

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2020/878)

M0019520-VITAMIN D3 (CHOLECALCIFEROL)



Version 1 Date of compilation: 29/10/2018
Version 4 (replaces version 3)

Revision date: 27/10/2023

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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING.

1.1 Product identifier.

Product Name: VITAMIN D3 (CHOLECALCIFEROL)
Product Code: M0019520
Chemical Name: colecalciferol; Vitamin D3
Index No: 603-180-00-4
CAS No: 67-97-0
EC No: 200-673-2

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

Raw material for master formulation

Uses advised against:

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.

Company: **ACOFARMA DISTRIBUCIÓN S.A.**
Address: C/ Llobregat, 20, Pol. Ind. Santa Margarita
City: Terrassa
Province: Barcelona
Telephone: 902362203
Fax: 937360090
E-mail: atencioncliente@acofarma.com
Web: www.acofarma.es

1.4 Emergency telephone number: 902362203 (Only available during office hours; Monday-Friday; 09:00-18:00)

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the substance or mixture.

In accordance with Regulation (EC) No 1272/2008:

STOT RE 1 : Causes damage to organs through prolonged or repeated exposure.
Acute Tox. 2 : Fatal if inhaled.
Acute Tox. 3 : Toxic in contact with skin.
Acute Tox. 3 : Toxic if swallowed.

2.2 Label elements.

Labelling in accordance with Regulation (EC) No 1272/2008:

Pictograms:



Signal Word:

Danger

Hazard statements:

H372 Causes damage to organs through prolonged or repeated exposure.
H330 Fatal if inhaled.
H311 Toxic in contact with skin.
H301 Toxic if swallowed.

Precautionary statements:

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...

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P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor/...
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P320	Specific treatment is urgent (see ... on this label).
P321	Specific treatment (see ... on this label).
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P312	Call a POISON CENTER/doctor/... if you feel unwell.
P311	Call a POISON CENTER/doctor/...

Contains:
colecalfiferol, Vitamin D3

2.3 Other hazards.

The substance is not PBT
The substance is not vPvB
Substance does not have endocrine disrupting properties.

In normal use conditions and in its original form, the product itself does not involve any other risk for health and the environment.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

3.1 Substances. Mono-constituent.

Identifiers	Name	Concentrate	(*)Classification - Regulation (EC) No 1272/2008	
			Classification	Specifics concentration limits and Acute toxicity estimate
Index No: 603-180-00-4 CAS No: 67-97-0 EC No: 200-673-2	colecalfiferol, Vitamin D3	25 - 100 %	Acute Tox. 2, H330 - Acute Tox. 3, H311 - Acute Tox. 3, H301 - STOT RE 1, H372	STOT RE 1, H372: C ≥ 3 % STOT RE 2, H373: 0,3 % ≤ C < 3 % Dermal: ETA = 50 mg/kg pc (ATP 13) Inhalation: ETA = 0.05 mg/l (polvos o nieblas, ATP13) Oral: ETA = 35 mg/kg pc (ATP 13)

Impurities or additives that affect the classification:

Identifiers	Name	Concentrate	(*)Classification - Regulation (EC) No 1272/2008	
			Classification	Specifics concentration limits and Acute toxicity estimate
Index No: 603-180-00-4 CAS No: 67-97-0 EC No: 200-673-2	colecalfiferol, Vitamin D3	25 - 100 %	Acute Tox. 2, H330 - Acute Tox. 3, H311 - Acute Tox. 3, H301 - STOT RE 1, H372	STOT RE 1, H372: C ≥ 3 % STOT RE 2, H373: 0,3 % ≤ C < 3 % Dermal: ETA = 50 mg/kg pc (ATP 13) Inhalation: ETA = 0.05 mg/l (polvos o nieblas, ATP13) Oral: ETA = 35 mg/kg pc (ATP 13)

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(*) The complete text of the H phrases is given in section 16 of this Safety Data Sheet.

3.2 Mixtures.

Not applicable.

SECTION 4: FIRST AID MEASURES.

