

## **Scientific Documentation**

**ZI120**, Zinc Sulfate, Heptahydrate, Granular, USP

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

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

769 Jersey Avenue New Brunswick, NJ 08901 Phone 732.214.1300

Ver4.02 3.May.2016



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 Senior Manager of Technical Services techservices@spectrumchemical.com

ZI120, Zinc Sulfate, Heptahydrate, Granular, USP

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Item Number	<u>ZI120</u>
Item	Zinc Sulfate, Heptahydrate, Granular, USP
CAS Number	7446-20-0
Molecular Formula	ZnSO <sub>4</sub> .7H <sub>2</sub> O
Molecular Weight	287.56
MDL Number	
Synonyms	

Test	Specification		
	Min	Max	
ASSAY ( $ZnSO_4.7H_2O$ )	99.0 - 108.7 %		
ACIDITY		TO PASS TEST	
ALKALIES AND ALKALI EARTH		0.9 %	
ARSENIC (As)		14 ppm	
LEAD (Pb)		0.002 %	
IDENTIFICATION		TO PASS TEST	
RETEST DATE			
RESIDUAL SOLVENTS		TO PASS TEST	

#### 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





### SAFETY DATA SHEET

Preparation Date: 01/30/2015 Product identifier	Revision Date: Not Applicable	Revision Number: Not Applicable
Product code:		
Product Name:	ZINC SULFATE, HEPTAHYDRATE, GRANULAR,	05P
Other means of identification		
Synonyms:	Sulfuric acid, zinc salt, heptahydrate; White vitriol ( (heptahydrate)	heptahydrate); Zinc vitriol
CAS #:	7446-20-0	
RTECS #	ZH5300000	
CI#:	Not available	
Recommended use of the chem	ical and restrictions on use	
Recommended use:	No information available.	
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	

#### 2. HAZARDS IDENTIFICATION

#### Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity - Oral	Category 4
Serious eye damage/eye irritation	Category 2A
Specific target organ toxicity (single exposure)	Category 3

#### Label elements

#### Warning

Hazard statements Harmful if swallowed Causes mild skin irritation Causes serious eye irritation May cause respiratory irritation. May cause drowsiness or dizziness



Hazards not otherwise classified (HNOC) Not Applicable

#### Other hazards

May be harmful if inhaled Very toxic to aquatic life with long lasting effects Very toxic to aquatic life

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

Wash face, hands and any exposed skin thoroughly after handling Do not eat, drink or smoke when using this product Wear eye/face protection Avoid breathing dust/fume/gas/mist/vapors/spray Use only outdoors or in a well-ventilated area

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 INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell. IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell Rinse mouth

### Precautionary Statements - Storage

Store in a well-ventilated place. Keep container tightly closed Store locked up

#### Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %	Trade Secret
Zinc Sulfate, Heptahydrate 7446-20-0	7446-20-0	100	*

#### 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)

#### 4. FIRST AID MEASURES

Skin Contact:	Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Get medical attention if irritation develops. Consult a physician if necessary.		
Eye Contact:	Flush eye with water for 15 minutes. Get medical attention.		
Inhalation:	Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. WARNING! It may be hazardous to the person providing aid to give mouth-to-mouth resuscitation when the inhaled or ingested material is toxic, infectious or corrosive. Do not use mouth-to-mouth resuscitation if victim ingested or inhaled the substance; induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Immediate medical attention is required.		
Ingestion:	Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Call a physician or Poison Control Center immediately.		
Most important symptoms and effec	ts, both acute and delayed		
Symptoms	Causes eye irritation. Eye contact may result in redness or pain. Harmful if swallowed. Skin contact may result in redness, pain, inflammation, itching, scaling. Mild skin irritation.		
Indication of any immediate medical	attention and special treatment needed		

Indication of any	/ immediate me	dical attention	n and spe	ecial trea	tment ne
Notes to Physici	an:	Treat sy	mptomat	tically	

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:	Not applicable
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:	No information available.
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. Use spark-proof tools and explosion-proof equipment. Avoid contact with skin, eyes and clothing. Keep people away from and upwind of spill/leak. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Remove all sources of ignition.
Environmental precautions	Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.
Methods and material for contain	ment and cleaning up
Methods for containment	Stop leak if you can do it without risk.
Methods for cleaning up	Sweep up and shovel into suitable containers for disposal. 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. Keep away from heat and sources of ignition. Do not ingest. Do not breathe vapours/dust. Handle in accordance with good industrial hygiene and safety practice.

