

# **Scientific Documentation**

**C1102**, Calcium Citrate, Tetrahydrate, Powder, USP

Not appropriate for regulatory submission. Please visit <u>www.spectrumchemical.com</u> or contact Tech Services for the most up-to-date information contained in this information package.

#### **Spectrum Chemical Mfg Corp**

769 Jersey Avenue New Brunswick, NJ 08901 Phone 732.214.1300

Ver4.03 18.August.2017



Dear Customer,

Thank you for your interest in Spectrum's quality products and services.

Spectrum has been proudly serving the scientific community for over 45 years. It is our mission to manufacture and distribute fine chemicals and laboratory products with Quality and delivery you can count on every time.

To accomplish our mission, Spectrum utilizes our sourcing leverage and supplier qualification expertise in offering one of the industry's most comprehensive line of fine chemical products under one brand, in packaging configurations designed to meet your research and production requirements. Our product grades include: USP, NF, BP, EP, JP, FCC, ACS, KSA, Reagent grade, as well as DEA controlled substances. We operate facilities in the United States on the East Coast, West Coast, as well as in Shanghai, China in order to provide the best logistical support for our customers.

At Spectrum, Quality is priority number one. Suppliers with the best qualifications are preferred and we employ full-functioning in-house analytical laboratories at each of our facilities. Our facilities and systems are USFDA registered and ISO certified. We frequently host customer audits and cherish opportunities for improvements. Quality is engrained into our culture. Quality is priority number one.

In the following pages, we have designed and prepared documented scientific information to aid you in your initial qualification or your continual use of our products. Please do not hesitate to contact us if further information or the most up-to-date documentation is desired from any of the covered areas.

We appreciate your business and we look forward to hearing from you.

Sincerely,

Alan Wang, MSQA, ASQ CQA Director of Technical Services techservices@spectrumchemical.com

C1102, Calcium Citrate, Tetrahydrate, Powder, USP

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Item Number	<u>C1102</u>
Item	Calcium Citrate, Tetrahydrate, Powder, USP
CAS Number	5785-44-4
Molecular Formula	C <sub>12</sub> H <sub>10</sub> Ca <sub>3</sub> O <sub>14</sub> .4H <sub>2</sub> O
Molecular Weight	570.50
MDL Number	
Synonyms	

Test	Specification		
	Min	Max	
ASSAY (DRIED BASIS)	97.5 - 100.5 %		
LOSS ON DRYING	10.0 - 13.3 %		
ARSENIC (As)		3 ppm	
FLUORIDE		0.003 %	
ACID-INSOLUBLE SUBSTANCES		0.2 %	
LEAD (Pb)		0.001 %	
HEAVY METALS		0.002 %	
IDENTIFICATION		TO PASS TEST	
RETEST DATE			
RESIDUAL SOLVENTS		TO PASS TEST	

#### Spectrum Chemical Mfg Corp

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





#### SAFETY DATA SHEET

Preparation Date: No data available Product identifier Revision Date: 03/25/2015

Revision Number: G1

Product code:	C1102
Product Name:	CALCIUM CITRATE, TETRAHYDRATE, POWDER, USP

Other means of identification	
Synonyms:	2-Hydroxy-1,2,3-propanetricarboxylic Acid Calcium Salt; Tricalcium Citrate; Calcium
0 A O 11	Citrate
CAS #:	5785-44-4
RTECS #	Not available
Cl#:	Not available
Recommended use of the chemi	cal and restrictions on use
Recommended use:	No information available.
Uses advised against	No information available
6	
Supplier:	Spectrum Chemicals and Laboratory Products, Inc.
<u></u>	14422 South San Pedro St.
	Gardena, CA 90248
	(310) 516-8000
Onder Online At	
Order Online At:	https://www.spectrumchemical.com
Emergency telephone number	Chemtrec 1-800-424-9300
Contact Person:	Martin LaBenz (West Coast)
Contact Person:	Ibad Tirmiz (East Coast)
001111011 613011.	

