

Scientific Documentation

Cholecalciferol, Crystal, 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
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Specification for Cholecalciferol, Crystal, USP (CH134)

Item Number	CH134
Item	Cholecalciferol, Crystal, USP
CAS Number	67-97-0
Molecular Formula	C ₂₇ H ₄₄ O
Molecular Weight	384.64
MDL Number	
Synonyms	Vitamin D3 ; Vitamin D ; Colecalciferol ; Activated 7-Dehydrocholesterol

Test	Specification	
	Min	Max
ASSAY (C ₂₇ H ₄₄ O)	97.0	103.0 %
SPECIFIC ROTATION [α] _D	+105 to +112°	
ELEMENTAL IMPURITIES		AS REPORTED
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)		3.0 %
IDENTIFICATION (C)	RETENTION TIME CORRESPONDS TO STANDARD	
CERTIFIED HALAL		
RETEST DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS		AS REPORTED

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	CH134	Lot Number	1MD0893
Item	Cholecalciferol, Crystal, USP	CAS Number	67-97-0
Molecular Formula	C ₂₇ H ₄₄ O	Molecular Weight	384.64

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (C ₂₇ H ₄₄ O)	97.0	103.0 %	99.5 %
SPECIFIC ROTATION [α] _D	+105 to +112°		+106°
ELEMENTAL IMPURITIES		AS REPORTED	COMPLIES WITH STANDARD
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)		3.0 %	1.2 %
IDENTIFICATION (C)	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD
CERTIFIED HALAL			CERTIFIED HALAL
RETEST DATE			31-AUG-2024
DATE OF MANUFACTURE			01-SEP-2021
APPEARANCE			WHITE CRYSTALS
RESIDUAL SOLVENTS		AS REPORTED	.
CLASS 1 (solvent) / BENZENE			<2 ppm
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm
CLASS 2 (solvent) / PYRIDINE			<200 ppm
CLASS 3 (solvent) / ACETONE			<5000 ppm
CLASS 3 (solvent) / ETHANOL			<5000 ppm
OTHER RESIDUAL SOLVENTS: METHYL FORMATE			<1000 ppm
OTHER RESIDUAL SOLVENTS: PETROLEUM ETHER			<290 ppm
MONOGRAPH EDITION			(USP) 2022

Certificate of Analysis Results Entered By:

HBERMUDEZ
Hernan Bermudez
02-MAY-23 15:17:01

Certificate of Analysis Results Approved By:

JAMAYA
Javier Amaya
03-MAY-23 07:27:25

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



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: 03/15/2016

Revision Date: 7/10/2018

Revision Number: G3

1. IDENTIFICATION

Product identifier

Product code: CH134
Product Name: CHOLECALCIFEROL, CRYSTAL, USP

Other means of identification

Synonyms: Colecalciferol; Activated 7-Dehydrocholesterol; Vitamin D3
CAS #: 67-97-0
RTECS # VS2900000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Medication. Dietary supplement.
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)

Acute toxicity - Oral	Category 2
Acute toxicity - Dermal	Category 2
Acute toxicity - Inhalation (Dusts/Mists)	Category 2
Specific target organ toxicity (repeated exposure)	Category 1

Label elements

Danger

Hazard statements

Fatal if swallowed
Fatal in contact with skin
Fatal if inhaled
Causes damage to organs through prolonged or repeated exposure

Product code: CH134

Product name: CHOLECALCIFEROL,
CRYSTAL, USP

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**Hazards not otherwise classified (HNOC)**

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
Do not get in eyes, on skin, or on clothing
Wear protective gloves/protective clothing/eye protection/face protection
Do not breathe dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area
Wear respiratory protection

Precautionary Statements - Response

IF ON SKIN: Wash with plenty of water
Remove/Take off immediately all contaminated clothing
Immediately call a POISON CENTER or doctor/physician
Wash contaminated clothing before reuse
IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.
IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
Rinse mouth

Precautionary Statements - Storage

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

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Cholecalciferol	67-97-0	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. First aider needs to protect himself. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Skin Contact:

Wash off immediately with soap and plenty of water. Continue flushing with plenty of water for at least 15 minutes. Get medical attention if irritation develops. Remove all contaminated clothes and shoes. Immediate medical attention is required. Call a physician or Poison Control Centre immediately.

