

Scientific Documentation

Sodium Citrate, Anhydrous, 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 Sodium Citrate, Anhydrous, USP (S1986)

| | |
|-------------------|--------------------------------|
| Item Number | S1986 |
| Item | Sodium Citrate, Anhydrous, USP |
| CAS Number | 68-04-2 |
| Molecular Formula | $C_6H_5Na_3O_7$ |
| Molecular Weight | 258.07 |
| MDL Number | |
| Synonyms | |

| Test | Specification | |
|-------------------------|----------------------|-------------|
| | Min | Max |
| ASSAY (ANHYDROUS BASIS) | 99.0 | 100.5 % |
| ALKALINITY | NO PINK COLOR | |
| WATER DETERMINATION | | 1.0 % |
| TARTRATE | NO PRECIPITATE FORMS | |
| ELEMENTAL IMPURITIES | | AS REPORTED |
| IDENTIFICATION A | POSITIVE FOR SODIUM | |
| IDENTIFICATION B | POSITIVE FOR CITRATE | |
| IDENTIFICATION C | ALKALINE RESIDUE | |
| CERTIFIED KOSHER | | |
| CERTIFIED HALAL | | |
| APPEARANCE | | |
| EXPIRATION DATE | | |
| DATE OF MANUFACTURE | | |
| RESIDUAL SOLVENTS | | AS REPORTED |
| MONOGRAPH EDITION | | |

Spectrum Chemical Mfg Corp

Corporate Headquarters: **West Coast Facility:**
769 Jersey Ave. 14422 S. San Pedro St.
New Brunswick, NJ 08901 Gardena, CA 90248

Spectrum Chemical Mfg Corp

Corporate Headquarters: West Coast Facility:

732.214.1300

310.516.8000

Certificate Of Analysis

| | | | |
|-------------------|--|------------------|---------|
| Item Number | S1986 | Lot Number | 1NC0215 |
| Item | Sodium Citrate, Anhydrous, USP | CAS Number | 68-04-2 |
| Molecular Formula | C ₆ H ₅ Na ₃ O ₇ | Molecular Weight | 258.07 |

| TEST | SPECIFICATION | | RESULT |
|-------------------------|----------------------|-------------|---------------------------------|
| | MIN | MAX | |
| ASSAY (ANHYDROUS BASIS) | 99.0 | 100.5 % | 99.8 % |
| ALKALINITY | NO PINK COLOR | | NO PINK COLOR |
| WATER DETERMINATION | | 1.0 % | 0.0 % |
| TARTRATE | NO PRECIPITATE FORMS | | NO PRECIPITATE FORMS |
| ELEMENTAL IMPURITIES | | AS REPORTED | NO ELEMENTAL IMPURITIES PRESENT |
| IDENTIFICATION A | POSITIVE FOR SODIUM | | POSITIVE FOR SODIUM |
| IDENTIFICATION B | POSITIVE FOR CITRATE | | POSITIVE FOR CITRATE |
| IDENTIFICATION C | ALKALINE RESIDUE | | ALKALINE RESIDUE |
| CERTIFIED KOSHER | | | CERTIFIED KOSHER |
| CERTIFIED HALAL | | | CERTIFIED HALAL |
| APPEARANCE | | | WHITE GRANULAR POWDER |
| EXPIRATION DATE | | | 01-FEB-2026 |
| DATE OF MANUFACTURE | | | 02-FEB-2023 |
| RESIDUAL SOLVENTS | | AS REPORTED | NO RESIDUAL SOLVENTS PRESENT |
| MONOGRAPH EDITION | | | (USP-NF) 2023 |

Certificate of Analysis Results Entered By:

HBERMUDEZ
Hernan Bermudez
01-APR-24 11:29:17

Certificate of Analysis Results Approved By:

SHANSEN
Selin Hansen
05-APR-24 08:45:27

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



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 10-January-2022

Revision Number 2

1. Identification

Product identifier

Product Name SODIUM CITRATE, ANHYDROUS, USP

Other means of identification

Product Code(s) S1986

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

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Hazard statements

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

The product contains no substances which at their given concentration, are considered to be hazardous to health.

Appearance Crystalline powder or
Granular powder or Prills

Physical state Solid

Odor Odorless

Other information

No information available.

3. Composition/information on ingredients**Substance**

| Chemical name | CAS No | Weight-% | Trade secret |
|---------------------------|---------|----------|--------------|
| Sodium Citrate, Anhydrous | 68-04-2 | 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. |
|----------|---------------------------|

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 (CO ₂). Sodium oxides. |
| 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.

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.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep container tightly closed in a dry 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 No special protective equipment required.

Skin and body protection No special protective equipment required.

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 Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid

| | |
|-----------------------|---|
| Appearance | Crystalline powder or Granular powder or Prills |
| Color | White |
| 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 °C / 302 °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 | 1.76 @ 18°C | None known |
| Water solubility | Soluble in water | None known |
| Solubility(ies) | no data available | None known |
| Partition coefficient | No data available | None known |
| Autoignition temperature | no data available | None known |
| Decomposition temperature | | None known |
| Kinematic viscosity | no data available | None known |
| Dynamic viscosity | No data available | None known |
| <u>Other information</u> | | |
| Explosive properties | No information available | |
| Oxidizing properties | No information available | |
| Softening point | No information available | |
| Molecular weight | 258.07 | |
| VOC Content (%) | No information available | |
| Liquid Density | No information available | |
| Bulk density | No information available | |

10. Stability and reactivity

| | |
|---|---|
| Reactivity | No information available. |
| Chemical stability | Stable under normal conditions. |
| Possibility of hazardous reactions | None under normal processing. |
| Conditions to avoid | 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

| | |
|---------------------|---|
| Inhalation | Specific test data for the substance or mixture is not available. |
| 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.

