

## **Scientific Documentation**

## Ammonium Sulfate, USP, ACS, Pyrogen Free, bioCERTIFIED (TM)

Not appropriate for regulatory submission.

Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

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





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## Specification for Ammonium Sulfate, USP, ACS, Pyrogen Free, bioCERTIFIED (TM) (A9400)

| Item Number       | A9400   |
|-------------------|---|
| Item              | Ammonium Sulfate, USP, ACS, Pyrogen Free, bioCERTIFIED (TM) |
| CAS Number        | 7783-20-2   |
| Molecular Formula | $(NH_4)_2SO_4$  |
| Molecular Weight  | 132.14  |
| MDL Number        |   |
| Synonyms          | Sulfuric Acid Diammonium Salt                               |

| Test                         | S    | pecification |
|------------------------------|------|--------------|
|                              | Min  | Max          |
| APPEARANCE                   |      |              |
| ASSAY $[(NH_4)_2SO_4]$       | 99.0 | 100.5 %      |
| pH OF A 5% SOLUTION @ 25°C   | 5.0  | 6.0          |
| INSOLUBLE MATTER             |      | 0.005 %      |
| RESIDUE AFTER IGNITION       |      | 0.005 %      |
| CHLORIDE (Cl)                |      | 5 ppm        |
| NITRATE (NO <sub>3</sub> )   |      | 0.001 %      |
| PHOSPHATE (PO <sub>4</sub> ) |      | 5 ppm        |
| HEAVY METALS (by ICP-OES)    |      | 5 ppm        |
| IRON (Fe)                    |      | 5 ppm        |
| ELEMENTAL IMPURITIES         |      | AS REPORTED  |
| MICROBIAL LIMITS             |      |              |
| ТАМС                         |      | 1000 CFU/g   |
| ТҮМС                         |      | 10 CFU/g     |
| ENDOTOXINS                   |      | 10 IU/g      |
| IDENTIFICATION               |      | TO PASS TEST |
| EXPIRATION DATE              |      |              |
| DATE OF MANUFACTURE          |      |              |
| RESIDUAL SOLVENTS            |      | AS REPORTED  |

### Spectrum Chemical Mfg Corp

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



## **Certificate Of Analysis**

| Item Number       | A9400   | Lot Number       | 4MI0081   |
|-------------------|---|------------------|-----------|
| Item              | Ammonium Sulfate, USP, ACS, Pyrogen Free, bioCERTIFIED (TM) | CAS Number       | 7783-20-2 |
| Molecular Formula | (NH <sub>4</sub> ) <sub>2</sub> SO <sub>4</sub>             | Molecular Weight | 132.14    |

| тгст   | SPECIFICATION |              |                              |
|--|---------------|--------------|------------------------------|
| TEST   | MIN           | MAX          | RESULT                       |
| APPEARANCE   |               |              | SMALL WHITE CRYSTALS         |
| ASSAY [(NH <sub>4</sub> ) <sub>2</sub> SO <sub>4</sub> | 99.0          | 100.5 %      | 99.4 %                       |
| pH OF A 5% SOLUTION @ 25°C                             | 5.0           | 6.0          | 5.08                         |
| INSOLUBLE MATTER                                       |               | 0.005 %      | 0.002 %                      |
| RESIDUE AFTER IGNITION                                 |               | 0.005 %      | <0.005 %                     |
| CHLORIDE (CI)  |               | 5 ppm        | < 5 ppm                      |
| NITRATE (NO <sub>3</sub> )                             |               | 0.001 %      | <0.001 %                     |
| PHOSPHATE (PO <sub>4</sub> )                           |               | 5 ppm        | < 5 ppm                      |
| HEAVY METALS (by ICP-OES)                              |               | 5 ppm        | 0.2 ppm                      |
| IRON (Fe)  |               | 5 ppm        | < 5 ppm                      |
| ELEMENTAL IMPURITIES                                   |               | AS REPORTED  | COMPLIES WITH STANDARD       |
| MICROBIAL LIMITS                                       |               |              |                              |
| ТАМС   |               | 1000 CFU/g   | <1000 CFU/g                  |
| ТҮМС   |               | 10 CFU/g     | <10 CFU/g                    |
| ENDOTOXINS   |               | 10 IU/g      | <9.6 IU/g                    |
| IDENTIFICATION   |               | TO PASS TEST | PASSES TEST                  |
| EXPIRATION DATE  |               |              | 15-MAY-2027                  |
| DATE OF MANUFACTURE                                    |               |              | 15-MAY-2022                  |
| RESIDUAL SOLVENTS                                      |               | AS REPORTED  | NO RESIDUAL SOLVENTS PRESENT |
| MONOGRAPH EDITION                                      |               |              | USP 2023                     |