#### 2. HAZARDS IDENTIFICATION

#### Classification

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

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

#### Label elements

Not classified

Hazards not otherwise classified (HNOC) Not Applicable

Other hazards Not available

#### **3. COMPOSITION/INFORMATION ON INGREDIENTS**

Components	CAS-No.	Weight %	Trade Secret
Calcium Citrate, Tetrahydrate	5785-44-4	100	*
5785-44-4			

#### 4. FIRST AID MEASURES

First aid measures General Advice:	Poison information centers in each State capital city can provide additional assistance for scheduled poisons (13 1126)
Skin Contact:	Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Get medical attention if irritation develops. Consult a physician if necessary.
Eye Contact:	Flush eye with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.
Inhalation:	Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
Ingestion:	Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.
Most important symptoms and e	ffects, both acute and delayed

Symptoms Health injuries are not known or expected under normal use.

#### Indication of any immediate medical attention and special treatment needed Notes to Physician: Treat symptomatically

#### **Protection of first-aiders**

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste

#### **5. FIRE-FIGHTING MEASURES**

Extinguishing Media	
Suitable Extinguishing Media:	Carbon dioxide (CO2). Dry chemical. Water spray mist or foam.
Unsuitable Extinguishing Media:	No information available.
Specific hazards arising from the chemical	
Hazardous Combustion Products:	Metallic Oxides
Specific hazards:	May be combustible at high temperatures Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard

#### **Special Protective Actions for Firefighters**

Special Protective Equipment for Firefighters:

No information available.

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

#### 6. ACCIDENTAL RELEASE MEASURES

# Personal precautions, protective equipment and emergency proceduresPersonal Precautions:Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes<br/>and clothing. Avoid dust formation. Keep people away from and upwind of spill/leak. Do not<br/>touch damaged containers or spilled material unless wearing appropriate protective clothing.<br/>Remove all sources of ignition.Environmental precautionsPrevent further leakage or spillage if safe to do so. Prevent product from entering<br/>drains. Prevent entry into waterways, sewers, basements or confined areas.Methods and material for containment and cleaning upMethods for containmentMethods for cleaning upStop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.Methods for cleaning upSweep up and shovel into suitable containers for disposal. Clean contaminated<br/>surface thoroughly.

#### 7. HANDLING AND STORAGE

Precautions for safe handling

#### **Technical Measures/Precautions:**

Provide sufficient air exchange and/or exhaust in work rooms. Keep away from incompatible materials.

#### Safe Handling Advice:

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Do not ingest. Do not breathe vapours/dust. Handle in accordance with good industrial hygiene and safety practice.

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

#### Technical Measures/Storage Conditions:

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials.

#### Incompatible Materials:

Oxidizing agents.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### **Control parameters**

#### National occupational exposure limits

Unite	ed S	States	5

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
	None	None	None	None
Calcium Citrate, Tetrahydrate - 5785- 44-4				

#### Canada

Components Alberta	British Columbia	Ontario	Quebec
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	None	None	None	None
Calcium Citrate, Tetrahydrate - 5785-				
44-4				

#### Australia and Mexico

Components	Australia	Mexico
Calcium Citrate, Tetrahydrate	None	None
5785-44-4		

#### Appropriate engineering controls

Engineering measures to reduce exposure:

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

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

#### Personal Protective Equipment

Eye protection:	Safety glasses. Safety glasses with side-shields.
Skin and body protection:	Chemical resistant apron. Gloves. Long sleeved clothing.
Respiratory protection:	Effective dust mask. Wear respirator with dust filter
Hygiene measures:	Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid.

Odor: Odorless.

