

1. Identification

Product identifier	Ergocalciferol	
Other means of identification		
Catalog number	1239005	
Chemical name	9,10-Secoergosta-5,7,10(19),22-tetraen-3-ol,(3beta,5Z,7E,22E)-	
Synonym(s)	Vitamin D2 Calciferol Oleovitamin D, synthetic	
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. Pharmacopeia	
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 2
	Acute toxicity, dermal	Category 3
	Acute toxicity, inhalation	Category 2
	Specific target organ toxicity, repeated exposure	Category 1 (kidney, bone)
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	Toxic in contact with skin. Fatal if swallowed. Fatal if inhaled. Causes damage to organs (kidney, bone) through prolonged or repeated exposure.
Precautionary statement	
Prevention	Do not breathe dust. Wash thoroughly after handling. Use only outdoors or in a well-ventilated area. Wear protective gloves/protective clothing. In case of inadequate ventilation wear respiratory protection.
Response	If swallowed: Immediately call a poison center/doctor. If on skin: Wash with plenty of water. If inhaled: Remove person to fresh air and keep comfortable for breathing. Immediately call a poison center/doctor. Rinse mouth. Take off immediately all contaminated clothing and wash it before reuse.
Storage	Store in a well-ventilated place. Keep container tightly closed. 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	%
Ergocalciferol	Vitamin D2 Calciferol Oleovitamin D, synthetic	50-14-6	100

4. First-aid measures

Inhalation Move to fresh air. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Call a physician or poison control center immediately.

Skin contact Take off immediately all contaminated clothing. Immediately flush skin with plenty of water. Get medical attention if irritation develops and persists.

Eye contact Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

Ingestion Call a physician or poison control center immediately. Rinse mouth thoroughly. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

Most important symptoms/effects, acute and delayed Irregular heart rate Skeletal pain.

Indication of immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. Administer activated charcoal as an aqueous slurry, unless contraindicated. To increase calcium excretion, employ forced saline diuresis with intravenous furosemide. Monitor urine, sodium, and potassium and replace lost fluids and electrolytes by intravenous infusion. Administering prednisone over one to two weeks may decrease plasma calcium. For cardiac arrhythmia, administer neostigmine, pyridostigmine, or propranolol. Monitor cardiac rhythm. For vitamin D intoxication, treatment with intramuscular injections of calcitonin may be useful. For hypercalcemia, administer sodium EDTA or mithramycin cautiously. For lowering serum calcium, cholestyramine may be helpful. (Meditext)

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 Use water spray to cool unopened containers. 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. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. 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

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

No exposure standards allocated.

Appropriate engineering controls

Engineering controls such as exhaust ventilation are recommended. 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

Wear suitable protective clothing. 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

White crystalline powder.

Physical state

Solid.

Form

Powder.

Odor

Odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

237.2 - 246.2 °F (114 - 119 °C) / 241.7 °F (116.5 °C)

Initial boiling point and boiling range

Sublimes.

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	< 0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Insoluble.
Partition coefficient (n-octanol/water)	8.89
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	9,10-Seco-derivative.
Molecular formula	C28H44O
Molecular weight	396.63
Solubility (other)	Soluble in acetone, in alcohol, in chloroform, in ether, and in fats.

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. Strong acids. Strong bases.
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	Fatal if inhaled.
Skin contact	Toxic in contact with skin.
Eye contact	Classification not possible.

Symptoms related to the physical, chemical, and toxicological characteristics Bone pain. Constipation. Diarrhea. Drowsiness. Muscle pain. Runny nose. Dry mouth. Itching. Headache. Thirst. Increased urination. Loss of appetite. Nausea. Vomiting. Tiredness. Weakness. Fever. Visual disturbances. Irregular heartbeat. Stomach pain. Weight loss. Mental status changes. Cloudy urine.

Delayed and immediate effects of exposure High blood pressure. Kidney failure. Hypercalcemia. Soft tissue calcification.

Medical conditions aggravated by exposure Hyperphosphatemia. Hypercalcemia. Hypervitaminosis D. Impaired kidney function. Impaired cardiac function. Malabsorption syndrome. Systemic lupus erythematosus. Arteriosclerosis. Kidney stones. Sarcoidosis.

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

Product	Species	Test Results
Ergocalciferol (CAS 50-14-6)		
Dermal		
LD50	Rat	61 mg/kg
Oral		
LD50	Rat	10 mg/kg
Skin corrosion/irritation	Classification not possible.	
Serious eye damage/eye irritation	Classification not possible.	
Respiratory or skin sensitization		
Respiratory sensitization	Classification not possible.	
Skin sensitization	Classification not possible.	
Germ cell mutagenicity	Classification not possible.	
Mutagenicity		
Chromosomal aberrations in Chinese hamster fibroblasts		
Result: Negative.		

Mutagenicity

S. typhimurium Ames assay
Result: Negative.

Carcinogenicity

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

Reproductive toxicity

Due to lack of data the classification is not possible.

Specific target organ toxicity - single exposure

Classification not possible.

Specific target organ toxicity - repeated exposure

Causes damage to organs (kidney, bone) 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**

This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. 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. (Ergocalciferol)

Transport hazard class(es)**Class**

6.1

Subsidiary risk

-

Packing group

II

IATA**UN number**

UN2811

UN proper shipping name

Toxic, solid, organic, n.o.s. (Ergocalciferol)

Transport hazard class(es)**Class**

6.1

Subsidiary risk

-

Packing group

II

Other information**Passenger and cargo aircraft**

Allowed.

Cargo aircraft only

Allowed.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not available.



15. Regulatory information

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

All components are on the U.S. EPA TSCA Inventory List.

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

Chemical name	CAS number	Reportable quantity	Threshold planning quantity	Threshold planning quantity, lower value	Threshold planning quantity, upper value
Ergocalciferol	50-14-6	1000		1000 lbs	10000 lbs

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)
 Total food additive
 Direct food additive
 GRAS food additive

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)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
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)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*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 06-05-2009

Revision date 09-09-2015

Material name: Ergocalciferol

1239005 Version #: 07 Revision date: 09-09-2015 Issue date: 06-05-2009

Version #	07
Further information	Not available.
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Revision Information	Physical & Chemical Properties: Multiple Properties Transport Information: Material Transportation Information