Eye Contact:	Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.
Inhalation:	Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. WARNING! It may be hazardous to the person providing aid to give mouth-to-mouth resuscitation when the inhaled or ingested material is toxic, infectious or corrosive. Do not use mouth-to-mouth resuscitation if victim ingested or inhaled the substance; induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Immediate medical attention is required.
Ingestion:	Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Immediate medical attention is required. Call a physician or Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed

Symptoms	<p>May cause eye/skin/respiratory tract irritation</p> <p>May cause hypercalcemia</p> <p>May cause anorexia</p> <p>Dryness of mouth</p> <p>May cause metallic taste</p> <p>May cause abdominal pain, nausea, vomiting, diarrhea</p> <p>May cause constipation</p> <p>May cause tinnitus</p> <p>May affect the cardiovascular system</p> <p>Hypertension</p> <p>Cardiac arrhythmias</p> <p>Central nervous system effects</p> <p>May cause headache</p> <p>Fatigue</p> <p>vertigo</p> <p>Weakness</p> <p>Seizures</p> <p>Confusion</p> <p>It may affect the urinary system</p> <p>May cause renal insufficiency manifested by polyuria, nocturia, polydipsia, and proteinuria</p> <p>May cause muscle and joint pain</p>
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Indication of any immediate medical attention and special treatment needed

Notes to Physician:	Treat symptomatically.
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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:	Dry chemical. Carbon dioxide (CO ₂). Water spray mist or foam.
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Unsuitable Extinguishing Media:	No information available.
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Specific hazards arising from the chemical

Hazardous Combustion Products:	Carbon Monoxide, Carbon Dioxide.
Specific hazards:	May be combustible at high temperatures.

Special Protective Actions for Firefighters

Specific Methods:

Water mist may be used to cool closed containers. Dike fire-control water for later disposal; do not scatter the material.

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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Avoid breathing dust. Remove all sources of ignition.

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

Sweep up and shovel into suitable containers for disposal. Avoid creating dust. 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 vapors/dust. Avoid dust formation. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep containers tightly closed in a dry, cool and well-ventilated place. Keep refrigerated. Store at 2-8 deg. C. Protect from light. Sensitive to light. Store in light-resistant containers. Air sensitive. Flushed with nitrogen. Store under nitrogen. Store away from incompatible materials. Store in a segregated and approved area.

Incompatible Materials:

Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Cholecalciferol	67-97-0	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Cholecalciferol	67-97-0	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Cholecalciferol	67-97-0	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

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

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection:

Goggles

Skin and body protection:

Long sleeved clothing
Chemical resistant apron
Gloves

Respiratory protection:

Wear respirator with dust filter.

Hygiene measures:

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:

Solid

Appearance:

Crystals.

Color:

White.

Odor:

Odorless.

Taste

No information available.

Formula:

C27H44O

Molecular/Formula weight (g/mole):

384.64

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):

84 - 89 °C/183 - 192 °F

Decomposition temperature(°C/°F):

No information available

Boiling point/range(°C/°F):

Product code: CH134

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No information available

Bulk density:
No information available

Density (g/cm³):
No information available

Specific gravity:
No information available

pH:
No information available

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

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):**
9.5 - 11

Viscosity:
No information available

Miscibility:
No information available

Solubility:
Insoluble in water
Soluble in Alcohol
Soluble in Ether
Soluble in fatty oils

10. STABILITY AND REACTIVITY

Reactivity

Reactive with strong oxidizing agents

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Avoid dust formation. Incompatible materials.

Incompatible Materials: Strong oxidizing agents

Hazardous decomposition products: When heated to decomposition it emits toxic fumes. Carbon monoxide.

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:
None.

