

Scientific Documentation

A1081, Aluminum Chlorohydrate, Dihydrate, 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

Ver4.04 6.April.2018



Dear Customer,

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

Spectrum has been proudly serving the 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, CQA Director, Global Supplier Quality Assurance awang@spectrumchemical.com

A1081, Aluminum Chlorohydrate, Dihydrate, USP

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Spectrum® Specification for Aluminum Chlorohydrate, Dihydrate, USP (A1081)

Item Number	<u>A1081</u>
Item	Aluminum Chlorohydrate, Dihydrate, USP
CAS Number	12359-72-7
Molecular Formula	$Al_{v}(OH)_{(3v-z)}Cl_{z}2H_{2}O$
Molecular Weight	210.48
MDL Number	
Synonyms	Aluminum Chloride Hydroxide ; Aluminum Hydroxychloride

Test	Specif	ication
	Min	Max
ANHYDROUS ALUMINUM CHLOROHYDRATE	AS REPORTED	
CONTENT OF ALUMINUM	AS REPORTED	
CONTENT OF CHLORIDE	AS REPORTED	
ALUMINUM/CHLORIDE ATOMIC RATIO	1.91:1	2.10:1
pH OF A 15 IN 100 (w/w) SOLUTION	3.0	5.0
ARSENIC (As)		2 ppm
ELEMENTAL IMPURITIES		AS REPORTED
IRON (Fe)		150 ppm
IDENTIFICATION		TO PASS TEST
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
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

spectrum®



SAFETY DATA SHEET

Preparation Date: 12/15/2016	Revision Date: 12/15/2016	Revision Number: G1
	1. IDENTIFICATION	
Product identifier		
Product code:	A1081	
Product Name:	ALUMINUM CHLOROHYDRATE, DIHYDRATE, USP)
Other means of identification		
Synonyms:	Aluminum Chloride Hydroxide, dihydrate	
	Aluminum Chlorohydroxide, dihydrate Aluminum Hydroxychloride, dihydrate	
CAS #:	12359-72-7	
RTECS # CI#:	Not available Not available	
CI#.	NOT available	
Recommended use of the chem		
Recommended use: Uses advised against	No information available.	
uses auvised against		
Supplier:	Spectrum Chemical Mfg. Corp	
	14422 South San Pedro St.	
	Gardena, CA 90248 (310) 516-8000.	
Order Online At:	https://www.spectrumchemical.com	
Emergency telephone number	Chemtrec 1-800-424-9300	
Contact Person:	Martin LaBenz (West Coast)	
Contact Person:	Ibad Tirmiz (East Coast)	

2. HAZARDS IDENTIFICATION

Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label elements

Not classified

Hazards not otherwise classified (HNOC) Not Applicable

Other hazards May be harmful if inhaled

Product code: A1081

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components		CAS-No.	Weight %		
		12359-72-7	100		
		4. FIRST AID MEASURES			
First aid measures					
I	nave a	al Capital Poison Center in the United poison emergency and need to talk t 222-1222.			
	Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops. Consult a physician if necessary.				
		eyes with water for 15 minutes. Get medica call a physician.	al attention if irritation occurs. If symptoms		
		o fresh air. If not breathing, give artificial re . Get medical attention.	espiration. If breathing is difficult, give		
		induce vomiting without medical advice. N cious person. Consult a physician if neces			
Most important symptoms and effect	s, both	acute and delayed			
SymptomsMay cause eye/skin irritation. May cause gastrointestinal disturbances. May cause abdominal discomfort. Ingestion may cause nausea, vomiting, and diarrhea.					
Indication of any immediate medical a	attenti	on and special treatment needed			
Notes to Physician:	Notes to Physician: Treat symptomatically.				
Protection of first-aiders First-Aid Providers: Avoid exposure to b contaminated clothing and equipment as		r body fluids. Wear gloves and other neco azardous waste.	essary protective clothing. Dispose of		
5. FIRE-FIGHTING MEASURES					
Extinguishing Media Suitable Extinguishing Media:			ammable. If it is involved in a fire, sing an agent suitable for the type of		
Unsuitable Extinguishing Media:		No information availa	able.		
Specific hazards arising from	the ch	nemical			
Hazardous Combustion Products	:	No information availa	able.		
Specific hazards:		No information availa	able.		
Special Protective Actions for Firefighters					
Desident and a Adopt					

Specific Methods:

Special Protective Equipment for Firefighters:

No information available.

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 proceduresPersonal Precautions:Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin,
eyes and clothing.Environmental precautionsPrevent further leakage or spillage if safe to do so. Prevent product from entering
drains.Methods and material for containment and cleaning upMethods for containmentMethods for containmentStop leak if you can do it without risk. Cover with plastic sheet to prevent
spreading.Methods for cleaning upSweep 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. Do not ingest. Do not breathe 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.

