

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 and according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Date of issue: 12/04/2012 Revision date: 11/06/2021 Supersedes: 24/12/2019 Version: 2.2

DLM-9107

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Substance

Substance name : 1,25-DIHYDROXYVITAMIN D3 (6,19,19-D3,97%) (CHEMICAL PURITY 95%)

EC-No. : 250-963-8 (Unlabeled)

CAS-No. : 128723-16-0
Product code : DLM-9107

Synonyms : Calcitriol / 1alpha,25-Dihydroxycholecalciferol

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category : Professional use

Industrial/Professional use spec : For professional use only

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Cambridge Isotope Laboratories, Inc. 50 Frontage Road Andover, MA 01810

USA

USA: 1-800-322-1174 Int: 1-978-749-8000 <u>cilsales@isotope.com</u> www.isotope.com

Emergency telephone number

Emergency numbers:

Chemtrec: 1-800-424-9300 (24 hours) International: 1-703-741-5970 (24 hours)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute Tox. 2 (Oral) H300
Acute Tox. 1 (Dermal) H310
Acute Tox. 2 (Inhalation:dust,mist) H330
Repr. 2 H361fd

Full text of hazard classes and H-statements : see section 16

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

T+; R26/27/28 Repr.Cat.3; R62 Repr.Cat.3; R63

Full text of R-phrases: see section 16

GHS-US classification

Acute Tox. 2 (Oral) H300 Acute Tox. 1 (Dermal) H310 Acute Tox. 2 (Inhalation) H330 Repr. 2 H361

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

Gastrointestinal tract, Bone, Kidney, Central nervous system.

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2.2. **Label elements**

Labeling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)





GHS06

Signal word (CLP) : Danger

Hazard statements (CLP) H300+H310+H330 - Fatal if swallowed, in contact with skin or if inhaled

H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.

P260 - Do not breathe dust, fume, gas, spray, mist, vapors. Precautionary statements (CLP)

P264 - Wash Both hands thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P271 - Use only outdoors or in a well-ventilated area. P280 - Wear protective clothing, protective gloves.

P284 - [In case of inadequate ventilation] wear respiratory protection.

P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor.

P302+P352 - IF ON SKIN: Wash with plenty of water.

GHS-US labeling

Hazard pictograms (GHS-US)





GHS06

GHS08

Signal word (GHS-US)

H300+H310+H330 - Fatal if swallowed, in contact with skin or if inhaled Hazard statements (GHS-US)

H361 - May damage fertility or the unborn child (Dermal, Inhalation, oral)

P201 - Obtain special instructions before use. Precautionary statements (GHS-US)

P202 - Do not handle until all safety precautions have been read and understood.

P260 - Do not breathe dust, fume, gas, mist, spray, vapors.

P262 - Do not get in eyes, on skin, or on clothing.

P264 - Wash Both hands thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.

P271 - Use only outdoors or in a well-ventilated area.

P280 - Wear protective clothing, protective gloves.

P284 - [In case of inadequate ventilation] wear respiratory protection. P301+P310 - If swallowed: Immediately call a poison center or doctor

P304+P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing

P308+P313 - If exposed or concerned: Get medical advice/attention.

P310 - Immediately call a poison center or doctor

P320 - Specific treatment is urgent (see Hazard pictograms (CLP) on this label)

P321 - Specific treatment (see Hazard pictograms (CLP) on this label)

P330 - Rinse mouth.

P361 - Take off immediately all contaminated clothing. P363 - Wash contaminated clothing before reuse.

P403+P233 - Store in a well-ventilated place. Keep container tightly closed.

P405 - Store locked up.