Acute Toxicity

Component Information

Cholecalciferol	
CAS-No.	67-97-0
LD50/oral/rat = 42 mg/kg Oral LD50 Rat	
LD50/oral/mouse = 42.5 mg/kg	

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LD50/dermal/rabbit = No information available
LD50/dermal/rat = 61 mg/kg Dermal LD50 Rat; 185 mg/kg Dermal LD50 Rat
LC50/inhalation/rat = 0.13-0.38 mg/l 4 hr
LC50/inhalation/mouse = No information available
Other LD50 or LC50information = No information available

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = 42 mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = 42.5 mg/kg

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

LD50/dermal/rat
VALUE -Acute Tox Dermal = 61 mg/kg

LC50/inhalation/rat
VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = 0.13 mg/l (4-hr.)

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

Symptoms

Skin Contact: Fatal if absorbed through skin. May cause skin irritation.

Eye Contact: May cause eye irritation.

Inhalation May cause irritation of respiratory tract. Fatal if inhaled.

Ingestion Fatal if swallowed. Ingestion may cause nausea, vomiting, diarrhea. May cause hypercalcemia. May cause abdominal pain. May cause constipation. May cause decreased appetite or anorexia. May cause dry mouth. May cause thirst. May cause electrolyte imbalance. May affect the cardiovascular system (tachycardia). May affect the cardiovascular system (hypertension). May affect the cardiovascular system (cardiac arrhythmias). May cause unusual fatigue, muscle weakness, vertigo, dizziness, headache. May cause bone or muscle pain. May affect behavior/central nervous system (confusion). May affect behavior/central nervous system (ataxia). May affect behavior/central nervous system (convulsions, seizures). May cause headache. May cause tinnitus. May cause skin rash, redness or itching. May cause metallic taste. May affect urinary system (kidneys).

Aspiration hazard No information available.

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

Chronic Toxicity Chronic exposure may affect the kidneys and cause kidney damage. Prolonged or repeated ingestion may affect the adrenal gland.

Sensitization: No information available.

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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
Cholecalciferol	67-97-0	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 Causes damage to organs through prolonged or repeated exposure.

Target Organs: Bones. Kidneys.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

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
Cholecalciferol	67-97-0	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: UN2811
Proper Shipping Name: Toxic solids, organic, n.o.s. (cholecalciferol)
Hazard Class: 6.1
Subsidiary Class: No information available
Packing group: II
Emergency Response Guide Number: 154
Marine Pollutant: No data available
DOT RQ (lbs): No information available
Special Provisions: IB8, IP2, IP4, T3, TP33
Symbol(s): [DOT]: (G) - Identifies proper shipping names for which one or more technical names of the hazardous material must be entered in parentheses, in association with the basic description.
Description: UN2811, Toxic solids, organic, n.o.s. (Cholecalciferol), 6.1, II

TDG (Canada)

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: II
Marine Pollutant: No Information available
Description: UN2811, Toxic solid, organic, n.o.s. (Cholecalciferol), 6.1, II

ADR

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Packing Group: II
Subsidiary Risk: No information available
Special Provisions: 274, 614
Description: UN2811, Toxic solid, organic, n.o.s. (Cholecalciferol), 6.1, II

IMO / IMDG

UN-No: UN2811
Proper Shipping Name: Toxic solids, organic, n.o.s. (cholecalciferol)
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: II
Marine Pollutant: No information available
EMS: F-A
Special Provisions: 274
Description: UN2811, Toxic solid, organic, n.o.s. (Cholecalciferol), 6.1, II

RID

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: II
Special Provisions: 274, 614
Description: UN2811, Toxic solid, organic, n.o.s. (Cholecalciferol), 6.1, II

ICAO

UN-No: UN2811

Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: II
Description: UN2811, Toxic solid, organic, n.o.s. (Cholecalciferol), 6.1, II
Special Provisions A3, A5

IATA

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: II
ERG Code: 6L
Special Provisions No information available
Description: UN2811, Toxic solid, organic, n.o.s. (Cholecalciferol), 6.1, II

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Cholecalciferol	67-97-0	Present(ACTI VE)	Present KE-30911	Present	Present (9)-1054	Present	Present	Present 200-673-2

U.S. Regulations

Cholecalciferol

New York Release Reporting - List of Hazardous Substances:

1 lb RQ

FDA - Food Additives Generally Recognized as Safe (GRAS): 21 CFR 184.1950

FDA - Direct Food Additives 21 CFR 172.380

FDA - 21 CFR - Total Food Additives 172.380, 184.1950, 582.5953

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:
Cholecalciferol	67-97-0	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
Cholecalciferol	67-97-0	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