Certificate of Analysis Results Entered By:

MCAMACHO Matheu Camacho 07-DEC-23 05:59:30

Spectrum Chemical Mfg Corp 777 Jersey Avenue New Brunswick 08901 NJ



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.

Certificate of Analysis Results Approved By:

GHERRERA Genaro Herrera 07-DEC-23 09:40:53

# **SAFETY DATA SHEET** spectrum®

Revision date 10-November-2022

| 1. Identification  |   |  |
|--|---|--|
| Product identifier   |   |  |
| Product Name   | AMMONIUM SULFATE, USP, ACS, PYROGEN FREE, bioCERTIFIED™ |  |
| Other means of identification  |   |  |
| Product Code(s)  | A9400   |  |
| Synonyms   | None  |  |
| Recommended use of the chemica   | l 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<br>Spectrum Chemical Mfg. Corp.<br>14422 South San Pedro St.<br>Gardena, CA 90248<br>(310) 516-8000 |   |  |
| Emergency telephone number   |   |  |
| Emergency Telephone  | Chemtrec 1-800-424-9300                                 |  |

## 2. Hazard(s) identification

#### Classification

| Skin corrosion/irritation         | Category 2  |
|-----------------------------------|-------------|
| Serious eye damage/eye irritation | Category 2B |

#### Hazards not otherwise classified (HNOC)

Not applicable

#### Label elements

Warning

Hazard statements

Causes skin irritation Causes eye irritation







Physical state Solid

Odor No information available

#### **Precautionary Statements - Prevention**

Wear protective gloves Wash face, hands and any exposed skin thoroughly after handling

#### Precautionary Statements - Response

Specific treatment (see .? on this label) IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing If eye irritation persists: Get medical advice/attention IF ON SKIN: Wash with plenty of water Take off contaminated clothing and wash it before reuse If skin irritation occurs: Get medical advice/attention

#### **Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

#### Unknown acute toxicity

#### Other information

May be harmful if swallowed. Harmful to aquatic life with long lasting effects. Harmful to aquatic life.

#### 3. Composition/information on ingredients

#### Substance

| Chemical name    | CAS No    | Weight-% |
|------------------|-----------|----------|
| Ammonium Sulfate | 7783-20-2 | 100      |

#### 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. Get medical attention immediately if symptoms occur.   |
| Eye contact                        | Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists. |
| Skin contact                       | Wash off immediately with soap and plenty of water for at least 15 minutes. If symptoms persist, call a physician.  |
| Ingestion                          | Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water.<br>Never give anything by mouth to an unconscious person. Call a physician.  |
| Self-protection of the first aider | Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Wear personal protective clothing (see section 8). Avoid contact with skin, eyes or clothing.            |

Most important symptoms and effects, both acute and delayed

Symptoms

No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

### 5. Fire-fighting measures

| Suitable Extinguishing Media                      | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.                            |
|---|--|
| Large Fire  | CAUTION: Use of water spray when fighting fire may be inefficient.   |
| Unsuitable extinguishing media                    | Do not scatter spilled material with high pressure water streams.  |
| Specific hazards arising from the chemical        | No information available.  |
| Hazardous combustion products                     | If it is involved in a fire the following can be released:. Sulfur oxides. Ammonia. Nitrogen oxides (NOx).                         |
| Explosion data<br>Sensitivity to mechanical impac | ct none.   |
| Sensitivity to static discharge                   | none.  |
| Special protective equipment for<br>fire-fighters | Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment. |
| 6 Appidental release mag                          |  |