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

#### **Technical Measures/Storage Conditions:**

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

#### Incompatible Materials:

Alkalis. Alkali hydroxides. Calcium. Lead. Silver protein. tannins. Strontium salts.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### **Control parameters**

#### National occupational exposure limits

#### **United States**

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
	None	None	None	None
Zinc Sulfate, Heptahydrate - 7446-20-				
0				

#### Canada

Components	Alberta	British Columbia	Ontario	Quebec
Zinc Sulfate, Heptahydrate - 7446-20- 0	None	None	None	None

#### Australia and Mexico

Components	Australia	Mexico
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Zinc Sulfate, Heptahydrate	None	None
7446-20-0		

#### Appropriate engineering controls

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

Individual protection measures, such as personal protective equipment

#### **Personal Protective Equipment**

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

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid.

Odor: Odorless.

Formula: ZnSO4•7H2O

Flash Point Tested according to: Not available

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

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

**Specific gravity:** 1.97

**Evaporation rate:** No information available

Odor threshold (ppm): No information available

**Miscibility:** No information available **Appearance:** Crystals. Granular.

Taste Astringent. Metallic.

Flash point (°C): No data available

Lower Explosion Limit (%): No information available

**pH:** No information available

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

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

Vapor density: No information available

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

Solubility: Easily soluble in cold water Practically insoluble in alcohol Solubility in Water: 1g/0.6ml Solubility in Glycerol: 1g/2.5ml Color: Colorless. White.

Molecular/Formula weight: 287.56

Flashpoint (°C/°F): No information available.

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

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

Bulk density: No information available

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

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

Viscosity: No information available

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

#### Reactivity

Reactive with alkalis Loses all water at 280°C. Decomposition above 500°C

Chemical stability Stability:	Hygroscopic.
Possibility of Hazardous Reactions:	Hazardous polymerization does not occur
Conditions to avoid:	Exposure to moisture.
Incompatible Materials:	Alkalis. Alkali hydroxides. Calcium. Lead. Silver protein. tannins. Strontium salts.
Hazardous decomposition products:	No information available
Other Information	
Corrosivity:	No information available
Special Remarks on Corrosivity:	No information available

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

#### Information on likely routes of exposure

Principal Routes of Exposure: Ingestion. Inhalation.

#### **Acute Toxicity**

#### **Component Information**

Zinc Sulfate, Heptahydrate - 7446-20-0 LD50/oral/rat = = 1260 mg/kg Oral LD50 Rat LD50/oral/mouse = 200 mg/kg Oral LD50 Mouse LD50/dermal/rat = No information available LD50/dermal/rabbit = No information available LC50/inhalation/rat = No information available LC50/inhalation/mouse = No information available Other LD50 or LC50information = 75 mg/kg Intraperitoneal LD50 Mouse; 200 mg/kg Intraperitoneal LD50 Rat

