

Provitas® D₂-400SD

Product Description-

Provitas® D₂-400SD is a uniform water-soluble powder, which is off-white to cream in color with a bland odor and taste. The active ingredient, ergocalciferol is dissolved in coconut derived MCT oil and homogenized with non-GMO modified food starch and maltodextrin and then dried to a uniform powder. BHA and BHT are added as antioxidants. The Vitamin D₂ contained in this product meets all requirements of USP and Ph. Eur when tested according to this compendium. Provitas® D₂-400SD is intended for the fortification of vitamin D₂ in foods, beverages and powdered nutritional supplements.

Item Number: D222

CAS-Number: 50-14-6

Country of Origin-

United States of America

Compendia Requirements-

A specific USP or FCC monograph does not exist for vitamin D₂ Powders preparations. USP grade ergocalciferol and USP/NF and/or FCC grade excipients are used to manufacture Provitas® D₂-400SD.

Generally Recognized as Safe-

Provitas® D₂-400SD is affirmed (GRAS) Generally Recognized As Safe by the US FDA with specific limitations as stated in the US FDA Code of Federal Regulations: 21CFR184.1950.

Harmonized Tariff Schedule Code-

2936.29.5020

Solubility-

 Provitas® D₂-400SD is soluble in water

TEST	METHOD	SPECIFICATIONS
Organoleptic Description: Color: Odor:	Observation	Solid - powder Off-white to cream Bland
Moisture Forced Air Oven, %	USP<731>	<5.00
Assay Vitamin D ₂ (Ergocalciferol) (IU/g), mg/g	J. Chromatogr. A870 (2000) 207-15 & Dionex Tech Note 89	≥ 400,000 10
Micro Aerobic Plate Count, cfu/g Coliforms, cfu/g Yeasts & molds, cfu/g E. coli, cfu/g Staphylococcus aureus, cfu/g Salmonella, cfu/g	USP<2021> USP<2021> USP<2021> USP<2022> USP<2022> USP<2022>	<1,000 <100 <100 Negative Negative Negative
Heavy Metals (HM) Arsenic, mg/kg Cadmium, mg/kg Lead, mg/kg Mercury, mg/kg	AOAC 993.14 AOAC 993.14 AOAC 993.14 DMA	<1.0 <0.3 <1.0 <0.1
Residual Solvents (RS)	USP <467>	Complies ¹
1. Specification is informational and not part of release testing but is determined by the use of USP grade vitamin D ₃ that meets USP (RS) specifications. Water is the only solvent used in the production of D ₂ -400SD powder.		

Stability and Storage-

The shelf life in sealed, original containers under normal storage conditions is 24 months after the date of manufacture. Store in tightly closed containers in dry conditions below 20°C. Protect from moisture, heat, light and oxygen.

GMP-

Provitas LLC confirms that Provitas® D₂-400SD is manufactured in a production facility that adheres to Good Manufacturing Practices as defined by the U.S. FDA, CFR Title 117. Provitas and the production Facilities are FDA registered, and 3rd party certified.

Non-GMO and Organic compliant statement-

Provitas® D₂-400SD is manufactured by physical and chemical means and is therefore not an organic product Provitas® D₂-400SD is organic compliant in accordance with *The Organic Foods Production Act of 1990* as stated in the United States Code of Federal Regulations 7CFR205.605(b) and *Canada Agricultural Products Act, Organic Products Regulations (SOR/2009-176), Part 3.24* and specifically stated in CAN/CGSB-32.311-2006 (6.4):

Provitas® D₂-400SD is free of Genetically Modified Organisms in accordance with European Union regulations.

Vegetarian/Vegan Statement-

Provitas® D₂-400SD is a vegetarian and vegan product. Provitas® D₂-400SD produced using raw materials derived from plants and synthetic sources. Ergocalciferol, the active ingredient in Provitas® D₂-400SD, is derived from molasses fermentate.