#### 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

| Personal precautions              | Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. |
|-----------------------------------|--|
| Other information                 | Refer to protective measures listed in Sections 7 and 8.   |
| Methods and material for containm | ent and cleaning up  |
| Methods for containment           | Prevent further leakage or spillage if safe to do so.  |
| Methods for cleaning up           | Pick up and transfer to properly labeled containers.   |

| 7. Handling and storage                                      |  |
|--|--|
| Precautions for safe handling                                |  |
| Advice on safe handling                                      | Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse. |
| Conditions for safe storage, including any incompatibilities |  |
| Storage Conditions   | Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up.  |

## 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<br>Eyewash stations<br>Ventilation systems.  |  |
| Individual protection measures, such as personal protective equipment |  |  |
| Eye/face protection   | Wear safety glasses with side shields (or goggles). None required for consumer use.  |  |
| Hand protection   | Wear suitable gloves. Impervious gloves.   |  |
| Skin and body protection  | Wear suitable protective clothing. Long sleeved clothing.  |  |
| Respiratory protection  | No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.   |  |
| General hygiene considerations  | Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product.   |  |

## 9. Physical and chemical properties

#### Information on basic physical and chemical properties

| Physical stateSolidAppearanceCrystals or Crystalline powderColorColorless to WhiteOdorNo information available |      |
|--|------|
| Color     Colorless to White       Odor     No information available   |      |
| Odor No information available  |      |
| ••••   |      |
|  |      |
| Odor threshold No information available  |      |
| Property Values Remarks • Met  | hod  |
| pH 5.0-6.0 at 132g/l @ 25°C None known   | liou |
| Melting point / freezing point 280 °C / 536 °F None known  |      |
|  |      |
| Boiling point / boiling rangeno data availableNone knownFlash pointno data availableNone known                 |      |
|  |      |
|  |      |
| Flammability (solid, gas) no data available None known   |      |
| Flammability Limit in Air None known   |      |
| Upper flammability or explosive No data available  |      |
| limits   |      |
| Lower flammability or explosive No data available  |      |
| limits   |      |
| Vapor pressure         No data available         None known  |      |
| Vapor density no data available None known   |      |
| Relative density1.8None known  |      |
| Water solubility         Soluble in water         None known   |      |
| Solubility(ies) Insoluble in Ethanol None known  |      |
| Insoluble in Acetone   |      |
| Partition coefficient         No data available         None known   |      |
| Autoignition temperature no data available None known  |      |
| Decomposition temperature >280 - °C °F None known  |      |
| Kinematic viscosity no data available None known   |      |
| Dynamic viscosity No data available None known   |      |
|  |      |

Other information

| Explosive properties | No information available |
|----------------------|--------------------------|
| Oxidizing properties | No information available |
| Softening point      | No information available |
| Molecular weight     | No information available |
| VOC Content (%)      | No information available |
| Liquid Density       | No information available |
| Bulk density         | No information available |

### 10. Stability and reactivity

| Reactivity                         | No information available.                            |
|------------------------------------|--|
| Chemical stability                 | Stable under normal conditions.                      |
| Possibility of hazardous reactions | None under normal processing.                        |
| Conditions to avoid                | None known based on information supplied.            |
| Incompatible materials             | Strong acids. Strong bases. Strong oxidizing agents. |
|                                    |  |

Hazardous decomposition products None known based on information supplied.

### 11. Toxicological information

#### Information on likely routes of exposure

| Product Information  |  |  |
|--|--|--|
| Inhalation   | Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.   |  |
| Eye contact  | Specific test data for the substance or mixture is not available. Irritating to eyes. (based on components). Causes eye irritation.  |  |
| Skin contact   | Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components).   |  |
| Ingestion  | Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. May be harmful if swallowed. |  |
| Symptoms related to the physical, chemical and toxicological characteristics |  |  |

Symptoms Redness. May cause redness and tearing of the eyes.

