

Scientific Documentation

Dibasic Calcium Phosphate, Dihydrate, Powder, USP

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 Dibasic Calcium Phosphate, Dihydrate, Powder, USP (CA160)

Item Number	CA160
Item	Dibasic Calcium Phosphate, Dihydrate, Powder, USP
CAS Number	7789-77-7
Molecular Formula	$\text{CaHPO}_4 \cdot 2\text{H}_2\text{O}$
Molecular Weight	172.09
MDL Number	
Synonyms	Calcium Monohydrogen Phosphate ; Phosphoric Acid Calcium Salt ; Dibasic Calcium Phosphate

Test	Specification	
	Min	Max
ASSAY	98.0	105.0%
LOSS ON IGNITION	24.5	26.5%
ACID-INSOLUBLE SUBSTANCES		0.2%
CARBONATE (CO_3)	NO EFFERVESCENCE OCCURS	
CHLORIDE (Cl)		0.25%
FLUORIDE		50 ppm
SULFATE		0.5%
ARSENIC (As)		3 $\mu\text{g/g}$
BARIUM	NO TURBIDITY PRODUCED	
ELEMENTAL IMPURITIES:		
CADMIUM (Cd)	AS REPORTED	
LEAD (Pb)	AS REPORTED	
MERCURY (Hg)	AS REPORTED	
IDENTIFICATION (A)	WHITE PRECIPITATE FORMS	
IDENTIFICATION (B)	YELLOW PRECIPITATE FORMS	
CERTIFIED HALAL		
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		

Test	Specification	
	Min	Max
RESIDUAL SOLVENTS	AS REPORTED	

Spectrum Chemical Mfg Corp

<i>Corporate Headquarters:</i>	<i>West Coast Facility:</i>
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	CA160	Lot Number	1NB0012
Item	Dibasic Calcium Phosphate, Dihydrate, Powder, USP	CAS Number	7789-77-7
Molecular Formula	CaHPO ₄ •2H ₂ O	Molecular Weight	172.09

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY	98.0	105.0%	99.1 %
LOSS ON IGNITION	24.5	26.5%	26.0 %
ACID-INSOLUBLE SUBSTANCES		0.2%	0.03 %
CARBONATE (CO ₃)	NO EFFERVESCENCE OCCURS		NO EFFERVESCENCE OCCURS
CHLORIDE (Cl)		0.25%	0.02 %
FLUORIDE		50 ppm	50 ppm
SULFATE		0.5%	0.2 %
ARSENIC (As)		3 µg/g	1 µg/g
BARIUM	NO TURBIDITY PRODUCED		NO TURBIDITY PRODUCED
ELEMENTAL IMPURITIES:			.
CADMIUM (Cd)	AS REPORTED		1 µg/g
LEAD (Pb)	AS REPORTED		0.05 µg/g
MERCURY (Hg)	AS REPORTED		1 µg/g
IDENTIFICATION (A)	WHITE PRECIPITATE FORMS		WHITE PRECIPITATE FORMS
IDENTIFICATION (B)	YELLOW PRECIPITATE FORMS		YELLOW PRECIPITATE FORMS
CERTIFIED HALAL			CERTIFIED HALAL
EXPIRATION DATE			12-NOV-2024
DATE OF MANUFACTURE			13-NOV-2021
APPEARANCE			WHITE POWDER

TEST	SPECIFICATION		RESULT
	MIN	MAX	
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS PRESENT
MONOGRAPH EDITION			(USP-NF) 2023

Certificate of Analysis Results Entered By:

HBERMUDEZ
Hernan Bermudez
21-FEB-24 08:20:31

Spectrum Chemical Mfg Corp
14422 South San Pedro Street
Gardena 90248 CA



Certificate of Analysis Results Approved By:

SHANSEN
Selin Hansen
21-FEB-24 13:23:45

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.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

SAFETY DATA SHEET

Preparation Date: 8/13/15

Revision Date: 9/17/2018

Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: CA160
Product Name: DIBASIC CALCIUM PHOSPHATE, DIHYDRATE, POWDER, USP

Other means of identification

Synonyms: Dicalcium Phosphate Dihydrate, DCPD
 Calcium Monohydrogen Phosphate
 Dicalcium Orthophosphate, Dihydrate
CAS #: 7789-77-7
RTECS # Not available
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: No information available.
Uses advised against No information available

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

Order Online At: <https://www.spectrumchemical.com>
Emergency telephone number Chemtrec 1-800-424-9300
Contact Person: Martin LaBenz (West Coast)
Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

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

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

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

Label elements

Warning

Hazard statements

Causes skin irritation
 Causes serious eye irritation
 May cause respiratory irritation

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**Hazards not otherwise classified (HNOC)**

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Wear protective gloves

Wear eye/face protection

Avoid breathing dust/fume/gas/mist/vapors/spray

Use only outdoors or in a well-ventilated area

Wash face, hands and any exposed skin thoroughly after handling

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. If eye irritation persists: Get medical advice/attention.

