

Scientific Documentation

Zinc Chloride, Granular, USP

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



Table of Contents

Product Specification
Certificate of Analysis
Safety Data Sheet (SDS)
Certification of Current Good Manufacturing Practices (cGMP)
Manufacturing Process Flowchart
Technical Statements
Elemental Impurities Statement
Residual Solvents Statement

Specification for Zinc Chloride, Granular, USP (ZI105)

Item Number	ZI105
Item	Zinc Chloride, Granular, USP
CAS Number	7646-85-7
Molecular Formula	ZnCl ₂
Molecular Weight	136.29
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
APPEARANCE		
ASSAY	97.0	102.0 %
OXYCHLORIDE	SOLUTION BECOMES CLEAR	
SULFATES (SO ₄)		0.03 %
ALKALIES AND ALKALINE EARTHS		1.0 %
AMMONIUM SALTS	NO ODOR OF AMMONIA IS PERCEPTIBLE	
LEAD (Pb)		0.005 %
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION A	RETENTION TIME CORRESPONDS TO STANDARD	
IDENTIFICATION B	POSITIVE FOR CHLORIDE	
CERTIFIED KOSHER		
CERTIFIED HALAL		
EXPIRATION DATE		
DATE OF MANUFACTURE		
MONOGRAPH EDITION		
RESIDUAL SOLVENTS	AS REPORTED	

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	ZI105	Lot Number	1NA0034
Item	Zinc Chloride, Granular, USP	CAS Number	7646-85-7
Molecular Formula	ZnCl ₂	Molecular Weight	136.29

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE			WHITE GRANULES
ASSAY	97.0	102.0 %	99.4 %
OXYCHLORIDE	SOLUTION BECOMES CLEAR		SOLUTION BECOMES CLEAR
SULFATES (SO ₄)		0.03 %	<0.01 %
ALKALIES AND ALKALINE EARTHES		1.0 %	0.1 %
AMMONIUM SALTS	NO ODOR OF AMMONIA IS PERCEPTIBLE		NO ODOR OF AMMONIA IS PERCEPTIBLE
LEAD (Pb)		0.005 %	0.0003 %
ELEMENTAL IMPURITIES	AS REPORTED		.
IDENTIFICATION A	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD
IDENTIFICATION B	POSITIVE FOR CHLORIDE		POSITIVE FOR CHLORIDE
CERTIFIED KOSHER			CERTIFIED KOSHER
CERTIFIED HALAL			CERTIFIED HALAL
EXPIRATION DATE			30-APR-2025
DATE OF MANUFACTURE			27-APR-2023
MONOGRAPH EDITION			(USP-NF) 2023
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS PRESENT
ELEMENTAL IMPURITIES:			.
CADMIUM (Cd)			0.6 µg/g
THALLIUM (TI)			2 µg/g

Certificate of Analysis Results Entered By:

SHANSEN
Selin Hansen
23-APR-24 15:16:19

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



Certificate of Analysis Results Approved By:

HBERMUDEZ
Hernan Bermudez
23-APR-24 15:18:48

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.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

SAFETY DATA SHEET

spectrum®



Revision date 31-May-2022

Revision Number 2

1. Identification

Product identifier

Product Name ZINC CHLORIDE, GRANULAR, USP, JP

Other means of identification

Product Code(s) ZI105

UN/ID no UN2331

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use No information available

Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Address

Spectrum Chemical Mfg. Corp.
14422 South San Pedro St.
Gardena, CA 90248
(310) 516-8000

Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification

Acute toxicity - Oral	Category 4
Skin corrosion/irritation	Category 1 Sub-category B
Serious eye damage/eye irritation	Category 1
Specific target organ toxicity (single exposure)	Category 3

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

Harmful if swallowed
Causes severe skin burns and eye damage
May cause respiratory irritation



Appearance Granular and Deliquescent

Physical state Solid

Odor Odorless

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
Do not breathe dusts or mists
Wear protective gloves/protective clothing/eye protection/face protection
Use only outdoors or in a well-ventilated area

Precautionary Statements - Response

Immediately call a POISON CENTER or doctor
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
Immediately call a POISON CENTER or doctor
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower
Wash contaminated clothing before reuse
IF INHALED: Remove person to fresh air and keep comfortable for breathing
Immediately call a POISON CENTER or doctor
IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell
Rinse mouth
Do NOT induce vomiting

Precautionary Statements - Storage

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

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Unknown acute toxicity

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Zinc Chloride	7646-85-7	100	*

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

4. First-aid measures

Description of first aid measures

General advice

Show this safety data sheet to the doctor in attendance. Immediate medical attention is required.

