Standard Questionnaire
FAQ 2024

Dear Valued Customer:

This Standard Questionnaire FAQ is made available to provide answers to typical Supplier Assessment Questionnaires. In so doing, we are confident your organization is receiving the important process information you are seeking. Should you need further details or assistance please feel free to contact our team as needed.

Vendor / Supplier Name:	Giles Chemical a Division of Premier Magnesia, LLC
Address:	200 Brown St., Greendale, IN 47025
Product Manufactured:	Magnesium Sulfate Heptahydrate (Epsom Salt)

Name	Title	Email / Phone
Matt Haynes	VP Operations	828-452-4784 ext. 648
Zach Sutton	National Sales Manager	828-452-4784 ext. 649
Bryan Butler	Material & Production Planner	828-452-4784 ext. 191
John Laursen	Director of Quality	828-452-4784 ext. 681
Michelle Shank	Quality Manager	812-537-4852 ext. 503
Bruce Dixon	Bulk Plant Manager	620-755-4553 ext. 501

GENERAL INFORMATION	
1. Company Organization	Giles Chemical a Division of Premier Magnesia, LLC
2. Is the facility FDA registered?	Yes - FDA Registration - 3008635020
3. Is the facility certified to any Quality System Standards?	Yes - 21 CFR 210/211
4. Total Number of employees/shifts:	16 production personnel/ 4 shifts
5. Are there other facilities of the company that manufacture the same product?	Yes
6. Date of the last FDA inspection if applicable:	July 14-27, 2022

ORGANIZATION/PERSONNEL/FACILITY	
1. Is a Quality Manual or plan in place and approved by Management?	Yes
2. Is responsibility and authority for product quality assigned to personnel that are independent of manufacturing? (An organization chart will be useful)	Yes
3. Is there a designated individual responsible for the QA Program?	Yes
4. Are resources adequate in areas such as management, operations, verification and internal audits?	Yes
5. Is there a written audit procedure?	Yes
6. Are internal quality audits conducted regularly?	Yes
7. Does management review the audits?	Yes
8. Does Quality Assurance review new/revised drawings and specifications?	Yes
9. Are current work instructions, drawings, etc. readily available at each operation or workstation?	Yes
10. Is there a formal deviation procedure?	Yes
11. Are personnel familiar with work instructions adequately trained or certified?	Yes
12. Is the training formally documented?	Yes
13. Are there proper dress requirements to reduce product contamination?	Yes
14. Are there procedures for contamination control for equipment and product? Examples include trash, sewage, byproducts, and pest control.	Yes
15. Are buildings of suitable design and contain enough space to perform necessary operations, prevent	

mix-ups and assure orderly handling?	
For: Production	Yes
Warehousing	Yes
Packaging/Labeling	Yes
Inspection/Measuring	Yes
16. Is there a maintenance schedule posted on process or inspection equipment for adjustment/calibration and cleaning?	Yes
17. Are there calibration procedures and records along with frequency of calibration?	Yes
18. Are automated data processes used as part of process or the quality system?	Yes
19. If used, is the computer software validated for its intended use with a protocol?	N/A
DOCUMENT CONTROL	
1. Is there control of accuracy and usage of current version of documents and the removal of obsolete documents?	Yes
2. Is there a system for tracking/monitoring document changes?	Yes
3. Does it include a record describing the change, signature of approving individuals, approval and effective date?	Yes
4. Are the changes communicated to affected personnel in a timely manner?	Yes
DESIGN CONTROL	
1. Is there a system to control the design of products? (design input, output, review, verification, validation, transfer, changes, and design history file)	Yes
PURCHASING CONTROLS	
1. Is there a formal program for supplier survey and evaluation?	Yes
2. Are specified requirements for materials/service maintained?	Yes
3. Are agreements in place with suppliers to notify the manufacturer of changes?	Yes
IDENTIFICATION AND TRACEABILITY	
1. Is there a system to prevent product mix-ups during stages of receipt, production and distribution?	Yes
2. Does traceability exist with each lot/batch with use of control numbers or other system that provides an identifier?	Yes
PRODUCTION AND PROCESS CONTROLS	
1. Are there procedures for process controls?	Yes
2. Is the following information recorded during the process?	Yes
Components used	Yes
Equipment	Yes
Dates	Yes
Operation	Yes
Test Results	Yes
3. Do they include documented instructions, standard operating procedures and methods that define and control the manner of production?	Yes
4. Is there monitoring and control of process parameters during production?	Yes
5. Is there compliance with reference standards or codes?	Yes
6. Are there procedures to document changes to a specification, method, process or procedure?	Yes
7. If environmental conditions could potentially affect product quality, are procedures in place to adequately control and monitor the conditions?	Yes
8. Have all production processes been verified through validation studies which include activities, results, approval of validation and major equipment validated?	Yes
ACCEPTANCE ACTIVITIES	
1. Are there procedures for acceptance activities for receiving, in-process and finished goods?	Yes
2. Are the results of acceptance activities documented?	Yes
3. Is identification of acceptance status maintained throughout manufacturing, packaging, labeling, and	

	installation to ensure that only products which have passed the required acceptance activities are distributed or used?	Yes
4.	Reserve samples of each lot are retained for 4 years.	Yes
	NONCONFORMING PRODUCT	
1.	Is there a system in place to ensure that product that does not conform to specified requirements is prevented from unintended use?	Yes
2.	Does the system address identification, documentation, evaluation, segregation, disposition of nonconforming product?	Yes
3.	Is responsibility defined for review and disposition of nonconforming product?	Yes
4.	Are there procedures for reprocessing?	Yes
	CORRECTIVE AND PREVENTITIVE ACTION	
1.	Is there a system for handling corrective and preventive actions?	Yes
2.	Do the procedures cover internal observations such as inspection and test records, internal audits?	Yes
3.	Do the procedures cover external observations such as customer complaints and service records?	Yes
	LABELING AND PACKAGING	
1.	Are there procedures to control labeling activities?	Yes
2.	Do they include integrity, inspection, storage, and operations?	Yes
3.	Is packaging designed to protect the material from damage?	Yes
	HANDLING, STORAGE, DISTRIBUTION	
1.	Are there procedures to ensure mix-ups, damage, deterioration or contamination of product do not occur during handling?	Yes
2.	Are materials used to facilitate stock rotation?	Yes
3.	Are there adequate distribution records?	Yes
	RECORDS	
1.	How long are records retained?	4 years
2.	Are records stored to prevent deterioration and loss?	Yes
3.	Are complaint files maintained?	Yes
4.	Who handles the complaints?	Quality Assurance in conjunction with Sales and Production
	STATISTICAL TECHNIQUES	
1.	What statistical techniques are utilized for process capability or product characteristics – Statistical Process Control (SPC) or Statistical Quality Control (SQC)?	Validations

UL VERIFICATION SERVICES INC. ISSUES THIS

CERTIFICATE OF CONFORMANCE

To:

Giles Chemical, div of Premier Magnesia, LLC

200 Brown Street,
Greendale, IN 47025 USA

FOLLOWING ASSESSMENT OF ITS GOOD MANUFACTURING PRACTICE & QUALITY SYSTEM AND FINDING IT IN CONFORMANCE WITH:

21 CFR Parts 210 & 211: 4-2022

UL Scheme: Retail Certification Program
Procedure for Certification, QSLP 7.1-1
Rev. 04/01/2022 RCP®

CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS FOR THE FOLLOWING SCOPE OF CERTIFICATION:

The Manufacturing, Packaging and Warehousing of USP Epsom Salt

Certificate Number: a19-346988-1
Issue Number: 2
Certificate Issue Date: 11/28/2022
Expiration Date: 1/30/2026

Authorized by:

Karen Sak, Manager, Client Programs

UL Verification Services Inc.
7036 Snowdrift Road, Suite 200
Allentown, PA 18106
United States of America
800-903-5660

The UL Logo, Enhanced Certification Mark, ANAB Accreditation Mark, and IAF Mark indicate satisfactory assessment against the above noted standard / requirements in accordance with the UL RCP® Procedure for Certification, the UL LLC Agreement for Use of Certification Symbols, and the scope of assessment. This certificate remains the property of UL, to whom it must be returned upon request. Revision 09/01/2022

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Authorized by:

Karen Sak, Manager, Client Programs

UL Verification Services Inc.
7036 Snowdrift Road, Suite 200
Allentown, PA 18106
United States of America
800-903-5660

Certificate of Compliance

Date of Issue:
01/10/2023

Expiration:
01/02/2025

Certificate Number:
34601

Authorized by:

Ariana Shnurman
Feed Program Manager

Issuing Officer:

Shelby Farnsworth

Validus Verification Services, LLC

hereby certifies that

Giles Chemical, a Division of Premier Magnesia, LLC

has been reviewed by an authorized representative of the American Feed Industry Association and is certified under the Safe Feed/Safe Food Certification Program for the following site:

200 Brown Street
Greendale, IN 47025
United States

Scope of Registration: FSC36: Safe Feed/Safe Food

Audit was conducted with FSC36: Safe Feed Safe Food checklist v7.0 in effect 12/2022

**For the validity of the certificate please check www.safefeedsafefood.org*

Validus Verification Services LLC
3331 109th Street
Urbandale, IA 50322

בס"ד

KOSHER CERTIFICATE

KC# 9249707 - 1
5 Adar I, 5784
February 14, 2024

KOSHER CERTIFICATION
Rabbi Don Yoel Levy OB"M
Kashruth Administrator 1987–2020

Giles Chemical, a division of Premier Magnesia, LLC
200 Brown St.
Greendale, IN 47025
Phone: 812-537-4852
Fax: 812-537-2382

The following products sold by Giles Chemical, a division of Premier Magnesia, LLC are certified Kosher with the listed restrictions.

Name	K-ID	Status		Restriction	Size
Epsom Salt (Magnesium Sulfate, Heptahydrate, Technical Grade)	TKJ-GSBC	Pareve	Passover	Ⓚ P SYMBOL	

This certificate is VALID UNTIL March 31, 2025

Verify authenticity by entering K-ID at www.digitalkosher.com

VAAD HAKASHRUS KOSHER CERTIFICATION

Powered by: K-ID DIGITALKOSHER.COM

The certification of the Certified Products is null and void if the sealed packaging of individual units is opened and/or if the Certified Products are served to customers in a retail store or food service establishment.

391 Troy Avenue, Brooklyn, New York 11213 U.S.A. • Tel: 718-756-7500 Fax: 718-756-7503 • E-Mail: info@ok.org

בס"ד

KOSHER CERTIFICATE

KC# 9245298 - 1
28 Shevat, 5784
February 7, 2024

KOSHER CERTIFICATION
Rabbi Don Yoel Levy OB"M
Kashruth Administrator 1987–2020

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Greendale, IN 47025
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Name	K-ID	Status		Restriction	Size
Epsom Salt (Magnesium Sulfate, Heptahydrate, USP)	GSL-HKFC	Pareve	Passover	Ⓚ P SYMBOL	

This certificate is VALID UNTIL March 31, 2025

Verify authenticity by entering K-ID at www.digitalkosher.com

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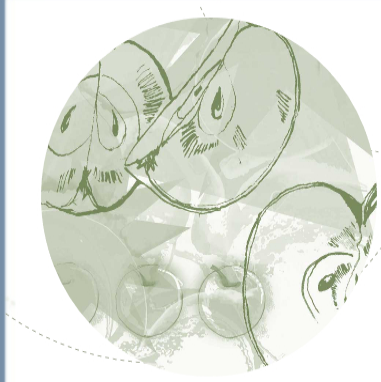


OMRI Listed®

The following product is OMRI Listed. It may be used in certified organic production or food processing and handling according to the USDA National Organic Program regulations.

Product

Magriculture Mg Magnesium Sulfate Heptahydrate Epsom Salt

Company

Giles Chemical, a Division of Premier Magnesia, LLC
John Laursen
PO Box 370
Waynesville NC 28786 United States

Status	Categories	Date Listed
Allowed with Restrictions	NOP: Magnesium Sulfate	25-Apr-2013

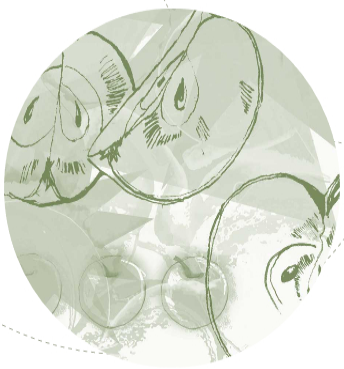
Product code	Use Class	Expiration
gcc-3863	Crop Fertilizers and Soil Amendments	1-Jun-2025

Restrictions

May be used as a plant or soil amendment if soil deficiency of magnesium is documented by testing.

Executive Director/CEO

Organic Materials Review Institute
P.O. Box 11558, Eugene, OR 97440-3758, USA
541.343.7600 · info@omri.org · OMRI.org



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Product

Magriculture Mg Magnesium Sulfate Heptahydrate Epsom Salt

Company

Giles Chemical, a Division of Premier Magnesia, LLC
John Laursen
PO Box 370
Waynesville NC 28786 United States

Status	Categories	Date Listed
Allowed	NOP: Magnesium Sulfate	8-Feb-2021

Product code	Use Class	Expiration
gcc-15356	Livestock Feed Ingredients	1-Jun-2025

Restrictions

Not applicable.

Executive Director/CEO

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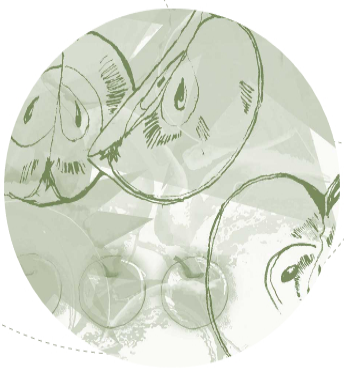

OMRI Listed®

The following product is OMRI Listed. It may be used in certified organic production or food processing and handling according to the USDA National Organic Program regulations.

Product

giles Epsom Salt Magnesium Sulfate, Heptahydrate, Technical Grade

Company

Giles Chemical, a Division of Premier Magnesia, LLC
John Laursen
PO Box 370
Waynesville NC 28786 United States

Status	Categories	Date Listed
Allowed	NOP: Magnesium Sulfate	18-Jan-2013

Product code	Use Class	Expiration
gcc-3669	Livestock Feed Ingredients	1-Jun-2025

Restrictions

Not applicable.

Executive Director/CEO

Product review is conducted according to the policies in the current *OMRI Policy Manual*© and based on the standards in the current *OMRI Standards Manual*©. This certificate may be out of date. Verify the current certficate online at OMRI.org, or contact OMRI for verification. OMRI listing is not equivalent to organic certification and is not a product endorsement, and cannot be construed as such. Final decisions on the acceptability of a product for use in a certified organic system are the responsibility of a USDA accredited certification agent. It is the operator's responsibility to properly use the product, including following any restrictions.

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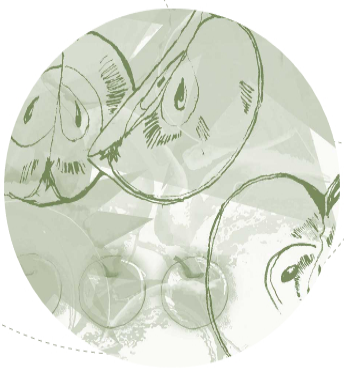

OMRI Listed®

The following product is OMRI Listed. It may be used in certified organic production or food processing and handling according to the USDA National Organic Program regulations.