#### **Product Information**

LD50/oral/rat = VALUE- Acute Tox Oral = 1260mg/kg

LD50/oral/mouse = Value - Acute Tox Oral = 200mg/kg

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

LD50/dermal/rat

Product code: ZI120

#### VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat VALUE-Vapor = No information availa VALUE-Gas = No information availa VALUE-Dust/Mist = No information	able
LC50/Inhalation/mouse VALUE-Vapor = No information avai VALUE - Gas = No information avai VALUE - Dust/Mist = No informatio	lable
Symptoms	
Skin Contact:	Mild skin irritation.
Eye Contact:	Causes serious eye irritation.
Inhalation Ingestion	May cause irritation of respiratory tract. Harmful if swallowed. Ingestion might produce gastrointestinal symptoms, including abdominal cramps, nausea, diarrhea, hypermotility, and vomiting. As with other soluble zinc salts, it may hydrolyze into acid and may cause severe irritation of the mouth, throat, It may also affect the cardiovascular system (increased pulse rate, hypotension), behavior (ataxia, somnolence, coma), and cause pulmonary edema and may cause pancreatitis, and kidney damage.
Aspiration hazard	No information available
Delayed and immediate effects as	well as chronic effects from short and long-term exposure
Chronic Toxicity	Chronic exposure via skin contact or inhalation may produce dermatitis and respiratory tract irritation. If the monohydrate liberates fumes, metal fume fever might occur. (Metal fume fever is a flu-like syndrome consisting of fever, aches and pains, labored breathing, headache, and sweating. Symptoms generally appear a few hours after exposure and subside within 48 hours. Prolonged or repeated ingestion may cause hypermotility and diarrhea, and may also affect the blood (normocytic anemia, agranulocytosis, microcytosis with or without anemia), liver (jaundice, hepatotoxicity), metabolism (calcium absorption, weight loss), kidneys (oliguria, renal failure), behavior/central nervous system (central nervous system depression, tremors and paralysis of extremities.
Sensitization:	No information available
Mutagenic Effects:	No information available

Carcinogenic effects:

Not considered carcinogenic

Components	ACGIH - Carcinogens	IARC	NTP	OSHA HCS - Carcinogens	Australia - Prohibited Carcinogenic Substances	Australia - Notifiable Carcinogenic Substances
Zinc Sulfate, Heptahydrate	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

Reproductive toxicity

No data is available

Reproductive Effects:	No information available
Developmental Effects:	No information available

Product code: ZI120

**Product name:** ZINC SULFATE, HEPTAHYDRATE, GRANULAR, USP

#### **Specific Target Organ Toxicity**

STOT - single exposure STOT - repeated exposure Target Organs: No information available No information available No information available

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

#### Ecotoxicity

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

#### **13. DISPOSAL CONSIDERATIONS**

#### **Disposal Methods**

#### Waste from residues / unused products:

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

#### Contaminated packaging:

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

Components	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Zinc Sulfate, Heptahydrate	None	None	None	None

#### 14. TRANSPORT INFORMATION

DOT

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

#### **TDG (Canada)**

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

#### ADR

IMO

Not Regulated No information available No information available No information available No information available No information available
No information available
No information available
Not Regulated No information available 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

Components	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Zinc Sulfate, Heptahydrate	Not Listed	Not present	Present	Present (1)- 542	Present	Present	Not present

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

#### Zinc Sulfate, Heptahydrate FDA - Food Additives Generally Recognized as Safe (GRAS): 21 CFR 182.90 21 CFR 182.8997 FDA - 21 CFR - Total Food Additives 182.8997 182.90 582.80

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

#### Chemicals Known to the State of California to Cause Cancer:

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

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

Components	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Zinc Sulfate, Heptahydrate	Not Listed	Not Listed	Not Listed	Not Listed

#### CERCLA/SARA

•	Substances and their	Hazardous	Section 302 Extremely Hazardous Substances and RQs	Chemical Category	Section 313 - Reporting de minimis
Zinc Sulfate, Heptahydrate	None	None	None	None	None

#### **U.S. TSCA**

•	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Zinc Sulfate, Heptahydrate	Not Applicable	Not Applicable

#### Canada

#### WHMIS hazard class:

Non-controlled

#### Zinc Sulfate, Heptahydrate

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

Components	Canada (DSL)	Canada (NDSL)
Zinc Sulfate, Heptahydrate	Present	Not Listed

Components	CEPA Schedule I - Toxic Substances	CEPA - 2010 Greenhouse Gases Subject to Manditory
		Reporting
Zinc Sulfate, Heptahydrate	Not listed	Not listed

#### **EU Classification**

#### R-phrase(s)

R22 - Harmful if swallowed.

R41 - Risk of serious damage to eyes.

R50 - Very toxic to aquatic organisms.

R53 - May cause long-term adverse effects in the aquatic environment.

#### S -phrase(s)

S22 - Do not breathe dust.

S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S39 - Wear eye/face protection.

S46 - If swallowed, seek medical advice immediately and show this container or label.

