

Scientific Documentation

Calcium Hydroxide, Powder, FCC

Not appropriate for regulatory submission.

Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp 769 Jersey Avenue New Brunswick, NJ 08901 Phone 732.214.1300





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Specification for Calcium Hydroxide, Powder, FCC (C1116)

Item Number	C1116
Item	Calcium Hydroxide, Powder, FCC
CAS Number	1305-62-0
Molecular Formula	Ca(OH) ₂
Molecular Weight	74.09
MDL Number	
Synonyms	Slaked Lime; Calcium Oxide, Hydrated

Test	Speci	fication
	Min	Max
ASSAY [Ca(OH) ₂]	95.0	100.5 %
ACID-INSOLUBLE SUBSTANCES		0.5 %
ARSENIC (As)		3 mg/kg
CARBONATE		TO PASS TEST
FLUORIDE		0.005 %
LEAD (Pb)		2 mg/kg
MAGNESIUM AND ALKALI SALTS		4.8 %
IDENTIFICATION		TO PASS TEST
APPEARANCE		
RETEST DATE		
DATE OF MANUFACTURE		
MONOGRAPH EDITION		

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



Certificate Of Analysis

Item Number	C1116	Lot Number	2MG0262
Item	Calcium Hydroxide, Powder, FCC	CAS Number	1305-62-0
Molecular Formula	Ca(OH) ₂	Molecular Weight	74.09

TECT	SPECIFICATION		DECLUIT.
TEST	MIN	MAX	RESULT
ASSAY [Ca(OH) ₂]	95.0	100.5 %	96.8 %
ACID-INSOLUBLE SUBSTANCES		0.5 %	<0.5 %
ARSENIC (As)		3 mg/kg	<1.5 mg/kg
CARBONATE		TO PASS TEST	PASSES TEST
FLUORIDE		0.005 %	<0.005 %
LEAD (Pb)		2 mg/kg	<0.25 mg/kg
MAGNESIUM AND ALKALI SALTS		4.8 %	<4.0 %
IDENTIFICATION		TO PASS TEST	PASSES TEST
APPEARANCE			FINE WHITE POWDER
RETEST DATE			30-APR-2025
DATE OF MANUFACTURE			01-APR-2023
MONOGRAPH EDITION			FCC 13th

Certificate of Analysis Results Entered By:

SVANGOOR Swetha Vangoor 07-AUG-23 08:37:41

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

TDAO Tiffany DAO 07-AUG-23 10:11:05

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

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

SAFETY DATA SHEET SPECTIUM®



Revision date 17-January-2022

Revision Number 2

1. Identification

Product identifier

Product Name CALCIUM HYDROXIDE, POWDER, FCC

Other means of identification

Product Code(s) C1116

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use No information available

Restrictions on useNo information available

Details of the supplier of the safety data sheet

Supplier Address

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

Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification

Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 1
Specific target organ toxicity (single exposure)	Category 3

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

Causes skin irritation Causes serious eye damage May cause respiratory irritation



Appearance powder Physical state Solid Odor No information available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling Avoid breathing dust/fume/gas/mist/vapors/spray Use only outdoors or in a well-ventilated area Wear protective gloves/eye protection/face protection

Precautionary Statements - Response

Specific treatment (see .? on this label)

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing Immediately call a POISON CENTER or doctor

IF ON SKIN: Wash with plenty of water and soap If skin irritation occurs: Get medical advice/attention Take off contaminated clothing and wash it before reuse

IF INHALED: Remove person to fresh air and keep comfortable for breathing

Call a POISON CENTER or doctor if you feel unwell

Precautionary Statements - Storage

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

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Calcium Hydroxide	1305-62-0	100	*

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

4. First-aid measures

Description of first aid measures

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

attendance.

Inhalation Remove to fresh air. Get medical attention immediately if symptoms occur. IF exposed or

concerned: Get medical advice/attention.

Eye contact Get immediate medical advice/attention. Rinse immediately with plenty of water, also under

the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do.

Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area.

Skin contact Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical

attention if irritation develops and persists.

Ingestion Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth

to an unconscious person. Do NOT induce vomiting. Call a physician.

Self-protection of the first aider Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Symptoms Burning sensation.

Indication of any immediate medical attention and special treatment needed

5. Fire-fighting measures

surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing media Do not scatter spilled material with high pressure water streams.

Specific hazards arising from the

chemical

No information available.

Explosion data

Sensitivity to mechanical impact none.

Sensitivity to static discharge none.

Special protective equipment for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout

gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

Ensure adequate ventilation. Evacuate personnel to safe areas.

Other information Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with

skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off

contaminated clothing and wash before reuse.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up.

Keep out of the reach of children.

8. Exposure controls/personal protection

Control parameters

Exposure Limits

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Calcium Hydroxide	No data available	15 mg/m³ TWA	-
1305-62-0		5 mg/m ³ TWA	

Appropriate engineering controls

Engineering controls Showers

Eyewash stations Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Tight sealing safety goggles.

Hand protection Wear suitable gloves. Impervious gloves.

