

Provitas® AP250SD

Product Description-

Provitas® AP250SD is a non-GMO water-soluble powder, which is light yellow to tan in color with a bland odor and taste. The active ingredient, retinyl palmitate is homogenized with non-GMO modified food starch and maltodextrin and then dried to a uniform powder. Provitas® AP250SD is intended for the fortification of vitamin A in foods, beverages and powdered nutritional supplements. Provitas® AP250SD is Kosher and Halal Certified.

Item Number: A304
CAS-Number: 79-81-2
Country of Origin-

Manufactured in the USA.

Compendia Requirements-

Provitas® AP250SD meets all requirements of the EC 953/2009 and EC 231/2021, USP37-NF32 monograph *Vitamin A*, FCC9 monograph *Vitamin A* and GB 14750-2010 *National Food Safety Standard Food Additive Vitamin A*.

Generally Recognized as Safe-

Provitas® AP250SD 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.

Harmonized Tariff Schedule Code-

2936.21.00.00

Solubility-

Provitas® AP250SD is soluble in cold water

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 preferably under inert gas. Protect from moisture, heat, light and oxygen.

GMP-

Provitas LLC confirms that Provitas® AP250SD 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® AP250SD is manufactured by physical and chemical means and is therefore not an organic product. Provitas® AP250SD 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® AP250SD 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.

TEST	METHOD	SPECIFICATIONS
Organoleptic: Description: Color: Odor:	Observation	Solid - powder Off-white to light yellow Bland
Identification: A B	USP monograph USP monograph	Complies Complies
Moisture: %	USP<731>	≤ 5
Assay: Retinyl palmitate, IU/g mg/g dl-α tocopherol, mg/g	J. Chrom. A 870 (2000) 207-15 & Dionex Tech Note 89	≥ 250,000 ≥ 137.50 > 2.0
Microbial purity*: APC, cfu/10g Enterobacteriaceae, cfu/25g Yeast & mold, cfu/10g Cronobacter sakazakii, cfu/10g E. Coli, cfu/10g Staphylococcus aureus, cfu/10g Salmonella, cfu/50g	USP <2021> USP <2021> USP <2021> USP <2022> USP <2022> USP <2022>	1,000 <100 <50 Negative Negative Negative Negative
Heavy Metals (HM) Arsenic, mg/kg Cadmium, mg/kg Lead, mg/kg Mercury, mg/kg	JAOAC 2016 99(3) 766-775 JAOAC 2016 99(3) 766-775 JAOAC 2016 99(3) 766-775 JAOAC 2016 99(3) 766-775	<1.0 <0.3 <1.0 <0.1
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 A that meets USP (RS) specifications. Water is the only solvent used in the production of Provitas® AP250SD powder.		

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Nutritional Data-

Item	Result	Item	Result
Total Calories	296 Kcal	Water	5 gram
Calories from Fat	0 Kcal	Ash	2 gram
Calories from Saturated Fat	0 Kcal	Vitamin A (IU) / (RE)	25,000,000 IU / 7,500 milligram RE
Kilojoules	1238	Vitamin E (α-tocopherol)	540 milligram
Protein	0gram	Vitamin D	0 milligram
Fat	0 gram	Calcium	8 milligram
Saturated Fat	0 gram	Iron	0 milligram
Carbohydrate	74 gram	Sodium	21milligram
Dietary Fiber	0 gram	Potassium	0 milligram
Sugar - Total	1 gram	Magnesium	0 milligram
Added sugar	0 gram		

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® AP250SD fully complies with Chemical test <467> USP/NF: Residual Solvents Limits. Water is the only solvent used in the Provitas® AP250SD manufacturing process.

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® AP250SD 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.

WADA-

Provitas LLC certifies that Provitas® AP250SD 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® AP250SD is not considered a nanomaterial. Therefore, it does not require labeling as such.

BSE/TSE/Irradiation/EtO Statements-

We certify that Provitas® AP250SD is free of radiation. Irradiation is not used in the production, packaging and/or storage of Provitas® AP250SD.

We certify that Provitas® AP250SD is free of ethylene oxide. Ethylene oxide sterilization is not used in the production, packaging and/or storage of AP250SD.

We certify that Provitas® AP250SD is free of BHA and BHT. BHA and BHT are not used in the production, packaging and/or storage of Provitas® AP250SD.

Contaminants and Impurities Statement-

To our knowledge, there is no contamination by potentially harmful materials in Provitas® AP250SD. This includes but not limited to heavy metals, PAHs, dioxins, propylene, melamine, mycotoxins, and solvents.

Vegetarian Statement-

Provitas® AP250SD 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.

Sewage-

We certify that Provitas® AP250SD has been produced, packaged and stored without the use of sewage sludge.

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Packaging Details-

100gm Sample A3047100	25 Kg carton A3047153
Aluminum pouch 100 gram net weight each / 100gm 4" x 6" (10cm x 15cm)	Fiber carton w/plastic liner 25 Kg net weight 26 Kg gross weight 15"x 11"x 20" (38cm x 28cm x 51cm) 27 Kg gross weight (over pack) 16"X 12"X 21" (41cm x 31cm x 53cm) 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	February 5, 2019	February 25 th , 2020	Updated to PDS 2020 Format, product number and footer
02	Emily Baird	February 25 th , 2020	April 16, 2020	Updated Prop 65 statement and added contaminates statement
03	Emily Moran	April 16, 2020	June 23, 2021	Updated compendia statement
04	Emily Moran	June 23, 2021	December 17 th , 2021	Updated spec table to include HM and format