

Technical Data Sheet

Product Name: Vitamin D3 100000iu/g CWS Powder

Specification		
Item	Standard	Method
Description	White to light yellow powder, no foreign matter and no odor.	Visual
Identification	The retention time of the principal peak conforms to which in the reference solution	HPLC
Particle Size	100% pass through sieve 40 mesh Min.90% pass through sieve 80 mesh	USP<786> Ph.Eur.2.9.12
Vitamin D3 Assay	≥100,000iu/g	HPLC
Loss on drying	≤5.0%	USP<731> Ph.Eur.2.2.32
Heavy Metals (as Pb)	≤10.00ppm	USP<231> II Ph.Eur.2.4.8
Lead (as Pb)	≤2.00ppm	USP<251> Ph.Eur.2.4.10
Arsenic (as As)	≤2.00ppm	USP<211> II Ph.Eur.2.4.2
*Cadmium (as Cd)	≤1.00ppm	USP<233>
*Mercury (as Hg)	≤0.10ppm	USP<233>
Total aerobic microbial count	≤1000CFU/g	USP<2021>
Total moulds and yeasts count	≤100CFU/g	Ph.Eur.2.6.12
Enterobacterial	≤10CFU/g	USP<2021> Ph.Eur.2.6.13
Escherichia coil *Salmonella *Staphylococcus aureus	n.d./10g n.d./25g n.d./10g	USP<2022> Ph.Eur.2.6.13

2.Origin & Ingredient

Country of origin of the product: China	Origin statement: available <input checked="" type="checkbox"/>
This product is a pure material <input checked="" type="checkbox"/>	This product is a compound material <input type="checkbox"/>
<input type="checkbox"/> bovine	Specific Source: /
<input type="checkbox"/> porcine	Specific Source: /
<input type="checkbox"/> Porcine	Specific Source: /
Animal origin	<input checked="" type="checkbox"/> others: Specific Source: Lanolin

Synthetic	<input type="checkbox"/>	Starting material:	Origin:
Biotechnological processing	<input type="checkbox"/> Catalysis By Enzymes	Name of Enzyme: / Sources of Enzymes: /	
	<input type="checkbox"/> Fermentation	Source of Medium: / Strain: /	
Botanical Origin	Botanical Name:	/	
	Part:	/	
	Wild or Cultivated:	/	
	Country of Origin:	/	
	Solvent Used:	/	

3. Nutrition Data

Nutritional Composition	<input checked="" type="checkbox"/> Per 100g	<input type="checkbox"/> Per Serving
<input type="checkbox"/> Energy (KJ) <input checked="" type="checkbox"/> Energy (Kcal)	400kcal	
Fat (g)	0	
Carbohydrates (g)	90	
Protein (g)	0	
Sodium (mg)	0	

Remarks: Nutrition Data Are Obtained By 3rd Party Lab; Tested on A Yearly Basis

4. Non-GMO Declaration

	YES	NO (Means Not Contain)
The product does not contain or consist of GMO	<input type="checkbox"/>	<input checked="" type="checkbox"/>
The product is not produced from GMO or not contain ingredients produced from GMO (irrespective of whether there is NDA or protein of GM origin in the final production)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
This product is not produced by means of GM microorganism including precursor substances, e.g., with GMOs or Genetically Modified microorganisms processing aids (bacteria, yeast,).	<input type="checkbox"/>	<input checked="" type="checkbox"/>
This product is not produced with the help of enzymes, which were obtained from GMOs	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does the product contain any ingredients from animal?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, are genetically modified crops contained in the feed for the animal?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
We confirm that this product complies with regulations EC/1829/2003 and EC1830/2003 and keep non-GMO statement available.	<input checked="" type="checkbox"/>	<input type="checkbox"/>

5. Allergen Declaration

We have carefully reviewed this product according to EU Regulation 1169/2011 and modifications and confirm the following:

	Direct incorporation as a base raw material or in a derivative form (don't forget the carriers, the additives, and the processing aids)		CROSS CONTAMINATION					
			Presence on the production line		Presence on the production workshop		Presence on the production factory	
	Yes (Precise nature)	No	Yes (precise the nature)	No	Yes (precise the nature)	No	Yes (precise the nature)	No
Cereals containing gluten (1) and products thereof		N		N		N		N
Crustaceans and products thereof		N		N		N		N
Eggs and products thereof		N		N		N		N
Fish and products thereof (2)		N		N		N		N
Peanuts and products thereof		N		N		N		N
Soybeans and products thereof (3)		N		N		N		N
Milk and products thereof (including lactose) (4)		N		N		N		N
Nuts (5) or products thereof		N		N		N		N
Celery and products thereof		N		N		N		N
Mustard and products thereof		N		N		N		N
Sesame seeds and product thereof		N		N		N		N
Sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10 mg/l expressed as SO ₂		N		N		N		N
Lupines and products thereof		N		N		N		N
Mollusc and product thereof		N		N		N		N

Cereals which contain gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) except: wheat-based glucose syrups including dextrose, wheat-based maltodextrins, glucose syrups based on

barley, cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;

Except: fish gelatine used as carrier for vitamin or carotenoid preparations, fish gelatine or Isinglass used as fining agent in beer and wine.

Except fully refined soybean oil and fat, natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources; vegetable oils derived phytosterols and phytosterol esters from soybean sources; plant stanol ester produced from vegetable oil sterols from soybean sources.

Except when used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages, lactitol.