Product

giles Epsom Salt Magnesium Sulfate, Heptahydrate, Technical Grade

Company

Giles Chemical, a Division of Premier Magnesia, LLC
John Laursen
PO Box 370
Waynesville NC 28786 United States

Status	Categories	Date Listed
Allowed with Restrictions	NOP: Magnesium Sulfate	27-Apr-2007

Product code	Use Class	Expiration
gcc-0769	Crop Fertilizers and Soil Amendments	1-Jun-2025

Restrictions

May be used as a plant or soil amendment if soil deficiency of magnesium is documented by testing.

Executive Director/CEO

Organic Materials Review Institute
P.O. Box 11558, Eugene, OR 97440-3758, USA
541.343.7600 · info@omri.org · OMRI.org

SAFETY DATA SHEET

Issue Date 17-February 2015
Revision Date 08-March 2021
Version 4

SECTION 1: Identification

Product identifier

Product Name **Epsom Salt, Magnesium Sulfate USP**

Other means of identification

Product Code Epsom Salt, Magnesium Sulfate, U.S.P.
Synonyms Magnesium Sulfate Heptahydrate USP

Recommended use of the chemical and restrictions on use

Recommended Use
Uses advised against No information available

Details of the supplier of the safety data sheet

Giles Chemical, a Division of Premier Magnesia, LLC, 75 Giles Place, Waynesville, NC 28786

Emergency telephone number

Company Phone Number 828-452-4784
24 Hour Emergency Phone Number Chemtrec 1-800-424-9300
Emergency Telephone Chemtrec 1-800-424-9300

SECTION 2. Hazard(s) identification

Classification GHS: Not classified EC: Not classified

Label elements Not Applicable

Hazards Summary: Spillages may be slippery. Dust may cause mild eye irritation. Ingestion may cause abdominal cramps and diarrhea.

SECTION 3. Composition / information on ingredients

Synonyms Magnesium sulfate heptahydrate, Epsom salts

Chemical Name	CAS No.	Weight-%	Trade Secret
Magnesium sulfate heptahydrate	10034-99-8	100	

SECTION 4. First aid measures

Eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Seek medical attention if irritation persists.

Skin contact: If irritation develops, seek medical attention.

Inhalation: Remove to fresh air. Administer oxygen if breathing is difficult. If breathing has stopped, give artificial respiration. Get medical attention immediately.

Ingestion: If large quantities of this material are swallowed, call a physician immediately. Do NOT induce vomiting unless directed to do so by a physician. Never give anything by mouth to an unconscious person.

Note to physicians Treat symptomatically.

5. Fire-fighting measures

Suitable extinguishing media
This material is compatible with all extinguishing media and standard firefighting techniques.

Unsuitable extinguishing media	None.

Specific hazards arising from the chemical
Oxides of sulfur may be generated during fire. Noncombustible

Protective equipment and precautions for firefighters
As in any fire, use self-contained breathing apparatus and suitable protective clothing.

SECTION 6. Accidental release measures

Personal precautions, protective equipment, and emergency procedures

Personal precautions	Wear goggles. If inhalation exposure potential is above local exposure limits, use appropriate respiratory protection for particulate, in accordance with prevailing regulatory requirements.

Environmental precautions

Environmental precautions	Sinks and mixes with water. No adverse effects known.

Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Sweep, scoop, or vacuum discharged material. Flush residue with water.

SECTION 7. Handling and storage

Precautions for safe handling

Advice on safe handling	Avoid generating dust. Promptly clean up spills. Material

Conditions for safe storage, including any incompatibilities

Storage Conditions	Keep containers closed and protected from extremes of temperature and humidity during storage. Material is not affected by impact.
Incompatible materials	Metal hydrides and other water reactive materials.

SECTION 8. Exposure controls / personal protection

Control parameters

Exposure Guidelines	ACGIH: Particulate not otherwise classified. TLV Inhalable: 10 mg/m3.TLV Respirable: 3 mg/m3. OSHA: PEL Total: 15mg/m3 Respirable: 5 mg/m3

Appropriate engineering controls

Engineering Controls	Ensure adequate ventilation. Ensure eye washes and safety showers are available.

Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses or chemical goggles.
Skin and body protection	Wear gloves if abrasion or irritation occurs.
Respiratory protection	Avoid inhalation of dust. Use suitable respiratory protection in accordance with requirements of 29 CFR 1910. 134, based on the level of exposure incurred.

General Hygiene Considerations Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Solid		
Appearance	Granular to fine granular	**Odor**	None
Color	White or transparent	**Odor threshold**	No information available

Property	**Values**	**Remarks • Method**
Ph	Approx. 6-7 at 5% w/w in water	
Melting point/freezing point	Melting point> 1000C	
Boiling point / boiling range	Not applicable	
Flash point	Not applicable	
Evaporation rate	Not applicable	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit:	No information available	
Lower flammability limit:	No information available	
Vapor pressure	Not applicable	
Vapor density	Not applicable	
Specific Gravity	1.76g/cm^3	
Water solubility	71g/100ml at 20° C 91g/100ml at 40° C	
Solubility in other solvents	No information available	
Partition coefficient	No information available	
Autoignition temperature	No information available	
Decomposition temperature	No information available	
Kinematic viscosity	No information available	
Dynamic viscosity	No information available	
Explosive properties	No information available	
Oxidizing properties	No information available	

Other Information

Softening point	No information available
Molecular weight	No information available
VOC Content (%)	No information available
Density	No information available
Bulk density	55-58 lb/ft3

SECTION 10. Stability and reactivity

Reactivity
No data available

Chemical stability
Stable under recommended storage conditions.

Possibility of Hazardous Reactions
None under normal processing.

Conditions to avoid
Extremes of temperature and direct sunlight.

Incompatible materials
Metal hydrides and other water reactive materials.

Hazardous Decomposition Products
At very high temperatures, magnesium oxide, sulfur dioxide and sulfur trioxide may be generated.

SECTION 11. Toxicological information

Information on likely routes of exposure

Product Information No data available

Inhalation No data available.

Eye contact Dust may be irritating to eyes

Skin Contact No data available.

Ingestion RTECS: Oral LDlo 428mg/kg in man; 351 mg/kg in woman

Information on toxicological effects

Symptoms No information available.

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

Sensitization No information available.
Germ cell mutagenicity No information available.
Carcinogenicity Not listed by IARC, NTP, or OSHA
Reproductive toxicity No information available.
STOT - single exposure Not classified
STOT - repeated exposure Not classified
Aspiration hazard No information available.

SECTION 12. Ecological information

Ecotoxicity Not classified as PBT vPvB

Persistence and degradability
No information available.

Bioaccumulation
Material does not bioaccumulate.

Mobility
Sinks and mixes with water.

Other adverse effects No information available

SECTION 13. Disposal considerations

Waste treatment methods

Disposal of wastes This product does not exhibit any characteristics of a hazardous waste. Follow all applicable federal, state, and local regulations for safe disposal.

Contaminated packaging Do not reuse container.

SECTION 14. Transport information

DOT Not regulated by DOT as a hazardous material. No hazard class, label or placard required, no UN or NA number assigned.

SECTION 15. Regulatory information

International Inventories

TSCA Listed as magnesium sulfate
DSL/NDSL Listed
EINECS/ELINCS 231-298-2
ENCS Listed
IECSC Listed

KECL	Listed
PICCS	Listed
AICS	Listed

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories HNOC- ingestion may cause gastrointestinal upset

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

US State Regulations

California Proposition 65

This product does not require a Proposition 65 warning statement.