Inhalation

Remove to fresh air. If breathing has stopped, give artificial respiration. Get medical attention immediately. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way

valve or other proper respiratory medical device. If breathing is difficult, (trained personnel should) give oxygen. Delayed pulmonary edema may occur. Get immediate medical advice/attention.

Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Do not rub affected area. Remove contact lenses, if present and easy to do. Continue rinsing. Get immediate medical advice/attention.
Skin contact	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Get immediate medical advice/attention.
Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.
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. Avoid contact with skin, eyes or clothing. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Symptoms	Burning sensation.
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Indication of any immediate medical attention and special treatment needed

Note to physicians	Product is a corrosive material. Use of gastric lavage or emesis is contraindicated. Possible perforation of stomach or esophagus should be investigated. Do not give chemical antidotes. Asphyxia from glottal edema may occur. Marked decrease in blood pressure may occur with moist rales, frothy sputum, and high pulse pressure.
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5. Fire-fighting measures

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
Specific hazards arising from the chemical	The product causes burns of eyes, skin and mucous membranes. Thermal decomposition can lead to release of irritating gases and vapors.
Explosion data	
Sensitivity to mechanical impact	none.
Sensitivity to static discharge	none.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions	Attention! Corrosive material. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.
Other information	Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
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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. In case of insufficient ventilation, wear suitable respiratory equipment. Handle product only in closed system or provide appropriate exhaust ventilation. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse. Avoid breathing vapors or mists.

Conditions for safe storage, including any incompatibilities**Storage Conditions**

Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Protect from moisture. Store locked up. Store away from other materials.

8. Exposure controls/personal protection

Control parameters**Exposure Limits**

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Zinc Chloride 7646-85-7	No data available	1 mg/m ³ TWA	-

Appropriate engineering controls**Engineering controls**

Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment**Eye/face protection**

Tight sealing safety goggles. Face protection shield.

Hand protection

Wear suitable gloves. Impervious gloves.

Skin and body protection

Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron.

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. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product.

9. Physical and chemical properties

Information on basic physical and chemical properties**Physical state**

Solid

Appearance

Granular and Deliquescent

Color

White

Odor	Odorless
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	no data available	None known
Melting point / freezing point	290 °C / 554 °F	None known
Boiling point / boiling range	732 °C / 1349.6 °F	None known
Flash point	no data available	None known
Evaporation rate	no data available	None known
Flammability (solid, gas)	no data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	4.7	None known
Relative density	2.907	None known
Water solubility	Soluble in water	None known
Solubility(ies)	Soluble in Acetone	None known
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known
<u>Other information</u>		
Explosive properties	No information available	
Oxidizing properties	No information available	
Softening point	No information available	
Molecular weight	136.29	
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	Exposure to air or moisture over prolonged periods.
Incompatible materials	Acids. Bases. Oxidizing agent.
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. Corrosive by inhalation. (based on components). Inhalation of corrosive fumes/gases may cause coughing, choking, headache, dizziness, and weakness for several hours. Pulmonary edema may occur with tightness in the chest, shortness of breath, bluish skin, decreased blood pressure, and increased heart rate. Inhaled corrosive substances can lead to a toxic edema of the lungs. Pulmonary edema can be fatal. May cause irritation of respiratory tract.
Eye contact	Specific test data for the substance or mixture is not available. Causes serious eye

damage. (based on components). Corrosive to the eyes and may cause severe damage including blindness. May cause irreversible damage to eyes.

Skin contact

Specific test data for the substance or mixture is not available. Corrosive. (based on components). Causes burns.

Ingestion

Specific test data for the substance or mixture is not available. Causes burns. (based on components). Ingestion causes burns of the upper digestive and respiratory tracts. May cause severe burning pain in the mouth and stomach with vomiting and diarrhea of dark blood. Blood pressure may decrease. Brownish or yellowish stains may be seen around the mouth. Swelling of the throat may cause shortness of breath and choking. May cause lung damage if swallowed. May be fatal if swallowed and enters airways.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms

Redness. Burning. May cause blindness. Coughing and/ or wheezing.

Acute toxicity

Numerical measures of toxicity

Unknown acute toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Zinc Chloride 7646-85-7	= 1100 mg/kg (Rat)	-	<= 1975 mg/m ³ (Rat) 10 min

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

Skin corrosion/irritation

Classification based on data available for ingredients. Causes burns.

Serious eye damage/eye irritation

Classification based on data available for ingredients. Risk of serious damage to eyes. Causes burns.

