

# **Scientific Documentation**

MA120, Magnesium Oxide, Light 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

Ver4.02 06.June.2016



Dear Customer,

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

Spectrum has been proudly serving our scientific community for over 45 years. It is our mission to manufacture and distribute fine chemicals and laboratory products with Quality and delivery you can count on every time.

To accomplish our mission, Spectrum utilizes our sourcing leverage and supplier qualification expertise in offering one of the industry's most comprehensive line of fine chemical products under one brand, in packaging configurations designed to meet your research and production requirements. Our product grades include: USP, NF, BP, EP, JP, FCC, ACS, KSA, Reagent grade, as well as DEA controlled substances. We operate facilities in the United States on the East Coast, West Coast, as well as in Shanghai, China in order to provide the best logistical support for our customers.

At Spectrum, Quality is priority number one. Suppliers with the best qualifications are preferred and we employ full-functioning in-house analytical laboratories at each of our facilities. Our facilities and systems are USFDA registered and ISO certified. We frequently host customer audits and cherish opportunities for improvements. Quality is engrained into our culture. Quality is priority number one.

In the following pages, we have designed and prepared documented scientific information to aid you in your initial qualification or your continual use of our products. Please do not hesitate to contact us if further information or the most up-to-date documentation is desired from any of the covered areas.

We appreciate your business and we look forward to hearing from you.

Sincerely,

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

MA120, Magnesium Oxide, Light Powder, USP

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Item Number	<u>MA120</u>
Item	Magnesium Oxide, Light Powder, USP
CAS Number	1309-48-4
Molecular Formula	MgO
Molecular Weight	40.30
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
ASSAY (MgO)	96.0 - 100.5 %	
BULK DENSITY	0.18 - 0.35 g/cc	
LOSS ON IGNITION		10.0 %
FREE ALKALI & SOLUBLE SALTS		2.0 %
ACID-INSOLUBLE SUBSTANCES		0.1 %
CALCIUM (Ca)		1.1 %
HEAVY METALS		20 ug/g
IRON (Fe)		0.05 %
IDENTIFICATION		TO PASS TEST
CERTIFIED KOSHER		
RETEST DATE		
RESIDUAL SOLVENTS		TO PASS TEST

#### Spectrum Chemical Mfg Corp

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

# spectrum



### SAFETY DATA SHEET

Preparation Date: 8/24/2015	<b>Revision Date:</b> 8/24/2015	Revision Number: G1		
	1. IDENTIFICATION			
Product identifier				
Product code:	MA120			
Product Name:	MAGNESIUM OXIDE, LIGHT POWDER, USP			
Other means of identification				
Synonyms:	Calcined brucite			
	Calcined magnesia			
	Calcined magnesite			
	Calcined brucite			
	Maglite			
	Magnesia 1309-48-4			
CAS #: RTECS #	OM3850000			
CI#:	Not available			
CI#.	Not available			
Recommended use of the chemical and restrictions on use				
Recommended use:	Ceramics. Fertilizer compositons.			
Uses advised against	No information available			
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 Hazardous

#### Other hazards Not available

#### **3. COMPOSITION/INFORMATION ON INGREDIENTS**

Components	CAS-No.	Weight %
Magnesium Oxide, light	1309-48-4	100
1309-48-4		

#### **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 effec	ts both acute and delayed		
Symptoms	May cause eye/skin/respiratory tract irritation. May cause digestive (gastrointestinal) tract irritation. Ingestion may cause nausea, vomiting, and diarrhea. May cause "Metal Fume Fever". Flu-like condition consisting of fever, chills, sweating, metallic taste in mouth, dry mouth and throat, cough, weakness, muscle aches and joint pain, headache, nausea, vomiting, chest tightness, and difficulty breathing.		
Indication of any immediate medical	attention and special treatment needed		
Notes to Physician:	Treat symptomatically		
<b>Protection of first-aiders</b> First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste			
	5. FIRE-FIGHTING MEASURES		
Extinguishing Media Suitable Extinguishing Media:	The product is not flammable. If it is involved in a fire, extinguish the fire using an agent suitable for the type of surrounding fire.		

#### Unsuitable Extinguishing Media:

#### Specific hazards arising from the chemical

Hazardous Combustion Products:

Specific hazards:

No information available.

Magnesium Oxide may ignite and explode when heated with sublimed sulfur, magnesium powder, or aluminum powder. It reacts violently with interhalogens (bromine pentafluoride, chlorine trifluoride) and produces flames. When combined with phosphorus pentachloride, it incandesces

#### **Special Protective Actions for Firefighters**

**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:Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled<br/>material unless wearing appropriate protective clothing. Use personal protective equipment.Environmental precautionsPrevent further leakage or spillage. Prevent product from entering drains.Methods and material for containment and cleaning upMethods 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<br/>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. Use only in well-ventilated areas. Handle in accordance with good industrial hygiene and safety practice.

