

Provitas® AD₃ 1000/100

Product Description-

Vitamin A Palmitate Oil USP and vitamin D₃ USP standardized in MCT Oil and stabilized with dl- α tocopherol as an antioxidant. AD₃ 1000/100 is kosher certified and produced in a cGMP facility. Provitas® AD₃ 1000/100 is intended as a source of vitamin A and D₃ in food fortification, food oil dispersions and dietary supplements.

Item Number: X406

CAS-Number: Vitamin A: 79-81-2
Vitamin D₃: 67-97-0

Country of Origin- Manufactured in the USA.

Generally Recognized as Safe-

Provitas® AD₃ 1000/100 is affirmed (GRAS) Generally Recognized As Safe by the US FDA with specific limitations as stated in the US FDA Code of Federal Regulations: 21CFR184.1930 and FDA Code of Federal Regulations: 21CFR184.1950.

Stability and Storage-

The shelf life in sealed, original containers under normal storage conditions is 12 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® AD₃ 1000/100 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® AD₃ 1000/100 is manufactured by physical and chemical means and is therefore not an organic product. Provitas® AD₃ 1000/100 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® AD₃ 1000/100 is free of genetically modified organisms defined as containing no ingredients, additives or processing aides derived from commodities that contain or are derived from genetically modified organisms.

Vegetarian Statement-

Provitas® AD₃ 1000/100 is produced using raw materials derived from plant sources or synthetic. This product is vegetarian and vegan since no animal source product is used in manufacturing.

TEST	METHOD	SPECIFICATIONS
Organoleptic: Description: Color: Odor:	Observation	Clear viscous oil Pale yellow Typical faint
Acid Value: Mg KOH/kg	AOCS Cd 3d-63	< 2.0
Assay: Retinyl palmitate; IU/g Retinyl palmitate; mg/g Cholecalciferol; IU/g Cholecalciferol; mg/g	J. Chrom. A 870 (2000) 207-15 & Dionex Tech Note 89	≥ 1,000,000 ≥ 550 ≥ 100,000 ≥ 2.5
Microbial purity: APC, cfu/10g Coliforms, cfu/10g Yeast & mold, cfu/10g E. Coli, cfu/10g Staphylococcus aureus, cfu/10g Salmonella, cfu/10g	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	JAOAC 993 766-775 JAOAC 993 766-775 JAOAC 993 766-775 JAOAC 993 766-775	<1.5 <0.3 <1.0 <0.2
Residual Solvents (RS)¹	USP <467>	Complies
1. Specification is informational and not part of release testing but is determined by the use of USP grade vitamin D ₃ and Vitamin A that meets USP (RS) specifications. Water is the only solvent used in the production of Provitas® AD ₃ 1000/100 powder.		

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Nutritional Data per 100g-

Item	Result	Item	Result
Total Calories	364 kcal	Water	0g
Calories from Fat	364 kcal	Ash	0g
Calories from Saturated Fat	364 kcal	Vitamin A (IU) / (RE)	100 kiu / 32.1 g
Protein	0g	Vitamin E (dl- α -tocopherol)	550 iu (500 mg)
Fat	40g	Vitamin D miu / mg	10 miu / 250 mg
Saturated Fat	40g	Calcium	0mg
Carbohydrate	0g	Iron	0mg
Dietary Fiber	0g	Sodium	0mg
Sugar - Total	0g	Potassium	0mg
Added sugar	0g	Magnesium	0mg

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® AD₃ 1000/100 fully complies with Chemical test <467> USP/NF: Residual Solvents Limits.

WADA-

Provitas LLC certifies that Provitas® AD₃ 1000/100 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® AD₃ 1000/100 is not considered a nanomaterial. Therefore, it does not require labeling as such.

Prop 65-

Vitamin A is known to the state of California to cause birth defects or other reproductive harm. We certify that all inert ingredients in Provitas® AD₃ 1000/100 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-

We certify that Provitas® AD₃ 1000/100 is free of radiation. Irradiation is not used in the production, packaging and/or storage of Provitas® AD₃ 1000/100.

We certify that Provitas® AD₃ 1000/100 is free of ethylene oxide. Ethylene oxide sterilization is not used in the production, packaging and/or storage of AD₃ 1000/100.

We certify that Provitas® AD₃ 1000/100 is free of BHA and BHT. BHA and BHT are not used in the production, packaging and/or storage of Provitas® AD₃ 1000/100.

Contaminants and Impurities Statement-

To our knowledge, there is no contamination by potentially harmful materials in Provitas® AD₃ 1000/100. This includes but not limited to heavy metals, PAHs, dioxins, propylene, melamine, mycotoxins, and solvents. Provitas® AD₃ 1000/100 is in compliance with the EU Commission regulation (EU) 1881/2006.

Sewage-

We certify that Provitas® AD₃ 1000/100 has been produced, packaged and stored without the use of sewage sludge.

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Packaging Details-

50gm Sample X4061300	10kg carton X4061355	190kg carton X4061323
Aluminum bottle, 50ml, 50 gram net weight 1.77" x 2.68" (45mm x 68mm)	Fiber carton containing 2 x 5kg aluminum bottles 10kg net weight 11kg gross weight 7"x14"x7" (18cm x 36cm x 18cm) Quantity Per 40" x 48" pallet: 1 layer of 15 cartons 150kg Maximum 4 layers / pallet 600kg	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 History				
Revision	Modified by	Previous Date	Date of Change	Description of Change
01	Emily Baird	February 5, 2019	February 25 th , 2020	Updated to PDS 2020 Format, product number and footer
02	Emily Baird	February 25 th , 2020	July 30 th , 2020	Updated to 2020PDS format
03	Emily Baird	July 30 th , 2020	August 11, 2020	Updated Specification Table
04	Emily Moran	August 11, 2020	August 25, 2020	Updated Specification Table
05	Emily Moran	August 25, 2020	February 23 rd , 2021	Updated Prop 65 statement