4.1 Description of first aid measures.

Immediate medical attention is required. It is recommended to move the affected person out of the exposure area. Delayed effects may occur after the exposure to the product.

Inhalation.

Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration. Do not administer anything orally. If unconscious, place them in a suitable position and seek medical assistance. The use of personal protective equipment is recommended for people providing first aid (see section 8).

Eye contact.

Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance.

Skin contact.

Remove contaminated clothing. Wash skin vigorously with water and soap or a suitable skin cleaner. NEVER use solvents or thinners. The use of personal protective equipment is recommended for people providing first aid (see section 8).

Ingestion.

If accidentally ingested, seek immediate medical attention. Keep calm. NEVER induce vomiting. The use of personal protective equipment is recommended for people providing first aid (see section 8).

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

Very Toxic Product, accidental contact may result in serious respiratory difficulties, alteration of the central nervous system and in extreme cases, unconsciousness. Immediate medical assistance is required.

Long-term chronic exposure may result in injury to certain organs or tissues.

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

Request immediate medical attention. Never administer anything orally to persons who are unconscious. Do not induce vomiting. If the person vomits, clear the respiratory tract. Keep the person comfortable. Turn him/her over to the left side and stay there while waiting for medical care.

SECTION 5: FIREFIGHTING MEASURES.

The product is NOT classified as flammable, in case of fire the following measures should be taken:

5.1 Extinguishing media.

Suitable extinguishing media:

Extinguisher powder or CO₂. In case of more serious fires, also alcohol-resistant foam and water spray.

Unsuitable extinguishing media:

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

5.2 Special hazards arising from the substance or mixture.

Special risks.

Exposure to combustion or decomposition products can be harmful to your health.

During a fire and depending on its magnitude the following may occur:

- Toxic vapors or gases.

5.3 Advice for firefighters.

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account. Prevent the products used to fight the fire from going into drains, sewers, or waterways.

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Fire protection equipment.

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots. During extinction and depending on the magnitude and proximity to the fire, additional protective equipment such as chemical protection gloves, heat-reflecting suits or gas-tight suits may be required.

SECTION 6: ACCIDENTAL RELEASE MEASURES.

6.1 Personal precautions, protective equipment and emergency procedures.

For exposure control and individual protection measures, see section 8.

6.2 Environmental precautions.

Product not classified as hazardous for the environment, avoid spillage as much as possible.

6.3 Methods and material for containment and cleaning up.

Contain and collect spillage with inert absorbent material (earth, sand, vermiculite, Kieselguhr...) and clean the area immediately with a suitable decontaminant.

Deposit waste in closed and suitable containers for disposal, in compliance with local and national regulations (see section 13).

6.4 Reference to other sections.

For exposure control and individual protection measures, see section 8.

For later elimination of waste, follow the recommendations under section 13.

SECTION 7: HANDLING AND STORAGE.

7.1 Precautions for safe handling.

For personal protection, see section 8.

In the application area, smoking, eating, and drinking must be prohibited.

Follow legislation on occupational health and safety.

Never use pressure to empty the containers. They are not pressure-resistant containers. Keep the product in containers made of a material identical to the original.

7.2 Conditions for safe storage, including any incompatibilities.

Store according to local legislation. Observe indications on the label. Store the containers between 2 and 8 °C, in a dry and well-ventilated place, far from sources of heat and direct solar light. Keep far away from ignition points. Keep away from oxidising agents and from highly acidic or alkaline materials. Do not smoke. Prevent the entry of non-authorised persons. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.

The product is not affected by Directive 2012/18/EU (SEVESO III).

7.3 Specific end use(s).

Raw material for compounding

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

8.1 Control parameters.

The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

8.2 Exposure controls.

Measures of a technical nature:

Provide adequate ventilation, which can be achieved by using good local exhaust-ventilation and a good general exhaust system.