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

#### Technical Measures/Storage Conditions:

Hygroscopic. Moisture sensitive. Protect from moisture. 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:

Chlorine trifluoride. Phosphorous Pentachloride. Performic acid. Bromine pentafluoride. Oxidizing agents. Powdered metals. Acids.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Control parameters** 

#### National occupational exposure limits

Product code: MA120

#### **United States**

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
Magnesium Oxide, light	15 mg/m³ TWA	None	10 mg/m <sup>3</sup> TWA inhalable	None
1309-48-4			fraction	

Canada

Components	Alberta	British Columbia	Ontario	Quebec
Magnesium Oxide, light	10 mg/m <sup>3</sup> TWA fume	10 mg/m <sup>3</sup> TWA fume,	10 mg/m <sup>3</sup> TWA inhalable	10 mg/m <sup>3</sup> TWAEV Mg fume
1309-48-4	_	inhalable	_	
		3 mg/m <sup>3</sup> TWA Mg		
		respirable dust and fume		
		10 mg/m <sup>3</sup> STEL Mg		
		respirable dust and fume		

#### **Australia and Mexico**

Components	Australia	Mexico
Magnesium Oxide, light	10 mg/m³ TWA	10 mg/m³ TWA
1309-48-4		

#### 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:	Chemical resistant apron. Gloves. Long sleeved clothing.
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:	Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wear suitable gloves and eye/face protection.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid

Odor: Odorless.

Molecular/Formula weight: No information available

Flash Point Tested according to: Not available

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

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

**Density (g/cm3):** 3.58

**Evaporation rate:** No information available

Odor threshold (ppm): No information available

**Miscibility:** No information available **Appearance:** Powder.

Taste No information available

Flammability: No information available

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

**pH:** No information available

Boiling point/range(°C/°F): 3600°C/6512°F

**Specific gravity:** No information available

Vapor density: No information available

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

**Solubility:** Soluble in dilute acids Soluble in ammonium salt solutions Insoluble in Ethanol Very slightly soluble in water Color: White.

Formula: No information available

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

Lower Explosion Limit (%): No information available

Melting point/range(°C/°F): 2500-2825 °C/4532-5117 °F

Bulk density: No information available

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

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

Viscosity: No information available

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

#### Reactivity

Magnesium Oxide may ignite and explode when heated with sublimed sulfur, magnesium powder, or aluminum powder. It reacts violently with interhalogens (bromine pentafluoride, chlorine trifluoride) and produces flames. When combined with phosphorus pentachloride, it incandesces.

Hygroscopic. Air Sensitive. Readily absorbs moisture and carbon dioxide when exposed to air. Hydrates slowly in contact with moisture. Reacts violently with chlorine trifluoride and phosphorous pentachloride

Reactive with oxidizing agents

Reactive with acids

Chemical stability Stability:	Stable under recommended storage conditions	
Possibility of Hazardous Reactions:	Hazardous polymerization does not occur	
Conditions to avoid:	Exposure to moisture. Exposure to moist air. Exposure to water. Excess Heat. Incompatible materials.	
Incompatible Materials:	Chlorine trifluoride. Phosphorous Pentachloride. Performic acid. Bromine pentafluoride. Oxidizing agents. Powdered metals. Acids.	
Hazardous decomposition products:	Oxygen. Magnesium.	
Other Information Corrosivity:	No information available	
Product code: MA120	Product name: MAGNESIUM OXIDE,	Ę

#### 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**

Magnesium Oxide, light - 1309-48-4

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 information 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

Eye Contact:

May cause eye irritation

Inhalation	May cause irritation of respiratory tract. May cause "metal fume fever". This is a flu- like illnes with symptoms such as metallic taste in the mouth, dryness of the mouth and throat, headache, fatigue, fever, chills, nausea, vomiting, muscle aches and joint pains, chest tightness and cough, difficulty breathing.
Ingestion	May cause gastrointestinal (digestive) tract irritation with nausea, vomiting, diarrhea.
Aspiration hazard	No information available
Delayed and immediate effects a	s well as chronic effects from short and long-term exposure
Chronic Toxicity	Chronic exposure may affect the brain. Prolonged or repeated exposure may affect the blood.
Sensitization:	No information available
Mutagenic Effects:	No information available

Carcinogenic effects: Not considered carcinogenic

Components	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Magnesium Oxide, light	Not listed	A4 Not Classifiable as a Human Carcinogen		Not listed	Not listed	Not listed