Incompatible Materials: Alkalis Oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WHEEL
Aluminum Chlorohydrate, dihydrate	12359-72-7	None	None	None	None

Canada

Product code: A1081

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Aluminum Chlorohydrate, dihydrate	12359-72-7	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Aluminum Chlorohydrate, dihydrate	12359-72-7	None	None

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:	Goggles or Safety glasses with side-shields
Skin and body protection:	Long sleeved clothing. Chemical resistant apron. Gloves.
Respiratory protection:	Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds), inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
Hygiene measures:	When using, do not eat, drink or smoke. Wash hands and face before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:	Appearance:	Color:
Solid	Crystalline powder. Powder.	Colorless to pale yellow.
Odor:	Taste	Formula:
Odorless.	No information available.	AL2CIH5O5.2H20
Molecular/Formula weight: 210.48	Flammability: No information available	Flashpoint (°C/°F): No information available.
Flash Point Tested according to:	Autoignition Temperature (°C/°F):	Lower Explosion Limit (%):
Not available	No information available	No information available
Upper Explosion Limit (%):	Melting point/range(°C/°F):	Decomposition temperature(°C/°F):
No information available	No information available	No information available
Boiling point/range(°C/°F):	Bulk density:	Density (g/cm3):
No information available	No information available	No information available
Product code: A1081	Product name: ALUMINUM CHLOROHYDRATE, DIHYDRATE,	4 / 10

USP

Specific gravity: 1.7

Evaporation rate: No information available

Odor threshold (ppm): No information available

Miscibility: No information available **pH:** No information available

Vapor density: No information available

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

Solubility: Soluble in Water Solubility in Water: 500 g/l at 20 deg. C

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

VOC content (g/L): No information available

Viscosity: No information available

10. STABILITY AND REACTIVITY

<u>Reactivity</u> No information available

Chemical stability	
Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions	- Hazardous polymerization does not occur
Conditions to avoid:	Incompatible materials.
Incompatible Materials:	Alkalis Oxidizing agents
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

Aluminum Chlorohydrate, dihydrate			
CAS-No.	12359-72-7		
LD50/oral/rat = No information	available		
LD50/oral/mouse = No information available			
LD50/dermal/rabbit = No information available			
LD50/dermal/rat = No information available			

LC50/inhalation/rat = No information available LC50/inhalation/mouse = No infomation available Other LD50 or LC50information = 9187nmg/kg oral LD50 Rat (for anhydrous form CAS no. 12042-91-0) >2000 mg/kg dermal LD50 Rat (for anhydrous form CAS no. 12042-91-0)

Product Information

LD50/oral/rat = VALUE- Acute Tox Oral = No information available

LD50/oral/mouse = Value - Acute Tox Oral = No information available

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

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

LC50/inhalation/rat VALUE-Vapor = No information available VALUE-Gas = No information available VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse VALUE-Vapor = No information available VALUE - Gas = No information available VALUE - Dust/Mist = No information available

Symptoms

Skin Contact:	May cause skin irritation.
Eye Contact:	May cause eye irritation.
Inhalation	May cause irritation of respiratory tract.
Ingestion	May cause abdominal discomfort. May cause gastrointestinal disturbances. Ingestion may cause nausea, vomiting, diarrhea.
Aspiration hazard	No information available.
Delayed and immediate effects a	as well as chronic effects from short and long-term exposure
Chronic Toxicity	No information available.
Sensitization:	No information available.
Mutagenic Effects:	No information available

Carcinogenic effects:

Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Aluminum Chlorohydrate,	12359-72-7	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

Product code: A1081

dihydrate						
ACGIH (American Confe	ACGIH (American Conference of Governmental Industrial Hygienists)					
IARC (International Agen	IARC (International Agency for Research on Cancer)					
NTP (National Toxicolog	y Program)					
OSHA (Occupational Sat	fety and Health Administration	on of the US Dep	artment of Lab	or)		
Reproductive toxicity	No data is av	ailable				
Reproductive Effects:	No informatio	n available				
Developmental Effects:	No informatio	n available				
Teratogenic Effects:	No informatio	n available				
Specific Target Organ Toxicity						
STOT - single exposure No information available.						
STOT - repeated expos						
Target Organs:	No informatio	n 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	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Aluminum Chlorohydrate, dihydrate	12359-72-7	None	None	None	None

