

# Scientific Documentation

## Ferric Ammonium Citrate, Brown, Powder, FCC

Not appropriate for regulatory submission.

Please visit [www.spectrumchemical.com](http://www.spectrumchemical.com) or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp  
769 Jersey Avenue  
New Brunswick, NJ 08901  
Phone 732.214.1300



## **Table of Contents**

Certificate of Analysis

Safety Data Sheet (SDS)

Certification of Current Good Manufacturing Practices (cGMP)

Manufacturing Process Flowchart

Technical Statements

General Label Information – Sample Label

# Specification for Ferric Ammonium Citrate, Brown, Powder, FCC (F1000)

Item Number	F1000
Item	Ferric Ammonium Citrate, Brown, Powder, FCC
CAS Number	1185-57-5
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	Iron Ammonium Citrate

Test	Specification	
	Min	Max
ASSAY (Fe)	16.5	18.5 %
FERRIC CITRATE		TO PASS TEST
OXALATE (C <sub>2</sub> O <sub>4</sub> )		TO PASS TEST
LEAD (Pb)		2 mg/kg
MERCURY		1 mg/kg
SULFATE		0.3 %
IDENTIFICATION		TO PASS TEST
APPEARANCE	thin, transparent brown, red-brown, or garnet red scales or granules, or as a brown-yellow powder	
CERTIFIED HALAL		
RETEST DATE		
DATE OF MANUFACTURE		
MONOGRAPH EDITION		

## *Spectrum Chemical Mfg Corp*

<b>Corporate Headquarters:</b>	<b>West Coast Facility:</b>
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

# Certificate Of Analysis

Item Number	F1000	Lot Number	2MK0233
Item	Ferric Ammonium Citrate, Brown, Powder, FCC	CAS Number	1185-57-5

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (Fe)	16.5	18.5 %	18.1 %
FERRIC CITRATE		TO PASS TEST	PASSES TEST
OXALATE (C <sub>2</sub> O <sub>4</sub> )		TO PASS TEST	PASSES TEST
LEAD (Pb)		2 mg/kg	0.01 mg/kg
MERCURY		1 mg/kg	< 1 mg/kg
SULFATE		0.3 %	< 0.3 %
IDENTIFICATION		TO PASS TEST	PASSES TEST
APPEARANCE	thin, transparent brown, red- brown, or garnet red scales or granules, or as a brown-yellow powder		BROWNISH YELLOW POWDER
RETEST DATE			25-APR-2026
DATE OF MANUFACTURE			25-APR-2023
MONOGRAPH EDITION			FCC 13TH

Certificate of Analysis Results Entered By:

MCAMACHO  
Matheu Camacho  
05-DEC-23 11:15:32

Spectrum Chemical Mfg Corp  
755 Jersey Avenue  
New Brunswick NJ 08901

Certificate of Analysis Results Approved By:

GHERRERA  
Genaro Herrera  
08-DEC-23 05:46:56



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

**Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.**

# SAFETY DATA SHEET

# spectrum®



Revision date 18-February-2022

Revision Number 3

## 1. Identification

### Product identifier

**Product Name** FERRIC AMMONIUM CITRATE, BROWN, POWDER, FCC

### Other means of identification

**Product Code(s)** F1000

**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 2B
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### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

#### Warning

#### Hazard statements

Causes eye irritation

**Appearance** Powder

**Physical state** Solid

**Odor** Slight

### Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling

#### 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

#### Other information

Causes mild skin irritation.

### 3. Composition/information on ingredients

#### Substance

Chemical name	CAS No	Weight-%	Trade secret
Ferric Ammonium Citrate, brown	1185-57-5	100	*

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

### 4. First-aid measures

#### Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Get medical attention if irritation develops and persists. Remove contact lenses, if present and easy to do. Continue rinsing.
Skin contact	Wash skin with soap and water.
Ingestion	Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Call a physician.

