

PRODUCT TECHNICAL DOSSIER

>< VITAMIN D2 (API) 40 MILLION IU/G

Product Code:

P22168

Raw Material Full Name:

Ergocalciferol Ph.Eur./USP

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

(5Z,7E,22E)-9,10-secoergosta-5,7,10(19),22-tetraen-3 β -ol

This material is Food Grade:

Yes

Vegan / Vegetarian Status:

Suitable for both

Limit/Range/Specification:

97-103%

CAS Number:

50-14-6

EC/EINECS Number:

200-014-9

Molecular Formula:

C₂₈H₄₄O

Average Molecular weight:

396.65g/mol

Solubility in Water:

Insoluble

Solubility in Alcohol:

Easily Soluble

Loss on Drying:

Max 0.5%

Melting Range:

115-119°C

Product Code: P22168

Version: 1

Page 1 of 14



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Specific Rotation:

+103 to + 107

Reducing Substances:

Max 20µg/g

Residual Solvents:

Methanol: Max 100mg/kg

Toluene: Max 100mg/kg

Pyridine: Max 200mg/kg

Country of Origin:

China

Country of Origin of the Manufacture:

Czech Republic

Base Source/Start Material:

Ergosterol

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

Synthetic

Synthetic: What are the starting materials of the synthesis and their sources?

Ergosterol, Ethyl Ether, Methanol, Pyridine, Butyl hydroxy toluene, Toluene, 3.5-dinitrobenzoyl chloride, Ethyl acetate.

Material is:

Content of ergosterol	Min 85%	Spectrophotometry
Content of ergosterol	Min 85 area %	HPLC
Sterols content		HPLC
L1	Max 2%	HPLC
L2	Max 1.5%	HPLC
L3	Min 85%	HPLC
L4	Max 2.6%	HPLC
Regenerated ergosterol		HPLC
L1	Max 2%	HPLC
L2	Max 1.5%	HPLC
L3	Min 85%	HPLC
L4	Max 2.6%	HPLC
Identification	Comply with HPLC standard	HPLC

Shelf Life from Date of Manufacture:

Minimum 2 Years

Storage Conditions:

Store in a cool, dry place.

Appearance (Fine/Crystals/Crystalline/Hygroscopic):

Crystals or Crystalline Powder

Colour:

White to slightly yellow

Flavour/Taste:

Characteristic

Odour:

Characteristic

Do any of the parameters change in different seasons?

No

Max Heavy Metals:

10ppm

Lead (Pb):

Max 3ppm

Cadmium (Cd):

Max 1ppm

Mercury (Hg):

Max 0.1ppm

Pharmacopeia Standard Used:

EU and US.

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 illinoensis (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	

