

PRODUCT TECHNICAL DOSSIER

VITAMIN D3 1.0 MIU/G

Product Code:

P22179

Raw Material Full Name:

Vitamin D3 1.0 MIU/g

Raw Material Full Botanical/Chemical/Latin/Trade Name/Synonyms:

(5Z, 7E) - (3S)-9, 10-secocholesta-5, 7, 10 (19)-trien-3-ol; (5Z, 7E) - (3S)-9, 10-secocholesta-5, 7, 10 (19)-trien-3 β -ol

This material is Food Grade:

✓

Vegan / Vegetarian Status:

Vegan Suitable: No

Vegetarian Suitable: Yes

Limit/Range/Specification:

0.9 MIU/g – 1.1 MIU/g Vitamin D3

CAS Number:

67-97-0

EC/EINECS Number:

200-673-2

Molecular Formula for the raw material:

C₂₇H₄₄O

Average Molecular weight:

384.65g/mol

Peroxide Value:

Max 2.0 mEq/kg

Acid Value:

Max 1.0mg KOH/g

Country of Origin:

Europe

Product Code: P22179

Version: 2

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success starts with the finest ingredients...

Country of Origin of the Manufacture:

Europe

Base Source/Start Material:

Cholesterol from wool grease (lanolin)

Origin of Product – Synthetic, Plant, Mineral, Animal, Fish or Fermented:

Animal

Material is:

2.5% Vitamin D3

0.25% dl-alpha-tocopherol

97.25% Medium Chain Triglycerides

Shelf Life from Date of Manufacture:

Min 3 Years

Storage Conditions:

Keep container tightly closed and dry. Store at a temperature of <15°C.

Appearance (Fine/Crystals/Crystalline/Hygroscopic):

Clear Oily Liquid

Colour:

Colourless to Slightly Yellowish

Flavour/Taste:

Characteristic

Odour:

Characteristic

There are no nuts in this recipe; however, we cannot guarantee that the raw materials entering the site are nut free.

Please note that surveillance testing may mean that not all the parameters stated on this specification are tested for every batch.



ALLERGENS	Product Free From YES/NO	Listed Item on Site at Manufacturer YES/NO	If YES, Please Comment
Free from Peanuts and Peanut Derivatives (including possible cross contamination)	YES	NO	
Free from other Nut and Nut Derivatives <i>Almond (Amygdalus communis L.), Hazelnut (Corylus avellana), Walnut (Juglans regia), Cashew (Anacardium occidentale), Pecan nut (Carya illinoiesis (Wangenh.) K. Koch), Brazil nut (Bertholletia excelsa), Pistachio nut (Pistacia vera), Macadamia nut and Queensland nut (Macadamia ternifolia)</i>	YES	NO	
Free from Sesame Seeds and Sesame Seed Derivatives	YES	NO	
Free from other Seeds and Seed Derivatives (Poppy Seeds, Cotton Seeds, Sunflower Seeds)	YES	NO	
Free from Milk and Milk Derivatives (including lactose)	YES	NO	
Free from Egg and Egg Derivatives	YES	NO	
Free from Cereals and Derivatives containing OR POTENTIALLY CONTAMINATED WITH Gluten (<i>wheat, wheatgrass, faro, freekeh, spelt, kamut, rye, oats, barley, barley grass</i>)	YES	NO	
Free from Soya and Soya Derivatives	YES	NO	
Free from Lupin and Lupin Derivatives	YES	NO	
Free from Mustard and Mustard Derivatives	YES	NO	
Free from Celery or Celery Derivatives (including Celeriac)	YES	NO	
Free from Fish and Fish Derivatives	YES	NO	
Free from Molluscs and their Derivatives	YES	NO	
Free from Crustaceans and their Derivatives	YES	NO	
Free from Sulphur Dioxide and Sulphites (E220, E228) at levels > 10mg/kg or 10mg/litre	YES	NO	