IF ON SKIN: Wash with plenty of water

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/physician 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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Calcium Phosphate, Dibasic, Dihydrate	7789-77-7	100

4. FIRST AID MEASURES

First aid measures**General Advice:**

National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

Skin Contact:

Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention. If skin irritation persists, call a physician.

Eye Contact:

Flush eyes with water for 15 minutes. Get medical attention.

Inhalation:

Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

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Ingestion: Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.

Most important symptoms and effects, both acute and delayed

Symptoms
Causes serious eye irritation
Causes skin irritation
Irritating to respiratory system
Ingestion may cause nausea, vomiting, and diarrhea
May affect the cardiovascular system
May cause central nervous system effects
It may affect the kidneys

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically.

Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: The product is not flammable. If it is involved in a fire, extinguish the fire using an agent suitable for the type of surrounding fire.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: No information available.

Specific hazards: No information available.

Special Protective Actions for Firefighters

Specific Methods: No information available.

Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Keep people away from and upwind of spill/leak. Ensure adequate ventilation. Avoid breathing dust. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up Use appropriate tools to put the spilled solid in a suitable waste disposal container. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Do not ingest. Do not breathe dust. Use only in well-ventilated areas. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Deliquescent. Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials.

Incompatible Materials:

Oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Calcium Phosphate, Dibasic, Dihydrate	7789-77-7	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Calcium Phosphate, Dibasic, Dihydrate	7789-77-7	None	None	None	None

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Australia and Mexico

Components	CAS-No.	Australia	Mexico
Calcium Phosphate, Dibasic, Dihydrate	7789-77-7	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection:	Safety glasses with side-shields. or Goggles
Skin and body protection:	Chemical resistant apron Long sleeved clothing Gloves
Respiratory protection:	Effective dust mask. or. Wear respirator with dust filter. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
Hygiene measures:	Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid	Appearance: Powder.	Color: White.
Odor: Odorless.	Taste No information available.	Formula: No information available
Molecular/Formula weight (g/mole): 172.09 g/mole	Flammability: No information available	Flashpoint (°C/°F): No information available.
Flash Point Tested according to: Not available	Autoignition Temperature (°C/°F): No information available	Lower Explosion Limit (%): No information available
Upper Explosion Limit (%): No information available	Melting point/range(°C/°F): 190°C (374°F)	Decomposition temperature(°C/°F): No information available
Boiling point/range(°C/°F): No information available	Bulk density: No information available	Density (g/cm3): No information available
Specific gravity: 2.31	pH: 7.2-7.5 (25% slurry)	Vapor pressure @ 20°C (kPa): No information available

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Evaporation rate:
No information available

Vapor density:
No information available

VOC content (g/L):
No information available

Odor threshold (ppm):
No information available

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

Viscosity:
No information available

Miscibility:
No information available

Solubility:
Insoluble in cold water
Insoluble in hot water
Insoluble in methanol
Insoluble en n-octanol
Soluble in dilute hydrochloric and nitric acids
Insoluble in Alcohol
Solubility in water: 0.032g/ 100ml water

10. STABILITY AND REACTIVITY

Reactivity:
Reactive with oxidizing agents

Chemical stability

Stability: Deliquescent. Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Incompatible materials. Exposure to moisture. Exposure to moist air.

Incompatible Materials: Oxidizing agents

Hazardous decomposition products: No information available.

Other Information
Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:
Ingestion. Inhalation.

Acute Toxicity

Component Information

Calcium Phosphate, Dibasic, Dihydrate

CAS-No. 7789-77-7

LD50/oral/rat = >2000 mg/kg Oral LD50 Rat (for anhydrous form CAS no. 7757-93-9)

LD50/oral/mouse = No information available

LD50/dermal/rabbit = >7940 mg/kg (for anhydrous form CAS no. 7757-93-9)

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LD50/dermal/rat = No information available
LC50/inhalation/rat = No information available
LC50/inhalation/mouse = No information available
Other LD50 or LC50information = No information available

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = > 2000 mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = No information available

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = > 7940 mg/kg

LD50/dermal/rat
VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat
VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse
VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact:	Causes skin irritation. May cause contact dermatitis.
Eye Contact:	Causes serious eye irritation.
Inhalation	Irritating to respiratory system. Symptoms may include coughing and sneezing.
Ingestion	May cause digestive (gastrointestinal) tract irritation with nausea, vomiting, diarrhea. May cause flatulence. May cause constipation. If large amounts are ingested, calcium salts may affect cardiovascular system (hypertension, atrial fibrillation, vasodilation), behavior/nervous system (confusion, somnolence, coma, decreased tendon reflexes, depression, fatigue, hallucinations, lethargy), kidneys (abnormal renal function, renal calculus) depending on the amount and duration of ingestion. May also cause acidosis or alkalosis, hypercalcemia. .
Aspiration hazard	No information available.