Skin and body protection Wear suitable protective clothing. Long sleeved clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are

exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do

not eat, drink or smoke when using this product.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid Appearance powder Color White

Odor No information available Odor threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

Alkaline None known Melting point / freezing point no data available None known no data available Boiling point / boiling range None known Flash point no data available None known no data available **Evaporation rate** None known Flammability (solid, gas) no data available None known Flammability Limit in Air None known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Vapor pressureNo data availableNone knownVapor densityno data availableNone knownRelative density2.2None knownWater solubilityVery slightly soluble in waterNone knownSolubility(ies)Soluble in GlycerolNone known

Insoluble in Alcohol

Partition coefficientNo data availableNone knownAutoignition temperatureno data availableNone known

Decomposition temperature580 - °C 1076 °FNone knownKinematic viscosityno data availableNone knownDynamic viscosityNo data availableNone known

Other information

Explosive properties

Oxidizing properties

No information available

10. Stability and reactivity

Reactivity No information available.

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions
None under normal processing.

Conditions to avoidNone known based on information supplied.

Incompatible materials Strong acids. Strong bases. Strong oxidizing agents.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Product Information .

Inhalation Specific test data for the substance or mixture is not available. May cause irritation of

respiratory tract.

Eye contact Specific test data for the substance or mixture is not available. Causes serious eye

damage. May cause irreversible damage to eyes. (based on components).

Skin contact Specific test data for the substance or mixture is not available. Causes skin irritation. (based

on components).

Ingestion Specific test data for the substance or mixture is not available. Ingestion may cause

gastrointestinal irritation, nausea, vomiting and diarrhea.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Redness. Burning. May cause blindness. May cause redness and tearing of the eyes.

Acute toxicity

Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Calcium Hydroxide	= 7340 mg/kg (Rat)	-	-
1305-62-0			

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

Skin corrosion/irritationClassification based on data available for ingredients. Irritating to skin.

Serious eye damage/eye irritation Classification based on data available for ingredients. Causes burns. Risk of serious

damage to eyes.

Respiratory or skin sensitization

Germ cell mutagenicity

No information available. No information available.

Reproductive toxicity No information available.

STOT - single exposure STOT - repeated exposure Target organ effects No information available. No information available. respiratory system, Eyes, Skin.

Aspiration hazard No information available.

Other adverse effects No information available.

Interactive effects No information available.

12. Ecological information

Ecotoxicity

Chemical name
Algae/aquatic plants
Fish
Toxicity to
microorganisms

Calcium Hydroxide
1305-62-0
LC50: =160mg/L (96h,
Gambusia affinis)

Persistence and degradability

Bioaccumulation

No information available. Inherently biodegradable.

Other adverse effects No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

Contaminated packaging Do not reuse empty containers.

14. Transport information

DOT not regulated

TDG not regulated

MEX not regulated

ICAO (air) not regulated

<u>IATA</u> not regulated

IMDG not regulated

RID not regulated

ADR not regulated

ADN not regulated

15. Regulatory information

International Inventories

TSCA Complies

DSL/NDSL Complies EINECS/ELINCS Complies

ENCS This product complies with ENCS: IECSC This product complies with China:

KECL Complies PICCS Complies

AICS All the constituents of this material are listed on the Australian Inventory of Chemical

Substances (AICS).

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/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

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product 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

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, 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 contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Calcium Hydroxide	0322	Present	Present
1305-62-0			

U.S. EPA Label Information

16. Other information

NFPA

Health hazards 3 Flammability 0 Instability 0

Physical and chemical properties -

HMIS

Health hazards 3 Flammability 0 Physical hazards 0 Personal protection X

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

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value

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

Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA) EPA (Environmental Protection Agency) Acute Exposure Guideline Level(s) (AEGL(s))

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

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

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

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

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

World Health Organization

Revision date 17-January-2022 Revision Note 17-January-2022 No information available.

Disclaimer

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

End of Safety Data Sheet



Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

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

Catalog Number	Product Name
C1116	Calcium Hydroxide, Powder, FCC

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

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

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

Sincerely,

Oralia Chavez

Quality Assurance Specialist

Order Clony



C1116, Calcium Hydroxide, Powder, FCC

Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy

- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

EU Fragrance Allergen Statement

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

GMO Statement

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

Melamine Statement

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



Nitrosamine Statement

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

Animal Testing Statement

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

Organic Compliance Statement

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

Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 24 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

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

- Aflatoxins
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives



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. Below you will find a typical label example for this catalog item.

DANGER

0000-00



 Causes serious eye damage • Causes skin irritation • May cause respiratory irritation.

 Wear protective gloves, eye protection, face protection • Avoid breathing dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling.

FIRST AID: Immediately call a POISON CENTER or physician. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing.

KEEP FROM CHILDREN

C1116 SIZ SY Calcium Hydroxide

(Calcium Oxide, Hydrated; Slaked Lime) Powder

FCC

CAS 1305-62-0

CAUTION: For manufacturing, processing or repacking. Read and understand the label and Safety Data Sheet (SDS) prior to use.

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

 $Ca(OH)_2$

F.W. 74.09

Assay [Ca(OH) ₂]	95.0-100.5%
` ´MAXIMUM LIMITS	3
Acid-Insoluble Substances	0.5%
Arsenic (as As)	3 mg/kg
Carbonate	To pass test
Fluoride	0.005%
Lead	2 mg/kg
Magnesium and Alkali Salts	4.8%

WARNING: Cancer and Reproductive Harmwww.P65Warnings.ca.gov

G 8/H7GHS ?

Lot No. XQ####

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