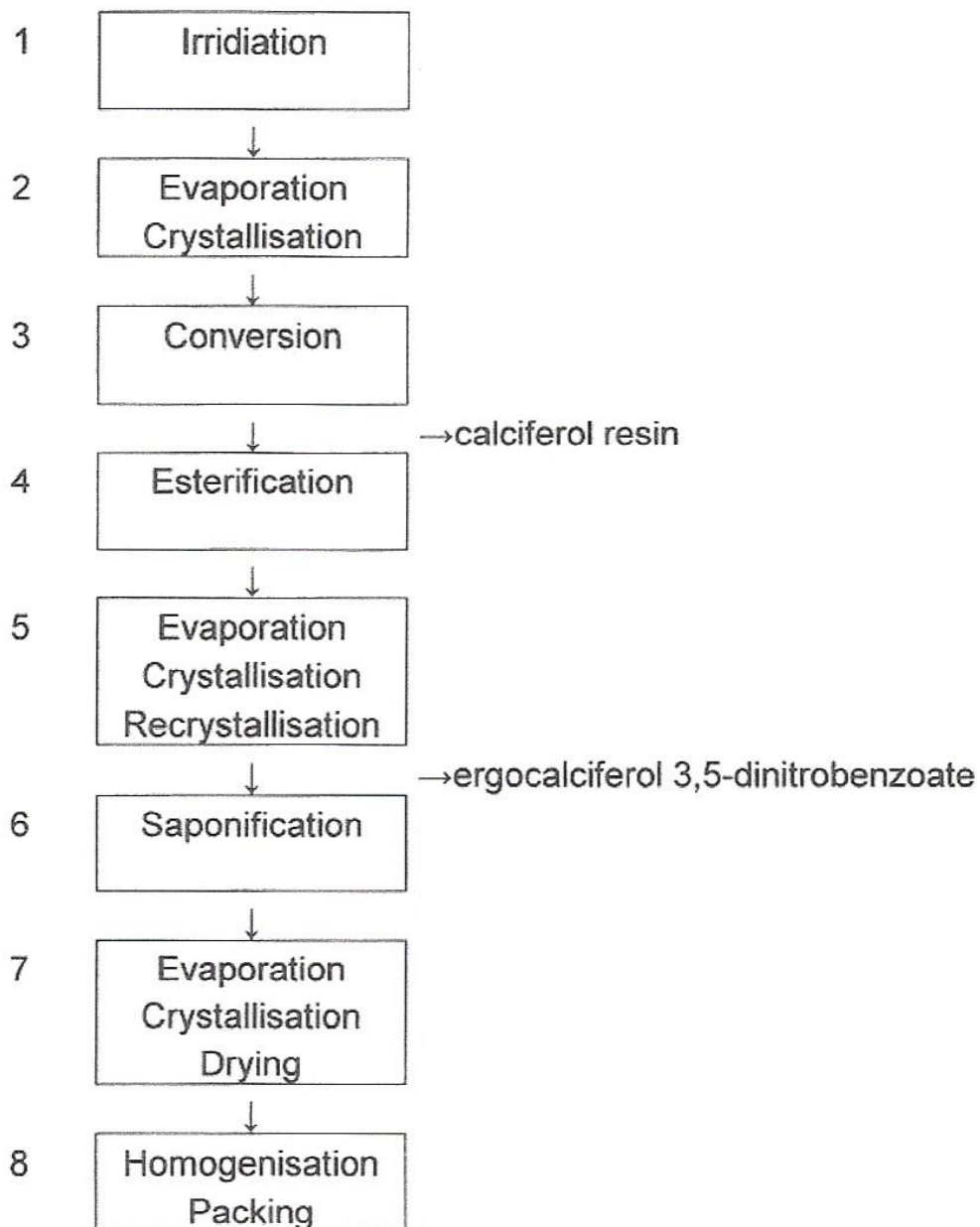


ADDITIVES / CONTAMINANTS / DIETARY REQUIREMENTS	Product Free From YES/NO	Listed Item on Site at Manufacturer YES/NO	If YES, Please Comment
Free from Additives	Yes	No	
Free from Antioxidants	Yes	No	
Free from Ethylene Oxide	Yes	No	
Free from Gelatine	Yes	No	
Free from Flavourings (Artificial / Nature 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)	No	Yes	Max limit is 0.3% for this product
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	No	Yes	Alternative solvent, not normally used.
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.)	Yes	No	
Free from Bovine Products or Derivatives (which may include growth/yield hormones, antibiotics etc.)	Yes	No	



PRODUCTION FLOW CHART

Process Flow Chart of the synthesis of ERGOCALCIFEROL



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 D2 (API) 40 Million Iu/G
Chemical formula: C₂₈H₄₄O
Company: Cambridge Commodities Limited
Lancaster Way, Ely, Cambridgeshire, CB6 3NX
Tel: 01353 667258. Email: qa@c-c-l.com

Section 2 Hazards Identification

2.1. Classification of the substance or mixture

Classification EC 67/548 or EC 1999/45

Classification: T+; R26
T; R24/25-R48/25

Hazard Class and Category Code(s), Regulation (EC) No 1272/2008 (CLP)