Acute toxicity

Numerical measures of toxicity

#### Unknown acute toxicity

| Chemical name                 | Oral LD50          | Dermal LD50        | Inhalation LC50 |
|-------------------------------|--------------------|--------------------|-----------------|
| Ammonium Sulfate<br>7783-20-2 | = 2840 mg/kg (Rat) | > 2000 mg/kg (Rat) | -               |

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

Skin corrosion/irritation Serious eye damage/eye irritation Respiratory or skin sensitization Germ cell mutagenicity Classification based on data available for ingredients. Irritating to skin. Classification based on data available for ingredients. Irritating to eyes. No information available. No information available.

| Reproductive toxicity   | No information available.   |
|---|---|
| STOT - single exposure<br>STOT - repeated exposure<br>Aspiration hazard | No information available.<br>No information available.<br>No information available. |
| Other adverse effects   | No information available.   |
| Interactive effects   | No information available.   |

## 12. Ecological information

| Ecotoxicity      | Harmful to ac        | quatic life with long lasting | effects.       |                        |
|------------------|----------------------|-------------------------------|----------------|------------------------|
| Chemical name    | Algae/aquatic plants | Fish                          | Toxicity to    | Crustacea              |
|                  |                      |                               | microorganisms |                        |
| Ammonium Sulfate | -                    | LC50: 123 - 128mg/L           | -              | LC50: =14mg/L (48h,    |
| 7783-20-2        |                      | (96h, Poecilia reticulata)    |                | Daphnia magna) EC50:   |
|                  |                      | LC50: 32.2 - 41.9mg/L         |                | =423mg/L (24h, Daphnia |
|                  |                      | (96h, Oncorhynchus            |                | magna)                 |
|                  |                      | mykiss) LC50: 460 -           |                |                        |
|                  |                      | 1000mg/L (96h,                |                |                        |
|                  |                      | Leuciscus idus) LC50:         |                |                        |
|                  |                      | 5.2 - 8.2mg/L (96h,           |                |                        |
|                  |                      | Oncorhynchus mykiss)          |                |                        |
|                  |                      | LC50: =126mg/L (96h,          |                |                        |
|                  |                      | Poecilia reticulata) LC50:    |                |                        |
|                  |                      | =18mg/L (96h, Cyprinus        |                |                        |
|                  |                      | carpio) LC50: =250mg/L        |                |                        |
|                  |                      | (96h, Brachydanio rerio)      |                |                        |
|                  |                      | LC50: =420mg/L (96h,          |                |                        |
|                  |                      | Brachydanio rerio) LC50:      |                |                        |
|                  |                      | =480mg/L (96h,                |                |                        |
|                  |                      | Brachydanio rerio) LC50:      |                |                        |
|                  |                      | >100mg/L (96h,                |                |                        |
|                  |                      | Pimephales promelas)          |                |                        |

## Persistence and degradability Bioaccumulation

No information available. Inherently biodegradable.

#### **Component Information**

| Chemical name                 | Partition coefficient |
|-------------------------------|-----------------------|
| Ammonium Sulfate<br>7783-20-2 | -5.1                  |

Other adverse effects

No information available.

## 13. Disposal considerations Waste treatment methods

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

## 14. Transport information

| TDG        | not regulated |
|------------|---------------|
| MEX        | not regulated |
| ICAO (air) | not regulated |
| IATA       | not regulated |
| IMDG_      | not regulated |
| RID        | not regulated |
| ADR        | not regulated |
| ADN        | not regulated |

#### 15. Regulatory information

#### International Inventories

| TSCA  | Complies  |
|---|---|
| DSL/NDSL<br>EINECS/ELINCS<br>ENCS<br>IECSC<br>KECL<br>PICCS<br>AICS | Complies<br>Complies<br>This product complies with ENCS:<br>This product complies with China:<br>Complies<br>Complies<br>All the constituents of this material are listed on the Australian Inventory of Chemical<br>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 contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

| Chemical name                | SARA 313 - Threshold Values % |
|------------------------------|-------------------------------|
| Ammonium Sulfate - 7783-20-2 | 1.0                           |

#### SARA 311/312 Hazard Categories

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

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

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

#### **CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level

pertaining to releases of this material.

