

## **Scientific Documentation**

# Citric Acid, Monohydrate, Crystalline Powder, USP

Not appropriate for regulatory submission.

Please visit 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, Crystalline Powder, USP (C1296)

| Item Number       | C1296  |
|-------------------|--|
| Item              | Citric Acid, Monohydrate, Crystalline Powder, USP              |
| 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   |
| MDL Number        |  |
| Synonyms          | 2-Hydroxy-1,2,3-propanetricarboxylic Acid                      |

| Test                            | Specification                        |             |  |
|---------------------------------|--------------------------------------|-------------|--|
|                                 | Min                                  | Max         |  |
| ASSAY (ANHYDROUS BASIS)         | 99.5                                 | 100.5%      |  |
| CLARITY OF SOLUTION             | NO MORE OPALESCENCE<br>THAN STANDARD |             |  |
| COLOR OF SOLUTION               | NO MORE COLOR THAN<br>STANDARD       |             |  |
| WATER DETERMINATION             | 7.5                                  | 9.0%        |  |
| RESIDUE ON IGNITION             |                                      | 0.1%        |  |
| READILY CARBONIZABLE SUBSTANCES | NOT DARKER THAN<br>STANDARD          |             |  |
| SULFATE                         |                                      | 0.015%      |  |
| ELEMENTAL IMPURITIES            |                                      | AS REPORTED |  |
| OXALIC ACID                     |                                      | 0.036 %     |  |
| IDENTIFICATION (FTIR)           | SPECTRUM MATCHES<br>REFERENCE        |             |  |
| CERTIFIED HALAL                 |                                      |             |  |
| EXPIRATION DATE                 |                                      |             |  |
| DATE OF MANUFACTURE             |                                      |             |  |
| APPEARANCE                      |                                      |             |  |
| RESIDUAL SOLVENTS               |                                      | AS REPORTED |  |

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       | C1296  | Lot Number       | 1LJ0395   |
|-------------------|--|------------------|-----------|
| Item              | Citric Acid, Monohydrate, Crystalline Powder, USP              | 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    |

| TECT                            | SPECIFICATION                              |             | 250117                               |  |
|---------------------------------|--|-------------|--------------------------------------|--|
| TEST                            | MIN  | MAX         | RESULT                               |  |
| ASSAY (ANHYDROUS BASIS)         | 99.5                                       | 100.5%      | 100.1 %                              |  |
| CLARITY OF SOLUTION             | NO MORE<br>OPALESCENCE<br>THAN<br>STANDARD |             | NO MORE OPALESCENCE THAN<br>STANDARD |  |
| COLOR OF SOLUTION               | NO MORE<br>COLOR THAN<br>STANDARD          |             | NO MORE COLOR THAN STANDARD          |  |
| WATER DETERMINATION             | 7.5  | 9.0%        | 8.5 %                                |  |
| RESIDUE ON IGNITION             |  | 0.1%        | <0.05 %                              |  |
| READILY CARBONIZABLE SUBSTANCES | NOT DARKER<br>THAN<br>STANDARD             |             | NOT DARKER THAN STANDARD             |  |
| SULFATE                         |  | 0.015%      | <0.010 %                             |  |
| ELEMENTAL IMPURITIES            |  | AS REPORTED | NO ELEMENTAL IMPURITIES PRESENT      |  |
| OXALIC ACID                     |  | 0.036 %     | <0.010 %                             |  |
| IDENTIFICATION (FTIR)           | SPECTRUM<br>MATCHES<br>REFERENCE           |             | SPECTRUM MATCHES REFERENCE           |  |
| CERTIFIED HALAL                 |  |             | CERTIFIED HALAL                      |  |
| EXPIRATION DATE                 |  |             | 30-NOV-2024                          |  |
| DATE OF MANUFACTURE             |  |             | 21-NOV-2021                          |  |
| APPEARANCE                      |  |             | WHITE CRYSTALLINE POWDER             |  |
| RESIDUAL SOLVENTS               |  | AS REPORTED | NO RESIDUAL SOLVENTS USED            |  |
| MONOGRAPH EDITION               |  |             | (USP) 2022                           |  |

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 24-OCT-22 17:15:59

Spectrum Chemical Mfg Corp 14422 South San Pedro Street Gardena 90248 CA



Certificate of Analysis Results Approved By:

JAMAYA Javier Amaya 25-OCT-22 07:25:17

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 23-December-2021

**Revision Number** 2

#### 1. Identification

**Product identifier** 

Product Name CITRIC ACID MONOHYDRATE, CRYSTALLINE POWDER, USP

Other means of identification

Product Code(s) C1296

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 Physical state Solid Odor Odorless

Granular

#### **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

#### **Precautionary Statements - Storage**

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

Call a POISON CENTER or doctor if you feel unwell

#### **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      | *            |

<sup>\*</sup>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**

Showers **Engineering controls** 

> **Evewash stations** Ventilation systems.

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

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

Wear suitable gloves. Hand protection

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

Crystalline powder or Granular **Appearance** 

Color White; Colorless

Odor Odorless

**Odor threshold** No information available

| Property                        | <u>Values</u>                 | Remarks • Method |
|---------------------------------|-------------------------------|------------------|
| 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 | No data available             |                  |
| limits                          |                               |                  |
| Lower flammability or explosive | No data available             |                  |

limits

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 None known

Easily soluble in hot water Solubility(ies)

Easily soluble in methanol None known

Soluble in Ether

Partition coefficient None known No data available

Autoignition temperature

no data available

None known None known

Decomposition temperature Kinematic viscosity

no data available No data available None known None known

Other information

Explosive properties

Oxidizing properties

No information available
No information available
No information available

Molecular weight 210.14

VOC Content (%)
Liquid Density
No information available
No information available
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**None known based on information supplied.