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Nutritional Data (per 100g)

Item	Result	Item	Result
Total Calories	388 Kcal	Water	<5 grams
Calories from Fat	35 Kcal	Ash	<1 grams
Calories from Saturated Fat	88 grams	Vitamin A (IU) / (RE)	0 IU
Protein	0 grams	Vitamin E (dl- α tocopherol)	0 IU
Fat	3.9 grams	Vitamin D	400,000 IU 10 mg/g
Saturated Fat	3.9 grams	Calcium	1,650 milligram
Carbohydrate	88 grams	Iron	0 milligram
Dietary Fiber	0.0 gram	Sodium	4,620 milligram
Sugar - Total	2.46 gram	Potassium	0 milligram
Added sugar	0 gram	Other	0.1 grams

Accuracy Disclaimer-

Provitas, LLC has taken great care to verify the correctness of these data and believes they are correct. However, since the data comes from various sources and are not verified analytically, we cannot warranty their accuracy. Provitas, LLC can only guarantee the minimum potency of the vitamins and other specifications found on the Product Data Sheet, which are available on request. For guaranteed accuracy of composition other than that guaranteed by Provitas, LLC, the customer is advised to submit for analytical testing by a reliable laboratory.

These values have been determined by using a nutritional database of ingredients, which were analyzed singularly. They are believed to be accurate but are not guaranteed.

Sewage-

We certify that Provitas® D₂-400SD has been produced, packaged and stored without the use of sewage sludge.

Residual Solvent Statement-

Provitas LLC certifies that Provitas® D₂-400SD fully complies with Chemical test <467> USP/NF: Residual Solvents Limits. No solvents are used in the manufacturing of Provitas® D₂-400SD.

WADA-

Provitas LLC certifies that Provitas® D₂-400SD does not contain nor comes into contact with any substance listed on the World Anti-Doping Agency banned list or other sports related banned lists. These include narcotics, hormones, diuretics and steroids.

Nanomaterial Statement-

Based on our current understanding of nanomaterial regulation EU No 1169/2011, Provitas® D₂-400SD is not considered a nanomaterial. Therefore, it does not require labeling as such.

Contaminants and Impurities Statement-

To our knowledge, there is no contamination by potentially harmful materials in Provitas® D₂-400SD. This includes but not limited to heavy metals, PAHs, dioxins, propylene, melamine, mycotoxins, and solvents.

Prop 65-

We certify that Provitas® D₂-400SD and all materials used to manufacture PROVITAS® D₂-400SD do not appear on the List Of Chemicals Known to Cause Cancer Or Reproductive Toxicity, under section 25249.8 of the CALIFORNIA SAFE WATER AND TOXIC ENFORCEMENT ACT OF 1986, Chapter 6.6 added by Proposition 65 in 1986.

BSE/TSE/Irradiation/EtO Statements-

Provitas® D₂-400SD is free of any animal origin organisms/ingredients. Product is PCR negative for any or animal-based organisms. Provitas, LLC guarantees that no BSE causing ingredients are present in Provitas® D₂-400SD.

Provitas LLC certifies that Provitas® D₂-400SD is free of radiation. Irradiation is not used in the production, packaging and/or storage of Provitas® D₂-400SD.

We certify that Provitas® D₂-400SD is free of ethylene oxide. Ethylene oxide sterilization is not used in the production, packaging and/or storage of Provitas® D₂-400SD.

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Packaging Details-

100gm Sample D2225500	25 kg carton D2225553
Aluminum pouch 100 gram net weight 4" x 6" (10cm x 15cm)	Fiber carton w/plastic liner 25kg net weight 26kg gross weight 15"x11"x22" (38cm x 28cm x 56cm) Quantity per 40" x 48" pallet: 1 layer of 9 cartons (225kg) Maximum 3 layers / pallet (675kg)

Revision History				
Revision	Modified by	Previous Date	Date of Change	Description of Change
01	Emily Baird	February 6, 2019	August 6, 2019	Update new item Number and footer
02	Emily Baird	August 6, 2019	March 9 th , 2020	Updated to 2020 Product data sheet template
03	Emily Baird	March 9 th , 2020	August 10, 2020	Added Contaminants statement
04	Emily Moran	August 10, 2020	March 12 th , 2021	Corrected the CAS#
05	Emily Moran	June 12, 2020	November 18, 2021	Updated vegan and vegetarian statement