1. Identification

Product identifier: Cholecalciferol

Other means of identification
- Catalog number: 1131009
- Chemical name: 9,10-Secocholesta-5,7,10(19)-trien-3-ol, (3β,5Z,7E)-
- Synonym(s): Vitamin D3 * Colecalciferol * Activated 7-Dehydrocholesterol

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
- Company name: U. S. Pharmacopeia
- Address: 12601 Twinbrook Parkway
- Rockville
- MD
- 20852-1790
- U. S.
- 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

Note: This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.

Physical hazards: Not classified.

Health hazards
- Acute toxicity, oral: Category 2
- Acute toxicity, dermal: Category 2
- Acute toxicity, inhalation: Category 2
- Specific target organ toxicity, repeated exposure: Category 1 (kidney, bone)

OSHA hazard(s): Not classified.

Label elements

Signal word: Danger

Hazard statement: Fatal if swallowed. Fatal in contact with skin. Fatal if inhaled. Causes damage to organs (kidney, bone) through prolonged or repeated exposure.

Precautionary statement
- Prevention: Use only outdoors or in a well-ventilated area. Do not breathe dust/fume. Do not get in eyes, on skin, or on clothing. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing. Wear respiratory protection.
- Response: If on skin: Wash with plenty of water/soap. If inhaled: Remove person to fresh air and keep comfortable for breathing. Immediately call a poison center/doctor/medical professional. Rinse mouth.
- Storage: Store in a well-ventilated place. Keep container tightly closed. Store locked up.
- Disposal: Dispose of contents/container to an approved disposal site.

Hazard(s) not otherwise classified (HNOC): Not classified.
3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance</th>
<th>Hazardous components</th>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Cholecalciferol</td>
<td>Vitamin D3</td>
<td>67-97-0</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Colecalciferol</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Activated 7-Dehydrocholesterol</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. First-aid measures

Inhalation
Remove victim to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim 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. Call a physician or poison control center immediately.

Skin contact
Take off immediately all contaminated clothing. IF ON SKIN: Gently wash with plenty of soap and water. Call a physician or poison control center immediately.

Eye contact
Rinse cautiously with water for several minutes. Call a physician or poison control center immediately.

Ingestion
Rinse mouth. Call a physician or poison control center immediately. 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. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Most important symptoms/effects, acute and delayed
Not available.

Indication of immediate medical attention and special treatment needed
Treatment of vitamin D overdose should be symptomatic and supportive and may include the following: Gastric decontamination is seldom necessary with acute ingestion, unless extremely large amounts are ingested. For chronic exposure, initiate a low calcium diet. Increase calcium excretion by forced diuresis with intravenous furosemide. Measure urinary volumes, sodium, and potassium as pooled samples at least once every day. Replace lost fluids, sodium, and potassium by intravenous infusions. To decrease plasma calcium, administer prednisone for a short one to two week course. Rebound elevations in plasma calcium may occur. Calcitonin has been used in one case of vitamin D intoxication with success. For severe hypercalcemia not responding to other therapies, treat with sodium EDTA or mithramycin. These agents should be used with caution. To lower calcium level, cholestyramine may be effective. (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
Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

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
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. 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
Combustible dust clouds may be created where operations produce fine material (dust). Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. 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

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholecalciferol (CAS 67-97-0)</td>
<td>TWA</td>
<td>0.01 mg/m³</td>
</tr>
</tbody>
</table>

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
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).

Thermal hazards
Not available.

General hygiene considerations
Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance
White or almost white crystals.

Physical state
Solid.

Form
Crystals.

Odor
Odorless.

Odor threshold
Not available.

pH
Not available.

Melting point/freezing point
183.2 - 192.2 °F (84 - 89 °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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability limit - lower (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flammability limit - upper (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Explosive limit - lower (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Explosive limit - upper (%)</td>
<td>Not available.</td>
</tr>
</tbody>
</table>

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): 11.1

Auto-ignition temperature: Not available.

Decomposition temperature: Not available.

Viscosity: Not available.

Other information

- Chemical family: 9,10-Seco-derivative.
- Dust explosion properties:
  - Minimum ignition energy (MIE) - dust cloud: < 1 mJ
  - Molecular formula: C27H44O
  - Molecular weight: 384.64
  - Potential for dust explosion: Dust explosion hazard.
  - Solubility (other): Soluble in alcohol, in chloroform, in ether, and in fatty oils.

10. Stability and reactivity

- Reactivity: No reactivity hazards known.
- Chemical stability: Stable at normal conditions.
- Possibility of hazardous reactions: No dangerous reaction known under conditions of normal use.
- Conditions to avoid: None known.
- 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: 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


Delayed and immediate effects of exposure


Medical conditions aggravated by exposure


Acute toxicity

Fatal if swallowed. Fatal if inhaled. Fatal in contact with skin.
<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholecalciferol (CAS 67-97-0)</td>
<td>Dermal</td>
<td>Rat 61 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Inhalation</td>
<td>LC50 Rat 0.13 - 0.38 mg/l, 4 hours</td>
</tr>
<tr>
<td></td>
<td>Oral</td>
<td>LD50 Mouse 42500 microg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rat 42 mg/kg</td>
</tr>
</tbody>
</table>

### 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: Irritant.
  - Species: Rabbit
  - Organ: Skin
  - Severity: Slight.
- **Irritancy test**
  - Result: Non-irritant.
  - Species: Rabbit
  - Organ: Eye

### Respiratory sensitization
Due to lack of data the classification is not possible.

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

### Sensitization
- **Sensitization test**
  - Result: Non-sensitizing.
  - Species: Guinea pig
  - Organ: Skin

### Germ cell mutagenicity
Due to lack of data the classification is not possible.

### Carcinogenicity
Due to lack of data the classification is not possible.
This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

### Reproductive toxicity
Based on available data, the classification criteria are not met.
Problems in humans have not been documented with intake of normal daily requirements of vitamin D during pregnancy. Maternal hypercalcemia may be associated with increased sensitivity to the effects of vitamin D, suppression of parathyroid function, or a syndrome of peculiar (elfin) facies, mental retardation, and congenital aortic stenosis in infants.
A related material has caused birth defects in animals. Adverse fetal effects were seen in animal studies with a related material.

### Specific target organ toxicity - single exposure
Based on available data, the classification criteria are not met.

### 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
Dispose of contents/container in accordance with local/regional/national/international 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

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN number</td>
<td>UN2811</td>
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<tr>
<td>UN proper shipping name</td>
<td>Toxic solid, organic, n.o.s. (Cholecalciferol)</td>
</tr>
<tr>
<td>Transport hazard class(es)</td>
<td>6.1</td>
</tr>
<tr>
<td>Subsidiary class(es)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Packing group</td>
<td>II</td>
</tr>
</tbody>
</table>

IATA

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
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</thead>
<tbody>
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<td>UN number</td>
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<td>Subsidiary class(es)</td>
<td>-</td>
</tr>
<tr>
<td>Packaging group</td>
<td>II</td>
</tr>
</tbody>
</table>

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

No information 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 - No
- Fire Hazard - No
- Pressure Hazard - No
- Reactivity Hazard - No

SARA 302 Extremely hazardous substance

No

SARA 311/312 Hazardous chemical

No

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

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

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

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

**Issue date**: 05-15-2006

**Revision date**: 09-06-2013

**Version #**: 02

**Further information**: Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

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**Revision Information**: This document has undergone significant changes and should be reviewed in its entirety.