Incompatible materials None known based on information supplied.

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. May cause irritation of

respiratory tract.

**Eye contact** Specific test data for the substance or mixture is not available. Causes serious eye irritation.

(based on components). May cause redness, itching, and pain.

**Skin contact** 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.

**Ingestion** 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

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

irritation.

**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 Serious eye damage/eye irritation May cause skin irritation. Classification based on data available for ingredients. Classification based on data available for ingredients. Causes serious eye irritation.

Respiratory or skin sensitization

Germ cell mutagenicity

No information available. No information available.

Reproductive toxicity

No information available.

STOT - single exposure STOT - repeated exposure

May cause respiratory irritation.
No information available.
No information available.

Aspiration hazard

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

Bioaccumulation

No information available. 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** not regulated

TDG not regulated

MEX not regulated

ICAO (air) not regulated

**IATA** not regulated

**IMDG** not regulated

RID not regulated

ADR not regulated

ADN not regulated

#### 15. Regulatory information

#### **International Inventories**

TSCA Complies

DSL/NDSL Complies
EINECS/ELINCS Does not Comply

**ENCS IECSC**This product complies with ENCS:
This product complies with China:

**KECL** Does not Comply

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 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**23-December-2021

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                                      |
|----------------|---|
| C1296          | Citric Acid, Monohydrate, Crystalline Powder, 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 <a href="mailto:qualityassurance@spectrumchemical.com">qualityassurance@spectrumchemical.com</a>

Sincerely,

Oralia Chavez

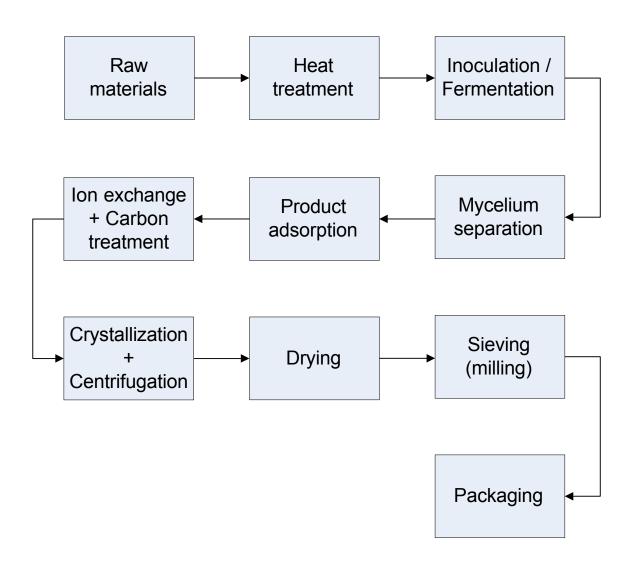
**Quality Assurance Specialist** 

Order Clony



## **Manufacturing Process Flowchart**

# Citric Acid Monohydrate, Crystalline Powder, USP - C1296



#### Spectrum Chemical Mfg Corp

West Coast Facility:



## C1296, Citric Acid, Monohydrate, Crystalline Powder, USP

#### **Source Statement**

The above mentioned catalog item is manufactured by chemical synthesis using row material derived from carbohydrate (glucose). 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
- Soy

- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- 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 this material.

#### **Animal Testing Statement**

The above mentioned catalog item has not been tested on animals.

#### **Organic Compliance Statement**

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

#### **Shelf Life Statement**

The above mentioned catalog item is typically assigned a shelf life of 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
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives



# RE: Elemental Impurities - Citric Acid, Monohydrate, Crystalline Powder, USP (Cat# C1296)

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 <a href="mailto:TechServices@spectrumchemical.com">TechServices@spectrumchemical.com</a>.

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 - Citric Acid, Monohydrate, Crystalline Powder, USP (Cat# C1296)

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 the USP <467> Residual Solvents and the 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 <a href="mailto:TechServices@spectrumchemical.com">TechServices@spectrumchemical.com</a>.

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



#### **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



 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** 

C1296

SIZ SY

# Citric Acid

(2-Hydroxy-1,2,3-propanetricarboxylic Acid) Monohydrate

Crystalline Powder, USP

**CAUTION:** For manufacturing, processing or repacking. Not intended for use in injectable dosage forms. **Read and understand the label and Safety Data Sheet** 

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

 $C_6H_8O_7 - H_2O$ 

F.W. 210.14

Not sterile.

| Assay (Anhydrous Basis)           | 99.5-100.5%  |
|-----------------------------------|--------------|
| Clarity of Solution               |              |
| Color of Solution                 | To pass test |
| Water Determination               | 7.5-9.0%     |
| MAXIMUM LIMITS                    |              |
| Residue on Ignition               | 0.1%         |
| Readily Carbonizable Substances . | To pass test |
| Sulfate                           | 0.015%       |
| Elemental Impurities              | As reported  |
| Oxalic Acid                       | To pass test |
| Residual Solvents                 | To pass test |

**WARNING:** Cancer and Reproductive Harmwww.P65Warnings.ca.gov

G 9/G12GHS ? Lot No. XQ####

#### Spectrum Chemical Mfg Corp

Corporate Headquarters: 769 Jersey Ave.

New Brunswick, NJ 08901

14422 S. San Pedro St. Gardena, CA 90248

West Coast Facility:

732.214.1300

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