

# Scientific Documentation

## Citric Acid, Monohydrate, Granular, FCC

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 Citric Acid, Monohydrate, Granular, FCC (C1283)

Item Number	C1283
Item	Citric Acid, Monohydrate, Granular, FCC
CAS Number	5949-29-1
Molecular Formula	$C_6H_8O_7 \cdot H_2O$
Molecular Weight	210.14
MDL Number	
Synonyms	2-Hydroxy-1,2,3-propanetricarboxylic Acid

Test	Specification	
	Min	Max
ASSAY ( $C_6H_8O_7$ ; ANHYD., BASIS)	99.5	100.5 %
LEAD (Pb)		0.5 mg/kg
OXALATE ( $C_2O_4$ )		100 mg/kg
READILY CARBONIZABLE SUBSTANCES		0.52
RESIDUE ON IGNITION		0.05 %
TRIDODECYLAMINE		0.1 mg/kg
WATER		8.8 %
IDENTIFICATION	POSITIVE FOR CITRATE	
APPEARANCE		
EXPIRATION DATE		
DATE OF MANUFACTURE		
MONOGRAPH EDITION		

## *Spectrum Chemical Mfg Corp*

<b>Corporate Headquarters:</b>	<b>West Coast Facility:</b>
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	C1283	Lot Number	2MK0250
Item	Citric Acid, Monohydrate, Granular, FCC	CAS Number	5949-29-1
Molecular Formula	C <sub>6</sub> H <sub>8</sub> O <sub>7</sub> •H <sub>2</sub> O	Molecular Weight	210.14

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (C <sub>6</sub> H <sub>8</sub> O <sub>7</sub> ;ANHYD.,BASIS)	99.5	100.5 %	100.1 %
LEAD (Pb)		0.5 mg/kg	<0.5 mg/kg
OXALATE (C <sub>2</sub> O <sub>4</sub> )		100 mg/kg	<100 mg/kg
READILY CARBONIZABLE SUBSTANCES		0.52	<0.52
RESIDUE ON IGNITION		0.05 %	<0.05 %
TRIDODECYLAMINE		0.1 mg/kg	<0.1 mg/kg
WATER		8.8 %	8.4 %
IDENTIFICATION	POSITIVE FOR CITRATE		POSITIVE FOR CITRATE
APPEARANCE			WHITE GRANULAR POWDER
EXPIRATION DATE			01-SEP-2025
DATE OF MANUFACTURE			11-SEP-2022
MONOGRAPH EDITION			FCC 13TH

Certificate of Analysis Results Entered By:

GHERRERA  
Genaro Herrera  
11-JAN-24 12:33:09

Spectrum Chemical Mfg Corp  
755 Jersey Avenue  
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

MCAMACHO  
Matheu Camacho  
11-JAN-24 12:34:01

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.

# SAFETY DATA SHEET

# spectrum®



Revision date 23-December-2021

Revision Number 2

## 1. Identification

### Product identifier

**Product Name** CITRIC ACID, MONOHYDRATE, GRANULAR, FCC

### Other means of identification

**Product Code(s)** C1283

**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

Serious eye damage/eye irritation	Category 2A
Specific target organ toxicity (single exposure)	Category 3

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

#### **Warning**

#### **Hazard statements**

Causes serious eye irritation  
May cause respiratory irritation



**Appearance** Crystalline powder or Granular

**Physical state** Solid

**Odor** Odorless

**Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling

Wear eye protection/ face protection

Avoid breathing dust/fume/gas/mist/vapors/spray

Use only outdoors or in a well-ventilated area

**Precautionary Statements - Response**

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

If eye irritation persists: Get medical advice/attention

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

Call a POISON CENTER or doctor if you feel unwell

**Precautionary Statements - Storage**

Store in a well-ventilated place. Keep container tightly closed

Store locked up.

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

**Other information**

Causes mild skin irritation.

### 3. Composition/information on ingredients

**Substance**

Chemical name	CAS No	Weight-%	Trade secret
Citric Acid, Monohydrate	5949-29-1	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.

**Inhalation**

Remove to fresh air. IF exposed or concerned: Get 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 medical attention if irritation develops and persists.

**Skin contact**

Wash skin with soap and water.

**Ingestion**

Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.

**Self-protection of the first aider**      Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

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

**Symptoms**      May cause redness and tearing of the eyes. Burning sensation. Prolonged contact may cause redness and irritation.

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

**Note to physicians**      Treat symptomatically.

## **5. Fire-fighting measures**

**Suitable Extinguishing Media**      Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Large Fire**      CAUTION: Use of water spray when fighting fire may be inefficient.

