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.
Dear Customer,

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

Spectrum has been proudly serving our 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

F1305, Ferric Subsulfate Solution, USP

Table of Contents

● Product Specification
● Safety Data Sheet (SDS)
● Manufacturer
● Certification of Quality Management System (QMS)
● Certification of current Good Manufacturing Practices (cGMP)
● Product BSE/TSE Statement
● Product Allergen Statement
● Product Aflatoxin Statement
● General Label Information – Sample Label
● Product Certificate of Analysis Sample(s)
● General Lot Numbering System Guidance
● Stability – Shelf Life Guidance
### Specification for Ferric Subsulfate Solution, USP (F1305)

<table>
<thead>
<tr>
<th>Item Number</th>
<th>F1305</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>Ferric Subsulfate Solution, USP</td>
</tr>
<tr>
<td>CAS Number</td>
<td>1310-45-8</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Fe₄(OH)₂(SO₄)₅</td>
</tr>
<tr>
<td>Molecular Weight</td>
<td>737.71</td>
</tr>
<tr>
<td>Synonyms</td>
<td>Basic Ferric Sulfate Solution ; Monsel's Solution</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASSAY (Fe)</strong></td>
<td>Min 20 - 22 g/100 ml Max</td>
</tr>
<tr>
<td><strong>NITRATE (NO₃)</strong></td>
<td>TO PASS TEST</td>
</tr>
<tr>
<td><strong>FERROUS SALTS</strong></td>
<td>TO PASS TEST</td>
</tr>
<tr>
<td><strong>IDENTIFICATION</strong></td>
<td>TO PASS TEST</td>
</tr>
<tr>
<td><strong>EXPIRATION DATE</strong></td>
<td></td>
</tr>
<tr>
<td><strong>RESIDUAL SOLVENTS</strong></td>
<td>TO PASS TEST</td>
</tr>
</tbody>
</table>

---

**Spectrum Chemical Mfg Corp**

**Corporate Headquarters:**
769 Jersey Ave.
New Brunswick, NJ 08901
732.214.1300

**West Coast Facility:**
1442 S. San Pedro St.
Gardena, CA 90248
310.516.8000
SAFETY DATA SHEET

Preparation Date: 04/09/2015
Revision Date: 04/09/2015
Revision Number: G1

Product code: F1305
Product Name: FERRIC SUBSULFATE SOLUTION, USP

Other means of identification
Synonyms: Monsel's Solution
CAS #: Mixture
RTECS #: Not available
CI#: Not available

Recommended use of the chemical and restrictions on use
Recommended use: Styptic agent used after minor surgical procedures, such as curettage and biopsies, to control bleeding and achieve hemostasis.
Uses advised against: No information available

Supplier: Spectrum Chemicals and Laboratory Products, Inc.
14422 South San Pedro St.
Gardena, CA 90248
(310) 516-8000
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)

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

Product code: F1305  Product name: FERRIC SUBSULFATE SOLUTION, USP
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Weight %</th>
<th>Trade Secret</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>78-80</td>
<td>*</td>
</tr>
<tr>
<td>Ferric Subsulfate</td>
<td>1310-45-8</td>
<td>20-22</td>
<td>*</td>
</tr>
</tbody>
</table>

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. Get medical attention if irritation develops.

Eye Contact: Flush eye with water for 15 minutes. Get medical attention if irritation occurs.

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 effects, both acute and delayed

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: The product is not flammable. If it is involved in a fire, extinguish the fire using an agent suitable for the type of surrounding fire.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: No information available.

Specific hazards: No information available.

Special Protective Actions for Firefighters
Specific Methods: Extinguish fire using an agent suitable for type of surrounding fire, the substance itself does not burn.

Special Protective Equipment for Firefighters: 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 procedures

Personal Precautions: Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes and clothing.

Environmental precautions: Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Prevent entry into waterways, sewers.