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

Symptoms	Prolonged contact may cause redness and irritation.
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#### Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.
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### 5. Fire-fighting measures

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.
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** Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

**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.

### Conditions for safe storage, including any incompatibilities

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

## 8. Exposure controls/personal protection

### Control parameters

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

### Appropriate engineering controls

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

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

**Eye/face protection** None required for consumer use. Wear safety glasses with side shields (or goggles).

**Hand protection** Wear suitable gloves.

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

**Respiratory protection** No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.



**General hygiene considerations**      Avoid contact with skin, eyes or clothing.

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

<b>Physical state</b>	Solid
<b>Appearance</b>	Powder
<b>Color</b>	Reddish-Brown; brown
<b>Odor</b>	Slight
<b>Odor threshold</b>	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>pH</b>	no data available	None known
<b>Melting point / freezing point</b>	no data available	None known
<b>Boiling point / boiling range</b>	no data available	None known
<b>Flash point</b>	no data available	None known
<b>Evaporation rate</b>	no data available	None known
<b>Flammability (solid, gas)</b>	no data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Vapor pressure</b>	No data available	None known
<b>Vapor density</b>	no data available	None known
<b>Relative density</b>	1.8	None known
<b>Water solubility</b>	Easily soluble in water	None known
<b>Solubility(ies)</b>	Practically insoluble in alcohol	None known
<b>Partition coefficient</b>	No data available	None known
<b>Autoignition temperature</b>	no data available	None known
<b>Decomposition temperature</b>		None known
<b>Kinematic viscosity</b>	no data available	None known
<b>Dynamic viscosity</b>	No data available	None known

### Other information

<b>Explosive properties</b>	No information available
<b>Oxidizing properties</b>	No information available
<b>Softening point</b>	No information available
<b>Molecular weight</b>	No information available
<b>VOC Content (%)</b>	No information available
<b>Liquid Density</b>	No information available
<b>Bulk density</b>	No information available

## 10. Stability and reactivity

<b>Reactivity</b>	No information available.
<b>Chemical stability</b>	Stable under normal conditions.
<b>Possibility of hazardous reactions</b>	None under normal processing.
<b>Conditions to avoid</b>	None known based on information supplied.
<b>Incompatible materials</b>	None known based on information supplied.
<b>Hazardous decomposition products</b>	None known based on information supplied.

## 11. Toxicological information

### Information on likely routes of exposure

**Product Information**      .

<b>Inhalation</b>	Specific test data for the substance or mixture is not available.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available. Causes eye irritation. May cause redness, itching, and pain.
<b>Skin contact</b>	Specific test data for the substance or mixture is not available. Causes mild skin irritation.
<b>Ingestion</b>	Specific test data for the substance or mixture is not available.

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

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

<b>Numerical measures of toxicity</b>	No information available
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#### **Delayed and immediate effects as well as chronic effects from short and long-term exposure**

<b>Skin corrosion/irritation</b>	May cause skin irritation. Classification based on data available for ingredients.
<b>Serious eye damage/eye irritation</b>	Classification based on data available for ingredients. Irritating to eyes.
<b>Respiratory or skin sensitization</b>	No information available.
<b>Germ cell mutagenicity</b>	No information available.
<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<b>Target organ effects</b>	liver, respiratory system, Eyes, Skin, Gastrointestinal tract (GI).
<b>Aspiration hazard</b>	No information available.
<b>Other adverse effects</b>	No information available.
<b>Interactive effects</b>	No information available.

### **12. Ecological information**

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

### **13. Disposal considerations**

#### **Waste treatment methods**

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

## 14. Transport information

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

## 15. Regulatory information

### International Inventories

<b>TSCA</b>	Complies
<b>DSL/NDSL</b>	Complies
<b>EINECS/ELINCS</b>	Complies
<b>ENCS</b>	This product complies with ENCS:
<b>IECSC</b>	This product complies with China:
<b>KECL</b>	Complies
<b>PICCS</b>	Complies
<b>AICS</b>	All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).