14. TRANSPORT INFORMATION

DOT

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

Product code: A1081

Product name: ALUMINUM CHLOROHYDRATE, DIHYDRATE, USP

Packing group: Emergency Response Guide	No information available No information available
Number Marine Pollutant DOT RQ (Ibs): Special Provisions Symbol(s): Description:	No data available No information available No Information available No information available No information available
TDG (Canada) UN-No: Proper Shipping Name: Hazard Class: Subsidiary Risk: Packing Group: Marine Pollutant Description:	Not Regulated No information available No information available No information available No information available No Information available No information available
ADR UN-No: Proper Shipping Name: Hazard Class: Packing Group: Subsidiary Risk:	Not Regulated No information available No information available No information available No information available
IMO / IMDG UN-No: Proper Shipping Name: Hazard Class: Subsidiary Risk: Packing Group: Marine Pollutant	Not Regulated No information available No information available No information available No information available No information available
RID UN-No: Proper Shipping Name: Hazard Class: Subsidiary Risk: Packing Group:	Not Regulated No information available No information available No information available No information available
ICAO UN-No: Proper Shipping Name: Hazard Class: Subsidiary Risk: Packing Group:	Not Regulated No information available No information available No information available No information available
IATA UN-No: Proper Shipping Name: Hazard Class: Subsidiary Risk: Packing Group: ERG Code: Special Provisions	Not Regulated No information available No information available No information available No information available No information available

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Aluminum Chlorohydrate, dihydrate	12359-72-7	Not Listed	Not present	Not present	Not present	Not present	Not present	Not present

U.S. Regulations

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

Chemicals Known to the State of California to Cause Cancer:

WARNING: This product contains a chemical known to the State of California to cause cancer. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm (See table below)

Components	CAS-No.	Carcinogen	Developmental Toxicity		Female Reproductive
				Toxicity	Toxicity:
Aluminum Chlorohydrate, dihydrate	12359-72-7	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	CAS-No.	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Aluminum Chlorohydrate, dihydrate	12359-72-7	None	None	None	None	None

U.S. TSCA

Components		TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	
Aluminum Chlorohydrate, dihydrate	12359-72-7	Not Applicable	Not Applicable

Canada

WHMIS hazard class:

Non-controlled

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	CAS-No.	Canada (DSL)	Canada (NDSL)
Aluminum Chlorohydrate, dihydrate	12359-72-7	Not Listed	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Aluminum Chlorohydrate, dihydrate	12359-72-7	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject
		to Mandatory Reporting
Aluminum Chlorohydrate, dihydrate	12359-72-7	Not listed

S -phrase(s)

none

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Aluminum Chlorohydrate,	12359-72-7		No information	
dihydrate				

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

Indication of danger: None.

16. OTHER INFORMATION

Preparation Date:	12/15/2016
Revision Date:	12/15/2016
Prepared by:	Sonia Owen

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet



Manufacturer

Product Covered: A1081, Aluminum Chlorohydrate, Dihydrate, 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, CQA Director, Global Supplier Quality Assurance <u>awang@spectrumchemical.com</u>



CERTIFICATE OF REGISTRATION

This is to certify that the quality management system of:

Spectrum Chemicals and Laboratory Products, Inc.

Main Site: 14422 South San Pedro Street, Gardena, California, 90248, USA,

Additional sites:13915 South Main Street, Los Angeles, California, 90061, USA

769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA
755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA
777 Jersey Avenue, New Brunswick, New Jersey, 08901, USA
400 N. Oracle, Suite 221, Tucson, Arizona, 85704, USA, USA

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

ISO 9001:2015

The quality management system is applicable to:

Main Site: 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. **Certificate Number:** 94-316m-03

Initial Certification Date: 27 December 1994

Certificate Issue Date: 31 July 2017

Certificate Expiry Date: 28 January 2019



Authorized Signature Calin Moldovean President Business Assurance

Intertek Testing Services NA, Inc. dba Intertek 900 Chelmsford Street, Lowell, MA, USA





In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request



APPENDIX TO CERTIFICATE OF REGISTRATION

This appendix identifies the locations by the management system of

Spectrum Chemicals and Laboratory Products, Inc.

755 and 769 Jersey Avenue: 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.

777 Jersey Avenue: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for Compounding Pharmacies.

7400 N. Oracle: 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.





In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

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



管理体系认证 注册证书

兹证明,以下组织:

斯百全化学(上海)

有限公司

上海市松江区申港路3802弄A20

的管理体系,符合以下标准要求并予以注册:

ISO 9001:2015

此管理体系适用于:

药用辅料销售,化学品销售

统一社会信用代码: 91310000777627048K

证书编号: 111310001

首次认证日期: 2015年11月17日

认证决定日期: 2017年12月26日

签发日期: 2017年12月26日

有效期至: 2018年11月10日



Calin Moldovean President, Business Assurance

Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom

Intertek Certification Limited 是 UKAS 认可的认证机构 , 注册号为 014



对于此证书的签署,Intertek仅对获证组织承担认证协议所规定的义务,而不对其他组织承担任何义务。此证书的有效性基于获证组织能够依照Intertek的体系认证要求使其体系得 到保持。可通过电子邮件certificate.validation@intertek.com或用智能手机扫描该代码对证书有效性进行确认。此证书的所有权归属为Intertek,在必要时证书持有者应按要求归还 证书。



CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Spectrum China Ltd.