S60 - This material and its container must be disposed of as hazardous waste.

S61 - Avoid release to the environment. Refer to special instructions/safety data sheets.

Components	Classification	Concentration Limits:	Safety Phrases
	Xn; R22 Xi; R41 N; R50 R53		S2 S22 S26 S39 S46 S60 S61

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

Indication of danger: None.

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

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

Preparation Date: Revision Date: Prepared by:

**Disclaimer:** 

01/30/2015 Not Applicable Sonia Owen

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: ZI120, Zinc Sulfate, Heptahydrate, Granular, 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.

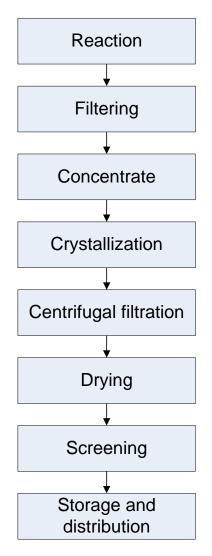
Sincerely,

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



### **Manufacturing Process Flowchart**

### Zinc Sulfate, Heptahydrate, Granular, USP - ZI120



#### 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

## **Certificate of Registration**



This is to certify that the quality management system of

### Spectrum Chemicals and Laboratory Products, Frc

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 gualifying distributors of Laboratory and Safety Equipment; processing bids and quotes to generate new sales opportunities; sourcing bulk chemicals in support of bulk bids and guotes; assisting production operations through order expediting and IT infrastructure support.

Certificate Number: 94-316m-01 Initial Certification Date: 27 December 1994 Certificate Issue Date: Certificate Expiry Date:

29 January 2016 14 September 2018

Calin Moldovean, President

Intertek Testing Services NA, Inc.

900 Chelmsford Street, Suite 301-3, Lowell, MA, USA



CERTIFICATION



Intertek Intertek

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.

## **Certificate of Registration**



This is to certify that the quality management system of

### Spectrum China Ltd.

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

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

### ISO 9001: 2008

The quality management system is applicable to:

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

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



014

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

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



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



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: Spectrum-New Brunswick, NJ: Spectrum -Shanghai, China: 2020632 2246824 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 <u>qualityassurance@spectrumchemical.com</u> if we may be of further assistance.

Sincerely,

Michelle Wester

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.

Catalog Number	Product Name
ZI120	Zinc Sulfate, Heptahydrate, Granular, USP

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

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

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

Sincerely,

Michelle Wester

Michelle Weston Quality Assurance Specialist



April 28, 2016

Re: Zinc Sulfate, Heptahydrate, Granular, USP- ZI120

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

Zinc Sulfate, Heptahydrate, Granular, USP- ZI120

is BSE/TSE free.

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

Sincerely,

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

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



April 28, 2016

Re: Zinc Sulfate, Heptahydrate, Granular, USP- ZI120

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

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

Zinc Sulfate, Heptahydrate, Granular, USP- ZI120

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

Sincerely,

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

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



April 28, 2016

Re: Zinc Sulfate, Heptahydrate, Granular, USP- ZI120

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.