Reproductive toxicity	No data is available
Reproductive Effects: Developmental Effects: Teratogenic Effects:	No information available No information available No information available
Specific Target Organ Toxicity	
STOT - single exposure	No information available

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

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

#### Ecotoxicity

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

#### **Disposal Methods**

#### Waste from residues / unused products:

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

#### Contaminated packaging:

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

Components	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Magnesium Oxide, light	None	None	None	None

#### 14. TRANSPORT INFORMATION

DOT

DOT		
	UN-No:	Not Regulated
	Proper Shipping Name:	No information available
	Hazard Class:	No information available
	Subsidiary Risk:	No information available
	Packing Group:	None
	ERG No:	No information available
	Marine Pollutant	No data available
	DOT RQ (lbs):	No information available
	Special Provisions	No Information available
	Symbol(s):	No information available
TDG	(Canada)	
	UN-No:	Not Regulated
	Proper Shipping Name:	No information available
	Hazard Class:	No information available
	Subsidiary Risk:	No information available
	Packing Group:	No information available
	Marine Pollutant	No Information available
ADR		
	UN-No:	Not Regulated
	Proper Shipping Name:	No information available
	Hazard Class:	No information available
	Packing Group:	No information available
	Subsidiary Risk:	No information available
	Subsidiary Risk.	NO INFORMATION AVAILABLE
IMO	/ IMDG	
	UN-No:	Not Regulated
	Proper Shipping Name:	No information available
	Hazard Class:	No information available
	Subsidiary Risk:	No information available
	Packing Group:	No information available
	Marine Pollutant	No information available
	Marine Poliutant	NO INFORMATION AVAILABLE
חום		
RID	UN-No:	Not Regulated
	Proper Shipping Name:	No information available
	Hazard Class:	No information available
	1122010 01233.	

Product code: MA120

Product name: MAGNESIUM OXIDE, LIGHT POWDER, USP

#### 14. TRANSPORT INFORMATION

Subsidiary Risk:	No information available	
Packing Group:	No information available	
ICAO		
UN-No:	Not Regulated	
Proper Shipping Name:	No information available	
Hazard Class:	No information available	
Subsidiary Risk:	No information available	
Packing Group:	No information available	
ΙΑΤΑ		
UN-No:	Not Regulated	
Proper Shipping Name:	No information available	
Hazard Class:	No information available	
Subsidiary Risk:	No information available	
Packing Group:	No information available	
ERG Code:	No information available	
Special Provisions	No information available	

#### **15. REGULATORY INFORMATION**

#### **International Inventories**

Components	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Magnesium Oxide, light	Present	Present KE- 22728	Present	Present (1)- 465	Present	Present	Present 215-171-9

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

Magnesium Oxide, light

Massachusetts RTK: Present New Jersey RTK Hazardous Substance List: 1144 Pennsylvania RTK: Present Minnesota - Hazardous Substance List: Present California Directors List of Hazardous Substances: Present FDA - Food Additives Generally Recognized as Safe (GRAS): 21 CFR 184.1431

FDA - 21 CFR - Total Food Additives 155.170 163.110 163.111 163.112 175.300 176.170 177.1680 177.2260 177.2400 177.2600 178.1010 178.3297 184.1431

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

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

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

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

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

Components	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Magnesium Oxide, light	Not Listed	Not Listed	Not Listed	Not Listed

#### CERCLA/SARA

Components	<b>CERCLA - Hazardous</b>	Section 302 Extremely	Section 302 Extremely	Section 313 -	Section 313 - Reporting
-	Substances and their	Hazardous	Hazardous	Chemical Category	de minimis
	<b>Reportable Quantities</b>	Substances and TPQs	Substances and RQs		
Magnesium Oxide, light	None	None	None	None	None

#### U.S. TSCA

	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Magnesium Oxide, light	Not Applicable	Not Applicable

#### Canada

#### WHMIS hazard class:

Non-controlled

#### Magnesium Oxide, light

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.

Components	WHMIS Ingredient Disclosure List -
Magnesium Oxide, light	1 %

#### Inventory

Components	Canada (DSL)	Canada (NDSL)
Magnesium Oxide, light	Present	Not Listed

Components	CEPA Schedule I - Toxic Substances
Magnesium Oxide, light	Not listed

Components	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Magnesium Oxide, light	Not listed

#### **EU Classification**

#### R-phrase(s)

not determined (not applicable)

#### S -phrase(s)

none

Components	Classification	Concentration Limits:	Safety Phrases
Magnesium Oxide, light		No information	

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

Indication of danger: None.

