

Scientific Documentation

MA115, Magnesium Hydroxide, Powder, 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

Ver4.03 21.September.2017



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, ASQ CQA Director of Technical Services techservices@spectrumchemical.com

MA115, Magnesium Hydroxide, Powder, USP

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spectrum®



SAFETY DATA SHEET

Preparation Date: 10/25/2016 Revision Date: Not Applicable Revision Number: Not Applicable **1. IDENTIFICATION** Product identifier MA115 Product code: **Product Name:** MAGNESIUM HYDROXIDE, POWDER, USP Other means of identification No information available Synonyms: **CAS #:** 1309-42-8 **RTECS #** OM3570000 CI#: Not available Recommended use of the chemical and restrictions on use Recommended use: For manufacturing, processing, or repacking. Uses advised against No information available Supplier: Spectrum Chemical Mfg. Corp 14422 South San Pedro St. Gardena, CA 90248 (310) 516-8000. https://www.spectrumchemical.com Order Online At: Chemtrec 1-800-424-9300 Emergency telephone number Contact Person: Martin LaBenz (West Coast) Ibad Tirmiz (East Coast) Contact Person:

2. HAZARDS IDENTIFICATION

Classification

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

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

| Serious e | ye damage/ | eye irritation |
|-----------|------------|----------------|
|-----------|------------|----------------|

Category 2B

Label elements

Warning

Hazard statements Causes eye irritation

Hazards not otherwise classified (HNOC) Not Applicable

Other hazards Not available

Precautionary Statements - Prevention Wash face, hands and any exposed skin thoroughly after handling

Precautionary Statements - Response

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

| Components | CAS-No. | Weight % |
|---------------------|-----------|----------|
| Magnesium Hydroxide | 1309-42-8 | 100 |

| | 4. FIRST AID MEASURES | | | |
|---|--|--|--|--|
| First aid measures | | | | |
| General Advice: | National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222. | | | |
| Skin Contact: | 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. | | | |
| Eye Contact: | Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician. | | | |
| Inhalation: | Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention. | | | |
| Ingestion: | Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary. | | | |
| Most important symptoms and effects, both acute and delayed | | | | |
| Symptoms | Causes eye irritation. | | | |
| Indication of any immediate medical attention and special treatment needed | | | | |
| Notes to Physician: | Treat symptomatically. | | | |
| Protection of first-aiders First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste. | | | | |
| 5. FIRE-FIGHTING MEASURES | | | | |
| <u>Extinguishing Media</u> Suitable Extinguishing Media: | Dry chemical. Carbon dioxide (CO2). Water spray, mist, or foam. | | | |
| Unsuitable Extinguishing Media | a: No information available. | | | |
| Specific hazards arising from the chemical | | | | |
| Hazardous Combustion Products: Magnesium oxides. | | | | |
| Product code: MA115 | Product name: MAGNESIUM 2 / 10 | | | |

HYDROXIDE, POWDER, USP

Specific hazards:

Special Protective Actions for Firefighters

Specific Methods:

Special Protective Equipment for Firefighters:

May be combustible at high temperatures

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 procedures

Personal Precautions:Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin,
eyes and clothing. Avoid dust formation. Remove all sources of ignition. Do not touch
damaged containers or spilled material unless wearing appropriate protective clothing.
Keep people away from and upwind of spill/leak.Environmental precautionsPrevent 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 containment and cleaning upAbsorb spill with inert material (e.g. dry sand or earth), then place in a chemical
waste container.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. Avoid dust formation. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Use only in well-ventilated areas. Do not breathe dust. Avoid dust formation. Do not ingest. Keep away from heat and sources of ignition. 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: Strong oxidizing agents Strong acids Powdered metals

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

| Components | CAS-No. | OSHA | NIOSH | ACGIH | AIHA WHEEL |
|---------------------|-----------|------|-------|-------|------------|
| Magnesium Hydroxide | 1309-42-8 | None | None | None | None |

