

Scientific Documentation

Calcium Carbonate, Heavy 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 Carbonate, Heavy Powder, FCC (C1077)

| | |
|-------------------|--------------------------------------|
| Item Number | C1077 |
| Item | Calcium Carbonate, Heavy Powder, FCC |
| CAS Number | 471-34-1 |
| Molecular Formula | CaCO ₃ |
| Molecular Weight | 100.09 |
| MDL Number | |
| Synonyms | |

| Test | Specification | |
|----------------------------|----------------|--------------|
| | Min | Max |
| ASSAY (DRIED BASIS) | 98.0 - 100.5 % | |
| ACID-INSOLUBLE SUBSTANCES | | 0.2 % |
| ARSENIC (As) | | 3 mg/kg |
| FLUORIDE | | 0.005 % |
| LEAD (Pb) | | 3 mg/kg |
| LOSS ON DRYING | | 2 % |
| MAGNESIUM AND ALKALI SALTS | | 1 % |
| IDENTIFICATION | | TO PASS TEST |
| EXPIRATION DATE | | |
| DATE OF MANUFACTURE | | |

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 | C1077 | Lot Number | 2MG0203 |
| Item | Calcium Carbonate, Heavy Powder, FCC | CAS Number | 471-34-1 |
| Molecular Formula | CaCO ₃ | Molecular Weight | 100.09 |

| TEST | SPECIFICATION | | RESULT |
|----------------------------|----------------|--------------|-------------------|
| | MIN | MAX | |
| ASSAY (DRIED BASIS) | 98.0 - 100.5 % | | 99.2 % |
| ACID-INSOLUBLE SUBSTANCES | | 0.2 % | 0.08 % |
| ARSENIC (As) | | 3 mg/kg | <3 mg/kg |
| FLUORIDE | | 0.005 % | <0.005 % |
| LEAD (Pb) | | 3 mg/kg | 0.22 mg/kg |
| LOSS ON DRYING | | 2 % | 0.1 % |
| MAGNESIUM AND ALKALI SALTS | | 1 % | 0.4 % |
| IDENTIFICATION | | TO PASS TEST | PASSES TEST |
| EXPIRATION DATE | | | 27-APR-2026 |
| DATE OF MANUFACTURE | | | 28-APR-2023 |
| APPEARANCE | | | FINE WHITE POWDER |
| MONOGRAPH EDITION | | | (FCC) 13 |

Certificate of Analysis Results Entered By:

DGARCIA
Dylan Garcia
31-JUL-23 12:14:24

Spectrum Chemical Mfg Corp
755 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

HBERMUDEZ
Hernan Bermudez
31-JUL-23 12:22:14

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

spectrum®



Revision date 06-June-2022

Revision Number 2

1. Identification

Product identifier

Product Name CALCIUM CARBONATE, HEAVY POWDER, FCC

Other means of identification

Product Code(s) C1077

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use No information available

Restrictions on use No 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

| | |
|-----------------|-------------|
| Carcinogenicity | Category 1A |
|-----------------|-------------|

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

May cause cancer



Appearance Powder

Physical state Solid

Odor No information available

Precautionary Statements - Prevention

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Wear protective gloves/protective clothing/eye protection/face protection

Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention

Precautionary Statements - Storage

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

Not applicable.

Mixture

| Chemical name | CAS No | Weight-% | Trade secret |
|-----------------------------|------------|----------|--------------|
| Calcium Carbonate | 471-34-1 | 100 | * |
| Quartz (Crystalline Silica) | 14808-60-7 | 0.1 - 1 | * |

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

4. First-aid measures

Description of first aid measures

General advice

IF exposed or concerned: Get medical advice/attention.

Inhalation

Remove to fresh air.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.
Consult a physician.

Skin contact

Wash skin with soap and water.

Ingestion

Clean mouth with water and drink afterwards plenty of water.

Most important symptoms and effects, both acute and delayed

Symptoms

No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. Fire-fighting measures

| | |
|---|---|
| Suitable Extinguishing Media | Use extinguishing measures that are appropriate to local circumstances and the 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. |
| Hazardous combustion products | Chloroform does not burn, but may decompose upon heating to produce the following if involved in a fire: carbon monoxide, carbon dioxide, hydrogen chloride and chlorine. Carbon dioxide (CO ₂). Hydrogen fluoride. |
| 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 | Ensure adequate ventilation. |
| 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. |
|--------------------------------|---|

Conditions for safe storage, including any incompatibilities

| | |
|---------------------------|---|
| Storage Conditions | Keep container tightly closed in a dry and well-ventilated place. |
|---------------------------|---|

8. Exposure controls/personal protection

Control parameters

| | |
|------------------------|--|
| Exposure Limits | The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure |
|------------------------|--|

limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

| Chemical name | ACGIH TLV | OSHA PEL | NIOSH IDLH |
|---|-------------------|---|------------|
| Quartz (Crystalline Silica) 14808-60-7 | No data available | 50 µg/m ³ TWA (250)/(%SiO ₂ + 5) mppcf TWArespirable fraction (10)/(%SiO ₂ + 2) mg/m ³ TWArespirable fraction | - |

Appropriate engineering controls

Engineering controls Showers
 Eyewash stations
 Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection No special protective equipment required.

