

## Provitas® D<sub>2</sub>-100SD

**Product Description-**

Provitas® D<sub>2</sub>-100SD 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 MCT oil and homogenized with non-GMO modified food starch and maltodextrin then dried to a uniform powder. dl-α tocopherol and sodium ascorbate are added as antioxidants. Silicon dioxide is added for flow. The Vitamin D<sub>2</sub> contained in this product meets all requirements of USP and Ph. Eur when tested according to this compendium. Provitas® D<sub>2</sub>-100SD is intended for the fortification of vitamin D<sub>2</sub> in foods, beverages and powdered nutritional supplements.

**Item Number:** D214

**CAS-Number:** 50-14-6

**Country of Origin-** United States of America

**Generally Recognized as Safe-**

Provitas® D<sub>2</sub>-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® D<sub>2</sub>-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® D<sub>2</sub>-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 3<sup>rd</sup> party certified.

**Non-GMO and Organic compliant statement-**

Provitas® D<sub>2</sub>-100SD is manufactured by physical and chemical means and is therefore not an organic product. Provitas® D<sub>2</sub> 100 SD 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® D<sub>2</sub>-100SD is not derived from genetically modified organisms. Provitas® D<sub>2</sub>-100SD does not contain ingredients, additives or processing aides derived from commodities that contain or are derived from genetically modified organisms.

Provitas® D<sub>2</sub>-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.

**Vegetarian/Vegan Statement-**

Provitas® D<sub>2</sub>-100SD is a vegetarian and vegan product. Provitas® D<sub>2</sub>-100SD produced using raw materials derived from plants and synthetic sources. Ergocalciferol, the active ingredient in D<sub>2</sub>-100SD, is derived from molasses fermentate.

TEST	METHOD	SPECIFICATIONS
<b>Organoleptic Properties</b>		
Description	Observation	Solid - powder
Color		Off-white to cream
Odor		Bland
<b>Assay</b>		
Ergocalciferol, IU/g	AOAC 979.24	≥ 100,000
mg/g	980.26	≥ 2.5
<b>Micro</b>		
Aerobic Plate Count, cfu/g	USP<2021>	<1,000
Coliforms, cfu/g	USP<2021>	<100
Yeasts & molds, cfu/g	USP<2021>	<100
E. coli, cfu/g	USP<2022>	Negative
Staphylococcus aureus, cfu/g	USP<2022>	Negative
Salmonella, cfu/g	USP<2022>	Negative
<b>Heavy Metals (HM)</b>		
Arsenic, mg/kg	AOAC 993.14	<1.5
Cadmium, mg/kg	AOAC 993.14	<0.3
Lead, mg/kg	AOAC 993.14	<1.0
Mercury, mg/kg	DMA	<0.2
<b>Residual Solvents (RS)<sup>3</sup></b>	USP <467>	Complies <sup>1</sup>
<b>Moisture:</b>		
Karl Fischer Moisture, %	AOAC 984.20	≤ 5
1. Specification is informational and not part of release testing but is determined by the use of USP grade vitamin D <sub>2</sub> that meets USP (RS) specifications. Water is the only solvent used in the production of D <sub>2</sub> -100SD powder.		

## Provitas® D<sub>2</sub>-100SD

**Nutritional Data (per 100g)-**

Nutrient	Result		Nutrient	Result
Calories (kcal)	421.15		Vitamin C (mg)	888.9
Calories from Fat (kcal)	97.2639		Ergocalciferol (mg)	2.5
Protein (g)	0.10795		D-L-alpha tocopherol (mg)	5
Carbohydrates (g)	82.261		D-L-alpha tocopherol (IU)	2.5
Total Sugars (g)	23		Calcium (mg)	28.5
Other Carbs (g)	24.4		Iron (mg)	0.1
Fat (g)	10.8071		Potassium (mg)	7
Trans Fatty Acid (g)	0.01075		Sodium (mg)	111
Water (g)	0.143		Vitamin C (mg)	888.9
Ash (g)	0.511			

**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® D<sub>2</sub>-100SD fully complies with Chemical test <467> USP/NF: Residual Solvents Limits and EU directive 2009/32/EC. No solvents are used in the manufacturing Provitas® D<sub>2</sub>-100SD.

**WADA-**

Provitas LLC certifies that Provitas® D<sub>2</sub>-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.

**Nanomaterial Statement-**

Based on our current understanding of nanomaterial regulation EU No 1169/2011, Provitas® D<sub>2</sub>-100SD is not considered a nanomaterial. Therefore, it does not require labeling as such.

**Prop 65-**

We certify that Provitas® D<sub>2</sub>-100SD and all materials used to manufacture Provitas® D<sub>2</sub>-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. Provitas® D<sub>2</sub>-100SD does not contain Carcinogen, Mutagen, or toxic for the Reproduction substances according to the 1272/2008 (EC) Regulation, directive 67/548/EWG.

**BSE/TSE/Irradiation/EtO Statements-**

D<sub>2</sub>100SD is free of any animal origin organisms/ingredients. Provitas, LLC guarantees that any BSE/TSE causing ingredients or animal originated ingredients are not present in D<sub>2</sub>100SD.

Provitas LLC certifies that Provitas® D<sub>2</sub>-100SD is free of radiation. Irradiation is not used in the production, packaging and/or storage of Provitas® D<sub>2</sub>-100SD.

We certify that Provitas® D<sub>2</sub>-100SD is free of ethylene oxide. Ethylene oxide sterilization is not used in the production, packaging and/or storage of Provitas® D<sub>2</sub>-100SD.

**Contaminants and Impurities Statement-**

To our knowledge, there is no contamination by potentially harmful materials in Provitas® D<sub>2</sub>-100SD. This includes but not limited to heavy metals, PAHs, dioxins, propylene, melamine, mycotoxins, and solvents. Provitas® D<sub>2</sub>-100SD is in compliance with the EU Commission regulation (EU) 1881/2006.

**Sewage-**

We certify that Provitas® D<sub>2</sub>-100SD has been produced, packaged and stored without the use of sewage sludge.

## Provitas® D<sub>2</sub>-100SD

**Packaging Details-**

<b>100gm Sample D2147100</b>	<b>25kg carton D2147153</b>
Aluminum bottle, 50ml  100 gram net weight each / 100gm 4" x 6" (10cm x 15cm)	Fiber carton w/plastic liner  25kg net weight 26kg gross weight 12"x15"x20" (31cm x 38cm x 51cm) 27kg gross weight (over pack) 13"x16"x21" (33cm x 40cm x 53cm)  Quantity Per 40" x 48" pallet: 1 layer of 10 cartons Maximum 3 layers / pallet

Revision History				
Revision	Modified by	Previous Date	Date of Change	Description of Change
01	Emily Baird	February 6, 2019	February 25 <sup>th</sup> , 2020	Updated to 2020 Product data sheet template
02	Emily Baird	February 25 <sup>th</sup> , 2020	June 12, 2020	Updated specification table to state Organoleptic test and Updated statements to include EU compliance in statements
03	Emily Moran	June 12, 2020	November 18, 2021	Updated vegan and vegetarian statement
04	Emily Moran	November 18, 2021	December 14, 2021	Removed sucrose from formula
05	Emily Moran	December 14 <sup>th</sup> , 2021	January 27, 2022	Added CMR Statement