Concentration:	100 %
Uses:	Raw material for master formulation
Breathing protection:	
PPE:	Particle filter mask



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Characteristics:	«CE» marking, category III. Made of filtering material, it covers nose, mouth and chin.		
CEN standards:	EN 149		
Maintenance:	Check for any tears, defects, etc. before use. Since it is disposable individual protection equipment, it should be replaced after use.		
Observations:	Does not protect worker unless properly adjusted. Follow the manufacturer's instructions regarding suitable use of the equipment.		
Filter Type needed:	P2		
Hand protection:			
PPE:	Non-disposable protective gloves against chemicals.		
Characteristics:	«CE» marking, category III. Check the list of chemicals for which the glove has been tested.		
CEN standards:	EN 374-1, En 374-2, EN 374-3, EN 420		
Maintenance:	A schedule for the periodical replacement of gloves should be established in order to guarantee their replacement before pollutants permeate them. The use of contaminated gloves could be more dangerous than not using gloves, since the pollutant can gradually accumulate in the glove's material.		
Observations:	They are to be replaced whenever tears, cracks or deformations are observed or when exterior dirt could reduce their strength.		
Material:	PVC (polyvinyl chloride)	Breakthrough time (min.):	> 480
		Material thickness (mm):	0,35
Eye protection:			
PPE:	Protective goggles against particle impacts.		
Characteristics:	«CE» marking, category II. Eye protector against dust and smoke.		
CEN standards:	EN 165, EN 166, EN 167, EN 168		
Maintenance:	Visibility through lenses should be ideal. Therefore, these parts should be cleaned daily. Protectors should be disinfected periodically following the manufacturer's instructions.		
Observations:	Some signs of wear and tear include: yellow colouring of the lenses, superficial scratching of the lenses, scraping etc.		
Skin protection:			
PPE:	Chemical protective clothing		
Characteristics:	«CE» marking, category III. Clothing should fit properly. The level of protection must be set according to a test parameter called BT (Breakthrough Time), which indicates how long it takes for the chemical to pass through the material.		
CEN standards:	EN 464, EN 340, EN 943-1, EN 943-2, EN ISO 6529, EN ISO 6530, EN 13034		
Maintenance:	In order to guarantee uniform protection, follow the washing and maintenance instructions provided by the manufacturer.		
Observations:	The protective clothing's design should facilitate correct positioning, staying in place without moving for the period of use expected, bearing in mind environmental factors as well as any movement or position the user might adopt while carrying out the activity.		
PPE:	Anti-static safety footwear against chemicals.		
Characteristics:	«CE» marking, category III. Check the list of chemicals against which the footwear is resistant.		
CEN standards:	EN ISO 13287, EN 13832-1, EN 13832-2, EN 13832-3, EN ISO 20344, EN ISO 20345		
Maintenance:	For correct maintenance of this kind of safety footwear, it is necessary to observe the instructions specified by the manufacturer. The footwear should be replaced as soon as any sign of damage is observed.		
Observations:	The footwear should be cleaned regularly and dried when damp, although it should not be placed too close to a source of heat in order to avoid any sharp changes in temperature.		

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.

Physical state: Solid

Colour: White or almost white

Odour: No data available

Odour threshold: Not available

Melting point: Not available

Freezing point: Not applicable

Boiling point or initial boiling point and boiling range: Not available

Flammability: Not applicable

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Lower explosion limit: Not applicable
Upper explosion limit: Not applicable
Flash point: Not applicable
Auto-ignition temperature: Not applicable
Decomposition temperature: Not available
pH: Not available (Substance/mixture is non-soluble (in water)).
Kinematic viscosity: Not applicable
Solubility: Readily soluble in ethanol (96%)
Hydrosolubility: Practically insoluble in water
Liposolubility: Soluble in fatty oils
Partition coefficient n-octanol/water (log value): Not available
Vapour pressure: Not available
Absolute density: Not available
Relative density: Not applicable
Relative vapour density: Not applicable
Particle characteristics: Not available

9.2 Other information

Not applicable/Not available due to the nature/properties of the product

SECTION 10: STABILITY AND REACTIVITY.