P501 - Dispose of contents/container to Comply with applicable regulations

Other hazards

No additional information available

SECTION 3: Composition/Information on ingredients

Substances

Name	Product identifier	%	Classification according to Directive 67/548/EEC
1,25-DIHYDROXYVITAMIN D3 (6,19,19-D3,97%) (CHEMICAL PURITY 95%)	(CAS-No.) 128723-16-0 (EC-No.) 250-963-8 (Unlabeled)	100	T+; R26/27/28 Repr.Cat.3; R62 Repr.Cat.3; R63

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Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
1,25-DIHYDROXYVITAMIN D3 (6,19,19-D3,97%) (CHEMICAL PURITY 95%)	(CAS-No.) 128723-16-0 (EC-No.) 250-963-8 (Unlabeled)	100	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Acute Tox. 2 (Inhalation:dust,mist), H330 Repr. 2, H361fd

Full text of R- and H- phrases: see section 16

Name	Product identifier	%	GHS-US classification
1,25-DIHYDROXYVITAMIN D3 (6,19,19-D3,97%) (CHEMICAL PURITY 95%) (Main constituent)	(CAS-No.) 128723-16-0	100	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Acute Tox. 2 (Inhalation), H330 Repr. 2, H361

Full text of H-phrases: see section 16

Mixtures

Not applicable

SECTION 4: First aid measures

Description of first aid measures

: Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of First-aid measures general dangerous area.

First-aid measures after inhalation If breathed in, move person to fresh air. If not breathing, give artificial respiration. Consult a

physician.

First-aid measures after skin contact Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a

physician.

First-aid measures after eye contact Flush eyes with water as a precaution.

First-aid measures after ingestion Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a

physician.

Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation : Toxic if inhaled. May cause respiratory tract irritation.

Symptoms/effects after skin contact : May be harmful if absorbed through skin. May cause skin irritation.

Symptoms/effects after eye contact : May cause eye irritation. Symptoms/effects after ingestion : May be fatal if swallowed.

Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

Extinguishing media

Suitable extinguishing media : Use water spray, alcohol-resistant foam, dry chemical, or carbon dioxide

Special hazards arising from the substance or mixture

No additional information available

Advice for firefighters

Firefighting instructions : Wear self-contained breathing apparatus when entering area unless atmosphere is proved to

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

General measures Not flammable or combustible.

For non-emergency personnel

Emergency procedures : Wear respiratory protection. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure

adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

6.1.2. For emergency responders

No additional information available

Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

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Methods and material for containment and cleaning up 6.3.

For containment

: Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

Reference to other sections

No additional information available

SECTION 7: Handling and storage

Precautions for safe handling

Additional hazards when processed

: Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.

Hygiene measures

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Conditions for safe storage, including any incompatibilities

Storage conditions : Store in freezer (-20°C). Protect from light.

Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

Control parameters

No additional information available

Exposure controls

Appropriate engineering controls

Personal protective equipment

: Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

: Gloves. Protective clothing. Protective goggles. Self-contained breathing apparatus.









Materials for protective clothing

Environmental exposure controls

Hand protection

Eve protection

Respiratory protection

Skin and body protection

: Wear suitable protective clothing and gloves. Wear suitable protective clothing and gloves. Wear safety glasses with side shields (or goggles) and a face shield.

Choose body protection according to the amount and concentration of the dangerous

substance at the work place. : When appropriate, use NIOSH/CEN approved respirator.

: Avoid release to the environment.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Physical state : Solid Solid Appearance

Molecular mass 419.66 g/mol (Labeled)

Color

No data available Odor Odor threshold No data available рΗ No data available Relative evaporation rate (butyl acetate=1) No data available Melting point No data available Freezing point : No data available : No data available **Boiling point** Flash point No data available Auto-ignition temperature No data available Decomposition temperature : No data available Flammability (solid, gas) No data available Vapor pressure No data available Relative vapor density at 20 °C : No data available Relative density : No data available

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: No data available Solubility Log Pow : No data available Log Kow : No data available Viscosity, kinematic No data available Viscosity, dynamic No data available **Explosive properties** : No data available Oxidizing properties : No data available **Explosion limits** : No data available

Other information

No additional information available

SECTION 10: Stability and reactivity

Reactivity

No additional information available

10.2 **Chemical stability**

Stable if stored under recommended conditions.

Possibility of hazardous reactions

No additional information available

Conditions to avoid

Air, moisture, light.

