

Provitas® E500SD

Product Description-

Provitas® E500SD is a non-GMO, uniform water-soluble powder that is white to light cream in color with a bland odor and taste. The active ingredient, dl- α tocopheryl acetate is homogenized with non-GMO modified food starch and then dried to a uniform powder. Silicon dioxide is added for flow at < 2%. E500SD is intended for the fortification of vitamin E in foods, beverages and powdered nutritional supplements. Provitas® E500SD is Kosher and Halal Certified.

Item Number: E109
CAS-Number: 7695-91-2

Country of Origin-

Manufactured in the USA with active ingredient of Western European origin.

Compendia Requirements-

Provitas® E500SD meets all requirements of the USP monograph *Vitamin E Preparation*. The dl-alpha tocopheryl acetate contained in this product as active ingredient, meets all the requirements of the USP, FCC and Ph. Eur. when tested according to these compendia.

Generally Recognized as Safe-

Provitas® E500SD is affirmed (GRAS) Generally Recognized As Safe by the US FDA as stated in the US FDA Code of Federal Regulations: 21CFR182.8892.

Harmonized Tariff Schedule Code- 2936.28.00

Solubility-

Provitas® E500SD is soluble in cold 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 cool and dry conditions. Protect from moisture, heat, light and oxygen.

GMP-

Provitas LLC confirms that Provitas® E500SD 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® E500SD is manufactured by physical and chemical means and is therefore not an organic product. Provitas® E500SD 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 subsequently *Nutritional Quality Guidelines for Foods* 21CFR104.20.

Provitas® E500SD 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® E500SD 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
Description:	Observation	Solid - powder
Color:	Observation	Off-white to light cream
Odor:	Observation	Bland
Identification: Identity (A) Optical Rotation (B) GC Peak Retention Time (C)	USP monograph USP monograph USP monograph	Red to orange No optical rotation 95.0% - 120.0%
Moisture:	USP<731>	≤ 5
Assay: dl- α tocopheryl acetate, IU/g mg/g	J. Chromatogr. A870 (2000) 207-15 & Dionex Tech Note 89	500 500
Microbial purity*: Aerobic Plate Count, cfu/g Coliforms, cfu/g Yeasts & molds, cfu/g E. coli, cfu/g Salmonella, cfu/g Staphylococcus aureus, cfu/g	USP <2021> USP <2021> USP <2021> USP <2022> USP <2022> USP <2022>	<1,000 <100 <100 Negative Negative Negative
Heavy Metals: Arsenic Cadmium Lead Mercury	AOAC 993.14 AOAC 993.14 AOAC 993.14 DMA	<1.0 ppm <0.3 ppm <1.0 ppm <0.1 ppm
Residual Solvents (RS)³	USP <467>	Complies

Provitas® E500SD

Nutritional Data (per 100 grams)-

Item	Result	Item	Result
Total Calories	172.5 Cal	Water	≤5.00 gram
Calories from Fat	00.63 Cal	Ash	≤2.00 gram
Calories from Saturated Fat	00.36 Cal	Vitamin A (IU) / (RE)	00.00
Kilojoules	00.722 Kilojoules	Vitamin E (α-tocopherol)	50,000 milligram / 50,000 IU
Protein	00.24 gram	Vitamin D	00.00
Fat	00.07 gram	Vitamin C	00.00
Saturated Fat	00.04 gram	Calcium	<12.00 milligram
Carbohydrate	42.72 gram	Iron	<00.24 milligram
Dietary Fiber	<0.48 gram	Sodium	00.245 milligram
Sugar - Total	00.24 gram	Potassium	<48.00 milligram
Added sugar	00.24 grams	Magnesium	00.00

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.

Sewage-

We certify that Provitas® E500SD has been produced, packaged and stored without the use of sewage sludge.

Residual Solvent Statement-

Provitas LLC certifies that Provitas® E500SD fully complies with Chemical test <467> USP/NF: Residual Solvents Limits.

Water is the only solvent used in the Provitas® E500SD manufacturing process.

WADA-

Provitas LLC certifies that Provitas® E500SD 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® E500SD is not considered a nanomaterial. Therefore, it does not require labeling as such.

Prop 65-

We certify that Provitas® E500SD and all materials used to manufacture E500SD 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® E500SD is free of radiation. Irradiation is not used in the production, packaging and/or storage of Provitas® E500SD.

We certify that Provitas® E500SD is free of ethylene oxide. Ethylene oxide sterilization is not used in the production, packaging and/or storage of E500SD.

We certify that Provitas® E500SD is free of BHA and BHT. BHA and BHT are not used in the production, packaging and/or storage of Provitas® E500SD.

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Packaging Details-

100gm Sample E1097100	25 Kg carton E1097153
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 9 cartons (225kg) Maximum 3 layers / pallet (675kg)

Revision History				
Revision	Modified by	Previous Date	Date of Change	Description of Change
01	Emily Baird	07/05/2019	April 3, 2020	Added revision table and updated Part number, updated to PDS 2020 Format, product number and footer