U.S. EPA Label Information

EPA Pesticide Registration Number	Not Applicable

SECTION 16. Other information

NFPA	**Health hazards** 1	**Flammability** 0	**Instability** 0	**Specific hazards**
HMIS	**Health hazards** 1	**Flammability** 0	**Physical hazards** 0	**Personal protection** X

Issue Date	17-February 2019
Revision Date	08- March 2021
Revision Note	Format update

Disclaimer

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

End of Safety Data Sheet

PREMIER MAGNESIA, LLC

PRODUCT SPECIFICATIONS
MAGNESIUM SULFATE CRYSTALS, USP
2024

CHARACTERISTICS

The material shall be colorless, solid at ambient temperatures, formed in small needle-like rhombic crystals and free of solid or fibrous foreign matter that will require the dissolved material to be filtered before being used.
Epsom salt is one of the most common forms of magnesium sulfate heptahydrate. EPSOM SALT is a hydrated salt with seven molecules of water, so caking or bridging can occur. Care should be taken to protect the material if it is stored in the granular form for long periods of time. EPSOM SALT is readily soluble in water.

PROPERTIES	Identification	Test of Magnesium	Positive
		Test of Sulfate	Positive
		Consistently Free of Volatile Organic Impurities	
	Chemical	pH	5.0 – 9.2
		Loss of ignition	40.0% - 52.0%
		Chloride, maximum, ppm	140
		Arsenic, maximum, ppm	3
		Heavy Metals, maximum, ppm	10
		Iron, maximum, ppm	20
		Selenium, maximum, ppm	30
		Assay	99%–100.5%
	Physical	Color	Colorless
		Crystal Form	Rhombic (monoclinic)

QUALITY ASSURANCE PROVISION

GENERAL:
The material specified herein shall be manufactured using acceptable industrial practices.
The material shall be guaranteed to meet chemical and physical properties specified herein.

RESPONSIBILITIES FOR TESTS & INSPECTIONS:
Unless otherwise specified by purchaser, the supplier is responsible for providing a lot analysis on the material. Except as otherwise specified, the supplier may utilize his own facilities or any commercial laboratory. Analysis' are available for each lot at an additional charge.

PACKAGING & SHIPPING

PACKAGING:
Shall be accomplished in accordance with acceptable commercial practices for domestic or foreign shipments unless otherwise indicated by the purchaser. It shall be the vendor's responsibility to determine that packaging, as done, is adequate to assure that all materials shall arrive at destination in an uncontaminated condition and ready for intended use.

SHIPPING:
Shall be accomplished in accordance with acceptable commercial practices for domestic or foreign shipment for this type of product unless otherwise indicated by the purchaser.

PRODUCERS OF MAGNESIUM SULFATE SINCE 1950
USA
102 Commerce Street • Waynesville, North Carolina 28786 • Tel 828-452-4784 • Fax 828-452-4786
142 Giles Place • Waynesville, North Carolina 28786 • Tel 828-452-4784 • Fax 828-452-4786
200 Brown Street • Greendale, Indiana 47025 • Tel 812-537-4852 • Fax 812-537-2382

PREMIER MAGNESIA, LLC

Product Specification For: Magnesium Sulfate Crystals, Tech 2024

CHARACTERISTICS

The material shall be colorless, solid at ambient temperatures, formed in small needle-like rhombic crystals and free of solid or fibrous foreign matter that will require the dissolved material to be filtered before being used.

Epsom salt is one of the most common forms of magnesium sulfate heptahydrate. EPSOM SALT is a hydrated salt with seven molecules of water, so caking or bridging can occur. Care should be taken to protect the material if it is stored in the granular form for long periods of time. EPSOM SALT is readily soluble in water and will yield a saturated 24.5 percent solution of magnesium sulfate at storage temperatures of 66 – 75 degrees F.

PROPERTIES	Identification	Test of Magnesium	Positive
		Test of Sulfate	Positive
	Chemical	pH	5.0 – 9.2
		Loss of ignition	40.0% - 52.0%
		Chloride, maximum, ppm	200
		Heavy Metals (as Pb), maximum, ppm	10
		Iron, maximum, ppm	20
		Selenium, maximum, ppm	30
		Assay	99%–100.5%
	Physical	Color	Colorless
		Crystal Form	Small; White

QUALITY ASSURANCE PROVISION

GENERAL:

Magnesium Sulfate Crystals shall be manufactured using current Good Manufacturing Practices (cGMP).
The material shall be guaranteed to meet chemical and physical properties specified herein, and said material is free from all Class I, II and III residual solvents as listed by the ICH Q3C guidance.

RESPONSIBILITIES FOR TESTS & INSPECTIONS:

Unless otherwise specified by purchaser, the supplier is responsible for providing a lot analysis on the material. Except as otherwise specified, the supplier may utilize his own facilities or any commercial laboratory. Analysis' are available for each lot at an additional charge.

PACKAGING & SHIPPING

PACKAGING:

Shall be accomplished in accordance with acceptable commercial practices for domestic or foreign shipments unless otherwise indicated by the purchaser. It shall be the vendor's responsibility to determine that packaging, as done, is adequate to assure that all materials shall arrive at destination in an uncontaminated condition and ready for intended use.

SHIPPING:

Shall be accomplished in accordance with acceptable commercial practices for domestic or foreign shipment for this type of product unless otherwise indicated by the purchaser.

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MAGRICULTURE® SPECIFICATIONS FOR MAGNESIUM SULFATE CRYSTALS *FEED & AGRICULTURAL USAGE* 2024

Characteristics:

MAGRICULTURE® Magnesium Sulfate Crystals shall be colorless, solid at ambient temperatures, formed in small needle-like rhombic crystals and free of solid or fibrous foreign matter that will require dissolved material to be filtered before being used.

PROPERTIES	Identification	Test of Magnesium	Positive
		Test of Sulfate	Positive
		Consistently Free of Volatile Organic Impurities	
	Chemical	pH	5.0 – 9.2
		Loss of ignition	40.0% - 52.0%
		Chloride, maximum, ppm	200
		Arsenic, maximum, ppm	3
		Heavy Metals (as Pb), maximum, ppm	10
		Iron, maximum, ppm	20
		Selenium, maximum, ppm	30
		Assay	99%–100.5%
	Physical	Color	Colorless
		Crystal Form	Rhombic (monoclinic)

Quality Assurance Provision:

GENERAL

MAGRICULTURE® Magnesium Sulfate Crystals shall be manufactured using current Good Manufacturing Practices (cGMP).
MAGRICULTURE® Magnesium Sulfate Crystals shall be guaranteed to meet the chemical and physical properties specified herein.

Characteristics Discussion

EPSOM SALT is one of the most common forms of magnesium sulfate. EPSOM SALT is a hydrated salt with seven molecules of water, so caking can occur. Therefore, care should be taken to protect the material if it is stored in the granular form for long periods of time. EPSOM SALT is readily soluble in water and will yield a saturated 24.5 percent solution of magnesium sulfate at storage temperatures of 66 - 75 degrees F.

PRODUCERS OF MAGNESIUM SULFATE SINCE 1950
USA
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142 Giles Place • Waynesville, North Carolina 28786 • Tel 828-452-4784 • Fax 828-452-4786
200 Brown Street • Greendale, Indiana 47025 • Tel 812-537-4852 • Fax 812-537-2382

Giles Chemical, a division of Premier Magnesia, LLC.
200 Brown St. Greendale, IN 47025
Phone: (812) 537-4852

USP Certificate of Analysis

Release Date: _____

CUSTOMER : _____

CUST. REF: _____ SHIP DATE: _____

PRODUCT: Magnesium Sulfate - **USP** TRAILER NUMBER: _____

SHELF LIFE: 3 Years BILL OF LADING #: _____

LOT NUMBER: _____ PO NUMBER #: _____

CARRIER: _____ MANUFACTURED: _____

CUST. CONTACT: _____ EXPIRATION: _____

I certify that this material meets all the requirements of the Giles Chemical sales specifications and the United States Pharmacopeia. Periodic testing has shown the samples to be consistently free of volatile organic impurities. Giles Chemical magnesium sulfate is manufactured under the guidelines of Current Good Manufacturing Practices (cGMP).