Formula: C12H10Ca3O14•4H2O

Flash Point Tested according to: Closed cup

Autoignition Temperature (°C/°F): No information available

**Boiling point/range(°C/°F):** No information available

**Specific gravity:** No information available

**Evaporation rate:** No information available

Odor threshold (ppm): No information available

**Miscibility:** No information available Appearance: Crystalline. Granular. Powder.

Taste No information available

Flash point (°C): No data available

Lower Explosion Limit (%): No information available

**pH:** No information available

**Decomposition temperature(°C/°F):** No information available

**Density (g/cm3):** No information available

Vapor density: No information available

Partition coefficient (n-octanol/water): No information available

**Solubility:** Very slightly soluble in cold water Color: White.

Molecular/Formula weight: 570.50

Flashpoint (°C/°F): >93.3°C/200°F

**Upper Explosion Limit (%):** No information available

Melting point/range(°C/°F): No information available

Bulk density: No information available

Vapor pressure @ 20°C (kPa): No information available

**VOC content (g/L):** No information available

Viscosity: No information available

#### **10. STABILITY AND REACTIVITY**

#### Reactivity

Reactive with oxidizing agents Loses all water at temperature above 120°C

Chemical stability Stability:	Stable under recommended storage conditions
Possibility of Hazardous Reactions:	Hazardous polymerization does not occur
Conditions to avoid:	Heat. Ignition sources. Incompatible materials. Avoid dust formation. Dust may form explosive mixture in air. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Incompatible Materials:	Oxidizing agents.
Hazardous decomposition products:	Metallic oxides.
Other Information	
Corrosivity:	No information available
Special Remarks on Corrosivity:	No information available

#### **11. TOXICOLOGICAL INFORMATION**

#### **11. TOXICOLOGICAL INFORMATION**

#### Information on likely routes of exposure

Principal Routes of Exposure: Ingestion. Inhalation.

#### **Acute Toxicity**

#### **Component Information**

Calcium Citrate, Tetrahydrate - 5785-44-4

LD50/oral/rat = No information available LD50/oral/mouse = No information available LD50/dermal/rat = No information available LD50/dermal/rabbit = No information available LC50/inhalation/rat = No information available LC50/inhalation/mouse = No infomation available Other LD50 or LC50information = No information available

#### **Product Information**

LD50/oral/rat = VALUE- Acute Tox Oral = No information available

LD50/oral/mouse = Value - Acute Tox Oral = No information available

LD50/dermal/rabbit VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat VALUE-Vapor = No information available VALUE-Gas = No information available VALUE-Dust/Mist = No information available

#### LC50/Inhalation/mouse

VALUE-Vapor = No information available VALUE - Gas = No information available VALUE - Dust/Mist = No information available

#### Symptoms

Skin Contact:	May cause skin irritation.
Eye Contact:	May cause eye irritation.
Inhalation Ingestion	May cause irritation of respiratory tract. May cause digestive (gastointestinal) tract irritation.
Aspiration hazard	No information available
Delayed and immediate effects as	s well as chronic effects from short and long-term exposure
Chronic Toxicity	No information available

#### Sensitization:

No information available

Mutagenic Effects:

No information available

No information available

Carcinogenic effects:

Not considered carcinogenic

Components	ACGIH - Carcinogens	IARC	NTP	OSHA HCS - Carcinogens	Australia - Prohibited Carcinogenic Substances	Australia - Notifiable Carcinogenic Substances
Calcium Citrate, Tetrahydrate	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

Reproductive toxicity	No data is available
Reproductive Effects:	No information available
Developmental Effects:	No information available
Teratogenic Effects:	No information available
Specific Target Organ Toxicity	
STOT - single exposure	No information available
STOT - repeated exposure	No information available

#### **12. ECOLOGICAL INFORMATION**

#### Ecotoxicity

**Target Organs:** 

Ecotoxicity effects:	No data available.
Persistence and degradability:	No information available
Bioaccumulative potential:	No information available
Mobility:	No information available

#### 13. DISPOSAL CONSIDERATIONS

#### **Disposal Methods**

#### Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

#### Contaminated packaging:

Empty containers should be taken for local recycling, recovery or waste disposal

Components	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
			Wastes	
Calcium Citrate, Tetrahydrate	None	None	None	None

#### DOT

UN-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Subsidiary Risk:	No information available
Packing Group:	None
ERG No:	No information available
Marine Pollutant	No data available
DOT RQ (lbs):	No information available

#### TDG (Canada)

UN-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Subsidiary Risk:	No information available
Packing Group:	No information available
Description:	No information available

#### ADR

UN-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Packing Group:	No information available
Subsidiary Risk:	No information available
Classification Code:	No information available
Description:	No information available
CEFIC Tremcard No:	No information available

#### IMO / IMDG

UN-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Subsidiary Risk:	No information available
Packing Group:	No information available
Description:	No information available
IMDG Page:	No information available
Marine Pollutant	No information available
MFAG:	No information available
Maximum Quantity:	No information available

Not Regulated

Not Regulated

No information available

No information available

No information available

No information available No information available

No information available

No information available

No information available

No information available

#### RID

UN-No: Proper Shipping Name: Hazard Class: Subsidiary Risk: Packing Group: Classification Code: Description:

#### ICAO

UN-No: Proper Shipping Name: Hazard Class: Subsidiary Risk:

#### Product code: C1102

#### 14. TRANSPORT INFORMATION

Packing Group:	
Description:	

#### No information available No information available

#### ΙΑΤΑ

UN-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Subsidiary Risk:	No information available
Packing Group:	No information available
Description:	No information available

#### **15. REGULATORY INFORMATION**

#### **International Inventories**

Components	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Calcium Citrate, Tetrahydrate	Not Listed	Not present	Present	Not present	Not present	Present	Not present

#### **U.S. Regulations**

#### California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

#### Chemicals Known to the State of California to Cause Cancer: This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

#### Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Calcium Citrate, Tetrahydrate	Not Listed	Not Listed	Not Listed	Not Listed

#### CERCLA/SARA

	Substances and their	Hazardous	Section 302 Extremely Hazardous Substances and RQs	<b>Chemical Category</b>	Section 313 - Reporting de minimis
Calcium Citrate, Tetrahydrate	None	None	None	None	None

#### U.S. TSCA

	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Calcium Citrate, Tetrahydrate	Not Applicable	Not Applicable

#### Canada

#### WHMIS hazard class:

Non-controlled

#### **Canada Controlled Products Regulation:**

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

#### Inventory

Components	Canada (DSL)	Canada (NDSL)
Calcium Citrate, Tetrahydrate	Not Listed	Not Listed

Components	CEPA Schedule I - Toxic Substances	CEPA - 2010 Greenhouse Gases Subject to Manditory Reporting
Calcium Citrate, Tetrahydrate	Not listed	Not listed

#### **EU Classification**

#### $\frac{\text{R-phrase(s)}}{\text{R-phrase(s)}}$

#### S -phrase(s) none

Components	Classification	Concentration Limits:	Safety Phrases
Calcium Citrate, Tetrahydrate		No information	

#### The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger: None.

#### **16. OTHER INFORMATION**

#### **16. OTHER INFORMATION**

Revision Date: Prepared by: 03/25/2015 Sonia Owen

**Disclaimer:** 

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

**End of Safety Data Sheet** 



#### Manufacturer

Product Covered: C1102, Calcium Citrate, Tetrahydrate, Powder, USP

Spectrum takes ownership as the manufacturer for the Spectrum product listed above and provides full quality assurance, customer service, and technical product support.

While information concerning the raw material manufacturer of our starting materials is considered proprietary, such information can be made available upon request contingent on demonstration of business volume justification and successful execution of confidential disclosure agreement (CDA).

Requests for disclosure of proprietary raw material manufacturer information may be submitted to the assigned account representative for consideration.

Sincerely,

Alan Wang, MSQA, ASQ CQA Director of Technical Services techservices@spectrumchemical.com



# **CERTIFICATE OF REGISTRATION**

This is to certify that the quality management system of:

# Spectrum Chemicals and Laboratory Products, Inc.

Main Site: 14422 South San Pedro Street, Gardena, California, 90248, USA,

Additional sites:13915 South Main Street, Los Angeles, California, 90061, USA

769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA
755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA
777 Jersey Avenue, New Brunswick, New Jersey, 08901, USA
400 N. Oracle, Suite 221, Tucson, Arizona, 85704, USA, USA

has been assessed and registered by Intertek as conforming to the requirements of:

### ISO 9001:2015

#### The quality management system is applicable to:

Main Site: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries. **Certificate Number:** 94-316m-03

Initial Certification Date: 27 December 1994

Certificate Issue Date: 31 July 2017

Certificate Expiry Date: 28 January 2019



Authorized Signature Calin Moldovean President Business Assurance

Intertek Testing Services NA, Inc. dba Intertek 900 Chelmsford Street, Lowell, MA, USA





In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request



# APPENDIX TO CERTIFICATE OF REGISTRATION

This appendix identifies the locations by the management system of

# Spectrum Chemicals and Laboratory Products, Inc.

755 and 769 Jersey Avenue: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.

777 Jersey Avenue: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for Compounding Pharmacies.

7400 N. Oracle: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.





In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

The certificate remains the property of Intertek, to whom it must be returned upon request.