#### US State Regulations

#### **California Proposition 65**

This product does not contain any Proposition 65 chemicals.

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

| nnsylvania    |
|---------------|
| mental hazard |
|               |

#### U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

#### 16. Other information

NFPA Health hazards 2 Flammability 0 Instability 0 Physical and chemical properties -HMIS Health hazards 2 Flammability 0 Physical hazards 0 Personal protection X Key or legend to abbreviations and acronyms used in the safety data sheet Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION TŴĂ TWA (time-weighted average) STEL (Short Term Exposure Limit) STEL Ceiling Maximum limit value Key literature references and sources for data used to compile the SDS Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database European Food Safety Authority (EFSA) EPA (Environmental Protection Agency) Acute Exposure Guideline Level(s) (AEGL(s)) U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act U.S. Environmental Protection Agency High Production Volume Chemicals Food Research Journal Hazardous Substance Database International Uniform Chemical Information Database (IUCLID) Japan GHS Classification Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS) NIOSH (National Institute for Occupational Safety and Health) National Library of Medicine's ChemID Plus (NLM CIP) National Library of Medicine's PubMed database (NLM PUBMED) National Toxicology Program (NTP) New Zealand's Chemical Classification and Information Database (CCID) Organization for Economic Co-operation and Development Environment, Health, and Safety Publications Organization for Economic Co-operation and Development High Production Volume Chemicals Program Organization for Economic Co-operation and Development Screening Information Data Set World Health Organization

| Revision date | 10-November-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** 

# spectrum

#### 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  |
|----------------|---|
| A9400          | Ammonium Sulfate, USP, ACS, Pyrogen Free,<br>bioCERTIFIED ™ |

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:       | <u>2020632</u> |
|-----------------------------|----------------|
| 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 <u>gualityassurance@spectrumchemical.com</u>

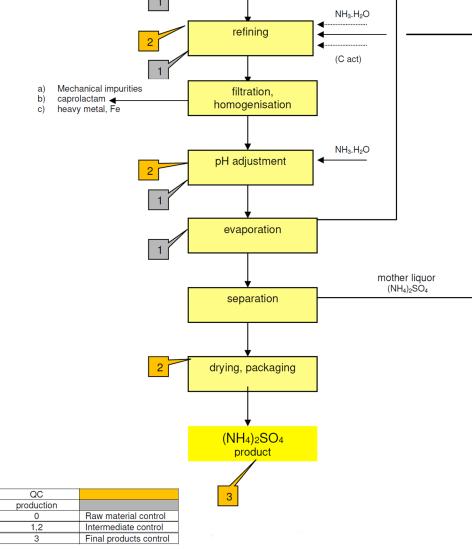
Sincerely,

Oulu Clony

Oralia Chavez Quality Assurance Specialist



# Manufacturing Process Flowchart Ammonium Sulfate, USP, ACS, Pyrogen Free, bioCERTIFIED ™ (Cat# A9400)



#### 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

AN ISO 9001:2015 REGISTERED COMPANY

# **A9400**, Ammonium Sulfate, USP, ACS, Pyrogen Free, bioCERTIFIED ™

## **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

spectrum

- 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 above mentioned catalog item 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 60 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

## **Other Chemicals Statement**

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- Aflatoxins
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives

# spectrum®

## RE: Elemental Impurities - Ammonium Sulfate, USP, ACS, Pyrogen Free, bioCERTIFIED ™ (Cat# A9400)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

| Elemental Impurity |    | Class | Expected Concentration |
|--------------------|----|-------|------------------------|
| Silver             | Ag | 2B    | < 7.5 ppm              |
| Lithium            | Li | 3     | < 27.5 ppm             |

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at <u>TechServices@spectrumchemical.com</u>.