Respiratory or skin sensitization

No information available.

Germ cell mutagenicity

No information available.

Reproductive toxicity

No information available.

STOT - single exposure

May cause respiratory irritation.

STOT - repeated exposure

No information available.

Target organ effects

respiratory system, Eyes, Skin, Central Vascular System (CVS).

Aspiration hazard

No information available.

Other adverse effects

No information available.

Interactive effects

No information available.

12. Ecological information

Ecotoxicity

The environmental impact of this product has not been fully investigated.

Persistence and degradability

No information available.

Bioaccumulation

Inherently biodegradable.

Other adverse effects

No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused 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

DOT

UN/ID no UN2331
Proper Shipping Name: Zinc chloride, anhydrous
Hazard class 8
Packing group: III
Special Provisions IB8, IP3, T1, TP33
Marine Pollutant Severe Marine Pollutant
Description: UN2331, Zinc chloride, anhydrous, 8, III
Emergency Response Guide Number 154

TDG

UN-No: UN2331
Proper Shipping Name: Zinc chloride, anhydrous
Hazard class 8
Packing Group: III
Description: UN2331, Zinc chloride, anhydrous, 8, III

MEX

UN-No UN2331
Proper Shipping Name Zinc chloride, anhydrous
Hazard class 8
Packing Group III
Description UN2331, Zinc chloride, anhydrous, 8, III

ICAO (air)

UN-No: UN2331
Proper Shipping Name: Zinc chloride, anhydrous
Hazard class 8
Packing Group: III
Description: UN2331, Zinc chloride, anhydrous, 8, III

IATA

UN number UN2331
Proper Shipping Name: Zinc chloride, anhydrous
Transport hazard class(es) 8
Packing group III
Description: UN2331, Zinc chloride, anhydrous, 8, III

IMDG

UN number UN2331
Proper shipping name Zinc chloride, anhydrous
Transport hazard class(es) 8
Packing group III
EmS-No F-A, S-B
Marine pollutant P
Description UN2331, Zinc chloride, anhydrous, 8, III, Marine pollutant

RID

UN number UN2331
Proper Shipping Name: Zinc chloride, anhydrous
Transport hazard class(es) 8
Packing group III
Classification code C2

Description: UN2331, Zinc chloride, anhydrous, 8, III, ENVIRONMENTALLY HAZARDOUS
Labels 8

ADR

UN number 2331
Proper Shipping Name: Zinc chloride, anhydrous
Transport hazard class(es) 8
Packing group III
Classification code C2
Tunnel restriction code (E)
Description: 2331, Zinc chloride, anhydrous, 8, III, (E), ENVIRONMENTALLY HAZARDOUS
Labels 8

ADN

UN/ID No UN2331
Proper shipping name Zinc chloride, anhydrous
Transport hazard class(es) 8
Packing Group III
Classification code C2
Description UN2331, Zinc chloride, anhydrous, 8, III, ENVIRONMENTALLY HAZARDOUS
Hazard label(s) 8
Limited quantity (LQ) 5 kg
Equipment Requirements PP, EP

15. Regulatory information

International Inventories

TSCA Complies

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

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDL - 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 %
Zinc Chloride - 7646-85-7	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, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302).

Chemical name	Hazardous Substances RQs	Extremely Hazardous Substances RQs
Zinc Chloride 7646-85-7	1000 lb final RQ 454 kg final RQ	-

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Zinc Chloride 7646-85-7	2030	Present	Environmental hazard

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA

Health hazards 3

Flammability 0

Instability 0

Physical and chemical properties -

HMIS

Health hazards 3

Flammability 0

Physical hazards 0

Personal protection X

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average)

STEL

STEL (Short Term Exposure Limit)

Ceiling Maximum limit value

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
World Health Organization

Revision date 31-May-2022
Revision Note No information available.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet

Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
ZI105	Zinc Chloride, Granular, USP