Methods and material for containment and cleaning up

Methods for containment: Stop leak if you can do it without risk. Absorb spill with inert material (e.g. vermiculite, dry sand or earth). In case of large spill, dike if needed. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up: Use appropriate tools to put the spilled material in a suitable chemical waste disposal container. Clean contaminated 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. Do not ingest. Do not breathe vapors or spray mist. Protect from light. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions: Sensitive to light. Store in light-resistant containers. Keep container tightly closed in a dry and well-ventilated place. Store at temperature over 22 deg. C. Crystallization may occur if the solution is exposed to temperatures below 22 deg. C. Crystals will redissolve up gentle warming.

Incompatible Materials: No information available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

<table>
<thead>
<tr>
<th>Components</th>
<th>OSHA</th>
<th>NIOSH</th>
<th>ACGIH</th>
<th>AIHA WHEEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water - 7732-18-5</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Ferric Subsulfate - 1310-45-8</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

Product code: F1305

Product name: FERRIC SUBSULFATE SOLUTION, USP
### Appropriate engineering controls

**Engineering measures to reduce exposure:**

Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors and mist below their respective threshold limit value.

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

#### Personal Protective Equipment

**Eye protection:**

Goggles.

**Skin and body protection:**

Chemical resistant apron. Gloves.

**Respiratory protection:**

Respiratory protection is not necessary for normal handling. Good room ventilation or use of local exhaust (fume hood) is sufficient. Use a vapor respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentrations of mist or vapor, inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.

**Hygiene measures:**

Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product.
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical state:</th>
<th>Appearance:</th>
<th>Color:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquid.</td>
<td>No information available</td>
<td>Reddish-Brown.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Odor:</th>
<th>Taste</th>
<th>Molecular/Formula weight:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slight. Practically odorless.</td>
<td>Astringent. Sour. Strong.</td>
<td>737.71 g/mol</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Formula:</th>
<th>Flash point (°C):</th>
<th>Flashpoint (°C/°F):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fe₄(OH)₂(SO₄)₅</td>
<td>No data available</td>
<td>No information available.</td>
</tr>
</tbody>
</table>

**Flash Point Tested according to:**
Not available

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

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

**Specific gravity:**
1.5-1.548

**Evaporation rate:**
No information available

**Odor threshold (ppm):**
No information available

**Miscibility:**
Miscible with water

**Solubility:**
Easily soluble in cold water
Easily soluble in hot water

10. STABILITY AND REACTIVITY

**Reactivity**
No information available

**Chemical stability**

<table>
<thead>
<tr>
<th>Stability</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitive to light. Exposure to light accelerates decomposition. Stable under recommended storage conditions.</td>
<td></td>
</tr>
</tbody>
</table>

**Possibility of Hazardous Reactions:**
Hazardous polymerization does not occur

**Conditions to avoid:**
Exposure to light. Temperatures below 22°C.

**Incompatible Materials:**
No information available.

**Hazardous decomposition products:**
No information available.

**Other Information**

<table>
<thead>
<tr>
<th>Corrosivity</th>
<th>Special Remarks on Corrosivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>No information available</td>
<td>No information available</td>
</tr>
</tbody>
</table>

11. TOXICOLOGICAL INFORMATION

**Information on likely routes of exposure**

**Product code:** F1305  **Product name:** FERRIC SUBSULFATE SOLUTION, USP
Principal Routes of Exposure:
Skin. Eyes. Ingestion.

Acute Toxicity

Component Information

Water - 7732-18-5
LD50/oral/rat = > 90 mL/kg Oral LD50 Rat
LD50/oral/mouse = No information available
LD50/dermal/rabbit = No information available
LD50/dermal/rat = No information available
LC50/inhalation/rat = No information available
LC50/inhalation/mouse = No information available
Other LD50 or LC50 information = No information available

Ferric Subsulfate - 1310-45-8
LD50/oral/rat = No information available
LD50/oral/mouse = No information available
LD50/dermal/rabbit = No information available
LD50/dermal/rat = No information available
LC50/inhalation/rat = No information available
LC50/inhalation/mouse = No information available
Other LD50 or LC50 information = 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: Splashes may cause eye irritation.
Inhalation Not expected to be an inhalation hazard. Inhalation of mist or vapors may cause respiratory tract irritation.