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

Chronic Toxicity	Prolonged or repeated skin contact may cause drying or chapping of skin.
Sensitization:	No information available.
Mutagenic Effects:	No information available
Carcinogenic effects:	Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Calcium Phosphate, Dibasic, Dihydrate	7789-77-7	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

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

Reproductive toxicity No data is available

Reproductive Effects: No information available
Developmental Effects: No information available
Teratogenic Effects: No information available

Specific Target Organ Toxicity

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: Aquatic environment.

Calcium Phosphate, Dibasic, Dihydrate - 7789-77-7

Water Flea Data: > 1000 mg/l LC50 96 hours (Daphnia)

Persistence and degradability: No information available

Bioaccumulative potential: No information available.

Mobility: No information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:

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

Contaminated packaging:

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

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Calcium Phosphate, Dibasic, Dihydrate	7789-77-7	None	None	None	None

14. TRANSPORT INFORMATION

Product code: CA160

Product name: DIBASIC CALCIUM
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DOT

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

TDG (Canada)

UN-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Subsidiary Risk:	No information available
Packing Group:	No information available
Marine Pollutant	No Information available
Description:	No information available

ADR

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

IMO / IMDG

UN-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Subsidiary Risk:	No information available
Packing Group:	No information available
Marine Pollutant	No information available

RID

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

ICAO

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

IATA

UN-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available

Subsidiary Risk: No information available
Packing Group: No information available
ERG Code: No information available
Special Provisions No information available

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Calcium Phosphate, Dibasic, Dihydrate	7789-77-7	Not listed. Exempt from TSCA 8(b) Inventory listing since it is a hydrate. However the anhydrous form (CAS no. 7757-3-9) is listed as ACTIVE on the TSCA 8(b) Inventory.	Not present	Present	Present (1)-183	Present	Present	Not present

U.S. Regulations

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

Chemicals Known to the State of California to Cause Cancer:

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

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

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

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Calcium Phosphate, Dibasic, Dihydrate	7789-77-7	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	CAS-No.	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Calcium Phosphate, Dibasic, Dihydrate	7789-77-7	None	None	None	None	None

U.S. TSCA

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Calcium Phosphate, Dibasic, Dihydrate	7789-77-7	Not Applicable	Not Applicable

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WHIMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

The WHMIS 2015 classification of this product has not been validated or reviewed yet.

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Calcium Phosphate, Dibasic, Dihydrate	7789-77-7	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Calcium Phosphate, Dibasic, Dihydrate	7789-77-7	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Calcium Phosphate, Dibasic, Dihydrate	7789-77-7	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Calcium Phosphate, Dibasic, Dihydrate	7789-77-7	No information

EU - CLP (1272/2008)

R-phrases(s)

R36/37/38 - Irritating to eyes, respiratory system and skin.

S -phrase(s)

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

S37 - Wear suitable gloves.

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Calcium Phosphate, Dibasic, Dihydrate	7789-77-7		No information	

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

Indication of danger:

Xi - Irritant.

16. OTHER INFORMATION

Preparation Date: 8/13/15
Revision Date: 9/17/2018
Prepared by: Sonia Owen

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product

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is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet



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
CA160	Dibasic Calcium Phosphate, Dihydrate, Powder, USP