EPSOM SALT, Magnesium Sulfate - Heptahydrate, USP

METHOD	TEST	LOWER	UPPER	Test Results
VISUAL	Appearance	~~	~~	
USP 43	Limit of Chloride <221>	~~	140 ppm	
USP 43	Limit of Iron <241>	~~	20 ppm	
USP 43	Selenium <291>	~~	30 ppm	
USP 43	Heavy Metals (as Pb) <231>	~~	10 ppm	
USP 43	pH (5% Solution) <791>	5.0	9.2	
USP 43	Loss on Ignition <733>	40.0	52.0	
USP 43	Assay, % $MgSO_4$ (Dry Basis)	99.0	100.5	
Calculated from Assay & LOI	% $MgSO_4$ (As is Basis)	47.52	60.3	
USP 43	ID, Magnesium <191>	~~	~~	
USP 43	ID, Sulfate <191>	~~	~~	

CONTACT: ANALYST:

Quality Assurance Laboratory SIGNATURE ON FILE

The United States-Mexico-Canada Agreement

Certificate of Origin

1. **Certified by**			2. **Certificate Usage**	
Importer	Exporter	Producer	Blanket Period (mm/dd/yyyy)	Single Use
		✓	FROM: 1/1/2024	Invoice #:
			TO: 12/31/2024	Inv. Date:

3. **Certifier:**	4. **Importer/Buyer:**

5. **Exporter/Seller:**	6. **Producer:**
	Premier Magnesia LLC 75 Giles Place Waynesville, Nc 28786

7. Part ID	Customer Part ID	Description of Goods	8. HS Number	9. Country of Origin	10. Origin Criterion
		Magnesium Sulfate Heptahydrate Tech	2833.21.0000	USA	C
		Epsom Salt USP	2833.21.0000	USA	C

I CERTIFY THAT

** I certify that the goods described in this document qualify as originating and the information contained in this document is true and accurate. I assume responsibility for proving such representations and agree to maintain and present upon request or to make available during a verification visit, documentation necessary to support this certification.*

THIS CERTIFICATES CONSIST OF 1 **PAGES, INCLUDING ALL ATTACHMENTS**

11a. AUTHORIZED SIGNATURE	11b. COMPANY
Lisa Hefner	Premier Magnesia LLC
11c. NAME Lisa Hefner	11d. TITLE Customer/Regulatory Support Specialist I

11e. DATE (mm/dd/yyyy)	11f. TELEPHONE NUMBERS	11g. EMAIL
11/7/2023	Voice: 828-452-4784 x.647	lhefner@premiermagnesia.com

November 21, 2023

Subject: Magnesium Sulfate Heptahydrate (Epsom Salt)

This letter is to inform you that the Epsom Salt (Magnesium Sulfate, Heptahydrate USP, CAS# 10034-99-8), supplied from Premier Magnesia, LLC, is not expected to contain nor is manufactured with substances listed on CA Proposition 65 List of chemicals. Moreover, the final Epsom Salt product does not fall within any of the categories listed in the CA Senate Bill 484. The definitions for chemicals "identified as causing cancer or reproductive toxicity" within the bill are:

a) Listed as known or reasonably anticipated to be a human carcinogen in a National Toxicology Report on carcinogens.
b) Given an overall carcinogenicity evaluation of Group 1, Group 2A, or Group 2B by the International Agency for Research on Cancer (IARC).
c) Identified as a Group A, Group B1, or Group B2 carcinogen, or as a known or likely carcinogen by the United States Environmental Protection Agency (EPA).
d) Identified as having some or clear evidence of adverse developmental, male reproductive, or female reproductive toxicity effects in a report by an expert panel of the National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction.

Our Epsom salt product is manufactured by reaction and subsequent crystallization of water, Magnesium Oxide and Sulfuric acid only.

Please contact me at the email below if you need additional information.

Sincerely,

John Laursen
Quality Manager

75 Giles Place
Waynesville, NC 28786
Email: jlaursen@premiermagnesia.com
(o) 828-452-4784 ext. 681
(c): 828-734-3561
www.premiermagnesia.com

March 19, 2024

Subject: PFAS, Pthalates and Hexavalent Chromium
RE: Chemical Name: Magnesium Sulfate Heptahydrate

To whom it may concern,

This letter is to inform you that the Epsom Salt (Magnesium Sulfate, Heptahydrate USP), supplied from Premier Magnesia, LLC, is not expected to contain nor is manufactured with the substances listed here:

1. Perfluoroalkyl and Polyfluoroalykyl substances
2. Phthalates (General class of compounds)
3. Hexavalent Chromium Cr(VI)

The Epsom Salt product is manufactured by reaction of water, Magnesium Oxide and Sulfuric acid only (Equation: $H_2SO_4+MgO_{(aq)}\rightarrow H_2O+MgSO_4* 7H_2O$). Our Epsom salt production process is a closed system process that does not inherently include or intentionally introduce the above listed substances and is an inorganic chemical reaction with no additional products. Moreover, our production facilities do not produce any measurable amounts of these substances (particularly Cr(VI)) during normal operations.

The Epsom Salt provided is packaged in either 2000LB Super Sacks or 50LB sealed bags. The constituent materials for these are free of and do not contain perfluoroalkyl and/or polyfluoroalkyl substances (PFAS).

However, it should be noted, that it is not identified in the current USP monograph to quantify these contaminants at a particular trace level. Therefore it is assumed the end user will inspect all material received for their specific use and regulatory requirements.

Sincerely,

John Laursen
Director of Quality

235 Lea Plant Rd
Waynesville, NC 28786
O: 828-452-4784 ext. 681
C: 828-734-3561
jlaursen@premiermagnesia.com

September 2023

Supplier Traceability Exercise Statement

Chemical Name: Magnesium Sulfate Heptahydrate, USP

To whom it may concern,

Standard Operating Procedure MOCK-100-001: Recall-Withdrawal Procedure defined in our Quality Management System as a Common Practice which applies to our Manufacturing and Repackaging facilities assures traceability from Raw Materials used through Finished Goods reporting.

Annual Product Recall-Withdrawal (Mock Recall Exercises) as defined, implemented, and reported per MOCK-100-001 indicate clear objectives: To stop distribution and sale of affected finished product while also assuring effective notification to Customers, Regulatory Authorities (i.e., FDA, HPFB CAN), and Senior Management, and efficiently removing and/or disposing of affected finished product from the marketplace and warehouses and/or distribution areas.

Annual Mock Recall Exercises ensure trace forward and trace backward of finished products, in a required timeframe and to achieve 99.5%-101.5% recovery. Senior Management is debriefed upon completion of the exercise to report Mock Recall performance and, if necessary, any specific Corrective Actions identified to ensure percent recovery and timeframe criteria are met.

John Laursen
Quality Manager

235 Lea Plant Rd
Waynesville, NC 28786
Email: jlaursen@premiermagnesia.com
(o) 828-452-4784 ext. 681
www.premiermagnesia.com

February 2024

Subject: Country of Manufacture & Customs Classification

1. Country of Manufacture: USA

2. Customs Classification (HS Code- 6 digit): 2833.21

3. U.S. HTS number: 2833.21.00.00

4. Indicate % U.S. content (% value considering materials, direct labor & overhead as per the FTC's Made in USA standard): 100%

5. Country of origin/manufacture of the raw materials used to make the ingredient: USA

6. CAS #: 10034-99-8

7. INCI Name: Magnesium Sulfate Heptahydrate

8. IUPAC Name: Magnesium Sulfate Heptahydrate

If you have any other questions, please do not hesitate to contact me.