Ingestion May be harmful if swallowed. There is a low toxicity in small quantities, but large doses may lead to iron poisoning and cause gastrointestinal tract irritation (gastroenteritis) with nausea, retching & vomiting, abdominal pain, hypermotility, diarrhea, colic or constipation, and black stool. Liver damage and kidney failure have also been reported from iron poisoning. Pink urine discoloration is a strong indicator of iron poisoning. Iron poisoning may also affect behavior/Central Nervous System (seizures/convulsions, lethargy, drowsiness, hyporeflexia, coma), respiratory system (cyanosis, pulmonary), cardiovascular system (weak pulse, tachycardia, hypotension), metabolism (metabolic acidosis), and blood (leukocytosis). It may also cause coagulation defects, and hypoglycemia.

Aspiration hazard No information available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chronic Toxicity Prolonged eye contact may cause a brownish discoloration of the eyes. Prolonged or repeated ingestion may lead to much Iron build-up in the body, particularly in the liver and cause liver damage. Symptoms of chronic iron poisoning may be similar that of acute ingestion.

Sensitization: No information available

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic

<table>
<thead>
<tr>
<th>Components</th>
<th>ACGIH - Carcinogens</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA HCS - Carcinogens</th>
<th>Australia - Prohibited Carcinogenic Substances</th>
<th>Australia - Notifiable Carcinogenic Substances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
</tr>
<tr>
<td>Ferric Subsulfate</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
</tr>
</tbody>
</table>

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
Target Organs: Liver.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Product code: F1305  Product name: FERRIC SUBSULFATE SOLUTION, USP
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

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Ferric Subsulfate</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: Not applicable
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

Product code: F1305  Product name: FERRIC SUBSULFATE SOLUTION, USP
### 14. TRANSPORT INFORMATION

**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

**RID**

- **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  
- **Classification Code:** No information available  
- **Description:** No information available

**ICAO**

- **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

**IATA**

- **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

<table>
<thead>
<tr>
<th>Components</th>
<th>U.S. TSCA</th>
<th>KOREA KECL (PICCS)</th>
<th>Philippines (PICCS)</th>
<th>Japan ENCS</th>
<th>CHINA</th>
<th>Australia (AICS)</th>
<th>EINECS-No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Present</td>
<td>Present KE-35400</td>
<td>Present</td>
<td>Not present</td>
<td>Present</td>
<td>Present</td>
<td>Present 231-791-2</td>
</tr>
<tr>
<td>Ferric Subsulfate</td>
<td>Present</td>
<td>Present KE-21089</td>
<td>Not present</td>
<td>Present (1)-359</td>
<td>Not present</td>
<td>Present</td>
<td>Present 215-179-2</td>
</tr>
</tbody>
</table>

#### 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)

<table>
<thead>
<tr>
<th>Components</th>
<th>Carcinogen</th>
<th>Developmental Toxicity</th>
<th>Male Reproductive Toxicity</th>
<th>Female Reproductive Toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Ferric Subsulfate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**Product code:** F1305  
**Product name:** FERRIC SUBSULFATE SOLUTION, USP
### CERCLA/SARA

<table>
<thead>
<tr>
<th>Components</th>
<th>CERCLA - Hazardous Substances and their Reportable Quantities</th>
<th>Section 302 Extremely Hazardous Substances and TPQs</th>
<th>Section 302 Extremely Hazardous Substances and RQs</th>
<th>Section 313 - Chemical Category</th>
<th>Section 313 - Reporting de minimis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Ferric Subsulfate</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