10.1 Reactivity.

The product does not present hazards by their reactivity.

10.2 Chemical stability.

Stable under the recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions.

The product does not present possibility of hazardous reactions.

10.4 Conditions to avoid.

Avoid any improper handling.

10.5 Incompatible materials.

Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

10.6 Hazardous decomposition products.

No decomposition if used for the intended uses.

SECTION 11: TOXICOLOGICAL INFORMATION.

11.1 Information on hazard classes as defined in Regulation (EC) N° 1272/2008.

Toxicological information.

Name	Acute toxicity			
	Type	Test	Kind	Value
colecalfiferol, Vitamin D3	Oral	ETA		35 mg/kg pc [1]
		[1] ATP 13		
CAS No: 67-97-0 EC No: 200-673-2	Dermal	ETA		50 mg/kg pc [1]
		[1] ATP 13		
colecalfiferol, Vitamin D3	Inhalation	ETA		0.05 mg/l [1]
		[1] (polvos o nieblas), ATP13		
colecalfiferol, Vitamin D3	Oral	ETA		35 mg/kg pc [1]
		[1] ATP 13		
	Dermal	ETA		50 mg/kg pc [1]

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CAS No: 67-97-0	EC No: 200-673-2	Inhalation	[1] ATP 13
			ETA 0.05 mg/l [1] [1] (polvos o nieblas), ATP13

a) acute toxicity;

Product classified:

Acute toxicity (Inhalation), Category 2: Fatal if inhaled.

Acute toxicity (Dermal), Category 3: Toxic in contact with skin.

Acute toxicity (Oral), Category 3: Toxic if swallowed.

Acute Toxicity Estimate (ATE):

Substances:

ATE (Dermal) = 50 mg/kg

ATE (Oral) = 5 mg/kg

b) skin corrosion/irritation;

Not conclusive data for classification.

c) serious eye damage/irritation;

Not conclusive data for classification.

d) respiratory or skin sensitisation;

Not conclusive data for classification.

e) germ cell mutagenicity;

Not conclusive data for classification.

f) carcinogenicity;

Not conclusive data for classification.

g) reproductive toxicity;

Not conclusive data for classification.

h) STOT-single exposure;

Not conclusive data for classification.

i) STOT-repeated exposure;

Product classified:

Specific target organ toxicity following a repeated exposure, Category 1: Causes damage to organs through prolonged or repeated exposure.

j) aspiration hazard;

Not conclusive data for classification.

11.2 Information on other hazards.

Endocrine disrupting properties

This product does not contain components with endocrine-disrupting properties with effects on human health.

Other information

There is no information available on other adverse health effects.

SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.

No information is available regarding the ecotoxicity.

12.2 Persistence and degradability.

No information is available regarding the biodegradability

No information is available on the degradability

No information is available about persistence and degradability of the product.

12.3 Bioaccumulative potential.

No information is available regarding the bioaccumulation.

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12.4 Mobility in soil.

No information is available about the mobility in soil.
The product must not be allowed to go into sewers or waterways.
Prevent penetration into the ground.

12.5 Results of PBT and vPvB assessment.

No information is available about the results of PBT and vPvB assessment of the product.

12.6 Endocrine disrupting properties.

This product doesn't contain components with environmental endocrine disrupting properties.

12.7 Other adverse effects.

The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.
No information is available about other adverse effects for the environment.

SECTION 13: DISPOSAL CONSIDERATIONS.

13.1 Waste treatment methods.

Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.
Follow the provisions of Directive 2008/98/EC regarding waste management.

SECTION 14: TRANSPORT INFORMATION.

Transport following ADR rules for road transport, RID rules for railway, ADN for inner waterways, IMDG for sea, and ICAO/IATA for air transport.

Land: Transport by road: ADR, Transport by rail: RID.

Transport documentation: Consignment note and written instructions

Sea: Transport by ship: IMDG.

Transport documentation: Bill of lading

Air: Transport by plane: ICAO/IATA.

Transport document: Airway bill.