Health hazards: Acute toxicity, Oral - Category 3 - Danger - (CLP : Acute Tox. 3) - H301
Acute toxicity, dermal - Category 3 - Danger - (CLP : Acute Tox. 3) - H311
Acute toxicity, Inhalation - Category 2 - Danger - (CLP : Acute Tox. 2) - H330 Specific
Target Organ Toxicity - Repeated exposure - Category 1 - Danger - (CLP : STOT RE 1) - H372

2.2. Label elements

Labelling EC 67/548 or EC 1999/45

: T+ : Very toxic

R Phrase(s): R24/25 : Toxic in contact with skin and if swallowed.

R26 : Very toxic by inhalation.

R48/25 : Toxic : danger of serious damage to health by prolonged exposure if swallowed.

R63 : Possible risk of harm to the unborn child.

S Phrase(s): S28 - After contact with skin, wash immediately with plenty of water.

S36/37 : Wear suitable protective clothing and gloves.

S45 : In case of accident or if you feel unwell, seek medical advice immediately (show the label when possible).

Labelling Regulation EC 1272/2008 (CLP)

Signal words: Danger

Hazard statements: Acute toxicity, Oral - Category 3 - Danger - (CLP : Acute Tox. 3) - H301
Acute toxicity, dermal - Category 3 - Danger - (CLP : Acute Tox. 3) - H311
Acute toxicity, Inhalation - Category 2 - Danger - (CLP : Acute Tox. 2) - H330

Specific Target Organ Toxicity - Repeated exposure - Category 1 - Danger - (CLP : STOT RE 1) - H372

Hazard classification: Classification and labelling according to Substances Directive 67/548/EEC.

Precautionary statements

Prevention: P280 - Wear protective gloves, protective clothing.

P260 - Do not breathe dust/fume/gas/mist/vapours/spray. P262 - Do not get in eyes, on skin, or on clothing



P264 - Wash thoroughly after handling.
Storage: P405 - Store locked up
Disposal considerations: P501 - Dispose of this material and its container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Section 3 Composition/Information on Ingredients

Components: This product is hazardous

Substance Name	Contents	CAS No	EC No	Classification
Ergocalciferol	>97%	50-14-6	200-014-9	Acute Tox. 3 (Dermal);H311 Acute Tox. 2 (Inhalation);H330 Acute Tox. 3 (Oral);H301 STOT RE 1;H372

Section 4 Emergency and First Aid Measures

4.1. Description of first aid measures

- Inhalation: Assure fresh air breathing. Allow the victim to rest. If needed administer oxygen or start resuscitation. Seek medical attention immediately.
- Skin contact: Wash skin with mild soap and water. Remove contaminated clothing and shoes. Wash clothing before reuse. Seek medical attention immediately.
- Eye contact: Rinse immediately with plenty of water while keeping the eyes wide open. Obtain medical attention if irritation persists.
- Ingestion: Seek medical attention immediately. If swallowed, rinse mouth with water (only if the person is conscious). Do not induce vomiting. Give oxygen or artificial respiration as needed.

4.2. Most important symptoms and effects, both acute and delayed

Eye irritant upon direct contact.

4.3. Indication of any immediate medical attention and special treatment needed

IF EXPOSED: Call a POISON CENTER or doctor. Specific treatment.

Section 5 Fire-fighting measures

5.1. Extinguishing media

Special hazards arising from the substance or mixture

Extinguishing media

-Suitable extinguishing media: Powder, AFFF, Carbon dioxide, Water, Water fog.

- Unsuitable extinguishing media: None.

5.2. Special hazards arising from the substance or mixture

Specific hazards: Flammable.

Potential dust explosion hazard.