Almond (*Amygdalus communis* L.) hazelnuts (*Corylus avellana*), walnut (*Juglans regia*), cashew (*Anacardium occidentale*), pecan nuts (*Carya illinoensis*), Brazil nut (*Bertholletia excelsa*), pistachio nut (*Pistacia vera*), macadamia nut and Queensland nut (*Macadamia terniflora*) and products thereof, except nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;

6. Non-Irradiation

(According to EU directive 1999/2/EC & 1999/3/EC)

This product has not been treated with ionising radiation	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO, not treated
None of the raw materials we used for this product have been treated with ionising radiation.	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO, not treated
We confirm above non-Irradiation statement is available	<input checked="" type="checkbox"/> YES	

7. Nanomaterial

(According to EU Regulation (EU) No. 1363/2013)

This product does not contain any nanomaterials as defined in EU food legislation	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO, does not contain
This product has not been made with nanotechnology	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO, is not made with nanotechnology
We confirm above non-Nanomaterial statement is available	<input checked="" type="checkbox"/> YES	

8. Residual Solvents

(According to UE Directive 2009/32 modified by (UE)2010/59; EP5.4; USP476; ICH Q3C(R7))

For this product following solvents are used during production process: Solvent A: max residual level:	<input type="checkbox"/> solvent used. <input checked="" type="checkbox"/> solvent not used
We confirm solvent residual of this product complies with:	<input checked="" type="checkbox"/> EP 7.0 <input checked="" type="checkbox"/> USP <476> <input checked="" type="checkbox"/> ICH Q3C(R7) <input checked="" type="checkbox"/> Directive 2010/59/EU <input type="checkbox"/> NA
We confirm Solvent residual statement is available	<input checked="" type="checkbox"/> YES

9. Pesticide Residual

(According to EC 396/2005; EP07; USP <561>)

This product is of vegetable origin	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
We confirm pesticide residual of this product complies with:	<input checked="" type="checkbox"/> EC 396/2005 <input checked="" type="checkbox"/> EP 07/2008 <input checked="" type="checkbox"/> USP<561> <input type="checkbox"/> N/A
Pesticide residual statement available	<input checked="" type="checkbox"/> YES

10.BSE/TSE Information	
(According to EU No. 2019/319; EP general chapter 5.2.8)	
Cattle, sheep, goats, and other animals naturally susceptible to infection with transmissible spongiform encephalopathy (TSE) agents, or those susceptible to infection through the oral route (excluding humans and non-human primates), are defined as "BSE-relevant animal species." Pigs and birds, however, are not naturally susceptible to infection via the oral route and, therefore, are not considered TSE-relevant species. Similarly, dogs, rabbits, and fish are also not classified as TSE-relevant animal species.	
The product contains no ingredients of ruminant origin and no materials derived from or exposed to ruminants affected by or under quarantine for Transmitting Transmissible Spongiform Encephalopathy (TSE) / Bovine Spongiform Encephalopathy (BSE).	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> NA
In the manufacturing of this product, there is not any raw or source material and /or reagent used that is of animal origin i.e., bovine, serum-albumin, enzymes, culture broths including those used to prepare working or master cell tanks.	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
Equipment/systems/tools use for processing or storage of the material do not come into contact at any time with materials of animal origin (e.g., components of media filler used to check such system).	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
The material is not purified by using solvents, chromatographic media or buffers that contain components of animal origin.	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
We confirm this product complies with:	<input checked="" type="checkbox"/> EU legislation 999/2001 & <input checked="" type="checkbox"/> EP general chapter 5.2.8
We confirm BSE/TSE statement is available	<input checked="" type="checkbox"/> YES

11. Contaminants Information	
(According to UE regulation NO.915/2023 and NO.629/2008 as regards maximum levels for certain contaminants in foodstuff)	
Aflatoxin B1 <5ppb Aflatoxins B1 + B2 + G1 + G2 <10ppb Ochratoxin A <15ppb	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
Melamine Free	<input checked="" type="checkbox"/> YES
Dioxins, Furans, Polychlorinated Biphenyls Free	<input checked="" type="checkbox"/> YES

<p>For polycyclic aromatic hydrocarbons, in cocoa fiber, banana chips, food supplements and their preparations, dried herbs <i>and dried spices</i>:</p> <p>Maximum level of 10 µg/kg of benzo(a)pyrene 50 µg/kg for the sum of PAH4 (PAH4; benzo[a]pyrene, chrysene, Benz[a]anthracene and benzo[b]fluoranthene) in food supplements</p>	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
<p>We confirm this product complies with NO.1881/2006 and NO.629/2008 and keep compliance statement available</p>	<input checked="" type="checkbox"/> YES

12. WADA Statement

We confirm that none of the products manufactured or stored within our facility contain any prohormones, stimulants, steroids, or other substances listed on the current WADA (World Anti-Doping Agency) list.

13. ETO Free Statement

We hereby confirm that ethylene oxide (ETO), 2-chloroethanol, or any other chemical sterilizing agents are not used during the manufacturing, storage, or transportation of our products.

14. Other Statements

<p>We confirm Nitrates of this product complies with EU No 1258/2011</p>	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
<p>We confirm Mycotoxins / Aflatoxins of this product complies with EU No 165/2010</p>	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
<p>We confirm 3-MCPD of this product complies with EU No. 2020/1322</p>	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
<p>We confirm Pyrrolizidine alkaloids of this product complies with Regulation (EU) 2020/2040</p>	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA

Vitamin D₃ Powder

Production Procedure

1. Words Specifications

First, dissolve Vitamin D₃, Vitamin E and Vegetable oil in the oil-dissolving kettle. Second, put the above mixed oil into the emulsifying kettle to emulsify and homogenize with purified water, maltodextrin, starch sodium octenyl succinate, Arabia gum and sodium ascorbate. Third, the microencapsulated powder has been produced by spray drying. Then, mix it with tricalcium phosphate and pass through the 40 mesh filter. Finally, after magnetic separation, packaging and testing, the qualified products will be stored in warehouse.

2. Chart specifications