ADDITIVES / CONTAMINANTS / DIETARY REQUIREMENTS	Product Free From YES/NO	Listed Item on Site at Manufacturer YES/NO	If YES, Please Comment
Free from Additives	NO	YES	dl-alpha-tocopherol is added as an antioxidant
Free from Antioxidants	YES	NO	
Free from Ethylene Oxide	YES	NO	
Free from Gelatine	YES	NO	
Free from Flavourings (Artificial / Nature Identical / Natural / Smoked)	YES	NO	
Free from Maize / Corn and any Derivatives	YES	NO	
Free from Legumes / Pulses	YES	NO	
Free from Rice and Rice Derivatives	YES	NO	
Free from Added Salt	YES	NO	
Free from Added Sugar / artificial or natural sweeteners	YES	NO	
Free from Aspartame	YES	NO	
Free from BHA / BHT (E320 / E321)	YES	NO	
Free from Caffeine	YES	NO	
Free from Colours (Artificial / Nature Identical / Natural / Smoked)	YES	NO	
Free from Dextrose	YES	NO	
Free from Dioxins	YES	NO	
Free from MSG (Added and Naturally Occurring E621) or Glutamates (E620 to E625)	YES	NO	
Free from Nucleotides (E627, E630, E631, E635)	YES	NO	
Free from Polyols (sugar alcohols)	YES	NO	
Free from Benzoates (E210 / E219)	YES	NO	
Free from Sorbic Acid (E200, E203)	YES	NO	
Free from any other Preservatives	YES	NO	
Free from Ethanol	YES	NO	
Free from Honey	YES	NO	
Free from Lactose	YES	NO	
Free from Yeast and Yeast Derivatives	YES	NO	
Free from All Animal Products (Beef, Pork, Poultry or other) and Derivatives (which may include growth/yield hormones, antibiotics etc.)	NO	YES	Cholesterol from wool grease (lanolin)
Free from Bovine Products or Derivatives (which may include growth/yield hormones, antibiotics etc.)	YES	NO	

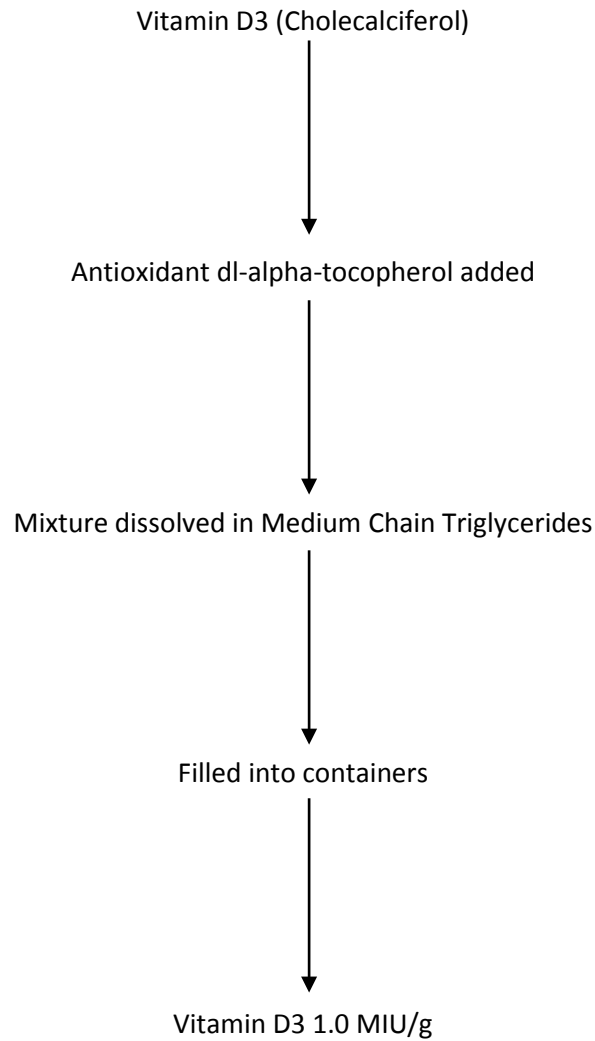


NUTRITIONAL DATA

Test	Calculated Value per 100gm
Energy KJ / Kcal	3,598KJ / 875Kcal
Fat	97.3g
- of which saturated fatty acids	97.3g
- of which mono-unsaturated fatty acids	0g
- of which poly-unsaturated fatty acids	0g
- of which trans fatty acids	0g
- of which Cholesterol	0g
Carbohydrate	0g
- of which sugars	0g
- of which polyols	0g
- of which starch	0g
Fibre	0g
Protein	0g
Salt	0g



PRODUCTION FLOW CHART



CONFIRMATION OF BSE/TSE STATUS

This is to certify that this product complies with all relevant current UK and EU Legislative requirements in regard to Transmissible Spongiform Encephalopathies (TSE) and Bovine Spongiform Encephalopathy (BSE) for human food, and so is free of TSE/BSE.