### **Legend:**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

### US Federal Regulations

#### **SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

#### **SARA 311/312 Hazard Categories**

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

#### **CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

#### **CERCLA**

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302).

Chemical name	Hazardous Substances RQs	Extremely Hazardous Substances RQs
Ferric Ammonium Citrate, brown 1185-57-5	1000 lb final RQ 454 kg final RQ	-

### US State Regulations

#### **California Proposition 65**

This product does not contain any Proposition 65 chemicals.

### U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Ferric Ammonium Citrate, brown 1185-57-5	0918	Present	Environmental hazard

### U.S. EPA Label Information

**EPA Pesticide Registration Number** Not applicable

## **16. Other information**

### NFPA

**Health hazards** 1

**Flammability** 0

**Instability** 0

**Physical and chemical properties** -

### HMIS

**Health hazards** 1

**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** 18-February-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
F1000	Ferric Ammonium Citrate, Brown, Powder, FCC

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

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

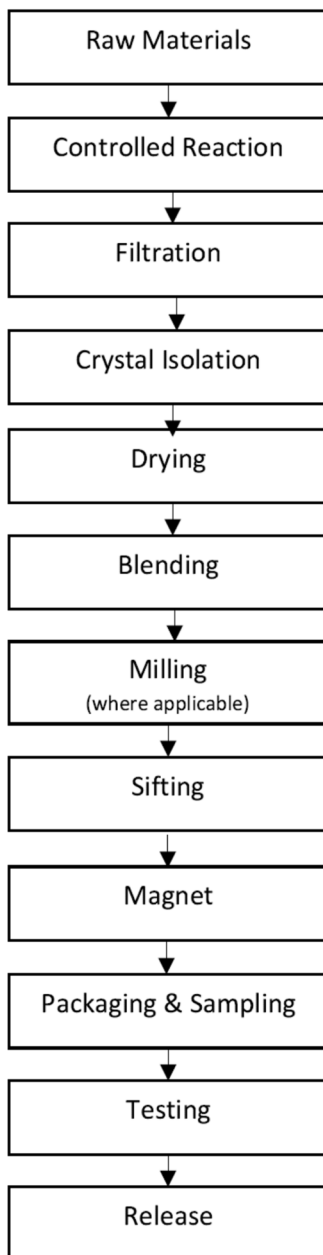
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com)

Sincerely,

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

Oralia Chavez  
Quality Assurance Specialist

## Manufacturing Process Flowchart Ferric Ammonium Citrate, Brown, Powder, FCC (Cat# F1000)



### 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

## **F1000, Ferric Ammonium Citrate, Brown, Powder, FCC**

### **Source Statement**

The above mentioned catalog item is manufactured by chemical synthesis. 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
- 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        | • Parabens      |
| • Antibiotics       | • Pesticides    |
| • Bisphenol A (BPA) | • Phthalates    |
| • CMR Substances    | • Preservatives |

## Label Information

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

**WARNING**  
 • Causes eye irritation • Causes mild skin irritation.  
 • 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 skin irritation occurs: Get medical attention.  
**KEEP FROM CHILDREN**

### F1000      SIZ SY

## Ferric Ammonium Citrate

Brown, Powder, FCC

CAS 1185-57-5

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

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

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

This compound is a complex salt of undetermined structure, composed of iron, ammonia and citric acid.

Assay (Fe) ..... 16.5-18.5%  
**MAXIMUM LIMITS**

Ferric Citrate ..... To pass test  
 Lead ..... 2 mg/kg  
 Mercury ..... 1 mg/kg  
 Oxalate ..... To pass test  
 Sulfate ..... 0.3%

**LIGHT SENSITIVE, DELIQUESCENT:** Keep tightly closed in light-resistant containers.

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

G 9/H6GHS      ?      Lot No. XQ####

### Spectrum Chemical Mfg Corp

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