Sincerely,

John Laursen
Director of Quality
235 Lea Plant Rd
Waynesville, NC 28786
Email: jlaursen@premiermagnesia.com
(o) 828-452-4784 ext. 681
www.premiermagnesia.com

July 2023

Subject: Magnesium Sulfate Heptahydrate (Epsom Salt)

To whom it may concern,

This letter is to inform you that Epsom Salt (Magnesium Sulfate, Heptahydrate USP), supplied from Premier Magnesia, LLC, has not (nor is intended to) had animal testing conducted on the raw material or the component ingredients. Premier Magnesia LLC has also not commissioned or been party to animal testing of our product by a third party.

Please contact me at the email below if you need additional information.

Sincerely,

John Laursen
Quality Manager
75 Giles Place
Waynesville, NC 28786
O: 828-452-4784 ext. 681
C: 828-734-3561
jlaursen@premiermagnesia.com

April 13, 2024

Subject: Elemental Impurities
RE: Magnesium Sulfate Heptahydrate

To whom it may concern,

Epsom Salt (Magnesium Sulfate Heptahydrate, CAS# 10034-99-8), supplied from Premier Magnesia, LLC, has been assessed for Elemental Impurities as identified in Table 3 of USP <232> Elemental Impurites-Limits for Oral-dose, Non-parenteral drug product. The current USP monograph identifies for the testing of the following Impurities; Chloride, Iron and Selenium. Premier Magnesia also performs testing for Lead via inclusion in the method for the above elements by way of ICP-OES analysis.

The Epsom Salt product is manufactured by reaction of water, Magnesium Oxide and Sulfuric acid only (Equation: $H_2SO_4+MgO_{(aq)}\rightarrow H_2O+MgSO_4*\ 7H_2O$). Raw materials are tested for impurites as well and CoAs are on record. Moreover, the Epsom salt produced at all manufacturing facilites undergoes regular expanded elemental impurity analysis (<232> Table 3 + Fe, Ca, Cl) by an independent 3rd party, ISO certified, laboratory.

For those customers of Premier utilizing the Epsom Salt as an API, should note, that any Class 1, 2A, 2B and 3 elements, not identified in the current USP monograph as impurites, should be assessed by that end user, for that finished product's specific use and regulatory requirements.

Sincerely,

John Laursen
Director of Quality

235 Lea Plant Rd
Waynesville, NC 28786
O: 828-452-4784 ext. 681
C: 828-734-3561
jlaursen@premiermagnesia.com

October 12, 2023

Subject: Microplastics Free Statement
Chemical Name: Magnesium Sulfate Heptahydrate

To whom it may concern,

This letter is to inform you that the Epsom Salt (Magnesium Sulfate, Heptahydrate USP), supplied from Premier Magnesia, LLC, is not expected to contain nor is manufactured with the substances listed here:

1. Microplastics or Microplastic Beads

The Epsom Salt product is manufactured by reaction of water, Magnesium Oxide and Sulfuric acid only. The additives listed above are not a component of the final product. Our Epsom salt production process is a closed system with no intentional or incidental exposure to microplastics.

Sincerely,

John Laursen

Quality Manager

235 Lea Plant Rd
Waynesville, NC 28786
Email: jlaursen@premiermagnesia.com
(o) 828-452-4784 ext. 681
www.premiermagnesia.com

February 2023

HALAL - ISA Statement

Chemical Name: Magnesium Sulfate

To whom it may concern,

Magnesium Sulfate (Epsom Salt) as manufactured by Giles Chemical at our Waynesville, NC, and Greendale, IN manufacturing facilities is produced in a "Closed System" and begins by neutralizing Magnesium bearing ore with Sulfuric Acid, and Water is added to the manufacturing process, after which these ingredients go through a reactive synthetic process which results in producing a pure crystal material Magnesium Sulfate (Epsom Salt).

To the above this HALAL - ISA Statement serves as confirmation that above ingredients / products do not contain any substances and/or processing aids that are forbidden according to Islamic Law.

Additionally, we confirm that above ingredients / products do not contain any of the following:

- No animal products or by-products are used as a raw material in the manufacture of magnesium sulfate or present in the final product.
- No pork or pork derivatives are used as a raw material in the manufacture of magnesium sulfate or present in the final product.
- No blood or blood (by-products) or derivatives thereof are used as a raw material in the manufacture of magnesium sulfate or present in the final product.
- No Drinking alcohol such as beer, wine, liquor is used in the manufacture of magnesium sulfate and are not present in the final product.
- No ethyl alcohol has been added as an ingredient or used in the manufacturing process of magnesium sulfate, and there is no ethyl alcohol present in the final product.

Regards,
Pete Schingen

Quality Assurance Manager
Giles Chemical, Div. of Premier Magnesia, LLC
pschingen@gileschemical.com
Tel: (828) 452-4784 ext. 633

January 2023

Re: Letter of Continuing Guarantee

To Whom It May Concern,

The Epsom salt comprising each shipment, or other delivery, hereafter to be made or distributed by Giles Chemical, a Division of Premier Magnesia, LLC are hereby guaranteed at the time of such shipment or delivery to be:

Not adulterated or misbranded within the meaning of the Federal Foods, Drug and Cosmetic Act or the laws of any of the states of the United States to the extent that such laws are then effective and applicable (including but not limited to the Federal Foods, Drug and Cosmetic Act) and that none of the said goods are articles which may not, under the provisions of Sections 404 or 505 of the Federal Food, Drug and Cosmetic Act, be introduced into instate commerce:

Not adulterated or misbranded with the meaning of the terms of the Federal Insecticide, Fungicide or Rodenticide Act, the Federal Hazardous Substances Labeling Act, the State Pure Foods Act or any applicable federal, state, or local law:

Not misbranded within the meaning of any federal, state, or local law when bearing labels furnished by the buyer in accordance with FDA instructions furnished by the buyer.

All operations in receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing said goods were conducted using Good Manufacturing Practices and in accordance with the FDA regulations including 21 CFR 110.80, 21 CFR 111, and 21 CFR 507.31

The guarantee is continuing and shall be in full force and effect until revoked in writing.

Pete Schingen

Pete Schingen
Quality Assurance Manager
Giles Chemical, Div. of Premier Magnesia, LLC

February 2023

Microbiological – Inorganic Statement

Chemical Name: Magnesium Sulfate Heptahydrate (Epsom Salt) USP Grade Material

To whom it may concern,

Magnesium Sulfate Heptahydrate (Epsom Salt) USP Grade material is an inorganic substance, which has inherent anti-microbiological properties, and is manufactured utilizing three components: Magnesium bearing ore, Sulfuric Acid, and Water.

Magnesium bearing ore as mined and received from our magnesium mining operations "is not" derived from any organic ingredients such as plant, fungi, or bacterial components. Said Magnesium Sulfate Heptahydrate (Epsom Salt) USP Grade Material as manufactured by Giles Chemical is produced in a "Closed System" and begins by neutralizing Magnesium bearing ore with Sulfuric Acid, and Water is added to the manufacturing process.

It is after this manufacturing process step i.e., synthetic process step that any presence of organics such as bacteria, molds, yeasts, mycotoxins, aflatoxins, and dioxins is virtually non-existent. Upon completion of this synthetic process step the material is filtered and then crystallized to produce a very pure salt.