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

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

#### CORPORATE HEADQUARTERS

769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132

#### WEST COAST FACILITY

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

AN ISO 9001:2015 REGISTERED COMPANY



RE: Residual Solvents - Ammonium Sulfate, USP, ACS, Pyrogen Free, bioCERTIFIED ™ (Cat# A9400)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of the USP <467> Residual Solvents and the ICH Q3C Residual Solvents Guideline. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture of this product.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at <u>TechServices@spectrumchemical.com</u>.

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

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

### CORPORATE HEADQUARTERS

769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132

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# spectrum®

**GREEN**: General Storage

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®  | Not sterile.   |   |
|--|--|--|---|
| * • Causes skin and eye irritation • May be  | A9400-0 <b>I</b> KG  |  | 00.0-100.5%   |
| <ul> <li>harmful if swallowed.</li> <li>Wear protective gloves • Wash face, hands</li> </ul>   |  | Assay [(NH <sub>4</sub> ) <sub>2</sub> SO <sub>4</sub> ]<br>pH of a 5% Solution @ 25°C   | 5 0-6 0   |
| and any exposed skin thoroughly after handling.  | Ammonium Sulfate   | MAXIMUM LIN  | NITS  |
| FIRST AID: IF IN EYES: Rinse cautiously with   |  | Insoluble Matter<br>Residue After Ignition   |   |
| water for several minutes. Remove contact  | (Sulfuric Acid Diammonium Salt)  | Chloride (Cl)  |   |
| ∾ lenses, if present and easy to do. Continue<br>∞ rinsing. If eye irritation persists: Get medical  | 🕒 USP, ACS, Pyrogen Free, 🍳  | Nitrate (NO <sub>2</sub> )   | 0.001%  |
| O attention IF ON SKIN: Wash with plenty of  |  | Phosphate (PO)   | 5 ppm   |
| water. Take off contaminated clothing and  | ⊎ bioCERTIFIED™ bio  | Heavy Metals (by ICP-OES)  | 5 ppm   |
| 📕 🚽 wash it before reuse. If skin irritation occurs:   | G CAS 7783-20-2 CERTIFIED  | Iron (Fe)<br>Elemental Impurities  |   |
| Get medical attention.   | CAUTION: For manufacturing, processing or  | Residual Solvents  |   |
| KEEP FROM CHILDREN   | repacking. Further processing and testing required   | Microbial Limits:  |   |
|  | for use in parenteral applications.  | TAMC   |   |
| Concer and Depreductive Horm   | Read and understand the label and Safety Data  | TYMC   |   |
| * www.P65Warnings.ca.gov   | Sheet (SDS) prior to use.  | Endotoxins   | IU IU/g   |
|  |  |  |   |
| * ************************************   | Chemical Emergency: (800)424-9300  |  | No 062222   |
|  | www.SpectrumChemical.com   | g 1/K10GHS A O LOt<br>8 • New Brunswick, NJ 0  | No. 062233<br>8901  |
| SPECTRUM CHEMICAL  | www.SpectrumChemical.com<br>MFG. CORP. Gardena, CA 9024<br>Chemical Abstracts Service  | <b>_</b>   | 8901  |
|  | www.SpectrumChemical.com<br>. MFG. CORP. Gardena, CA 9024  | 8 • New Brunswick, NJ 0  | 8901<br>ormula Weight a                                       |
| Bar Code<br>GHS Hazard Pictograms  | www.SpectrumChemical.com<br>MFG. CORP. Gardena, CA 9024<br>Chemical Abstracts Service<br>(CAS) Registry Number   | 8 • New Brunswick, NJ 0<br>Empirical Formula,      | 8901<br>ormula Weight a<br>ons Panel                          |