## **Certificate of Registration**



This is to certify that the quality management system of

#### Spectrum China Ltd.

#### Building A20, No. 3802, Shengang Road, Songjiang District, Shanghai, China

has been assessed and registered by Intertek as conforming to the requirements of

#### ISO 9001: 2008

The quality management system is applicable to:

Provision of service of purchase, testing and sales for chemical products, repacking of non-hazardous chemical products.

Organization Code: Certificate Number: Certificate Issue Date: Certificate Expiry Date: 77762704-8 111310001-01 17 November 2015 14 September 2018



014

Authorised Signature: Calin Moldovean – President, Business Assurance Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom Intertek Certification Limited is a UKAS accredited body under schedule of accreditation no. 014.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at <u>certificate.validation@intertek.com</u> or by scanning the code to the right with a smartphone. The annual validity of the certificate a also be checked through the website <u>http://www.cnca.gov.cn</u> of CNCA in China.



The certificate remains the property of Intertek, to whom it must be returned upon request.



July 13, 2017

#### Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that our USP, NF, FCC, EP, BP, JP and food grade products are 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.

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: Spectrum-New Brunswick, NJ: Spectrum-Shanghai, China: 2020632 2246824 3006174778

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 <u>gualityassurance@spectrumchemical.com</u>

Sincerely,

Oula Clany

Oralia Chavez Quality Assurance Specialist



August 18, 2017

#### 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
C1102	Calcium Citrate, Tetrahydrate, 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: Spectrum-New Brunswick, NJ: Spectrum-Shanghai, China: 2020632 2246824 3006174778

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 <u>qualityassurance@spectrumchemical.com</u>

Sincerely,

Oula Clany

Oralia Chavez Quality Assurance Specialist



Aug 9, 2017

Re: Calcium Citrate, Tetrahydrate, Powder, USP- C1102

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding Bovine Spongiform Encephalopathy (BSE). Please be assured that the chemical

Calcium Citrate, Tetrahydrate, Powder, USP- C1102

is BSE/TSE free.

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at <u>techservices@spectrumchemical.com</u>.

Sincerely,

Darlene Dagdag-Lyudmirskiy Technical Services Spectrum Chemical Mfg. Corp.

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



Aug 9, 2017

Re: Calcium Citrate, Tetrahydrate, Powder, USP- C1102

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding the presence of allergens in raw materials. Please be assured that the following chemical does not contain (Milk; Egg; Fish; Shellfish; Sulfur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO<sub>2</sub>; Lupin; Tree nuts; Mollusks; Wheat; Peanuts; Soy; Cereals containing Gluten; Celery; Mustard; Sesame Seed).

Calcium Citrate, Tetrahydrate, Powder, USP- C1102

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at <u>techservices@spectrumchemical.com</u>.

Sincerely,

Darlene Dagdag-Lyudmirskiy Technical Services Spectrum Chemical Mfg. Corp.

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



Aug 9, 2017

Re: Calcium Citrate, Tetrahydrate, Powder, USP- C1102

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfg. Corp. understand the concern regarding Aflatoxins in raw materials. To the best of our knowledge, the product listed below is not contaminated with Aflatoxins. Based on the raw materials and processing conditions, aflatoxin contamination is not considered a significant risk. Aflatoxins are not used in production. The following product does not come in contact with Aflatoxins at any stage of production.

Calcium Citrate, Tetrahydrate, Powder, USP- C1102

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at <u>techservices@spectrumchemical.com</u>.

Sincerely,

Darlene Dagdag-Lyudmirskiy Technical Services Spectrum Chemical Mfg. Corp.

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

# Spectrum®

#### **Certificate Of Analysis**

Item Number	C1102	Lot Number	2ED0470
Item	Calcium Citrate, Tetrahydrate, Powder, USP		
CAS Number	5785-44-4		
Molecular Formula	$C_{12}H_{10}Ca_3O_{14}.4H_2O$	Molecular Weight	570.50

Test	Specification		Result
	min	max	
ASSAY (DRIED BASIS)	97.5 - 100.5 %		98.8 %
LOSS ON DRYING	10.0 - 13.3 %		12.5 %
ARSENIC (As)		3 ppm	<3 ppm
FLUORIDE		0.003 %	0.0016 %
ACID-INSOLUBLE SUBSTANCES		0.2 %	0.020 %
LEAD (Pb)		0.001 %	0.000004 %
HEAVY METALS		0.002 %	<0.002 %
IDENTIFICATION		TO PASS TEST	PASSES TEST
RETEST DATE			23-MAR-2018
RESIDUAL SOLVENTS		TO PASS TEST	NO RESIDUAL SOLVENTS USED
APPEARANCE			WHITE POWDER
DATE OF MANUFACTURE			23-MAR-2015

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate Of Analysis Results Certified by

Ibad Tirmizi Director of Quality Spectrum Chemical Mfg. Corp.