14.1 UN number or ID number.

UN No: UN2811

14.2 UN proper shipping name.

Description:

ADR/RID: UN 2811, TOXIC SOLID, ORGANIC, N.O.S. (CONTAINS COLECALCIFEROL VITAMIN D3), 6.1, PG II, (D/E)

IMDG: UN 2811, TOXIC SOLID, ORGANIC, N.O.S. (CONTAINS COLECALCIFEROL VITAMIN D3), 6.1, PG II

ICAO/IATA: UN 2811, TOXIC SOLID, ORGANIC, N.O.S. (CONTAINS COLECALCIFEROL VITAMIN D3), 6.1, PG II

14.3 Transport hazard class(es).

Class(es): 6.1

14.4 Packing group.

Packing group: II

14.5 Environmental hazards.

Marine pollutant: No

Transport by ship, FEm – Emergency sheets (F – Fire, S - Spills): F-A,S-A

14.6 Special precautions for user.

Labels: 6.1

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Hazard number: 60

Provisions concerning carriage in bulk ADR: Not authorized carriage in bulk in accordance with ADR.
Proceed in accordance with point 6.

ADR LQ: 500 g
IMDG LQ: 500 g
ICAO LQ: 1 kg

14.7 Maritime transport in bulk according to IMO instruments.

The product is not transported in bulk.

SECTION 15: REGULATORY INFORMATION.

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

The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

Substances including by Regulation (EU) No 649/2012 concerning the export and import of dangerous chemicals:

Name	
colecalfiferol; Vitamin D3 CAS No: 67-97-0 EC No: 200-673-2	
Annex I Part 1 - Subcategory	Limitation
Pesticide in the group of plant protection products	Ban

Name	
colecalfiferol; Vitamin D3 CAS No: 67-97-0 EC No: 200-673-2	
Annex I Part 1 - Subcategory	Limitation
Pesticide in the group of plant protection products	Ban

15.2 Chemical safety assessment.

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16: OTHER INFORMATION.

Complete text of the H phrases that appear in section 3:

H301 Toxic if swallowed.
H311 Toxic in contact with skin.
H330 Fatal if inhaled.
H372 Causes damage to organs through prolonged or repeated exposure.
H373 May cause damage to organs through prolonged or repeated exposure.

Classification codes:

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Acute Tox. 2 : Acute toxicity (Inhalation), Category 2
Acute Tox. 3 : Acute toxicity (Dermal), Category 3
Acute Tox. 3 : Acute toxicity (Oral), Category 3
STOT RE 1 : Specific target organ toxicity following a repeated exposure, Category 1

Changes regarding to the previous version:

- Removal of precautionary statements/hazard statements/pictograms/signal word (SECTION 2.2).
- Addition of precautionary statements/hazard statements/pictograms/signal word (SECTION 2.2).
- Modification of the information of the stability and reactivity conditions (SECTION 10.3).
- Modification of the information of the stability and reactivity conditions (SECTION 10.4).
- Modification of the information of the stability and reactivity conditions (SECTION 10.5).
- Modification of the information of the stability and reactivity conditions (SECTION 10.6).

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Physical hazards	On basis of test data
Health hazards	Calculation method
Environmental hazards	Calculation method

It is advisable to carry out basic training with regard to health and safety at work in order to handle this product correctly.

Abbreviations and acronyms used:

ADR/RID: Agreement concerning the International Carriage of Dangerous Goods by Road.

CEN: European Committee for Standardization.

PPE: Personal protection equipment.

IATA: International Air Transport Association.

ICAO: International Civil Aviation Organization.

IMDG: International Maritime Code for Dangerous Goods.

RID: Regulations Concerning the International Transport of Dangerous Goods by Rail.

Key literature references and sources for data:

<http://eur-lex.europa.eu/homepage.html>

<http://echa.europa.eu/>

Regulation (EU) 2020/878.

Regulation (EC) No 1907/2006.

Regulation (EC) No 1272/2008.

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemical substances and mixtures (REACH).

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.