Canada

| Components | CAS-No. | Canada - Alberta | Canada - British Columbia | Canada - Ontario | Canada - Quebec |
|---------------------|-----------|------------------|------------------------------|------------------|-----------------|
| Magnesium Hydroxide | 1309-42-8 | None | None | None | None |

Australia and Mexico

| Components | CAS-No. | Australia | Mexico |
|---------------------|-----------|-----------|--------|
| Magnesium Hydroxide | 1309-42-8 | None | None |

Appropriate engineering controls

Engineering measures to reduce exposure:

Ensure adequate ventilation, especially in confined areas. 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: | Gloves. Chemical resistant apron. Long sleeved clothing. |
| Respiratory protection: | Effective dust mask. or. Wear respirator with dust filter. |
| Hygiene measures: | Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product. |

9. PHYSICAL AND CHEMICAL PROPERTIES

| Physical state: | Appearance: | Color: |
|-----------------------------------|---|--|
| Solid | Powder. | White. |
| Odor: | Taste | Formula: |
| Odorless. | No information available. | Mg(OH)2 |
| Molecular/Formula weight: 58.32 | 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 | 350°C (662°F) | No information available |
| Boiling point/range(°C/°F): | | |
| Product code: MA115 | Product name: MAGNESIUM | 4 / 10 |

HYDROXIDE, POWDER, USP

No information available

Specific gravity: 2.36

Evaporation rate: No information available

Odor threshold (ppm): No information available

Miscibility: No information available Bulk density: No information available

pH: 9.5 - 10.5

Vapor density: No information available

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

Solubility: Very slightly soluble in water

10. STABILITY AND REACTIVITY

Density (g/cm3): No information available

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

VOC content (g/L): No information available

Viscosity: No information available

<u>Reactivity</u> Reactive with strong oxidizing agents

| Chemical stability | |
|--------------------------------------|--|
| Stability: | Stable under recommended storage conditions. |
| Possibility of Hazardous Reactions | : Hazardous polymerization does not occur |
| Conditions to avoid: | Heat. Avoid dust formation. Incompatible materials. |
| Incompatible Materials: | Strong oxidizing agents Strong acids Powdered metals |
| 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: Eyes.

Acute Toxicity

The following values are calculated based on chapter 3.1 of the GHS document Component Information

| Magnesium Hydroxide | | |
|--|--------------------------|--|
| CAS-No. | 1309-42-8 | |
| LD50/oral/rat = = 8500 mg/kg Oral LD50 Rat | | |
| LD50/oral/mouse = | No information available | |

LD50/dermal/rabbit = No information available LD50/dermal/rat = = 8500 mg/kg Oral LD50 LC50/inhalation/rat = No information available LC50/inhalation/mouse = No infomation available Other LD50 or LC50information = No information available **Product Information** LD50/oral/rat = VALUE- Acute Tox Oral = No information available LD50/oral/mouse = Value - Acute Tox Oral = No information available LD50/dermal/rabbit VALUE-Acute Tox Dermal = No information available LD50/dermal/rat VALUE -Acute Tox Dermal = No information available LC50/inhalation/rat **VALUE-Vapor** = No information available **VALUE-Gas** = No information available VALUE-Dust/Mist = No information available LC50/Inhalation/mouse VALUE-Vapor = No information available **VALUE - Gas =** No information available VALUE - Dust/Mist = No information available Symptoms Skin Contact: May cause skin irritation. Causes eye irritation. Eye Contact: Inhalation May cause irritation of respiratory tract. Ingestion May cause diarrhea. May affect behavior/central nervous system (somnolence). Aspiration hazard No information available. Delayed and immediate effects as well as chronic effects from short and long-term exposure No information available. **Chronic Toxicity** Sensitization: No information available. Mutagenic Effects: No information available Carcinogenic effects: Not considered carcinogenic. **OSHA HCS** -Components CAS-No. IARC ACGIH -NTP Australia -Australia -Carcinogens Carcinogens Notifiable Prohibited Carcinogenic Carcinogenic

