

Provitas® D₃ 1.0 MIU/g MCT Oil

Product Description-

Vitamin D₃ USP is standardized in Palm derived MCT Oil; synthetic dl-α tocopherol is added as an antioxidant. Provitas® Vitamin D₃ 1.0 MIU/g MCT Oil is kosher certified and produced in a cGMP facility. Provitas® Vitamin D₃ 1.0 MIU/g MCT Oil is designed for use in oil dispersions, encapsulated products, and fortified foods.

Item Number: D202

CAS-Number: 67-97-0

Country of Origin-

United States of America

Compendia Requirements-

Provitas® Vitamin D₃ 1.0 MIU/g MCT Oil meets USP monograph *Cholecalciferol Solution*.

Generally Recognized as Safe-

Provitas® Vitamin D₃ 1.0 MIU/g MCT Oil 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

TEST	Method	SPECIFICATIONS
Organoleptic: Description: Color: Odor:	Observation	Clear viscous oil Clear to slight yellow Typical faint
Assay: Cholecalciferol (vitamin D ₃), IU/g mg/g	J. Chromatogr. A870(2000)207-15 & Dionex Tech Note 89	≥ 1,000,000 – 1,200,000 ≥ 25.0 – 30.0
Heavy Metals: Arsenic, ppm Cadmium, ppm Lead, ppm Mercury, ppm	AOAC 993.14 AOAC 993.14 AOAC 993.14 DMA	<1.5 <0.3 <1.0 <0.2
Microbial purity: APC, cfu/g Coliforms, cfu/g Yeast & Mold, 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 Absent Absent Absent
Residual Solvents (RS): %	USP <467>	Meets USP Requirements 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.		

Solubility- Provitas® Vitamin D₃ 1.0 MIU/g MCT Oil is miscible in fats and oils.

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 cool and dry conditions. Protect from heat, light and oxygen. Avoid freezing temperatures.

GMP-

Provitas LLC confirms that Provitas® Vitamin D₃ 1.0 MIU/g MCT Oil 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® Vitamin D₃ 1.0 MIU/g MCT Oil is manufactured by physical and chemical means and is therefore not an organic product. Provitas® Vitamin D₃ 1.0 MIU/g MCT Oil 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® Vitamin D₃ 1.0 MIU/g MCT Oil not derived from genetically modified organisms. Provitas® Vitamin D₃ 1.0 MIU/g MCT Oil does not contain ingredients, additives or processing aides derived from commodities that contain or are derived from genetically modified organisms.

Provitas® Vitamin D₃ 1.0 MIU/g MCT Oil 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® Vitamin D₃ 1.0 MIU/g MCT Oil 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.

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Nutritional Data (per 100g)

Item	Result	Item	Result
Total Calories	870 Kcal	Water	0 grams
Calories from Fat	870 Kcal	Ash	0 grams
Protein	0 grams	Vitamin A (IU) / (RE)	0 IU
Fat	97 grams	Vitamin E (dl-α tocopherol)	100 mg/g ¹
Saturated Fat	89 grams	Vitamin D	100,000,000 IU 25 mg/g
Carbohydrate	0 grams	Calcium	0 grams
Dietary Fiber	0 grams	Iron	0 grams
Sugar - Total	0 grams	Sodium	0 grams
Added sugar	0 grams	Potassium	0 grams
		Other	3 grams
1. 1 mg vitamin E (label claim) = 1mg RRR-α-tocopherol = 2 mg all-rac-α-tocopherol as according to 21 CFR 101.9 (101.9(c)(8)(iv))			
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.			

Contaminants and Impurities Statement-

To our knowledge, there is no contamination by potentially harmful materials in Vitamin D₃ 1.0miu/g MCT Oil. This includes but not limited to heavy metals, pesticides, PAHs, PHO's, Propylene, dioxins, melamine, BPA, aflatoxins, mycotoxins, phthalates, and solvents.

Sewage-

We certify that Provitas® Vitamin D₃ 1.0 MIU/g MCT Oil has been produced, packaged, and stored without the use of sewage sludge.

Residual Solvent Statement-

Provitas LLC certifies that Provitas® Vitamin D₃ 1.0 MIU/g MCT Oil fully complies with Chemical test <467> USP/NF: Residual Solvents Limits. No solvents are used in the manufacturing of Provitas® Vitamin D₃ 1.0 MIU/g MCT Oil.

WADA-

Provitas LLC certifies that Provitas® Vitamin D₃ 1.0 MIU/g MCT Oil 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® Vitamin D₃ 1.0 MIU/g MCT Oil and all materials used to manufacture Provitas® Vitamin D₃ 1.0 MIU/g MCT Oil 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® Vitamin D₃ 1.0 MIU/g MCT Oil is not considered a nanomaterial. Therefore, it does not require labeling as such.

BSE/TSE/Irradiation/EtO Statements-

Provitas, LLC guarantees that no BSE/TSE causing ingredients are present in Provitas® Vitamin D₃ 1.0 MIU/g MCT Oil.

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® Vitamin D₃ 1.0 MIU/g MCT Oil is free of radiation. Irradiation is not used in the production, packaging and/or storage of Provitas® Vitamin D₃ 1.0 MIU/g MCT Oil.

We certify that Provitas® Vitamin D₃ 1.0 MIU/g MCT Oil is free of ethylene oxide. Ethylene oxide sterilization is not used in the production, packaging and/or storage or Provitas® Vitamin D₃ 1.0 MIU/g MCT Oil.

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Packaging Details-

100gm Sample D2021300	10kg carton D2021353	190kg carton D2021323
Aluminum bottle, 50ml 50 gram net weight 1.77" x 2.68" (45mm x 68mm)	Fiber carton w/plastic liner 10kg net weight 11kg gross weight 12"x8"x12" (31cm x 20cm x 31cm) Quantity per 40" x 48" pallet: 1 layer of 10 cartons (250kg) Maximum 3 layers / pallet (750kg)	Metal open-head drum 190kg net weight 211kg gross weight 24"x24"x34.5" (61cm x 61cm x 88cm) Quantity per 40" x 48" pallet: 1 layer of 4 drums (760kg) Maximum 1 layer / pallet (760kg)

Revision	Modified by	Date of Change	Description of Change	Approved by
05	Emily Moran	July 30 th , 2021	Updated GMO statement	-
06	Emily Moran	December 9, 2021	Added BE statement	-
07	Emily Moran	March 30 th , 2022	Updated nutritional statement	MW
08	Emily Moran	April 1, 2022	Updated BSE/TSE statement	EM