ Tree Nuts | ▪ Corn                      |
| ▪ Wheat     | ▪ Latex                     |
| ▪ Peanuts   | ▪ Sulfites > 10 ppm         |

### EU Fragrance Allergen Statement

The above-mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore, are not expected to be present.

### GMO Statement

The above-mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

### Melamine Statement

The above-mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

### Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in the above-mentioned 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 36 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 |
| ▪ Antibiotics       | ▪ Pesticides     |
| ▪ Bisphenol A (BPA) | ▪ Phthalates     |

## Elemental Impurities - Lactose, Monohydrate, Powder, NF (Catalog No. LA106)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above 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 the 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.

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## Residual Solvents - Lactose, Monohydrate, Powder, NF (Catalog No. LA106)

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. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture of this product.

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.

## Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.

**WARNING**

- May form combustible dust concentrations in air.
- Keep away from all ignition sources including heat, sparks and flame
- Keep container closed and grounded
- Prevent dust accumulations to minimize explosion hazard.

This material has been evaluated per GHS criteria and is not classified as hazardous under GHS. All chemicals may pose unknown hazards and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional properties and precautions. If adverse reaction occurs seek medical attention.

**KEEP FROM CHILDREN**

**LA106**

**SIZ SY**

**Lactose**

(4-*O*-β-Galactopyranosyl-D-glucose)

Monohydrate

Powder, NF

CAS 64044-51-5

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

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

[www.SpectrumChemical.com](http://www.SpectrumChemical.com)

$C_{12}H_{22}O_{11} \cdot H_2O$       F.W. 360.31

Clarity and Color of Solution ..... To pass test

Specific Rotation,  $[\alpha]_D^{20}$  ..... +54.4° to +55.9°

Acidity or Alkalinity ..... To pass test

Water Determination ..... 4.5-5.5%

**MAXIMUM LIMITS**

Microbial Limits:

Total Aerobic Microbial Count .....  $10^2$  cfu/g

Total Molds and Yeasts .....  $5 \times 10^1$  cfu/g

Test for *Escherichia coli* ..... Negative

Loss on Drying ..... 0.5%

Residue on Ignition ..... 0.1%

Protein and Light-Absorbing Impurities ..... To pass test

Elemental Impurities ..... As reported

Residual Solvents ..... To pass test

G 16/K12GHS      ?      Lot No. XQ####

### Spectrum Chemical Mfg Corp

**Corporate Headquarters:**

769 Jersey Ave.  
New Brunswick, NJ 08901  
732.214.1300

**West Coast Facility:**

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