 Magnesium Hydroxide
 1309-42-8
 Not listed
 Not listed
 Not listed

 ACGIH (American Conference of Governmental Industrial Hygienists)

Substances

Not listed

Substances

Not listed

Not listed

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

| Reproductive toxicity | No data is available |
|------------------------|--------------------------|
| Reproductive Effects: | No information available |
| Developmental Effects: | No information available |
| Teratogenic Effects: | No information available |

Specific Target Organ Toxicity

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

| 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 |
|---------------------|-----------|---------------------------|---------------------------|---------------------------|---------------------------|
| Magnesium Hydroxide | 1309-42-8 | None | None | None | None |

14. TRANSPORT INFORMATION

DOT

| UN-No: | Not Regulated |
|--------------------------|--------------------------|
| Proper Shipping Name: | No information available |
| Hazard Class: | No information available |
| Subsidiary Class | No information available |
| Packing group: | No information available |
| Emergency Response Guide | No information available |
| Number | |
| Marine Pollutant | No data available |
| DOT RQ (lbs): | No information available |
| | |

Special Provisions Symbol(s): **Description:**

TDG (Canada)

UN-No: **Proper Shipping Name:** Hazard Class: Subsidiary Risk: Packing Group: **Marine Pollutant Description:**

ADR

UN-No: **Proper Shipping Name:** Hazard Class: Packing Group: **Subsidiary Risk:**

IMO / IMDG

UN-No: **Proper Shipping Name:** Hazard Class: Subsidiary Risk: Packing Group: Marine Pollutant

RID

| UN-No: | |
|-----------------------|--|
| Proper Shipping Name: | |
| Hazard Class: | |
| Subsidiary Risk: | |
| Packing Group: | |

ICAO

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

ΙΑΤΑ

UN-No: **Proper Shipping Name:** Hazard Class: Subsidiary Risk: Packing Group: ERG Code: **Special Provisions**

No Information available No information available No information available

Not Regulated

No information available No information available

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

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

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

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Not Regulated 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. |
|---------------------|-----------|-----------|---------------------|------------------------|--------------------|---------|---------------------|----------------------|
| Magnesium Hydroxide | 1309-42-8 | Present | Present KE-22716 | Present | Present (1)-386 | Present | Present | Present 215-170-3 |

U.S. Regulations

Magnesium Hydroxide

FDA - Food Additives Generally Recognized as Safe (GRAS): 21 CFR 184.1428 FDA - 21 CFR - Total Food Additives 155.170, 176.180, 176.210, 184.1428

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 | CAS-No. | Carcinogen | Developmental Toxicity | Male | Female |
|---------------------|-----------|------------|------------------------|--------------|--------------|
| | | - | | Reproductive | Reproductive |
| | | | | Toxicity | Toxicity: |
| Magnesium Hydroxide | 1309-42-8 | 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 |
|------------------------|-----------|---|---|--|------------------------------------|--|
| Magnesium Hydroxide | 1309-42-8 | None | None | None | None | None |

U.S. TSCA

| Components | | TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS) | TSCA 8(d) -Health and Safety Reporting |
|---------------------|-----------|---|---|
| Magnesium Hydroxide | 1309-42-8 | Not Applicable | Not Applicable |

Canada

WHMIS hazard class:

D2B Toxic materials

Components Magnesium Hydroxide

WHIMHAZ

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 | CAS-No. | Canada (DSL) | Canada (NDSL) |
|---------------------|-----------|--------------|---------------|
| Magnesium Hydroxide | 1309-42-8 | Present | Not Listed |

| Components | CAS-No. | CEPA Schedule I - Toxic Substances |
|---------------------|-----------|--------------------------------------|
| Magnesium Hydroxide | 1309-42-8 | Not listed |
| Components | CAS-No. | CEPA - 2010 Greenhouse Gases Subject |
| | | to Mandatory Reporting |
| Magnesium Hydroxide | 1309-42-8 | Not listed |

EU Classification <u>R-phrase(s)</u>

S -phrase(s)

S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S37 - Wear suitable gloves.

| Components | CAS-No. | Concentration Limits: | Safety Phrases |
|---------------------|-----------|------------------------------|----------------|
| Magnesium Hydroxide | 1309-42-8 | No information | |

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

Indication of danger:

Xi - Irritant.