Based upon said 3rd Party Microbial Test Reporting it has been determined that Annual Microbial Testing shall be the defined method for purposes of addressing FDA-2021-D-0432-0002 Regulatory Guidance concerning; Microbial Quality Considerations in Non-Sterile Drug Manufacturing "Guidance for Industry", and Elemental Impurities Analysis.

Regards,
Pete Schingen

Quality Assurance Manager
Giles Chemical, Div. of Premier Magnesia, LLC
pschingen@gileschemical.com
Tel: (828) 452-4784 ext. 633

March 1, 2023

Pesticide Statement

Giles Chemical is an FDA registered facility and any chemical used in the production areas are listed with, and used in accordance with, the U.S. Federal Insecticide, Fungicide and Rodenticide Act. No pesticides are kept on the premises, as pest control services are provided by a registered Pest Management Company. Only low odor, no odor, or organic products are used.

Pete Schingen

Pete Schingen
Quality Assurance Manager
Giles Chemical, Div. of Premier Magnesia, LLC
pschingen@gileschemical.com
Tel: (828) 4524784

January 2023

Batch / Lot Code Statement

Chemical Name: Magnesium Sulfate

To whom it may concern,

As of December 2022, Batch / Lot Codes for finished goods as produced by Premier Magnesia manufacturing facilities shall be denoted as follows:

Batch-Lot Number Assignment-Use Process: Lot & Batch Numbers are assigned to Bulk "finished goods" and are updated annually. Said Lot & Batch Numbers denote specific year in which said "finished goods" were produced. A "new" Lot & Batch is generated and implemented for use "post" Annual Plant shut down operations at our Bulk Manufacturing facilities. Said Annual Plant shut down operations typically occur each September. However, each Bulk Mfg. facility may coordinate-schedule Annual Plant shut down operations depending upon finished goods demand.

Batch-Lot Number Designation (for each Bulk Mfg. Facility): With inclusion of latest Hazelwood Bulk manufacturing facility the following Lot & Batch Numbering designations have been identified and agreed upon for use by Operations-Quality Mgmt. Said Lot & Batch Numbering designations shall be used by Bulk Mfg. facilities for purposes of "finished goods" traceability and "positive recall".

Lot & Batch numbers for Bulk Plants shall now appear as 8-digit codes instead of 6-digit codes. Each plant shall have its own two digit "Plant Code" which will appear before the six-digit lot number. Plant codes are as follows:

Greendale Bulk: 77 Waynesville Bulk: 88 Hazelwood Bulk: 99

All Bulk Plant Lot Numbers shall now appear as follows: 2-digit Plant Code, 4-digit Lot with Batch Number, and 2-digit Affirmation Number.

- Greendale Bulk: 77012301 **Plant Code** [77] **Lot w/Batch Number** [0123] **Affirmation Number** [01]
- Waynesville Bulk: 88012301 **Plant Code** [88] **Lot w/Batch Number** [0123] **Affirmation Number** [01]
- Hazelwood Bulk: 99012301 **Plant Code** [99] **Lot w/Batch Number** [0123] **Affirmation Number** [01]

Documentation – In Batch Records & On Samples: Affirmation Number may be hyphenated as is current practice.

Examples: Greendale 770123-01, Waynesville 880123-01, Hazelwood 990723-01.

Regards,
Pete Schingen

Quality Assurance Manager
Giles Chemical, Div. of Premier Magnesia, LLC
pschingen@gileschemical.com
Tel: (828) 452-4784 ext. 633

February 2023

Allergen Statement

Chemical Name: Magnesium Sulfate

To whom it may concern,

Giles Chemical, a Div. of Premier Magnesia, LLC. guarantees that Magnesium Sulfate Heptahydrate does not contain any allergens as outlined in the Food Allergen Labeling and Consumer Protection Act (FALCPA) and the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act which declared sesame as the 9th major food allergen.

Our Magnesium Sulfate contains two raw materials, Sulfuric Acid and Magnesium Oxide, in which have no potential for contamination of allergens in our USP or Technical Grade Product due to the nature of our chemical process. Also, Epsom Salt is the only product produced in our facilities, so there is also no potential for cross-contamination.

Regards,
Pete Schingen

Quality Assurance Manager
Giles Chemical, Div. of Premier Magnesia, LLC
pschingen@gileschemical.com

November 2022

Statement Concerning: DSL Listing
Chemical Name: EPSOM SALT HEPTAHYDRATE

To whom it may concern,

EPSOM SALT HEPTAHYDRATE as produced by Premier Magnesia "is listed" on the DSL and is "not listed" on the NDSL.

Additionally:

- Not on the Priority Substance List 1 or 2
- Not on the Toxic Substance List
- Not on the Export Control List

EPSOM SALT HEPTAHYDRATE as produced by Premier Magnesia complies with specific listing information associated with and in regard to: CAN/CGSB-32.311-2020

- 4.2 Permitted for Crop Production
- 5.3 Permitted for Livestock Production
- 6.3 Permitted Food Additive
- 7.3 Permitted for Cleaners, Disinfectants and Sanitizers

Any additional and/or further information concerning DSL Listing can be directed to Premier Magnesia Sr. Management.

Pete Schingen

Quality Assurance Manager
Giles Chemical, Div. of Premier Magnesia, LLC
pschingen@gileschemical.com
Tel: (828) 452-4784 ext. 633

August 2022

Shelf-Life Statement

Giles Chemical guarantees a shelf life of three years, from date of manufacture, for our Magnesium Sulfate Heptahydrate USP Grade product.

If you have any questions, please feel free to contact me.

Pete Schingen

Pete Schingen
Quality Assurance Manager
Giles Chemical, Div. of Premier Magnesia, LLC
pschingen@gileschemical.com
Tel: (828) 4524784

August 2022

RE: (USP) Magnesium Sulfate Heptahydrate – CCPs Statement

Magnesium Sulfate Heptahydrate, as manufactured at both our Waynesville and Greendale facilities is manufactured in a "closed loop" system environment and produced in accordance with Current Good Manufacturing Practices (cGMP) as outlined by the FDA (reference 21 CFR 210-211).

Each facility has completed Failure Modes and Effects Analysis (FMEA) Risk Assessments and the risk assessment process indicated identification of Critical Control Points was not necessary.

Regards,

Pete Schingen

Pete Schingen
Quality Assurance Manager
Giles Chemical, Div. of Premier Magnesia,

August 2022

Food Defense Plan Statement

Magnesium Sulfate Heptahydrate (Epson Salt) as produced at our Waynesville, NC and Greendale IN manufacturing facilities has in place a "Common Practice" Standard Operating Procedure; FFP-100-001 entitled "Food Fraud Prevention Plan" which assures prevention of unauthorized access by people or entry of unapproved materials where Magnesium Sulfate Heptahydrate (Epson Salt) is manufactured.

Said Standard Operating Procedure defines overall security measures for site, shipping, receiving, and raw materials indicating specific procedural elements needed to ensure proper security and defense measures are in place to protect materials and/or product from malicious attacks that would adulterate the finished product.

Regards,

Pete Schingen
Quality Manager
Giles Chemical, Div. of Premier Magnesia, LLC
pschingen@gileschemical.com
Tel: (828) 452-4784 ext.633

March 2023

GMO Statement

Chemical Name: Magnesium Sulfate

To whom it may concern,

Magnesium Sulfate (Epsom Salt) as manufactured by Giles Chemical Waynesville, NC, and Greendale, IN manufacturing facilities does not contain genetically modified organisms in accordance with EC regulations 1829/2003 and 1830/2003 as well as the Directive 2001/18/EC and does not require additional labelling in relation to the presence or use of GMO.