### U.S. TSCA

<table>
<thead>
<tr>
<th>Components</th>
<th>TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)</th>
<th>TSCA 8(d) - Health and Safety Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Ferric Subsulfate</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

### Canada

**WHMIS hazard class:**
Non-controlled

**Water**
Uncontrolled product according to WHMIS classification criteria

**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

<table>
<thead>
<tr>
<th>Components</th>
<th>Canada (DSL)</th>
<th>Canada (NDSL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Ferric Subsulfate</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>CEPA Schedule I - Toxic Substances</th>
<th>CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Not listed</td>
<td>Not listed</td>
</tr>
<tr>
<td>Ferric Subsulfate</td>
<td>Not listed</td>
<td>Not listed</td>
</tr>
</tbody>
</table>

### EU Classification

**S -phrase(s)**
none

<table>
<thead>
<tr>
<th>Components</th>
<th>Classification</th>
<th>Concentration Limits:</th>
<th>Safety Phrases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td></td>
<td>No information</td>
<td></td>
</tr>
<tr>
<td>Ferric Subsulfate</td>
<td></td>
<td>No information</td>
<td></td>
</tr>
</tbody>
</table>

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

**Indication of danger:**
None.

**Product code:** F1305

**Product name:** FERRIC SUBSULFATE SOLUTION, USP
16. OTHER INFORMATION

Preparation Date: 04/09/2015
Revision Date: 04/09/2015
Prepared by: 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: F1305, Ferric Subsulfate Solution, 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

Intertek

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
755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA
769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA
7400 North Oracle Road, Suite 221, Tucson, Arizona, 85704, USA

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

ISO 9001:2008

The quality management system is applicable to

California and New Jersey sites: 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.

Arizona site: Supporting Spectrum’s two manufacturing facilitates by: selecting and qualifying distributors of Laboratory and Safety Equipment; processing bids and quotes to generate new sales opportunities; sourcing bulk chemicals in support of bulk bids and quotes; assisting production operations through order expediting and IT infrastructure support.

Certificate Number: 94-316m-01
Initial Certification Date: 27 December 1994
Certificate Issue Date: 29 January 2016
Certificate Expiry Date: 14 September 2018

Calin Moldovean, President
Intertek Testing Services NA, Inc.
900 Chelmsford Street, Suite 301-3, 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.

CT-ISO 9001-2008-ANAB-EN-LT-L-26,jun.15
Certificate of Registration

[Logo]

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

[Signature]

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 certificate.validation@intertek.com or by scanning the code to the right with a smartphone.
The annual validity of the certificate can also be checked through the website http://www.cnca.gov.cn of CNCA in China.

The certificate remains the property of Intertek, to whom it must be returned upon request.
March 28, 2016

Certificate of cGMP

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify 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: 2020632
Spectrum-New Brunswick, NJ: 2246824
Spectrum -Shanghai, China: 3006174778

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

Sincerely,

[Signature]

Michelle Weston
Quality Assurance Specialist
April 25, 2016

Certificate of cGMP

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify 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.

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Product Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1305</td>
<td>Ferric Subsulfate Solution, USP</td>
</tr>
</tbody>
</table>

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
Spectrum-Shanghai, China: 3006174778

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

Sincerely,

Michelle Weston
Quality Assurance Specialist
May 4, 2016

Re: Ferric Subsulfate Solution, USP- F1305

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 Ferric Subsulfate Solution, USP- F1305

is BSE/TSE free.

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

Sincerely,

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

This document has been produced electronically and is valid without a signature
May 4, 2016

Re: Ferric Subsulfate Solution, USP- F1305

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 SO₂; Lupin; Tree nuts; Mollusks; Wheat; Peanuts; Soy; Cereals containing Gluten; Celery; Mustard; Sesame Seed).

Ferric Subsulfate Solution, USP- F1305

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

Sincerely,

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

This document has been produced electronically and is valid without a signature
June 15, 2016

Re: Ferric Subsulfate Solution, USP- F1305

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. Aflatoxins are not used in production. The following product does not come in contact with Aflatoxins at any stage of production.