Acute toxicity

Numerical measures of toxicity

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|--------------------------------------|--------------------|-------------|-----------------|
| Sodium Citrate, Anhydrous 68-04-2 | 6500 mg/kg (Rat) | - | - |

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

| Chemical name | Algae/aquatic plants | Fish | Toxicity to microorganisms | Crustacea |
|--------------------------------------|---|--|----------------------------|---|
| Sodium Citrate, Anhydrous 68-04-2 | EC50: 18000 - 32000mg/L (96h, Chlorella vulgaris) | LC50: 18000 - 32000mg/L (96h, Poecilia reticulata) | - | EC50: 5600 - 10000mg/L (48h, Daphnia magna) |

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

| | |
|----------------------|---|
| 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 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 10-January-2022

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 |
|----------------|--------------------------------|
| S1986 | Sodium Citrate, Anhydrous, 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

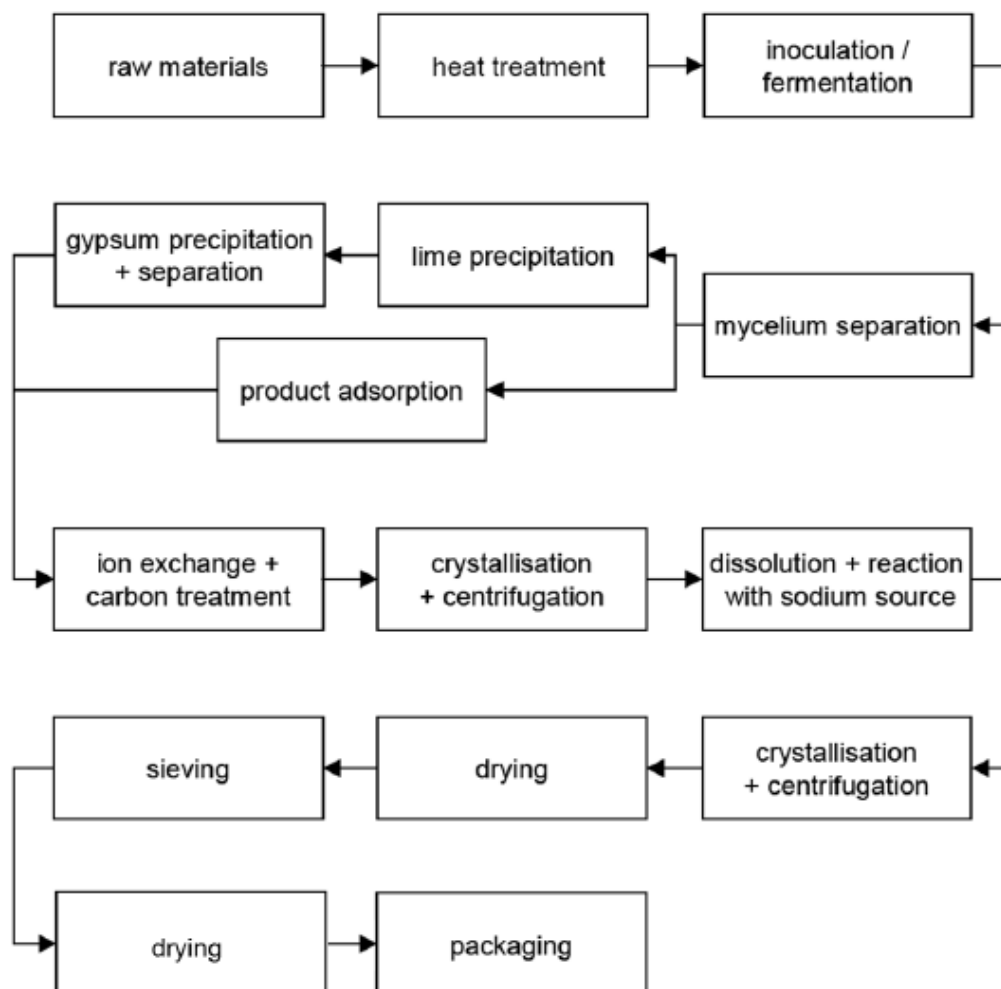
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

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

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart [Sodium Citrate, Anhydrous, USP] (S1986)



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

S1986, Sodium Citrate, Anhydrous, USP

Source Statement

The above mentioned catalog item is manufactured by Fermentation derived material. 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
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Soy
- 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 | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • Preservatives |



RE: Elemental Impurities - Sodium Citrate, Anhydrous, USP (Cat# S1986)

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.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS

769 Jersey Avenue
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WEST COAST FACILITY

14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843



RE: Residual Solvents - Sodium Citrate, Anhydrous, USP (Cat# S1986)

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 TechServices@spectrumchemical.com.

Sincerely,

Technical Services
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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. Below you will find a typical label example for this catalog item.

S1986 11-10-2017 gm ghs

$C_6H_5Na_3O_7$ F.W. 258.07

USE CARE: This material has been evaluated per GHS/OSHA criteria and is not classified as hazardous. 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

S1986

SIZ SY

Sodium Citrate

Anhydrous

U.S.P.

CAS 68-04-2



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

Assay (Anhydrous Basis) 99.0-100.5%
MAXIMUM LIMITS
 Alkalinity To pass test
 Water Determination 1.0%
 Tartrate To pass test
 Elemental Impurities As reported
 Residual Solvents To pass test

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

G 7/G11GHS

?

Lot No. XQ####

Spectrum Chemical Mfg Corp

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