Regards,
Pete Schingen

Quality Assurance Manager
Giles Chemical, Div. of Premier Magnesia, LLC
pschingen@gileschemical.com
Tel: (828) 452-4784 ext. 633

August 2022

CONFLICT MINERALS STATEMENT

For purposes of this statement, "Covered Countries" means the Democratic Republic of Congo (the "DRC") and any country that shares an internationally recognized border with the DRC, which presently includes Angola, Burundi, Central African Republic, the Republic of the Congo, Rwanda, South Sudan, Tanzania, Uganda, and Zambia.

Giles Chemical hereby declares that material supplied is "DRC conflict free" as that term is defined in the "conflict minerals" laws for the following reason(s) (please select all that apply):

- ☒ The products and/or materials do not contain or utilize gold, tantalum, tin or tungsten or related minerals covered by the "conflict minerals" laws (collectively, the "minerals").
- ☐ For any products and/or materials that contain or utilize the minerals, the minerals specifically used did not originate from any of the Covered Countries. Supplier has implemented reasonable procedures to identify and monitor the country of origin of products and/or materials that contain or utilize the minerals.
- ☐ The materials that contain or utilize contain or utilize gold, tantalum, tin or tungsten are 100% from recycled or scrap sources.

Pete Schingen

Pete Schingen
Quality Manager
Giles Chemical, Div. of Premier, LLC

LETTER OF CONFORMANCE

Magnesium Sulfate Heptahydrate (MgSO4-7H2O, CAS 10034-99-8) is listed on the FDA GRAS "Generally Recognized as Safe" registry in accordance with 21 CFR 184 Direct Food Substances Affirmed as Generally Recognized As Safe. Therefore, Magnesium Sulfate Heptahydrate may be safely used as a component of the uncoated or coated food-contact surface of paper and paperboard intended for use in producing, manufacturing, packaging, processing, preparing, treating, packing, transporting, or holding aqueous, fatty and dry foods complying with 21 CFR 176.170 and 21 CFR 176.180.

Magnesium Sulfate Solution (MgSO4, CAS 7487-88-9, H2O 7732-18-5) meets modified testing requirements equivalent to the tests required for the crystal (heptahydrate) form of magnesium sulfate as listed in the Food Chemicals Codex (FCC). Currently there is not a FCC listing for liquid magnesium sulfate. Therefore, Magnesium Sulfate Solution, by inference, may be safely used as a component of the food-contact surface of paper and paperboard.

Best Regards,

Pete Schingen

Pete Schingen
Quality Manager
Giles Chemical, Div. of Premier Magnesia, LLC

August 2022

RE: Residual Solvents – USP Grade Magnesium Sulfate, Heptahydrate

This letter is to inform you that the Magnesium Sulfate, Heptahydrate manufactured at *200 Brown Street, Greendale IN* and *102 Commerce Street, Waynesville NC* does not utilize the described residual solvents in the manufacturing process nor does the product exceed the limits described in the ICH Q3C or USP Chapter <467> for Class I, II, III or Other Residual Solvents.

Regards,

Pete Schingen

Pete Schingen
Quality Manager
Giles Chemical, Div. of Premier Magnesia, LLC
pschingen@gileschemical.com
Tel: (828) 452-4784 ext.33

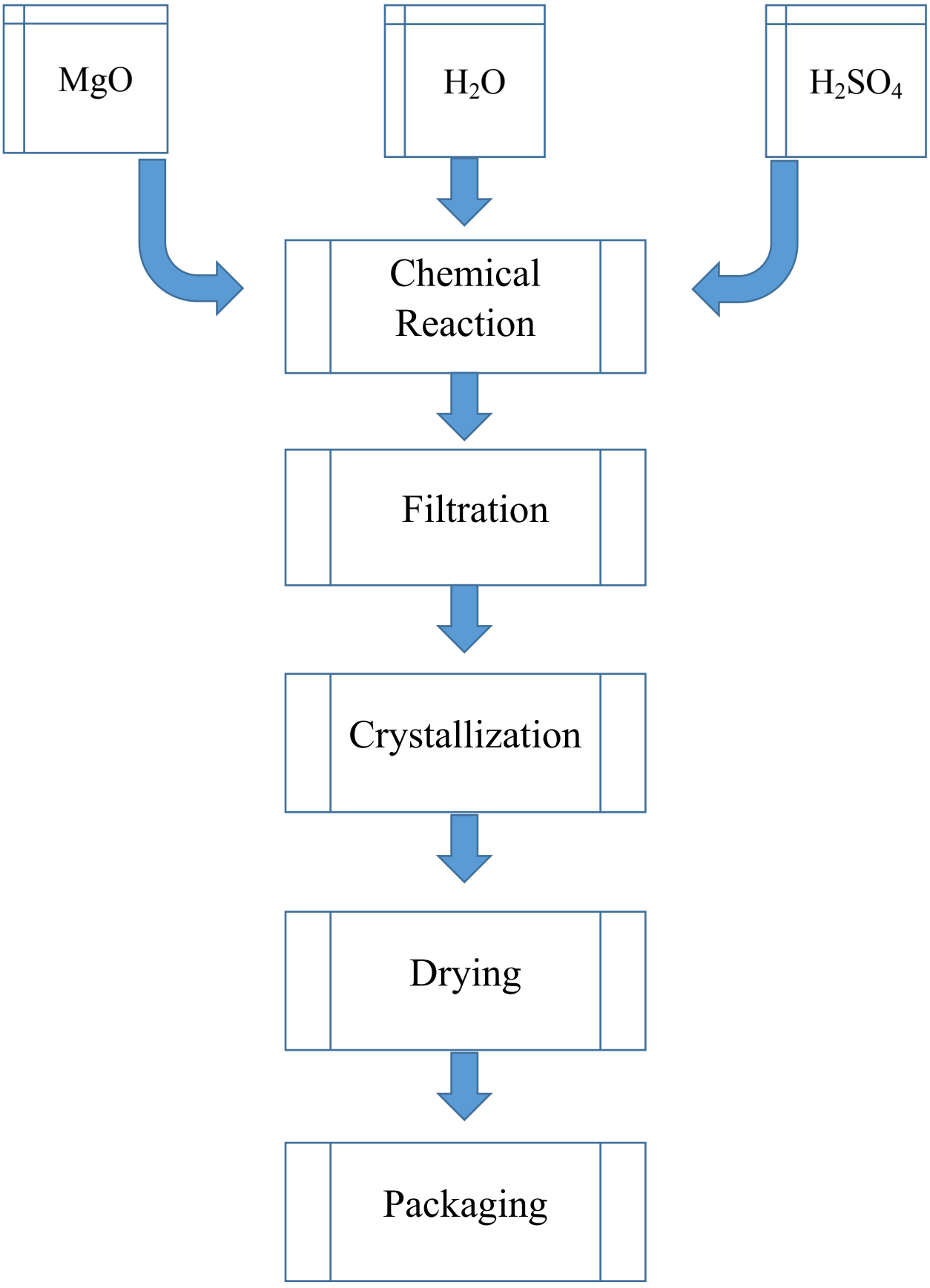
August 2023

Quality Policy Statement

To achieve excellence in all that we do, exceeding the expressed needs and expectations of our customers, focusing on never-ending Quality Improvement, using World Class Manufacturing, Engineering, and Information Systems resulting in employee and customer trust within an environment that embodies the philosophy of **"*Do it right the first time, every time*"**.

Giles' management is committed to the Quality Policy as the cornerstone of our quality management system. This policy is a living document that guides our strategic quality direction. Giles' Quality Policy is consistent with its organizational goals, the expectations and needs of its customers, complies with applicable regulatory requirements, and facilitates continual improvement.

Giles ensures that this policy is understood, implemented, and maintained at all levels throughout the company.


MgO
H_2O
H_2SO_4
Chemical Reaction
Filtration
Crystallization
Drying
Packaging