Product code: CH134

Product name: CHOLECALCIFEROL,
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Cholecalciferol	67-97-0	Not Applicable	Not Applicable
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Canada

WHMIS 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

WHMIS 1988 Hazard Class

D1B Toxic materials

D1A Very toxic materials

Canada Controlled Products Regulation:

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Cholecalciferol	67-97-0	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Cholecalciferol	67-97-0	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Cholecalciferol	67-97-0	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Cholecalciferol	67-97-0	Acute toxicity - Oral - Acute Tox. 3: H301 Toxic if swallowed. (Minimum classification); Acute toxicity - Dermal - Acute Tox. 3: H311 Toxic in contact with skin. (Minimum classification); Acute toxicity - Inhalation - Acute Tox. 2: H330 Fatal if inhaled. (Minimum classification); Specific target organ toxicity - Repeated exposure - STOT RE 1: H372 Causes damage to organs through prolonged or repeated exposure. (No information to prove exclusion of certain routes of exposure)603-180-00-4

EU - CLP (1272/2008)

R-phrases(s)

R26 - Very toxic by inhalation.

R24/25 - Toxic in contact with skin and if swallowed.

R48/25 - Toxic: danger of serious damage to health by prolonged exposure if swallowed.

S -phrase(s)

S28 - After contact with skin, wash immediately with plenty of water

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S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

S 1/2 - Keep locked up and out of the reach of children.

S36/37 - Wear suitable protective clothing and gloves.

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Cholecalciferol	67-97-0	T; R24/25-48/25 T+; R26	No information	S1/2 S28 S36/37 S45

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

Indication of danger:

T - Toxic

T+ - Very toxic.

T+



T



16. OTHER INFORMATION

Preparation Date: 03/15/2016
Revision Date: 7/10/2018
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 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
CH134	Cholecalciferol, Crystal, 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

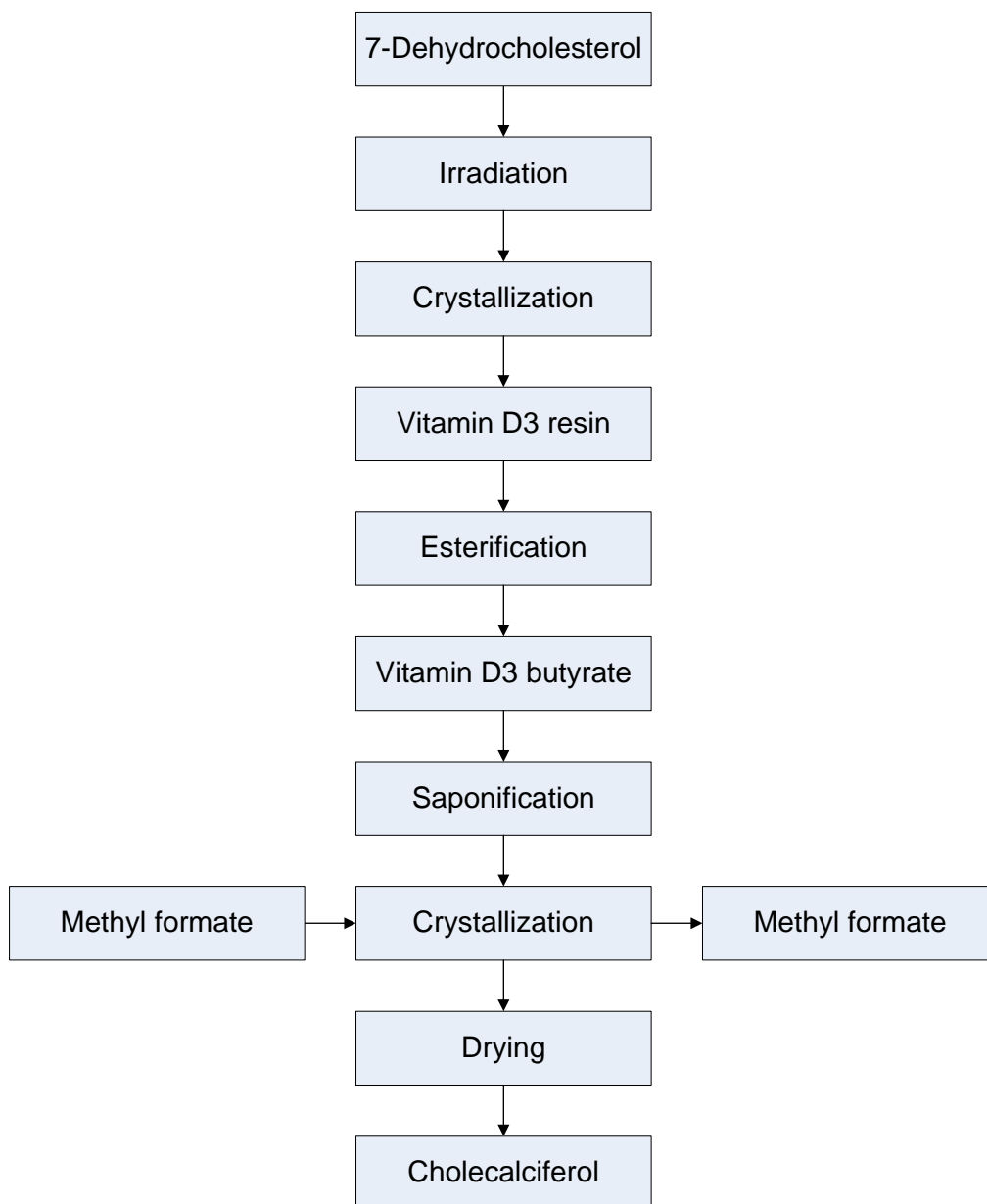
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