This is also to certify that, during the course of their manufacture, the above-mentioned product did not come into contact with any materials, which could be derived from TSE/BSE risk materials.

CONFIRMATION OF GM STATUS

This is to certify that this product is not manufactured from GM raw materials and is therefore not subject to labelling under regulations 1829/2003/EC and 1830/2003/EC.

CONFIRMATION OF NON IRRADIATION STATUS

This is to certify that this product, whole or in part, has not been subjected to Ionising Radiation as per European Directives 1999/3/EC.

CONFIRMATION OF NANDROLONE STATUS

This is to certify that this product, whole or in part, has not come into contact with Nandrolone or any of its precursors in any way.

CONFIRMATION OF IOC PRODUCT STATUS

This is to certify that this product, whole or in part, has not come into contact with any product/s, which is banned by the IOC (International Olympics Committee) and or WADA.

CONFIRMATION OF ANIMAL TESTING STATUS

This is to certify that all the products sold by Cambridge Commodities have not been tested on animals in any part of its manufacture in accordance with regulation 86/609/EEC.

CONFIRMATION OF PESTICIDES STATUS

This is to certify that the above-mentioned product complies with the regulation (EC) No.396/2005 of 23rd February 2005 and commission Regulation (EU) No. 559/2011 of 7th June 2011 amending annexes II and III of the above Regulation.

CONFIRMATION OF NANOPARTICLE STATUS

This is to certify that unless otherwise stated, the above-mentioned product is free of nanoparticles. Commission Recommendation 2011/696/EU, defines as follows: "'Nanomaterial' means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm".



MATERIAL SAFETY DATA SHEET

Section 1 Identification of the Substance/Mixture and of the Company/Undertaking

Product name: Vitamin D3 1.0 MIU/g
Product code: P22179
Company: Cambridge Commodities Limited
Lancaster Way, Ely, Cambridgeshire, CB6 3NX
Tel: 01353 667258. Email: qa@c-c-l.com

Section 2 Hazards Identification

Most important hazards: Toxic by inhalation.
Harmful: Danger of serious damage to health by prolonged exposure if swallowed.

Section 3 Composition/Information on Ingredients

Brief description of the product: Mixture (preparation) containing active ingredient and auxiliary substances.
Chemical Name: Cholecalciferol
CAS Number: 67-97-0
EC Number: 200-673-2
Classification: T; R24/25-R48/25
T+; R26
Concentration (%): $\geq 1 - <3$

For the full text of the R-phrases mentioned in this section, see section 16.

Section 4 Emergency and First Aid Measures

General advice: Move out of dangerous area. Show this safety data sheet to the doctor in attendance. Symptoms of poisoning may only appear several hours later.
Inhalation: Call a physician or poison control centre immediately. Remove to fresh air. Keep patient warm and at rest. If unconscious place in recovery position and seek medical advice. Keep respiratory tract clear.
Skin contact: Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water.
Eye contact: Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing. If eye irritation persists, consult a specialist.



Ingestion: Clean mouth with water and drink afterwards plenty of water.
Induce vomiting if person is conscious. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person.
Obtain medical attention.

Section 5 Fire-fighting measures

Suitable extinguishing media: Dry chemical & Alcohol-resistant foam. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media: High volume water jet.

Special protective equipment for fire-fighters: In the event of fire, wear self-contained breathing apparatus.

Further information: Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

Section 6 Accidental Release Measures

Personal precautions: Use personal protective equipment. Ensure adequate ventilation. Evacuate personnel to safe areas.

Environmental precautions: Do not flush into surface water or sanitary sewer system. Prevent further leakage or spillage if safe to do so. If the product contaminates rivers and lakes or drains inform respective authorities.

Methods for cleaning up: Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Keep in suitable, closed containers for disposal.

Section 7 Handling and Storage

Advice on safe handling: Avoid formation of aerosol. Avoid exceeding of the given occupational exposure limits (see section 8). For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area. Provide sufficient air exchange and/or exhaust in work rooms. Dispose of rinse water in accordance with local and national regulations.

Advice on protection against fire and Explosion: Take precautionary measures against static discharges.



Requirements for storage areas and containers:

Keep under inert gas. Protect against light. Prevent unauthorized access. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Keep container tightly closed and dry.

Storage temperature:

<15 °C

Other data:

No decomposition if stored and applied as directed.