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

Preparation Date:	
<b>Revision Date:</b>	
Prepared by:	

8/24/2015 8/24/2015 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: MA120, Magnesium Oxide, Light 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 Senior Manager of Technical Services techservices@spectrumchemical.com

# **Certificate of Registration**



This is to certify that the quality management system of

## Spectrum Chemicals and Laboratory Products, Frc

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

Additional Sites: 13915 South Main Street, Los Angeles, California, 90061, USA 755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA 769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA 7400 North Oracle Road, Suite 221, Tucson, Arizona, 85704, USA

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

# **ISO 9001:2008**

The quality management system is applicable to

**California and New Jersey sites:** The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.

Arizona site: Supporting Spectrum's two manufacturing facilitates by: selecting and gualifying distributors of Laboratory and Safety Equipment; processing bids and quotes to generate new sales opportunities; sourcing bulk chemicals in support of bulk bids and guotes; assisting production operations through order expediting and IT infrastructure support.

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

29 January 2016 14 September 2018

Calin Moldovean, President

Intertek Testing Services NA, Inc.

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



CERTIFICATION



Intertek Intertek

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

# **Certificate of Registration**



This is to certify that the quality management system of

# Spectrum China Ltd.

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

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

## ISO 9001: 2008

The quality management system is applicable to:

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

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



014

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

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



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



March 28, 2016

#### Certificate of cGMP

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify that our USP, NF, FCC, EP, BP, JP, and food grade products are produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

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

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

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

Sincerely,

Michelle Wester

Michelle Weston Quality Assurance Specialist



June 1, 2016

#### Certificate of cGMP

Dear Valued Customer:

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

Catalog Number	Product Name	
MA120	Magnesium Oxide, Light 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 with Spectrum products. Please feel free to contact the Quality Assurance department at 310-516-8000 or via email at <u>qualityassurance@spectrumchemical.com</u> if we may be of further assistance.

Sincerely,

Michelle Wester

Michelle Weston Quality Assurance Specialist



June 3, 2016

Re: Magnesium Oxide, Light Powder, USP- MA120

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 Oxide, Light Powder, USP- MA120

is BSE/TSE free.

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

Sincerely,

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

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



June 3, 2016

Re: Magnesium Oxide, Light Powder, USP- MA120

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

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

Magnesium Oxide, Light Powder, USP- MA120

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

Sincerely,

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

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



June 3, 2016

Re: Magnesium Oxide, Light Powder, USP- MA120

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfg. Corp. understand the concern regarding Aflatoxins in raw materials. To the best of our knowledge, the product listed below is not contaminated with Aflatoxins. Aflatoxins are not used in production. The following product does not come in contact with Aflatoxins at any stage of production.

Magnesium Oxide, Light Powder, USP- MA120

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

Sincerely,

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

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**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.

	<b>G</b> <u>P</u> ELIKUM°	MgO F.W. 40.30
	MA120-0 -2.5 KG	Assay
	Magnesium Oxide	Loss on Ignition
and must be used with caution. Use ∞ personal protection and safe handling	Light Powder	Heavy Metals 20 µg. Iron
s methods consistent with proper workplace safety practices. Consult	U.S.P. O-RSA	Residual Solvents To pass te WARNING: This product contains a chemical known
SDS for additional properties and	G CAS 1309-48-4	the State of California to cause cancer.
$\mathbb{C}$ seek medical attention.	CAUTION: For manufacturing, processing or repacking. Read and understand the label and Safety Data	WARNING: This product contains a chemical known the State of California to cause birth defects or oth reproductive harm.
	Sheet (SDS) prior to use.	MOISTURE SENSITIVE, HYGROSCOPIC: Keep tight
*	Chemical Emergency: (800)424-9300	closed.
SPECTRUM CHEMICAL N	www.SpectrumChemical.com	G 11/E4GHS A 🔮 Lot No. 06223 248 • New Brunswick, NJ 08901
Bar Code	Size/Quantity	🗴 Empirical Formula, Formula
Bar Code GHS Hazard Pictograms	<ul> <li>Size/Quantity</li> <li>Chemical Abstracts Service</li> </ul>	Weight and Technical
	Chemical Abstracts Service	Weight and Technical Specifications Panel
GHS Hazard Pictograms	Chemical Abstracts Service	Weight and Technical
<ul> <li>GHS Hazard Pictograms</li> <li>Warning, Safety Data and Precautiona</li> </ul>	<ul> <li>Chemical Abstracts Service (CAS) Registry Number</li> <li>Caution Information</li> </ul>	Weight and Technical Specifications Panel
<ul> <li>GHS Hazard Pictograms</li> <li>Warning, Safety Data and Precautiona Information</li> </ul>	<ul> <li>Chemical Abstracts Service (CAS) Registry Number</li> <li>Caution Information</li> <li>DOT Shipping Information</li> </ul>	<ul> <li>Weight and Technical Specifications Panel</li> <li>Expiration Information</li> <li>Lot Number</li> </ul>
<ul> <li>GHS Hazard Pictograms</li> <li>Warning, Safety Data and Precautiona Information</li> <li>Product Catalog Number</li> </ul>	<ul> <li>Chemical Abstracts Service (CAS) Registry Number</li> <li>Caution Information</li> </ul>	<ul> <li>Weight and Technical Specifications Panel</li> <li>Expiration Information</li> <li>Lot Number</li> <li>Kosher Certified by Kosher Supervision of America (KSA)</li> </ul>