Disclaimer:

16. OTHER INFORMATION

| Preparation Date: | 10/25/2016 |
|-------------------|--------------------|
| Revision Date: | Not Applicable |
| Prepared by: | Roumann Pangilinan |

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: MA115, Magnesium Hydroxide, Powder, USP

Spectrum takes ownership as the manufacturer for the Spectrum product listed above and provides full quality assurance, customer service, and technical product support.

While information concerning the raw material manufacturer of our starting materials is considered proprietary, such information can be made available upon request contingent on demonstration of business volume justification and successful execution of confidential disclosure agreement (CDA).

Requests for disclosure of proprietary raw material manufacturer information may be submitted to the assigned account representative for consideration.

Sincerely,

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



CERTIFICATE OF REGISTRATION

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.

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.



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



September 21, 2017

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 |
|----------------|----------------------------------|
| MA115 | Magnesium Hydroxide, Powder, 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 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>qualityassurance@spectrumchemical.com</u>

Sincerely,

Outu Umy

Oralia Chavez Quality Assurance Specialist



Aug 16, 2017

Re: Magnesium Hydroxide, Powder, USP- MA115

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

Magnesium Hydroxide, Powder, USP- MA115

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



Aug 16, 2017

Re: Magnesium Hydroxide, Powder, USP- MA115

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding the presence of allergens in raw materials. Please be assured that the following chemical does not contain (Milk; Egg; Fish; Shellfish; Sulfur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO₂; Lupin; Tree nuts; Mollusks; Wheat; Peanuts; Soy; Cereals containing Gluten; Celery; Mustard).

Magnesium Hydroxide, Powder, USP- MA115

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 | MA115 | Lot Number | 1FG0237 |
|-------------------|----------------------------------|------------------|---------|
| Item | Magnesium Hydroxide, Powder, USP | | |
| CAS Number | 1309-42-8 | | |
| Molecular Formula | Mg(OH) ₂ | Molecular Weight | 58.32 |

| Test | Specif | ïcation | Result |
|------------------------------|---------------|---------|------------------------------|
| | min | max | |
| ASSAY [Mg(OH) ₂] | 95.0 - 100.5% | | 96.4 % |
| LOSS ON IGNITION | 30.0 - 33.0% | | 30.9 % |
| MICROBIAL LIMIT (E.COLI) | TO PASS TEST | | PASSES TEST |
| LOSS ON DRYING | | 2.0% | 0.4 % |
| SOLUBLE SALTS | TO PASS TEST | | PASSES TEST |
| CARBONATE (CO_3) | TO PASS TEST | | PASSES TEST |
| CALCIUM (Ca) | | 1.5% | 0.3 % |
| HEAVY METALS | | 20 μg/g | <20 µg/g |
| LEAD (Pb) | | 1.5 ppm | 0.1 ppm |
| IDENTIFICATION | TO PASS TEST | | PASSES TEST |
| RETEST DATE | | | 02-APR-2018 |
| RESIDUAL SOLVENTS | TO PASS TEST | | NO RESIDUAL SOLVENTS USED |
| APPEARANCE | | | WHITE POWDER |
| MANUFACTURE DATE | | | 02-APR-2015 |

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 MSDS/SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personal only. The customer must ensure to provide its users adequate hazardous material training and appropriate protective gears before handling our chemicals.