Ferric Subsulfate Solution, USP- F1305

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

Sincerely,

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

This document has been produced electronically and is valid without a signature
**Ferric Subsulfate Solution**

(Basic Ferric Sulfate Solution; Monsel’s Solution)

**U.S.P.**

**CAS 1310-45-8**

**Fe₄(OH)₂(SO₄)₅**

F.W. 737.71

Prepared from Ferrous Sulfate, Water, Sulfuric Acid, and Nitric Acid. Crystallization may occur if the solution is exposed to temperatures below 22°C. Warming will redissolve the crystals.

Assay (as Fe) .....................................20-22 g/100ml

MAXIMUM LIMITS

Nitrate .................................................... To pass test
Ferrous Salts .......................................... To pass test
Residual Solvents .................................. To pass test

LIGHT SENSITIVE: Keep tightly closed in light-resistant containers. Store over 22°C.

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**

**GHS Hazard Pictograms**

- **YELLOW**: Oxidizer
- **RED**: Flammable
- **GREEN**: General Storage
- **BLUE**: Health Hazard
- **WHITE**: Corrosive

**Bar Code**

**GHS Hazard Pictograms**

**Warning, Safety Data and Precautionary Information**

**Product Catalog Number**

**Item Name, Form, Grade**

**Storage Color Band**

**Size/Quantity**

**Chemical Abstracts Service (CAS) Registry Number**

**Caution Information**

**DOT Shipping Information**

**Toll-Free 24-Hour Chemical Emergency Telephone Number**

**Empirical Formula, Formula Weight and Technical Specifications Panel**

**Expiration Information**

**Lot Number**

**Kosher Certified by Kosher Supervision of America (KSA).**
## Certificate Of Analysis

<table>
<thead>
<tr>
<th>Item Number</th>
<th>F1305</th>
<th>Lot Number</th>
<th>2EL0379</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>Ferric Subsulfate Solution, USP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAS Number</td>
<td>1310-45-8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Fe₄(OH)₂(SO₄)₅</td>
<td>Molecular Weight</td>
<td>737.71</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test</th>
<th>Specification</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASSAY (Fe)</td>
<td>20 - 22 g/100 ml</td>
<td>21.5 g/100ml</td>
</tr>
<tr>
<td>NITRATE (NO₃)</td>
<td>TO PASS TEST</td>
<td>PASSES TEST</td>
</tr>
<tr>
<td>FERROUS SALTS</td>
<td>TO PASS TEST</td>
<td>PASSES TEST</td>
</tr>
<tr>
<td>IDENTIFICATION</td>
<td>TO PASS TEST</td>
<td>PASSES TEST</td>
</tr>
<tr>
<td>EXPIRATION DATE</td>
<td></td>
<td>19-AUG-2017</td>
</tr>
<tr>
<td>RESIDUAL SOLVENTS</td>
<td>TO PASS TEST</td>
<td>NO RESIDUAL SOLVENTS USED</td>
</tr>
<tr>
<td>APPEARANCE</td>
<td></td>
<td>REDDISH BROWN LIQUID</td>
</tr>
<tr>
<td>DATE OF MANUFACTURE</td>
<td></td>
<td>19-AUG-2015</td>
</tr>
</tbody>
</table>

Spectrum Chemical Mfg Corp  
755 Jersey Avenue  
New Brunswick 08901 NJ

Certificate of Analysis Results Certified By:  
Mulbah F. Dwanah  
Laboratory Supervisor  
Spectrum Chemicals & Laboratory Products

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.
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 928th 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 706th 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 qualityassurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Michael Dang
Manager, GMP Compliance
Stability – Shelf Life Guidance

Product Covered: F1305, Ferric Subsulfate Solution, USP

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

The product, F1305, Ferric Subsulfate Solution, USP, is assigned a 24 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

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