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective 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 Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the 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> |
|--|--------------------|-------------------------|
| pH | no data available | None known |
| Melting point / freezing point | no data available | None known |
| Boiling point / boiling range | no data available | None known |
| Flash point | no data available | None known |
| Evaporation rate | no data available | None known |
| Flammability (solid, gas) | no data available | None known |
| Flammability Limit in Air | | None known |
| Upper flammability or explosive limits | No data available | |
| Lower flammability or explosive limits | No data available | |
| Vapor pressure | No data available | None known |
| Vapor density | no data available | None known |
| Relative density | 2.7 - 2.8 | None known |
| Water solubility | Insoluble in water | None known |
| Solubility(ies) | no data available | None known |
| Partition coefficient | No data available | None known |
| Autoignition temperature | no data available | None known |
| Decomposition temperature | | None known |
| Kinematic viscosity | no data available | None known |
| Dynamic viscosity | No data available | None known |

Other information

| | |
|-----------------------------|--------------------------|
| Explosive properties | No information available |
| Oxidizing properties | No information available |
| Softening point | No information available |
| Molecular weight | No information available |
| VOC Content (%) | No information available |
| Liquid Density | No information available |
| Bulk density | 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 avoid | None known based on information supplied. |
| Incompatible materials | None known based on information supplied. |
| 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. |
| Eye contact | Specific test data for the substance or mixture is not available. |
| Skin contact | Specific test data for the substance or mixture is not available. |
| Ingestion | Specific test data for the substance or mixture is not available. |

Symptoms related to the physical, chemical and toxicological characteristics

| | |
|-----------------|---------------------------|
| Symptoms | No information available. |
|-----------------|---------------------------|

Acute toxicity**Numerical measures of toxicity**

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|-------------------------------|----------------------|-------------|-----------------|
| Calcium Carbonate 471-34-1 | = 6450 mg/kg (Rat) | - | - |

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

| | |
|--|---|
| Skin corrosion/irritation | No information available. |
| Serious eye damage/eye irritation | No information available. |
| Respiratory or skin sensitization | No information available. |
| Germ cell mutagenicity | No information available. |
| Carcinogenicity | Contains a known or suspected carcinogen. Classification based on data available for ingredients. May cause cancer. |

The table below indicates whether each agency has listed any ingredient as a carcinogen.

| Chemical name | ACGIH | IARC | NTP | OSHA |
|---------------|-------|------|-----|------|
|---------------|-------|------|-----|------|

| | | | | |
|---|---|--|---|---|
| Quartz (Crystalline Silica) 14808-60-7 | - | Group 1 - Carcinogenic to humans - Monograph 100C [2012] Crystalline silica inhaled in the form of quartz or cristobalite from occupational sources Monograph 68 [1997] | - | - |
|---|---|--|---|---|

Legend

| | |
|---------------------------------|---------------------------------|
| Reproductive toxicity | No information available. |
| STOT - single exposure | No information available. |
| STOT - repeated exposure | No information available. |
| Target organ effects | respiratory system, Eyes, Skin. |
| Aspiration hazard | No information available. |
| Other adverse effects | No information available. |
| Interactive effects | No information available. |

12. Ecological information

| | |
|--------------------------------------|---|
| Ecotoxicity | The environmental impact of this product has not been fully investigated. |
| Persistence and degradability | No information available. |
| Bioaccumulation | 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

| | |
|--------------------------|---------------|
| <u>DOT</u> | not regulated |
| <u>TDG</u> | not regulated |
| <u>MEX</u> | not regulated |
| <u>ICAO (air)</u> | not regulated |
| <u>IATA</u> | not regulated |
| <u>IMDG</u> | not regulated |
| <u>RID</u> | not regulated |
| <u>ADR</u> | not regulated |
| <u>ADN</u> | 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

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 contains the following Proposition 65 chemicals:.

| Chemical name | California Proposition 65 |
|--|---------------------------|
| Quartz (Crystalline Silica) - 14808-60-7 | carcinogen |

U.S. State Right-to-Know Regulations

| Chemical name | New Jersey | Massachusetts | Pennsylvania |
|---|------------|---------------|--------------|
| Quartz (Crystalline Silica) 14808-60-7 | 1660 | Present | Present |

