

Provitas® D₃-100SD

Product Description-

Provitas® D₃-100SD is a uniform water-soluble powder, which is off-white to cream in color with a bland odor and taste. The active ingredient, cholecalciferol is dissolved in MCT oil and homogenized with non-GMO modified food starch and non-GMO maltodextrin then dried to a uniform powder. dl- α tocopherol and sodium ascorbate are added as antioxidants. Silicon dioxide is added for flowability. Provitas® D₃-100SD is kosher certified. Provitas® D₃-100SD is intended for the fortification of vitamin D₃ in foods, beverages and powdered nutritional supplements.

Item Number: D207

CAS-Number: 67-97-0

Country of Origin- United States of America

Compendia Requirements-

Provitas® D₃-100SD meets USP monograph *Cholecalciferol Solution*.

Generally Recognized as Safe-

Provitas® D₃-100SD 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® D₃-100SD is soluble in water

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® D₃-100SD 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® D₃-100SD is manufactured by physical and chemical means and is therefore not an organic product Provitas® D₃-100SD 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® D₃-100SD is not derived from genetically modified organisms. Provitas® D₃-100SD does not contain ingredients, additives or processing aides derived from commodities that contain or are derived from genetically modified organisms.

Provitas® D₃-100SD does not contain detectable modified genetic materials, as according to the USDA National Bioengineered Food Disclosure Standard (NBFDS), 7 CFR Part 66. This product does not require disclosure as a BE substance.

Sewage-

We certify that Provitas® D₃-100SD has been produced, packaged, and stored without the use of sewage sludge.

Vegetarian/Vegan Statement-

Provitas® D₃-100SD is produced using raw materials derived from plant, animal, and synthetic sources. This product is vegetarian but is not vegan since Cholecalciferol (Vitamin D₃) is derived from the wool grease of sheep.

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 ₃ , cholecalciferol, IU/g mg/g	J. Chromatogr. A870 (2000) 207-15 & Dionex Tech Note 89	100,000 – 120,000 2.5 – 3.0
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	<0.5 <0.3 <0.5 <0.1
Residual Solvents (RS)	USP <467>	Complies ¹
Particle Distribution:	USP<786>	≥ 95.0% through #40 mesh ≥ 80.0% through #80 mesh ≤ 60.0% through #200 mesh
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 ₃ -100SD powder.		

Provitas® D₃-100SD

Nutritional Data (per 100g)-

Nutrients	Result	Nutrients	Result
Calories (kcal)	268	Ash (g)	0.51
Calories from Fat (kcal)	92.27	Vitamin A - IU	0
Calories from Sat Fat (kcal)	92.25	Vitamin A - RAE	0
Protein (g)	0.11	Vitamin C (mg)	888.9
Carbohydrates (g)	82.7	Ergocalciferol	0
Dietary Fiber (g)	0	Cholecalciferol (mg)	2.5
Total Sugars (g)	23	D-L-alpha tocopherol	227.5
Added Sugars (g)	0	Calcium (mg)	28.48
Other Carbs (g)	24.4	Iron (mg)	0.095
Fat (g)	10.31	Magnesium (mg)	0
Saturated Fat (g)	10.25	Manganese (mg)	0
Trans Fatty Acid (g)	0.01	Potassium (mg)	6.48
Cholesterol (mg)	0	Sodium (mg)	111.02
Water (g)	0.14		

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.

Residual Solvent Statement-

Provitas LLC certifies that Provitas® D₃-100SD fully complies with Chemical test <467> USP/NF: Residual Solvents Limits. No solvents are used in the manufacturing of Provitas® D₃-100SD.

WADA-

Provitas LLC certifies that Provitas® D₃-100SD 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.

Prop 65-

We certify that Provitas® D₃-100SD and all materials used to manufacture Provitas® D₃-100SD 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.

Nanomaterial Statement-

Based on our current understanding of nanomaterial regulation EU No 1169/2011, Provitas® D₃-100SD is not considered a nanomaterial. Therefore, it does not require labeling as such.

BSE/TSE/Irradiation/EtO Statements-

Provitas® D₃-100SD 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® D₃-100SD.

Vitamin D₃ lanolin is the initial raw material used in the manufacturing of D₃ USP crystals. Lanolin is extracted from wool grease of Australian and New Zealand sheep. As a result of the various chemical process steps converting lanolin to D₃ USP crystals, no proteins and/or amino acids exist in D₃ USP crystals.

Provitas LLC certifies that Provitas® D₃-100SD is free of radiation. Irradiation is not used in the production, packaging and/or storage of Provitas® D₃-100SD.

We certify that Provitas® D₃-100SD is free of ethylene oxide. Ethylene oxide sterilization is not used in the production, packaging and/or storage of Provitas® D₃-100SD.

Contaminants and Impurities Statement-

To our knowledge, there is no contamination by potentially harmful materials in Provitas® D₃-100SD. This includes but not limited to heavy metals, PAHs, dioxins, propylene, melamine, mycotoxins, and solvents.

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Packaging Details-

100gm Sample D2077100	25kg carton D2077153
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 10 cartons (250kg) Maximum 3 layers / pallet (750kg)

Revision History				
Revision	Modified by	Previous Date	Date of Change	Description of Change
01	Emily Baird	May 13 th , 2019	September 18, 2019	Update new item Number and footer
02	Emily Baird	September 18, 2019	March 2nd, 2020	Updated to 2020 Product data sheet template
03	Emily Moran	March 2nd, 2020	April 23 rd , 2021	Added BE statement and corrected format
04	Emily Moran	April 23 rd , 2021	November 22, 2021	Updated PDS for formula change