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

has been registered by Intertek as conforming to the requirements of:

ISO 9001:2015

The management system is applicable to:

Sales for Pharmaceutical Excipients, Sales for Chemicals

Unified Social Credit Identifier: 91310000777627048K

Certificate Number: 111310001

Initial Certification Date: 17 November 2015

Date of Certification Decision: 26 December 2017

Issuing Date: 26 December 2017

Valid Until: 10 November 2018



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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 organisation maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request.

The annual validity of the certificate can also be checked through the website http://www.cnca.gov.cn of CNCA in China.



July 13, 2017

Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies 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 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,

Oula Clany

Oralia Chavez Quality Assurance Specialist



April 6, 2018

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	
A1081	Aluminum Chlorohydrate, Dihydrate, 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 03006174778

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



Aug 16, 2017

Re: Aluminum Chlorohydrate, Dihydrate, USP- A1081

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

Aluminum Chlorohydrate, Dihydrate, USP- A1081

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 Mfg. Corp.

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

Spectrum®

Certificate Of Analysis

Item Number	A1081	Lot Number	1GG0725
Item	Aluminum Chlorohydrate, Dihydrate, USP		
CAS Number	12359-72-7		
Molecular Formula	$Al_{v}(OH)_{(3y-z)}Cl_{z}.2H_{2}O$	Molecular Weight	210.48

Test	Specification		Result
	min	max	
ANHYDROUS ALUMINUM CHLOROHYDRATE	AS REPORTED		79.6 %
CONTENT OF ALUMINUM	AS REPORTED		24.6 %
CONTENT OF CHLORIDE	AS REPORTED		16.3 %
ALUMINUM/CHLORIDE ATOMIC RATIO	1.91:1	2.10:1	1.98:1
pH OF A 15 IN 100 (w/w) SOLUTION	3.0	5.0	4.2
ARSENIC (As)		2 ppm	<0.5 ppm
ELEMENTAL IMPURITIES		AS REPORTED	COMPLIES WITH STANDARD
IRON (Fe)		150 ppm	64 ppm
IDENTIFICATION		TO PASS TEST	PASSES TEST
EXPIRATION DATE			30-JUN-2020
DATE OF MANUFACTURE			01-JUN-2017
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS		TO PASS TEST	NO RESIDUAL SOLVENTS USED

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



Certificate of Analysis Results Certified By:

Adan Hernandez Quality Control Manager Spectrum Chemicals & Laboratory Products

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.

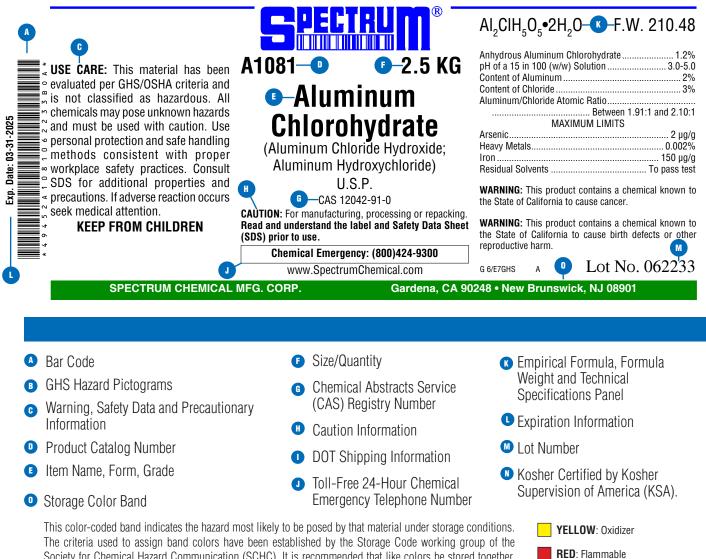


GREEN: General Storage

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.



This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. 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



January 26, 2016

RE: Lot Numbering System

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products' Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of **six characters**, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum's Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

Example: ZI0928 = The 928th material produced in California in September 2010

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

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

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

Example: 2AA0706 = The 706th material produced in New Jersey in January 2011

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

Sincerely,

1 lan

Michael Dang Manager, GMP Compliance



Stability – Shelf Life Guidance

Product Covered: A1081, Aluminum Chlorohydrate, Dihydrate, USP

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

The product, A1081, Aluminum Chlorohydrate, Dihydrate, 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