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA

Health hazards 0

Flammability 0

Instability 0

Physical and chemical properties -

HMIS

Health hazards * 1

Flammability 0

Physical hazards 0

Personal protection X

Chronic Hazard Star Legend

* = Chronic Health Hazard

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 06-June-2022

Revision Note 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 |
|----------------|--------------------------------------|
| C1077 | Calcium Carbonate, Heavy 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

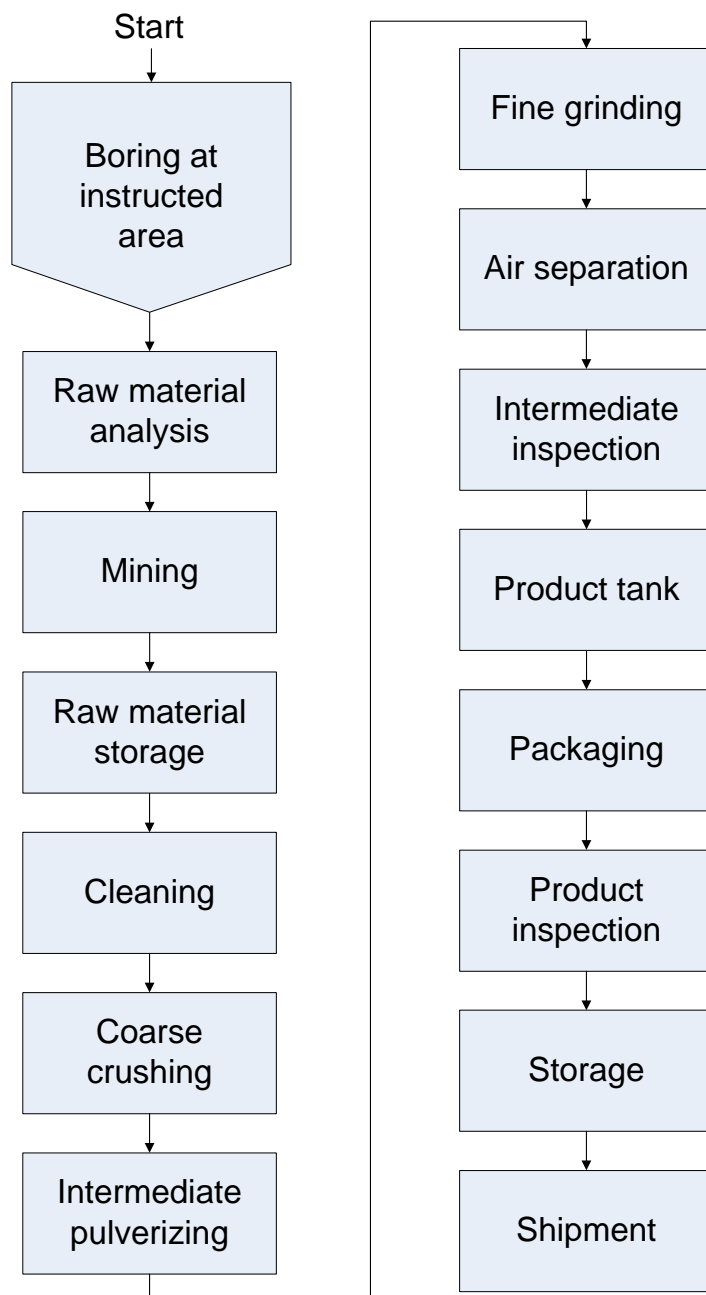
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

Calcium Carbonate, Heavy Powder, FCC - C1077



Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.
New Brunswick, NJ 08901
732.214.1300

West Coast Facility:

14422 S. San Pedro St.
Gardena, CA 90248
310.516.8000

C1077, Calcium Carbonate, Heavy Powder, FCC

Source Statement

The above mentioned catalog item is manufactured from mineral origin (limestone). 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 36 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 | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • 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

- May cause cancer.
- Obtain special instructions before use • Do not handle until all safety precautions have been read and understood • Wear protective gloves, protective clothing, eye protection, face protection.

FIRST AID: If exposed or concerned: Get medical attention.

KEEP FROM CHILDREN



C1077

SIZ SY

Calcium Carbonate

Heavy Powder
FCC

CAS 471-34-1

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

CaCO₃ F.W. 100.09

Assay (CaCO₃; Dried Basis)..... 98.0-100.5%

MAXIMUM LIMITS

Acid-Insoluble Substances.....0.2%

Arsenic (as As)..... 3 mg/kg

Fluoride.....0.005%

Lead 3 mg/kg

Loss on Drying.....2%

Magnesium and Alkali Salts1%

HYGROSCOPIC: Keep tightly closed.

WARNING: Cancer and Reproductive Harm-
www.P65Warnings.ca.gov

G 6/G12GHS ? Lot No. XQ####

Spectrum Chemical Mfg Corp

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