#### 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

732.214.1300

310.516.8000

# Spectrum®

# **Certificate Of Analysis**

Item Number	MA120	Lot Number	1EK0210
Item	Magnesium Oxide, Light Powder, USP		
CAS Number	1309-48-4		
Molecular Formula	MgO	Molecular Weight	40.30

Test	Specif	ication	Result
	min	max	
ASSAY (MgO)	96.0 - 100.5 %		97.6 %
BULK DENSITY	0.18 - 0.35 g/cc		0.29 g/cc
LOSS ON IGNITION		10.0 %	3.1 %
FREE ALKALI & SOLUBLE SALTS		2.0 %	<2.0 %
ACID-INSOLUBLE SUBSTANCES		0.1 %	0.015 %
CALCIUM (Ca)		1.1 %	0.07 %
HEAVY METALS		20 ug/g	<20 ug/g
IRON (Fe)		0.05 %	0.0024 %
IDENTIFICATION		TO PASS TEST	PASSES TEST
CERTIFIED KOSHER			KOSHER
RETEST DATE			01-SEP-2016
RESIDUAL SOLVENTS		TO PASS TEST	NO RESIDUAL SOLVENTS USED
APPEARANCE			WHITE POWDER
MANUFACTURE DATE			02-SEP-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.

# Spectrum®

# **Certificate Of Analysis**

Item Number	MA120	Lot Number	2FE0038
Item	Magnesium Oxide, Light Powder, USP		
CAS Number	1309-48-4		
Molecular Formula	MgO	Molecular Weight	40.30

Test	Specif	ication	Result
	min	max	
ASSAY (MgO)	96.0 - 100.5 %		97.6 %
BULK DENSITY	0.18 - 0.35 g/cc		0.31 g/cc
LOSS ON IGNITION		10.0 %	3.0 %
FREE ALKALI & SOLUBLE SALTS		2.0 %	<2.0 %
ACID-INSOLUBLE SUBSTANCES		0.1 %	0.05 %
CALCIUM (Ca)		1.1 %	0.03 %
HEAVY METALS		20 ug/g	<20 ug/g
IRON (Fe)		0.05 %	0.0023 %
IDENTIFICATION		TO PASS TEST	PASSES TEST
CERTIFIED KOSHER			KOSHER
RETEST DATE			05-SEP-2016
RESIDUAL SOLVENTS		TO PASS TEST	NO RESIDUAL SOLVENTS USED
APPEARANCE			WHITE POWDER
DATE OF MANUFACTURE			06-SEP-2015

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Certified By:

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Mulbah F. Dwanah Laboratory Supervisor Spectrum Chemicals & Laboratory Products

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



January 26, 2016

#### RE: Lot Numbering System

Dear Valued Customer:

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

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

**Example**: ZI0928 = The 928<sup>th</sup> material produced in California in September 2010

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

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

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

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

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

Sincerely,

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Michael Dang Manager, GMP Compliance



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

#### Product Covered: MA120, Magnesium Oxide, Light Powder, USP

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

The product, MA120, Magnesium Oxide, Light Powder, USP, is assigned a 12 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



בס"ד Feb 08, 2016

The following product(s) prepared by the named company are certified kosher with the stated requirements:

#### Spectrum Laboratory Products, Inc.

S-0032

14422 S. San Pedro Street Gardena CA 90248 USA		
	Product Name	Magnesium Oxide, Light Powder, USP - MA120
	Brand	Spectrum
	UKD-ID	KSAV3-M8Y7T42
	D/P/M	Р
	Symbol Required	KSA
This certificate expires on <b>Feb 28, 2017</b>	<b>Special Conditions</b>	

Rabbi Binyomin Lisbon Kashrus Administrator

Placing the KSA logo on products not listed above constitutes an un-authorized use of the KSA symbol, which is a federally registered trademark.