Spectrum®

Certificate Of Analysis

| Item Number | MA115 | Lot Number | 2FE0405 |
|-------------------|----------------------------------|------------------|---------|
| Item | Magnesium Hydroxide, Powder, USP | | |
| CAS Number | 1309-42-8 | | |
| Molecular Formula | Mg(OH) ₂ | Molecular Weight | 58.32 |

| Test | Specif | ication | Result |
|------------------------------|---------------|---------|------------------------------|
| | min | max | |
| ASSAY [Mg(OH) ₂] | 95.0 - 100.5% | | 96.4 % |
| LOSS ON IGNITION | 30.0 - 33.0% | | 30.9 % |
| MICROBIAL LIMIT (E.COLI) | TO PASS TEST | | PASSES TEST |
| LOSS ON DRYING | | 2.0% | 0.4 % |
| SOLUBLE SALTS | TO PASS TEST | | PASSES TEST |
| CARBONATE (CO_3) | TO PASS TEST | | PASSES TEST |
| CALCIUM (Ca) | | 1.5% | 0.3 % |
| HEAVY METALS | | 20 μg/g | <20 µg/g |
| LEAD (Pb) | | 1.5 ppm | 0.1 ppm |
| IDENTIFICATION | TO PASS TEST | | PASSES TEST |
| RETEST DATE | | | 02-APR-2018 |
| RESIDUAL SOLVENTS | TO PASS TEST | | NO RESIDUAL SOLVENTS USED |
| APPEARANCE | | | OFF WHITE POWDER |
| DATE OF MANUFACTURE | | | 02-APR-2015 |

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate Of Analysis Results Certified by

Ibad Tirmizi Director of Quality Spectrum Chemical Mfg. Corp.

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

Read and understand label and MSDS/SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personal only. The customer must ensure to provide its users adequate hazardous material training and appropriate protective gears before handling our chemicals.



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.

| Causes eye irritation. Wash face, hands and any exposed skin thoroughly after handling. FIRST AID: 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 attention. KEEP FROM CHILDREN | CAS 1309-42-8 AUTION: For manufacturing, processing or epacking. Tead and understand the label and Safety Data heet (SDS) prior to use. | Mg(OH)2 F.W. 58.32 Assay (Dried Basis) 95.0-100.5% Loss on Ignition 30.0-33.0% MAXIMUM LIMITS Microbial Limits (<i>Escherichia coli</i>) To pass test Loss on Drying 2.0% Soluble Salts To pass test Carbonate To pass test Calcium 1.5% Heavy Metals 20 µg/g Lead 1.5 ppm Residual Solvents To pass test WARNING: This product contains a chemical known to the State of California to cause cancer. WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm. |
|--|--|--|
| ■* | Chemical Emergency: (800)424-9300 www.SpectrumChemical.com | G 10/E7GHS A O LOt No. 062233 |
| | | 040 - New Drugewield NLL00001 |
| SPECTRUM CHEMICAL M | FG. CORP. Gardena, CA 90 | 248 • New Brunswick, NJ 08901 |
| A Bar CodeB GHS Hazard Pictograms | Size/Quantity Chemical Abstracts Service | Kew Brunswick, NJ 08901 Empirical Formula, Formula Weight and Technical Specifications Panel |
| A Bar Code | F Size/Quantity Chemical Abstracts Service (CAS) Registry Number | Empirical Formula, Formula Weight and Technical |
| A Bar Code B GHS Hazard Pictograms G Warning, Safety Data and Precautionar Information Product Catalog Number Item Name, Form, Grade | Size/Quantity Chemical Abstracts Service (CAS) Registry Number Caution Information DOT Shipping Information Toll-Free 24-Hour Chemical | Content of the second state of th |
| A Bar Code B GHS Hazard Pictograms c Warning, Safety Data and Precautionar Information P Product Catalog Number | Size/Quantity Chemical Abstracts Service (CAS) Registry Number Caution Information DOT Shipping Information | Empirical Formula, Formula Weight and Technical Specifications Panel Expiration Information Lot Number |

Spectrum Chemical Mfg Corp

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

storing hazardous chemicals.

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

732.214.1300

310.516.8000



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: MA115, Magnesium Hydroxide, Powder, USP

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

The product, MA115, Magnesium Hydroxide, Powder, 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