Incompatible materials

Strong oxidizing agents, Acid chlorides, Acid anhydrides.

Hazardous decomposition products

Formed under fire conditions: Carbon oxides.

SECTION 11: Toxicological information

Information on toxicological effects

Acute toxicity : Oral: Fatal if swallowed. Dermal: Fatal in contact with skin. Inhalation:dust,mist: Fatal if inhaled.

1,25-DIHYDROXYVITAMIN D3 (6,19,19-D3,97%) (CHEMICAL PURITY 95%) (128723-16-0)	
ATE CLP (oral)	5.000 mg/kg body weight
ATE CLP (dermal)	5.000 mg/kg body weight
ATE CLP (dust, mist)	0.050 mg/l/4h

Skin corrosion/irritation : Not classified Serious eye damage/irritation : Not classified Respiratory or skin sensitization Not classified Germ cell mutagenicity Not classified Carcinogenicity Not classified

Reproductive toxicity : Suspected of damaging fertility. Suspected of damaging the unborn child.

Specific target organ toxicity - single exposure : Not classified

No data available

Specific target organ toxicity - repeated

exposure

: Not classified

: Not classified Aspiration hazard

Potential Adverse human health effects and

symptoms

Symptoms of exposure may include burning sensation, coughing, wheezing, laryngitis, shortness of breath, headache, nausea, and vomiting. This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Symptoms/effects after inhalation Toxic if inhaled. May cause respiratory tract irritation.

May be harmful if absorbed through skin. May cause skin irritation. Symptoms/effects after skin contact

Symptoms/effects after eye contact May cause eye irritation. Symptoms/effects after ingestion : May be fatal if swallowed.

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SECTION 12: Ecological information

Toxicity

Ecology - general

: The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

Persistence and degradability

No additional information available

Bioaccumulative potential

No additional information available

Mobility in soil

No additional information available

Results of PBT and vPvB assessment

No additional information available

Other adverse effects

No additional information available

SECTION 13: Disposal considerations

Waste treatment methods

Regional legislation (waste)

: Waste materials should be disposed of under conditions which meet Federal, State, and local

environmental control regulations

Product/Packaging disposal recommendations

Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed

professional waste disposal service to dispose of this material.

Ecology - waste materials : Dispose of as unused product.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. **UN** number

UN-No.(DOT) : 2811 DOT NA no. UN2811

UN proper shipping name

Proper Shipping Name (DOT)

: Toxic solids, organic, n.o.s.

Class (DOT)

: 6.1 - Class 6.1 - Poisonous materials 49 CFR 173.132

Hazard labels (DOT) : 6.1 - Poison



DOT Symbols

: G - Identifies PSN requiring a technical name

Packing group (DOT)

: I - Great Danger

DOT Special Provisions (49 CFR 172.102)

: IB8 - Authorized IBCs: Metal (11A, 11B, 11N, 21A, 21B, 21N, 31A, 31B and 31N); Rigid plastics (11H1, 11H2, 21H1, 21H2, 31H1 and 31H2); Composite (11HZ1, 11HZ2, 21HZ1 21HZ2, 31HZ1 and 31HZ2); Fiberboard (11G); Wooden (11C, 11D and 11F); Flexible (13H1, 13H2, 13H3, 13H4, 13H5, 13L1, 13L2, 13L3, 13L4, 13M1 or 13M2).

IP2 - When IBCs other than metal or rigid plastics IBCs are used, they must be offered for transportation in a closed freight container or a closed transport vehicle.

IP4 - Flexible, fiberboard or wooden IBCs must be sift-proof and water-resistant or be fitted with a sift-proof and water-resistant liner.