Zinc Sulfate, Heptahydrate, Granular, USP- ZI120

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

Sincerely,

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

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



**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.

<sup>∼</sup> attention. If skin irritation occurs: Get medical <sup>∽</sup> attention. IF INHALED: Remove person to <sup>+</sup> track air and loan comfortable for broathing	ZI120 D F-2.5 KG Zinc Sulfate F-Heptahydrate Granular, U.S.P. G-CAS 7446-20-0 AUTION: For manufacturing, processing or epacking. tead and understand the label and Safety Data heet (SDS) prior to use. Chemical Emergency: (800)424-9300 www.SpectrumChemical.com	AcidityTo pass te MAXIMUM LIMITS Alkalies and Alkali Earths0.9 Arsenic (As)14 pp Lead (Pb)002 Residual SolventsTo pass te WARNING: This product contains a chemical know to the State of California to cause cancer. WARNING: This product contains a chemical know to the State of California to cause birth defects other reproductive harm. HYGROSCOPIC: Keep tightly closed.
SPECTRUM CHEMICAL MFG	i. CORP. Gardena, CA 9	0248 • New Brunswick, NJ 08901
Bar Code	e. CORP. Gardena, CA 9 © Size/Quantity	🗴 Empirical Formula, Formula
<ul> <li>Bar Code</li> <li>GHS Hazard Pictograms</li> </ul>	<ul> <li>Size/Quantity</li> <li>Chemical Abstracts Service</li> </ul>	
Bar Code	<ul> <li>Size/Quantity</li> <li>Chemical Abstracts Service</li> </ul>	<ul> <li>Empirical Formula, Formula Weight and Technical</li> </ul>
<ul> <li>Bar Code</li> <li>GHS Hazard Pictograms</li> <li>Warning, Safety Data and Precautionar</li> </ul>	<ul> <li>Size/Quantity</li> <li>Chemical Abstracts Service (CAS) Registry Number</li> </ul>	<ul> <li>Empirical Formula, Formula Weight and Technical Specifications Panel</li> </ul>

The criteria used to assign band colors have been established by the Storage Code working 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 West Coast Facility: 14422 S. San Pedro St. Gardena, CA 90248

310.516.8000

732.214.1300

# Spectrum®

### **Certificate Of Analysis**

Item Number	ZI120	Lot Number	1EG0302
Item	Zinc Sulfate, Heptahydrate, Granular, USP		
CAS Number	7446-20-0		
Molecular Formula	ZnSO <sub>4</sub> .7H <sub>2</sub> O	Molecular Weight	287.56

Test	Specification		Result
	min	max	
ASSAY (ZnSO <sub>4</sub> .7H <sub>2</sub> O)	99.0 - 108.7 %		101.5 %
ACIDITY		TO PASS TEST	PASSES TEST
ALKALIES AND ALKALI EARTH		0.9 %	0.4 %
ARSENIC (As)		14 ppm	<14 ppm
LEAD (Pb)		0.002 %	<0.002 %
IDENTIFICATION		TO PASS TEST	PASSES TEST
RETEST DATE			04-NOV-2017
RESIDUAL SOLVENTS		TO PASS TEST	NO RESIDUAL SOLVENTS USED
APPEARANCE			WHITE GRANULES
MANUFACTURE DATE			04-NOV-2014

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



Certificate of Analysis Results Certified By:

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Adan Hernandez Quality Control Manager Spectrum Chemicals & Laboratory Products

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

# Spectrum®

### **Certificate Of Analysis**

Item Number	ZI120	Lot Number	2EJ0256
Item	Zinc Sulfate, Heptahydrate, Granular, USP		
CAS Number	7446-20-0		
Molecular Formula	ZnSO <sub>4</sub> .7H <sub>2</sub> O	Molecular Weight	287.56

Test	Specification		Result
	min	max	
ASSAY ( $ZnSO_4$ .7H <sub>2</sub> O)	99.0 - 108.7 %		101.5 %
ACIDITY		TO PASS TEST	PASSES TEST
ALKALIES AND ALKALI EARTH		0.9 %	0.4 %
ARSENIC (As)		14 ppm	<14 ppm
LEAD (Pb)		0.002 %	<0.002 %
IDENTIFICATION		TO PASS TEST	PASSES TEST
RETEST DATE			04-NOV-2017
RESIDUAL SOLVENTS		TO PASS TEST	NO RESIDUAL SOLVENTS USED
APPEARANCE			WHITE CRYSTALLINE POWDER
DATE OF MANUFACTURE			04-NOV-2014

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



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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 928<sup>th</sup> material produced in California in September 2010

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

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

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

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

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

Sincerely,

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Michael Dang Manager, GMP Compliance



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

#### Product Covered: ZI120, Zinc Sulfate, Heptahydrate, Granular, USP

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

The product, ZI120, Zinc Sulfate, Heptahydrate, Granular, USP, is assigned a 36 months shelf life from date of manufacturing. The quality and integrity of the chemical depends on the handling and storage conditions. Please refer to the Safety Data Sheet for proper storage and handling procedures.

Adan R. Hernandez Quality Control Manager

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