**Unsuitable extinguishing media**      Do not scatter spilled material with high pressure water streams.

**Specific hazards arising from the chemical**      No information available.

**Hazardous combustion products**      Carbon Monoxide, Carbon Dioxide.

**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**      Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid contact with skin, eyes or clothing.

**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. Do not eat, drink or smoke when using this product. Ensure adequate ventilation. Avoid breathing vapors or mists. In case of insufficient ventilation, wear suitable respiratory equipment.

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

**Storage Conditions**      Keep containers tightly closed in a dry, cool and well-ventilated place.

## 8. Exposure controls/personal protection

### Control parameters

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

### Appropriate engineering controls

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

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

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

**Hand protection** Wear suitable gloves.

**Skin and body protection** Wear suitable protective clothing.

**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** Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product.

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

**Physical state** Solid  
**Appearance** Crystalline powder or Granular  
**Color** White; Colorless  
**Odor** Odorless  
**Odor threshold** No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	no data available	None known
Melting point / freezing point	150 - 153 °C / 302 - 307.4 °F	None known
Boiling point / boiling range	no data available	None known
Flash point	no data available	None known
Evaporation rate	no data available	None known
Flammability (solid, gas)	no data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	1.54	None known
Water solubility	Easily soluble in cold water Easily soluble in hot water	None known
Solubility(ies)	Easily soluble in methanol Soluble in Ether	None known
Partition coefficient	No data available	None known



<b>Autoignition temperature</b>	no data available	None known
<b>Decomposition temperature</b>		None known
<b>Kinematic viscosity</b>	no data available	None known
<b>Dynamic viscosity</b>	No data available	None known

#### **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>	210.14
<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>	None known based on information supplied.
<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**

<b>Inhalation</b>	Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.
<b>Skin contact</b>	Specific test data for the substance or mixture is not available. May cause irritation. Prolonged contact may cause redness and irritation. Causes mild skin irritation.
<b>Ingestion</b>	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

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

<b>Symptoms</b>	May cause redness and tearing of the eyes. Prolonged contact may cause redness and irritation.
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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**

<b>Skin corrosion/irritation</b>	May cause skin irritation. Classification based on data available for ingredients.
<b>Serious eye damage/eye irritation</b>	Classification based on data available for ingredients. Causes serious eye irritation.

<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>	May cause respiratory irritation.
<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

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

## 14. Transport information

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

## 15. Regulatory information

### International Inventories

<b>TSCA</b>	Complies
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<b>DSL/NDSL</b>	Complies
<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** 2

**Flammability** 0

**Instability** 0

Physical and chemical properties -

HMIS

Health hazards 2

Flammability 0

Physical hazards 0

Personal protection X

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

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

TWA TWA (time-weighted average)

STEL

STEL (Short Term Exposure Limit)

Ceiling Maximum limit value

**Key literature references and sources for data used to compile the SDS**

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGl(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications

Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

World Health Organization

**Revision date** 23-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
C1283	Citric Acid, Monohydrate, Granular, FCC

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

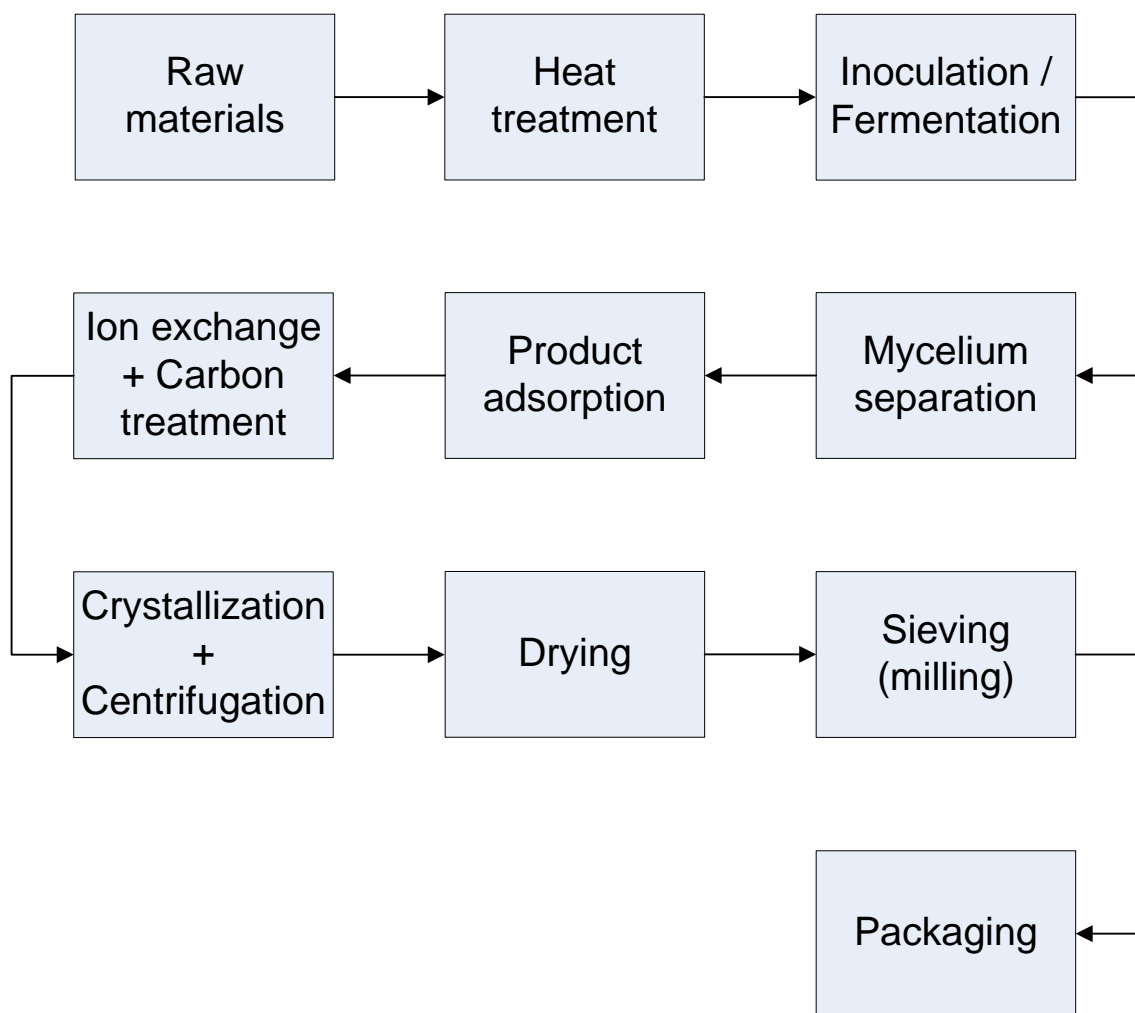
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com)

Sincerely,

Oralia Chavez  
Quality Assurance Specialist

## Manufacturing Process Flowchart

### Citric Acid, Monohydrate, Granular, FCC - C1283



#### ***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

## **C1283, Citric Acid, Monohydrate, Granular, FCC**

### **Source Statement**

The above mentioned catalog item is manufactured by fermentation of carbohydrates (glucose syrup from corn). No animal 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
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Soy
- Latex
- Sulfites > 10 ppm

### **GMO Statement**

During the production of the raw material glucose syrup, genetically modified DNA from corn is denatured, degraded, or removed through successive processing steps including physical separation, heating, purification and filtration. For this reason, DNA from genetically modified corn is not present in measureable amounts in above mentioned material.

### **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 been tested on animals.

## **Organic Compliance Statement**

The above mentioned catalog item has not been produced using 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        | • Parabens      |
| • Antibiotics       | • Pesticides    |
| • Bisphenol A (BPA) | • Phthalates    |
| • CMR Substances    | • Preservatives |



## Label Information

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

**Exp. Date:** 00-00-0000



**WARNING**  
 • Causes serious eye irritation • May cause respiratory irritation • Causes mild skin irritation.  
 • Wear eye protection, face protection • Avoid breathing dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling.  
**FIRST AID:** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or physician if you feel unwell. If skin irritation occurs: Get medical attention.  
**KEEP FROM CHILDREN**



**C1283**

**SIZ SY**

**Citric Acid**  
 (2-Hydroxy-1,2,3-propanetricarboxylic Acid)  
 Monohydrate  
 Granular  
 FCC  
 CAS 5949-29-1

**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)

$C_6H_8O_7 \cdot H_2O$  F.W. 210.14

Assay ( $C_6H_8O_7$ ; Anhydrous Basis) ..... 99.5-100.5%

MAXIMUM LIMITS

Lead ..... 0.5 mg/kg  
 Oxalate ..... To pass test  
 Readily Carbonizable Substances ..... To pass test  
 Residue on Ignition ..... 0.05%  
 Tridodecylamine ..... 0.1 mg/kg  
 Water ..... 8.8%

**WARNING:** Cancer and Reproductive Harm-  
[www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)

G 8/H5GHS ?

Lot No. XQ####

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