T3 - 2.65 178.274(d)(2) Normal..... 178.275(d)(2)

TP33 - The portable tank instruction assigned for this substance applies for granular and powdered solids and for solids which are filled and discharged at temperatures above their melting point which are cooled and transported as a solid mass. Solid substances transported or offered for transport above their melting point are authorized for transportation in portable tanks conforming to the provisions of portable tank instruction T4 for solid substances of packing group III or T7 for solid substances of packing group II, unless a tank with more stringent requirements for minimum shell thickness, maximum allowable working pressure, pressure-relief devices or bottom outlets are assigned in which case the more stringent tank instruction and special provisions shall apply. Filling limits must be in accordance with portable tank special provision TP3. Solids meeting the definition of an elevated temperature material must be transported in accordance with the applicable requirements of this subchapter.

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DOT Packaging Exceptions (49 CFR 173.xxx) : 153
DOT Packaging Non Bulk (49 CFR 173.xxx) : 212
DOT Packaging Bulk (49 CFR 173.xxx) : 242

14.3. Additional information

Other information : No supplementary information available.

Overland transport

EAC : 2X

Transport by sea

DOT Vessel Stowage Location : B - (i) The material may be stowed "on deck" or "under deck" on a cargo vessel and on a

passenger vessel carrying a number of passengers limited to not more than the larger of 25 passengers, or one passenger per each 3 m of overall vessel length; and (ii) "On deck only" on passenger vessels in which the number of passengers specified in paragraph (k)(2)(i) of this

section is exceeded.

MFAG-No : 154

Air transport

DOT Quantity Limitations Passenger aircraft/rail : 25 kg

(49 CFR 173.27)

DOT Quantity Limitations Cargo aircraft only (49 : 100 kg

CFR 175.75)

Civil Aeronautics Law : Toxic and infectious substances/Toxic substances

14.4. Environmental hazards

Other information : No supplementary information available.

14.5. Special precautions for user

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

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

1,25-DIHYDROXYVITAMIN D3 (6,19,19-D3,97%) (CHEMICAL PURITY 95%) (128723-16-0)		
SARA Section 302 Threshold Planning Quantity (TPQ)	Not subject to reporting requirements of the United States SARA Section 302	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard Delayed (chronic) health hazard	
SARA Section 313 - Emission Reporting	Not subject to reporting requirements of the United States SARA Section 313	

15.2. International regulations

CANADA

No additional information available

15.2.1. National regulations

No additional information available

15.3. US State regulations

1,25-DIHYDROXYVITAMIN D3 (6,19,19-D3,97%) (CHEMICAL PURITY 95%)(128723-16-0)		
U.S California - Proposition 65 - Carcinogens List	No No	
U.S California - Proposition 65 - Developmental Toxicity	No	
U.S California - Proposition 65 - Reproductive Toxicity - Female	No	
U.S California - Proposition 65 - Reproductive Toxicity - Male	No	
State or local regulations	U.S Pennsylvania - RTK (Right to Know) List U.S New Jersey - Right to Know Hazardous Substance List	

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SECTION 16: Other information

Other information

: This product is not radioactive. The data given for this product are those of the corresponding unlabeled compound, unless specifically indicated otherwise. Health and safety data for labeled compounds are generally not available, but are assumed to be similar or identical to the corresponding unlabeled compound.

Full text of R-, H- and EUH-phrases:

Acute toxicity (dermal) Category 1
Acute toxicity (inhalation:dust,mist) Category 2
Acute toxicity (oral) Category 2
Reproductive toxicity Category 2
Fatal if swallowed
Fatal in contact with skin
Fatal if inhaled
Suspected of damaging fertility. Suspected of damaging the unborn child.
Very toxic by inhalation, in contact with skin and if swallowed
Possible risk of impaired fertility
Possible risk of harm to the unborn child
Very toxic

NFPA health hazard

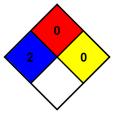
: 2 - Materials that, under emergency conditions, can cause temporary incapacitation or residual injury.

NFPA fire hazard

 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.

NFPA reactivity

0 - Material that in themselves are normally stable, even under fire conditions.



Hazard Rating

Health

: 4 Severe Hazard - Life-threatening, major or permanent damage may result from single or repeated overexposures

Flammability Physical : 0 Minimal Hazard: 0 Minimal Hazard

CIL Substance SDS

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

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