Cholecalciferol (Vitamin D3)

SAFETY DATA SHEET

Section 1 Identification of the substance/mixture and of the company/undertaking

Product Identifier: Cholecalciferol

Identification of the Product:
Formula: \( \text{C}_{27}\text{H}_{44}\text{O} \)
Chemical Name: \((1S,3Z)-3-[(2E)-2-[(1R,3aS,7aR)-7a-methyl-1-[(2R)-6-methylheptan-2-yl]2,3,3a,5,6,7-hexahydro-1H-inden-4-ylidene]ethylidene]-4-methylidenecyclohexan-1-ol\)
CAS: 67-97-0

Relevant identified uses of the substance and uses advised against:
Identified Uses: Active pharma ingredients
Uses Advised Against: No information available

Name, address, and telephone number of the manufacturer:
Refer to Supplier

Name, address, and telephone number of the supplier:
Encore Scientific 801 West New Orleans Street Broken Arrow, OK, USA 74011
Supplier’s Telephone # 800-454-2304 Monday to Friday 8:00 am to 6:00 pm (Central time)
24 Hr. Emergency Tel # INFOTRAC: (800) 535-5053 (Within Continental US and Canada); (352)323-3500 (International)

Section 2 Hazards 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 Hazards (s): Not classified.

Label Elements:
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Section 2 Hazards Identification (Continued)

Signal Word: Danger
Hazard Statement:
- Acute Tox. 3 H301 Toxic if swallowed.
- Acute Tox. 3 H311 Toxic in contact with skin.
- Acute Tox. 2 H330 Fatal if inhaled.
- Acute Tox. 1 H372 Causes damage to organs through prolonged or repeated exposure.

Precautionary Statement:
- P260 Do not breathe dust/fume/gas/mist/vapors/spray.
- P284 Wear respiratory protection.
- P280 Wear protective gloves / protective clothing.
- P301+P310 If swallowed: Immediately call a poison center/doctor.
- P320 Specific treatment is urgent (see on this label).
- P405 Store locked up.

Hazard(s) not otherwise classified (HNOC): Not classified.

Section 3 Composition/information on ingredients

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS No.</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholecalciferol</td>
<td>67-97-0</td>
<td>100</td>
</tr>
</tbody>
</table>

Section 4 First aid measures

Description of first aid measures

Eye Contact: Rinse cautiously with water for several minutes. Get medical attention if irritation develops and persists.

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.

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.

After 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.
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Section 4 First aid measures (Continued)

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

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.

Section 5 Fire-Fighting measures

EXTINGUISHING MEDIA: Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding 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.

FIREFIGHTING EQUIPMENT/INSTRUCTIONS: As with all fires, evacuate personnel to a safe area. Fire fighters 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.
Section 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.

Section 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. 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.

Section 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.
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### Section 8 Exposure Controls/Personal Protection (Continued)

**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 cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

**Thermal hazards:** Wear appropriate thermal protective clothing, when necessary.

**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.

### Section 9 Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical State</strong></td>
<td>Solid</td>
</tr>
<tr>
<td><strong>Appearance</strong></td>
<td>White or almost white crystals.</td>
</tr>
<tr>
<td><strong>Odor</strong></td>
<td>Odorless</td>
</tr>
<tr>
<td><strong>Odor Threshold</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>9-10</td>
</tr>
<tr>
<td><strong>Melting Point/Range</strong></td>
<td>105.8 - 114.8 °F (41 - 46 °C)</td>
</tr>
<tr>
<td><strong>Boiling Point/Range</strong></td>
<td>565.009°C at 760 mmHg</td>
</tr>
<tr>
<td><strong>Flash Point</strong></td>
<td>238.43°C</td>
</tr>
<tr>
<td><strong>Evaporation Rate</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Flammability (solid, gas)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Flammability or explosive limits</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Upper</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Lower</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Vapor Pressure</strong></td>
<td>&lt; 0.0000001 kPa at 25 °C</td>
</tr>
<tr>
<td><strong>Vapor Density</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Solubility</strong></td>
<td>Soluble in alcohol, in chloroform, in ether, and in fatty oils; insoluble in water.</td>
</tr>
<tr>
<td><strong>Partition coefficient (n-octanol/water)</strong></td>
<td>11.1</td>
</tr>
<tr>
<td><strong>Auto-ignition temperature</strong></td>
<td>Not available</td>
</tr>
</tbody>
</table>
Cholecalciferol (Vitamin D3)

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Section 9 Physical and chemical properties (Continued)

Viscosity:
  Dynamic: Not applicable.
  Kinematic: Not applicable.

Chemical Family: 9,10-Seco-derivative

Dust explosion properties
  Minimum ignition energy (MIE) - dust cloud: < 1 mJ

Molecular formula: C_{27}H_{44}O
Molecular weight: 384.64
Potential for dust explosion: Dust explosion hazard

Section 10 Stability and reactivity

Reactivity: No reactivity hazards known.
Chemical stability: Material is stable under 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.

Section 11 Toxicological information

Information on likely routes of exposure
  Inhalation: Fatal if inhaled.
  Skin contact: Fatal in contact with skin.
  Eye contact: Based on available data, the classification criteria are not met.
  Ingestion: Fatal if swallowed.


Acute toxicity: Fatal if swallowed. Fatal if inhaled. Fatal in contact with skin.
Cholecalciferol (Vitamin D3)

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Section 11 Toxicological information (Continued)

<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></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>61 mg/kg</td>
</tr>
<tr>
<td>Inhalation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LC50</td>
<td>Rat</td>
<td>0.13 - 0.38 mg/l, 4 hours</td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Mouse</td>
<td>42500 micro/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>42 mg/kg</td>
</tr>
</tbody>
</table>

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

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

Irritation

Local Effects:
- 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 - Based on available data, the classification criteria are not met.
- single exposure

Specific target organ toxicity - Causes damage to organs (kidney, bone) through prolonged or repeated exposure.
- repeated exposure

Aspiration hazard: Based on available data, the classification criteria are not met.
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Section 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.

Section 13 Disposal considerations

Disposal instructions: Dispose in accordance with all applicable regulations. 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.
Local disposal regulations: Not available.
Hazardous waste code: Not available.

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

Section 14 Transport information

DOT

<table>
<thead>
<tr>
<th>UN number</th>
<th>Toxic solid, organic, n.o.s. (Cholecalciferol)</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN2811</td>
<td></td>
</tr>
</tbody>
</table>

IATA

<table>
<thead>
<tr>
<th>UN number</th>
<th>Toxic solid, organic, n.o.s. (Cholecalciferol)</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN2811</td>
<td></td>
</tr>
</tbody>
</table>

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

DOT; IATA

No information available.
Section 14 Transport information (Continued)

Section 15 Regulation 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
- 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.
Tetracaine USP

SDS Preparation Date 07/05/2017

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Section 15 Regulation information (Continued)

<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>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>Yes</td>
</tr>
</tbody>
</table>
| 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)

Section 16 Other information

Date of Preparation/Last Revision: 07/05/2017/

Further information: This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

Notice to reader: Employers should use this information only as a supplement to other information gathered by them, and should make independent judgment of suitability of this information to ensure proper use and protect the health and safety of employees. This information is furnished without warranty, and any use of the product not in conformance with this Safety Data Sheet, or in combination with any other product or process, is the responsibility of the user.