| Bar Code<br>GHS Hazard Pictograms<br>Warning, Safety Data and Precautionary  | www.SpectrumChemical.com<br>MFG. CORP. Gardena, CA 9024<br>Chemical Abstracts Service  | <ul> <li>8 • New Brunswick, NJ 0</li> <li>K Empirical Formula, Form</li></ul> | 8901<br>ormula Weight a<br>ons Panel                          |
| Bar Code<br>GHS Hazard Pictograms<br>Warning, Safety Data and Precautionary<br>Information   | www.SpectrumChemical.com<br>MFG. CORP. Gardena, CA 9024<br>Chemical Abstracts Service<br>(CAS) Registry Number   | 8 • New Brunswick, NJ 0<br>Empirical Formula,      | 8901<br>ormula Weight a<br>ons Panel                          |
| Bar Code<br>GHS Hazard Pictograms<br>Warning, Safety Data and Precautionary  | <ul> <li>www.SpectrumChemical.com</li> <li>MFG. CORP. Gardena, CA 9024</li> <li>Chemical Abstracts Service<br/>(CAS) Registry Number</li> <li>Caution Information</li> <li>DOT Shipping Information</li> </ul>                                     | <ul> <li>New Brunswick, NJ 0</li> <li>Empirical Formula, F<br/>Technical Specificati</li> <li>Expiration Informatio</li> <li>Lot Number</li> </ul>   | 8901<br>ormula Weight a<br>ons Panel<br>n                     |
| Bar Code<br>GHS Hazard Pictograms<br>Warning, Safety Data and Precautionary<br>Information<br>Product Catalog Number                           | <ul> <li>www.SpectrumChemical.com</li> <li>MFG. CORP. Gardena, CA 9024</li> <li>Chemical Abstracts Service<br/>(CAS) Registry Number</li> <li>Caution Information</li> <li>DOT Shipping Information</li> <li>Toll-Free 24-Hour Chemical</li> </ul> | <ul> <li>8 • New Brunswick, NJ 0</li> <li>&amp; Empirical Formula, Formula, Formula, Formula, Formula, Formula, Formula, Specificati</li> <li>1 Expiration Informatio</li> <li>M Lot Number</li> <li>M Kosher Certified by K</li> </ul>  | 8901<br>ormula Weight a<br>ons Panel<br>n                     |
| Bar Code<br>GHS Hazard Pictograms<br>Warning, Safety Data and Precautionary<br>Information   | <ul> <li>www.SpectrumChemical.com</li> <li>MFG. CORP. Gardena, CA 9024</li> <li>Chemical Abstracts Service<br/>(CAS) Registry Number</li> <li>Caution Information</li> <li>DOT Shipping Information</li> </ul>                                     | <ul> <li>New Brunswick, NJ 0</li> <li>Empirical Formula, Frechnical Specificati</li> <li>Expiration Informatio</li> <li>Lot Number</li> <li>Kosher Certified by Kof America (KSA).</li> </ul>  | 8901<br>ormula Weight a<br>ons Panel<br>n                     |
| Bar Code<br>GHS Hazard Pictograms<br>Warning, Safety Data and Precautionary<br>Information<br>Product Catalog Number<br>Item Name, Form, Grade | <ul> <li>www.SpectrumChemical.com</li> <li>MFG. CORP. Gardena, CA 9024</li> <li>Chemical Abstracts Service<br/>(CAS) Registry Number</li> <li>Caution Information</li> <li>DOT Shipping Information</li> <li>Toll-Free 24-Hour Chemical</li> </ul> | <ul> <li>8 • New Brunswick, NJ 0</li> <li>&amp; Empirical Formula, Formula, Formula, Formula, Formula, Formula, Formula, Specificati</li> <li>1 Expiration Informatio</li> <li>M Lot Number</li> <li>M Kosher Certified by K</li> </ul>  | 8901<br>ormula Weight a<br>ons Panel<br>n                     |
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group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

### Spectrum Chemical Mfg Corp

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

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