Cholecalciferol, Crystal, USP - CH134



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

CH134, Cholecalciferol, Crystal, USP

Source Statement

The above mentioned catalog item is manufactured by animal derived material (Sheep Wool). No plant derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item is manufactured using any animal derived products (Sheep Wool) and is therefore, BSE/TSE free.

Allergen Statement

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

- | | |
|-------------|-----------------------------|
| • Milk | • Cereals containing Gluten |
| • Egg | • Celery |
| • Fish | • Mustard |
| • Shellfish | • Sesame Seed |
| • Tree Nuts | • Corn |
| • Wheat | • Latex |
| • Peanuts | • Soy |

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 |



RE: Elemental Impurities - Cholecalciferol, Crystal, USP (Cat# CH134)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are 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 - Cholecalciferol, Crystal, USP (Cat# CH134)

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 USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Methanol	2	< 3000 ppm
Pyridine	2	< 200 ppm
Acetone	3	< 5000 ppm
Ethanol	3	< 5000 ppm

No Class 1 or other solvents are used or produced in the manufacturing process of this material.

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
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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.

Retest Date: 00-00-0000



DANGER
 • Fatal if swallowed, in contact with skin or if inhaled • Causes damage to organs through prolonged or repeated exposure.
 • Do not eat, drink or smoke when using this product • Wear respiratory protection, protective gloves, protective clothing • Do not get in eyes, on skin, or on clothing • Do not breathe 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 ON SKIN: Wash with plenty of water. Take off immediately all contaminated clothing and wash it before reuse. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth.

KEEP FROM CHILDREN



CH134 **SIZ SY**

Cholecalciferol
 (Activated 7-Dehydrocholesterol;
 Colecalciferol; Vitamin D₃)
 Crystal, USP
 CAS 67-97-0

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

DOT: UN2811, Toxic solid, organic, n.o.s. (cholecalciferol), 6.1, PG II

Chemical Emergency: (800)424-9300
www.SpectrumChemical.com

REFRIGERATE

$C_{27}H_{44}O$ F.W. 384.64

Assay 97.0-103.0%
 Specific Rotation, $[\alpha]_D^{25}$ +105° to +112°
MAXIMUM LIMITS
 Elemental Impurities As reported
 Residual Solvents To pass test

LIGHT SENSITIVE, AIR SENSITIVE: Keep tightly closed in light-resistant containers.

FLUSHED WITH NITROGEN, VACUUM SEALED.

B 16/11GHS ? Lot No. XQ####

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