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

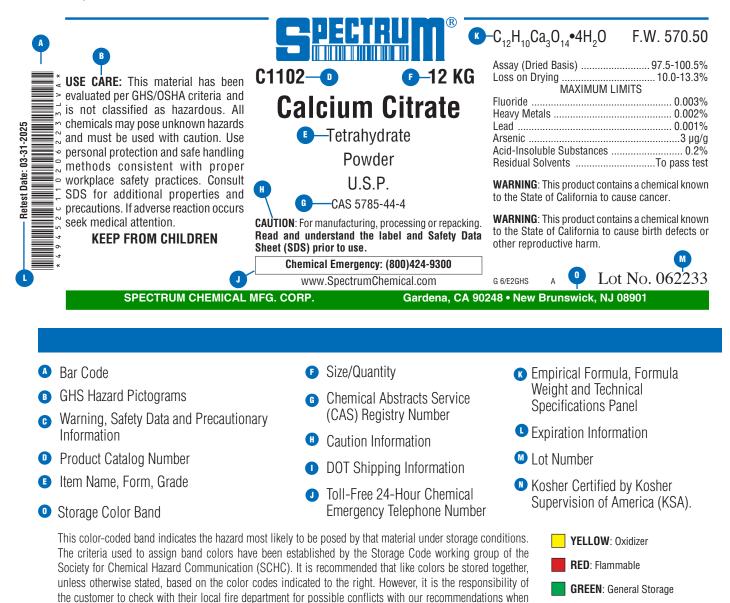
Read and understand label and MSDS/SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personal only. The customer must ensure to provide its users adequate hazardous material training and appropriate protective gears before handling our chemicals.



BLUE: Health Hazard WHITE: Corrosive

#### **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.



#### Spectrum Chemical Mfg Corp

Corporate Headquarters: 769 Jersey Ave. New Brunswick, NJ 08901

storing hazardous chemicals.

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

310.516.8000

732.214.1300



January 26, 2016

#### RE: Lot Numbering System

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products' Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of **six characters**, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum's Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

**Example**: ZI0928 = The 928<sup>th</sup> material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of **seven characters**. The first character, a number, represents the production facility:

1 = Gardena, CA Facility 2 = New Brunswick, NJ Facility 3 = China Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

**Example**: 2AA0706 = The 706<sup>th</sup> material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at <u>qualityassurance@spectrumchemical.com</u> if we may be of further assistance.

Sincerely,

1 lan

Michael Dang Manager, GMP Compliance



#### **Stability – Shelf Life Guidance**

#### Product Covered: C1102, Calcium Citrate, Tetrahydrate, Powder, USP

Spectrum Chemical's manufacturing partner has assigned the following shelf life guidance for the product listed above.

The product, C1102, Calcium Citrate, Tetrahydrate, Powder, USP, is assigned a 36 months shelf life from date of manufacturing. The quality and integrity of the chemical depends on the handling and storage conditions. Please refer to the Safety Data Sheet for proper storage and handling procedures.

Adan R. Hernandez Quality Control Manager

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Corporate Headquarters 769 Jersey Avenue New Brunswick, NJ 08901-3605



#### شهادة حلال IFANCA HALAL PRODUCT CERTIFICATE

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

Date: February 24, 2017 Document #: 11205.11206.II170394

00001 110

oducts, Inc. 769-Jersey Ave New Brunswi		Product Certificate #
C1102	C17530	HC-17SPBU26
		Page 1 of 1 MEMBER
	oducts, Inc. 769-Jersey Ave New Brunswi Product Code C1102 This certificate is valid until August 3	C1102 C17530 C17530 This certificate is valid until August 31, 2017 and subject to renewal a