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

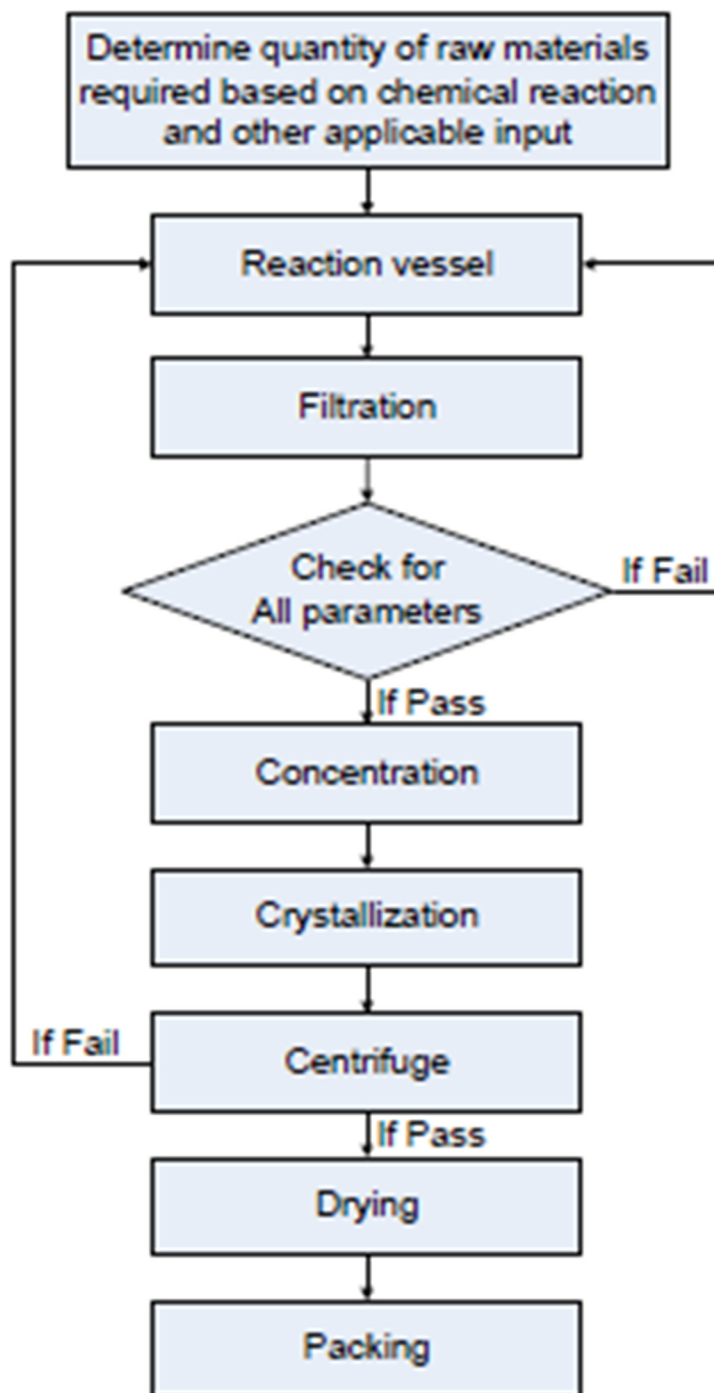
Spectrum-Gardena, CA:	2020632
Spectrum-New Brunswick, NJ:	2246824

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

Sincerely,
Quality Assurance
Spectrum Chemical Mfg. Corp.

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

Manufacturing Process Flowchart - Zinc Chloride, Granular, USP (Catalog No. ZI105)



ZI105, Zinc Chloride, Granular, USP

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 | ▪ Cereals containing Gluten |
| ▪ Egg | ▪ Celery |
| ▪ Fish | ▪ Mustard |
| ▪ Shellfish | ▪ Sesame Seed |
| ▪ Tree Nuts | ▪ Corn |
| ▪ Wheat | ▪ Latex |
| ▪ Peanuts | ▪ Sulfites > 10 ppm |
| ▪ Soy | |

EU Fragrance Allergen Statement

The above-mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore, are not expected to be present.

GMO Statement

The above-mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

Melamine Statement

The above-mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in the above-mentioned material.

Animal Testing Statement

The above-mentioned catalog item has not been tested on animals.

Organic Compliance Statement

The above-mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

Shelf Life Statement

The above-mentioned catalog item is typically assigned a shelf life of 36 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

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

- | | |
|---------------------|-----------------|
| ▪ Aflatoxins | ▪ Parabens |
| ▪ Antibiotics | ▪ Pesticides |
| ▪ Bisphenol A (BPA) | ▪ Phthalates |
| ▪ CMR Substances | ▪ Preservatives |

Elemental Impurities - Zinc Chloride, Granular, USP (Catalog No. ZI105)

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
Lead	Pb	1	< 0.005% (USP monograph)

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 the 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 TechServices@spectrumchemical.com.

Sincerely,
Technical Services
Spectrum Chemical Mfg. Corp.

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

Residual Solvents - Zinc Chloride, Granular, USP (Catalog No. ZI105)

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 USP <467> Residual Solvents and 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 TechServices@spectrumchemical.com.

Sincerely,
Technical Services
Spectrum Chemical Mfg. Corp.

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