5.3. Advice for firefighters

Special protective equipment for firefighters: Wear a compressed air respirator, wear proper protective equipment, wear fire/flame resistant /retardant clothing.

Special procedures: Use water spray or fog for cooling exposed containers, avoid dust production.

Section 6 Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Avoid dust production, keep away from open flames, hot surfaces and other sources of ignition sources.

6.2. Environmental precautions

Environmental precautions: Prevent entry to sewers and public waters, avoid release to the environment

6.3. Methods and material for containment and cleaning up

Clean up methods: Sweep or shovel spills.

Avoid dust production. Contain in properly labelled containers. Use suitable and closed disposal containers.

6.4. Reference to other sections

Take notice of the measurements mentioned in Chapter 7 and 8.

Section 7 Handling and Storage

7.1. Precautions for safe handling

Handling: Should always be handled in a closed system, local exhaust is needed at source of dust. Keep away from heat and ignition sources.

7.2. Conditions for safe storage, including any incompatibilities Storage:

Packaging materials: Glass, aluminium.

Storage: Protect from direct sunlight and heat. Keep in original containers. Keep container tightly closed.

Store under nitrogen. Store in a dry place. Preserve at maximum 8 °c.

Use: Contact supplier if guidance is required.

Further information: Avoid dust production. Keep away from ignition sources such as heat, sparks and open flame. – No smoking. Exposure to extreme heat can give rise to thermal decomposition.

Section 8 Exposure Controls/Personal Protection

8.1. Control parameters

Not established.

TLV - ACGIH [mg/m³]: Not established.

8.2. Exposure controls

Exposure controls: Local exhaust is needed at source of dust. Follow the exposure limits given on this material safety data sheet.

Personal protection

-Respiratory protection: Where excessive vapour, mist, or dust may result, use approved respiratory protection equipment. P3. Use only respiratory protection that conforms to international/national standards.

-Skin protection: Wear suitable protective clothing. Wear dust impermeable clothing when dust forming occurs.



- Eye protection: Chemical goggles or face shield with safety glasses.
 - Hand protection: Wear suitable gloves. Use PVC, neoprene or rubber gloves.
 - Ingestion: Use good personal hygiene practices.
- Industrial hygiene: Do not eat, drink or smoke during the use of this product. Wash hands afterwards and before eating, smoking, going to the lavatory and at the end of the day. High standards of skin care and personal hygiene should be exercised at all times.
- Handle in accordance with good industrial hygiene and safety procedures.
- Occupational Exposure Limits: Ergocalciferol
- Environmental exposure controls: Dispose of rinse water in compliance with all local/national laws and regulations.
- SAEL (Solvay Acceptable Exposure Limit) 2007: TWA (8 hour, skin, mg/m³) 0.01

Section 9 Physical and Chemical Properties

Information on basic physical and chemical properties
Physical state at 20 °C: Crystals. Powder.
Colour: White. Light.
Melting zone [°C]: 115 – 119
Solubility in water [mg/l]: < 0.01
Log P octanol / water at 20°C: 8.89 calculated value.
Explosion hazard: Danger of explosion.

Section 10 Stability and Reactivity

Stability and reactivity: Stable under recommended storage conditions.
Conditions to avoid: Keep away from heat, flames and sparks.
Hazardous decomposition products: Carbon monoxide.

Section 11 Toxicological Information

Human health effects: Prolonged exposure to the product may produce hypercalcemia and cause soft tissue calcification. Symptoms may be delayed.

Acute toxicity

- Dermal: Toxic in contact with skin. Possible absorption through the skin.
- Ocular: Dust forming can result in mechanical irritation.
- Ingestion: Symptoms may include headache and dizziness. Muscle weakness. May produce irregular heartbeat. Ingestion may cause nausea, vomiting and diarrhoea. Risk of serious damage.

