

1. Identification

Product identifier	Calcitriol	
Other means of identification		
Catalog number	1086301	
Chemical name	9,10-Secocholesta-5,7,10(19)-triene-1,3,25-triol, monohydrate, (1 α ,3 β ,5Z,7E)- (9CI)	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacoepia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 1
	Acute toxicity, dermal	Category 1
	Reproductive toxicity	Category 2
	Specific target organ toxicity, repeated exposure	Category 1 (kidney, endocrine system, cardiovascular system)
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	Fatal if swallowed. Fatal in contact with skin. Suspected of damaging fertility or the unborn child. Causes damage to organs (kidney, endocrine system, cardiovascular system) through prolonged or repeated exposure.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get in eyes, on skin, or on clothing. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth. If on skin: Wash with plenty of water. Immediately call a poison center/doctor. Take off immediately all contaminated clothing and wash it before reuse. If exposed or concerned: Get medical advice/attention. Get medical advice/attention if you feel unwell.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	Not classified.

Other hazards which do not result in classification None known.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Calcitriol		77326-95-5	100

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse cautiously with water for several minutes. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if victim ingested the substance. Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed	Hypercalcemia.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Gastric lavage may prevent absorption following recent ingestion.
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting equipment/instructions	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

7. Handling and storage

Precautions for safe handling	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Exposure limit values

Industrial Use Material	Type	Value
Calcitriol (CAS 77326-95-5)	TWA	0.1 micrograms/m3

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Avoid any open handling of this material, particularly for grinding, crushing, weighing or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection	
Hand protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. This material is extremely potent. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.
Other	For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.
Respiratory protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	Colorless or white crystalline powder.
Physical state	Solid.
Form	Powder.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	231.8 - 239 °F (111 - 115 °C)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Practically insoluble.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	9,10-seco derivative.
Molecular formula	C27H44O3 . H2O

Molecular weight 434.65
Solubility (other) Freely soluble in alcohol and in ether; soluble in fatty oils; slightly soluble in methanol, in ethyl acetate, and in tetrahydrofuran.

10. Stability and reactivity

Reactivity Not available.
Chemical stability Stable at normal conditions.
Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.
Conditions to avoid None known.
Incompatible materials Strong oxidizing agents. Acid chlorides.. Acid anhydrides..
Hazardous decomposition products Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion Fatal if swallowed.
Inhalation Classification not possible.
Skin contact Fatal in contact with skin.
Eye contact Based on available data, the classification criteria are not met.

Symptoms related to the physical, chemical, and toxicological characteristics Vitamin D analogs: Nausea. Vomiting. Constipation. Diarrhea. Loss of appetite. Weight loss. Black, tarry stools. Increased urination. Thirst. Dry mouth. Metallic taste. Bone or muscle pain. Swelling. Tiredness. Weakness. Headache. Confusion. Depression. Vertigo. Irregular heartbeat. Seizures. Fever. Chills. Red eyes. Increased sensitivity of eyes to light. Itching. Runny nose. Decreased sex drive.

Delayed and immediate effects of exposure Vitamin D analogs: Hypercalcemia. Calcium deposits in tissue. Hyperphosphatemia. Electrolyte imbalance. Edema. Hypercalciuria. Proteinuria. High blood pressure. Kidney damage. Gastrointestinal bleeding. Nervous system problems. Bone demineralization.

Medical conditions aggravated by exposure Vitamin D analogs: Hyperphosphatemia. Hypercalcemia. Hypervitaminosis D. Impaired kidney function or kidney stones. Heart disease. Arteriosclerosis. Hypoparathyroidism. Sarcoidosis. Seizure disorders.

Acute toxicity Fatal if swallowed. Fatal in contact with skin.

Product	Species	Test Results
Calcitriol (CAS 77326-95-5)		
Oral		
LD50	Mouse	1350 microg/kg (anhydrous)
	Rat	620 µg/kg (anhydrous)

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Based on available data, the classification criteria are not met.

Local effects

Irritancy test
Result: Non-irritant (in anhydrous form).
Species: Rabbit
Organ: Eye.
Irritancy test
Result: Non-irritant (in anhydrous form).
Species: Rabbit
Organ: Skin.

Respiratory or skin sensitization

Respiratory sensitization Classification not possible.
Skin sensitization Based on available data, the classification criteria are not met.
Skin sensitization
Sensitization test
Result: Non-sensitizing (in anhydrous form).
Species: Guinea pig
Organ: Skin.

Germ cell mutagenicity Classification not possible.

Mutagenicity
In vitro Ames assay
Result: Negative (in anhydrous form).

Mutagenicity

In vivo chromosomal aberration assay in bone marrow cells
Result: Negative (in anhydrous form).
Species: Rat
In vivo micronucleus test
Result: Negative (in anhydrous form).
Species: Mouse

Carcinogenicity

Classification not possible.
This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Reproductive toxicity

Suspected of damaging fertility or the unborn child.

Reproductivity

0.08 - 0.3 microgram/kg Reproductivity test
Result: Increase in birth defects (with anhydrous form).
Species: Rabbit
0.3 - 0.8 microgram/kg Reproductivity test
Result: Hypercalcemia occurred in offspring (with anhydrous form).
Species: Rat
0.3 microgram/kg Reproductivity test
Result: Decreased fetal body weight and number of surviving newborns; maternal effects also occurred (with anhydrous form).
Species: Rabbit
0.45 microgram/kg Reproductivity test
Result: No increase in birth defects (with anhydrous form).
Species: Rat
3 microgram/kg Reproductivity test
Result: Did not impair fertility or reproductive performance (with anhydrous form).
Species: Rat

Specific target organ toxicity - single exposure

Classification not possible.

Specific target organ toxicity - repeated exposure

Causes damage to organs (kidney, endocrine system, cardiovascular system) through prolonged or repeated exposure.

Aspiration hazard

Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity

No ecotoxicity data noted for the ingredient(s).

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

Not available.

Mobility in soil

Not available.

Other adverse effects

Not available.

13. Disposal considerations

Disposal instructions

Dispose in accordance with all applicable regulations.

Local disposal regulations

Not available.

Hazardous waste code

Not regulated.

Waste from residues / unused products

Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

UN number UN2811
UN proper shipping name Toxic solid, organic, n.o.s. (Calcitriol)
Transport hazard class(es)
Class 6.1
Subsidiary risk -
Packing group I

IATA

UN number UN2811
UN proper shipping name Toxic solid, organic, n.o.s. (Calcitriol)

Transport hazard class(es)

Class 6.1

Subsidiary risk -

Packing group I

Other information

Passenger and cargo aircraft Allowed.

Cargo aircraft only Allowed.

Transport in bulk according to Not available.

Annex II of MARPOL 73/78 and the IBC Code

DOT; IATA

**15. Regulatory information**

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
 Delayed Hazard - Yes
 Fire Hazard - No
 Pressure Hazard - No
 Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

SARA 313 (TRI reporting)
Not regulated.**Other federal regulations**

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations**US. California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	10-07-2008
Revision date	03-15-2016
Version #	07
Further information	Not available.
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Revision Information	Physical & Chemical Properties: Multiple Properties Transport Information: Material Transportation Information