Section 8 Exposure Controls/Personal Protection

Components:

Cholecalciferol

CAS Number:

67-97-0

Value:

TWA

Control Parameters:

0.005mg/m³

Respiratory protection:

Breathing apparatus needed only when aerosol or mist is formed.

Hand protection:

Glove material: Chloroprene. Nitrile rubber. Consider the hazard characteristics of this product and any special workplace conditions when selecting the appropriate type of protective gloves.

Eye protection:

Safety glasses with side-shields.

Skin and body protection:

Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Hygiene measures:

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

Section 9 Physical and Chemical Properties

Form:

Clear Oily Liquid

Colour:

Colourless to Slightly Yellowish

Flash point:

244°C

Ignition temperature:

390°C (DIN 51794)

Density:

0.948 g/cm³ (at 20°C)

0.925 g/cm³ (at 50°C)

Viscosity, dynamic:

31.85 mPa.s (at 20°C)

10.51 mPa.s (at 50°C)

Section 10 Stability and Reactivity

Conditions to avoid:

Heat. Exposure to light.

Materials to avoid:

Strong acids and strong bases. Strong oxidizing agents.

Hazardous reactions:

No decomposition if used as directed.

Section 11 Toxicological Information

Acute oral toxicity cholecalciferol:	LD50 (rat): 5 - 50mg/kg (OECD Test Guideline 423) LD50 (mouse): 4.5mg/kg
Acute inhalation toxicity cholecalciferol:	LC50 (rat): 0.13 – 0.18mg/l
Acute dermal toxicity cholecalciferol:	LD50 (rat): 61mg/kg
Skin irritation:	No skin irritation (rabbit)
Sensitisation:	Did not cause sensitization on laboratory animals. (guinea pig)
Repeated dose toxicity cholecalciferol:	NOAEL (Oral rat): 0,06 mg/kg/day Sub-chronic toxicity study (90-day) (OECD Test Guideline 408)
Genotoxicity in vivo cholecalciferol:	not genotoxic (, rat, Bone marrow, Mutagenicity (micronucleus test))
Teratogenicity cholecalciferol:	May lead to malformations at dose levels that cause maternal toxicity.; NOAEL: 0,0095mg/kg/day (rabbit female, OECD Test Guideline 414)
Experience with human exposure cholecalciferol:	RDA (Recommended Daily Allowance) 0.005 – 0.01mg/day
Experience with human exposure:	Ingestion: Acute overdose produces the following symptoms: Nausea, Vomiting, Headache, Weakness, Abdominal pain, Dry mouth, Metallic taste, Loss of appetite.

Section 12 Ecological Information

Additional ecological information: There is no data available for this product.

Section 13 Disposal Considerations

Product: Do not dispose of waste into sewer. Do not contaminate ponds, waterways or ditches with chemical or used container. Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging: Dispose of as unused product. Do not re-use empty containers.

Section 14 Transport Information

ADR: Not dangerous goods
IATA: Not dangerous goods
IMDG: Not dangerous goods
RID: Not dangerous goods

Not classified as dangerous in the meaning of transport regulations.



Section 15 Regulatory Information

Labelling according to EC Directives
1999/45/EC:

Symbol (s): T - Toxic

R-phrase (s): R23 - Toxic by inhalation. R48/22 – Harmful. Danger of serious damage to health by prolonged exposure if swallowed.

S-phrase (s): S23 - Do not breathe spray. S37 - Wear suitable gloves. S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Hazardous components which must be listed on the label:

67-97-0 Cholecalciferol

Section 16 Other Information

This advice is given by Cambridge Commodities Ltd who accepts no legal liability for it. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should not therefore be construed as guaranteeing specific properties.

Individuals working with chemicals should consider all chemicals to be potentially hazardous even if their individual hazards may be uncharacterised or unknown.


This Information provided in this document is subject to change and the batch specific Certificate of Analysis should always be referenced.

To be used as per local legislation.

Change History

Version	Change	Customer Notification required Yes / No
1	First Issue	N/A
2	Amended to Clarify Source Material According to Manufacturers specification	Yes

Document Approval

Originator Job Title	QC Technician	Approver Job Title	Quality Specialist
<i>Alan Feetham</i>		 Shannon McKenna (Dec 23, 2016)	





P22179-Vitamin D3 1.0 MIU g- Technical Dossier

Adobe Sign Document History

12/23/2016

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By:	Alan Feetham (alan.feetham@c-c-l.com)
Status:	Signed
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