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

Spectrum-Gardena, CA: 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

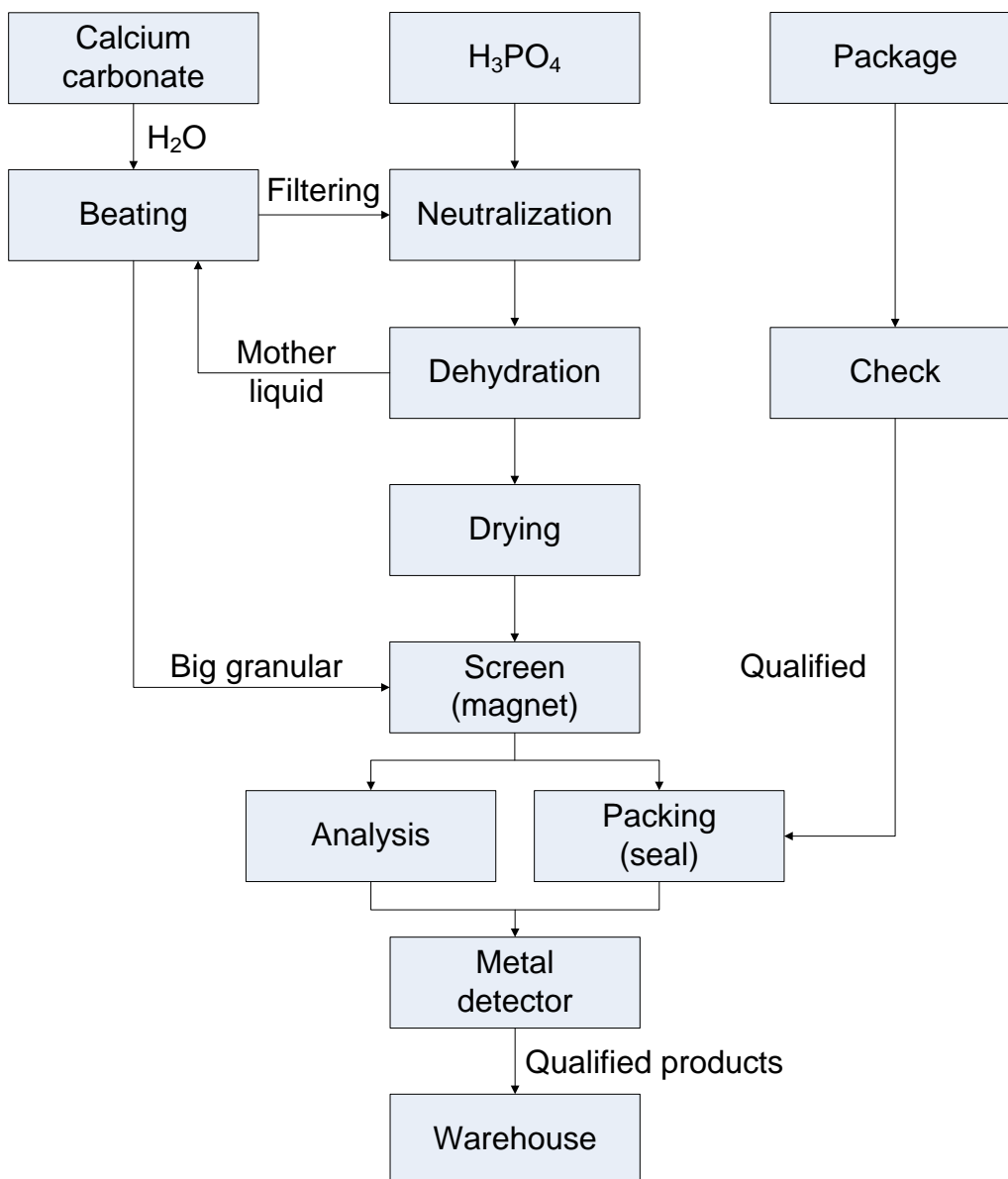
Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

Dibasic Calcium Phosphate, Dihydrate, Powder, USP-CA160



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

CA160, Dibasic Calcium Phosphate, Dihydrate, Powder, USP

Source Statement

The above mentioned catalog item is manufactured by chemical synthesis from natural inorganic material. 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 | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • Preservatives |



RE: Elemental Impurities - Dibasic Calcium Phosphate, Dihydrate, Powder, USP (Cat# CA160)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	< 1 ppm
Lead	Pb	1	< 0.5 ppm
Arsenic	As	1	< 1 ppm
Mercury	Hg	1	< 1 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS

769 Jersey Avenue
New Brunswick, NJ 08901
PHONE 732.214.1300
FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843



**RE: Residual Solvents - Dibasic Calcium Phosphate, Dihydrate, Powder, USP
(Cat# CA160)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of the USP <467> Residual Solvents and the ICH Q3C Residual Solvents Guideline. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture of this product.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

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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.

WARNING

- Causes serious eye irritation • 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: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention. 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. Call a POISON CENTER or physician if you feel unwell.

KEEP FROM CHILDREN


CA160 **SIZ SY**

Dibasic Calcium Phosphate

(Calcium Monohydrogen Phosphate; Phosphoric Acid Calcium Salt)

Dihydrate, Powder
USP

CAS 7789-77-7



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

$\text{CaHPO}_4 \cdot 2\text{H}_2\text{O}$ F.W. 172.09

Assay 98.0-105.0%
Loss on Ignition 24.5-26.5%

MAXIMUM LIMITS

Acid-Insoluble Substances 0.2%
Carbonate To pass test
Chloride 0.25%
Fluoride 50 ppm
Sulfate 0.5%
Arsenic 3 µg/g
Barium To pass test
Elemental Impurities As reported
Residual Solvents To pass test

DELIQUESCENT: Keep tightly closed.

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

G 11/G12GHS ? Lot No. XQ####

Spectrum Chemical Mfg Corp

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