Rat oral LD50 [mg/kg]: 10-56
Rat dermal LD50 [mg/kg]: 61-185 (cholecalciferol)
Rat inhalation LC50 [mg/l/4h]: 0.13-0.38
Chronic toxicity: Oral, repeated exposure (rat): LOEL (target organ: kidney): 0.032 mg/kg (cholecalciferol)
Oral, repeated exposure (rabbit): LOEL (target organs: heart, vascular system): 0.019 mg/kg (cholecalciferol)
Teratogenicity: > 45 Oral, rat [mg/kg]: teratogenic effect.

Product Code: P22168

Version: 1

Page 11 of 14



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Genetic toxicity in vitro: Non-mutagenic. (Cholecalciferol)

Possible hazards (summary): Harmful by inhalation, in contact with skin and if swallowed. Danger of serious damage to health by prolonged exposure. Risk of damage to kidneys. Absorption through the skin.

Section 12 Ecological Information

12.1. Toxicity Ecotoxicity

Acute toxicity: The substance showed no toxicity to fish at the solubility limit. (Cholecalciferol)

12.2. Bioaccumulative potential

Bioaccumulative potential: Log POW: > 3 Suspected to bio accumulate.

12.4. Mobility in soil

Mobility: Low solubility. Low mobility (water). Low mobility (soil). No significant leaching.

12.5. Other adverse effects The Netherlands

Water hazard (NL; ABM): Slightly toxic to aquatic organisms.

Water hazard category (NL; ABM): 11

Remediation effort (NL; ABM): Treatment B

Section 13 Disposal Considerations

13.1. Waste treatment methods

Dispose in a safe manner in accordance with local/national regulations.

Disposal method: Dispose in a safe manner in accordance with local/national regulations. Burn in an approved incinerator.

Industrial waste number: Hazardous waste under European Waste Catalogue (Directive 2000/532/EC).

18 01 06 - Wastes from human health care/chemicals consisting of or containing dangerous substances. (to be considered)

Packaging: Dispose of as unused product.

Section 14 Transport Information

14.1. UN number

UN No.: 2811

14.2. UN proper shipping name

Shipping name: TOXIC SOLID, ORGANIC, N.O.S. ((5Z, 7E, 22E)-9, 10-secoergosta-5, 7, 10(19), 22-tetraene-3beta-ol)

14.3. Transport hazard class(es)

Land transport

ADR/RID: 6.1

H.I. nr: 60

Proper shipping name: UN2811, TOXIC SOLID, ORGANIC, N.O.S. ((5Z, 7E, 22E)-9,10-secoergosta-5,7,10(19),22-tetraene-3beta-ol), 6.1, II (D/E)

-ADR Class: 6.1

-ADR Packing group: II

Emergency action in case of accident: No naked lights. No smoking.

Product Code: P22168

Version: 1

Page 12 of 14



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Keep public away from danger area.

NOTIFY POLICE AND FIRE BRIGADE IMMEDIATELY.

Sea transport

-IMO-IMDG code: Class 6.1

-IMO Packing group: II

-IMDG-Marine pollution: Yes ò

-EMS-Nr: F-A S-A

Air transport

-ICAO/IATA: Packaging instructions cargo Aircraft: 676 Packaging instructions passenger Aircraft: 669

-IATA - Class or division: 6.1

-IATA Packing group: II

14.4. Environmental hazards

In case of spillage and/or leakage: Clean up even minor leaks or spills if possible without unnecessary risk.

14.5. Special precautions for user

Personal precautions: The driver shall not attempt to deal with any fire of the load.

Additional information: None.

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

-Labelling: Toxic

Section 15 Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture:

Ensure all national/local regulations are observed.

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

Document Approval

Originator Job Title	QC Technician	Approver Job Title	QC Technician
 <u>Ash Bean</u> Ash Bean (May 31, 2016)		 <u>Adam Mulcahy</u> Adam Mulcahy (May 11, 2016)	











P22168-Vitamin D2-Technical Dossier

Adobe Sign Document History

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