

## Provitas® E350MT/SD

**Product Description-**

Provitas® E350MT/SD is a uniform water-soluble powder that is light cream to tan or beige in color with a bland odor and taste. The active ingredient, high  $\alpha$ -mixed tocopherols are derived from natural sources, i.e., edible vegetable oils, and are produced by suitable physical and chemical means. The active ingredient, high  $\alpha$ -mixed tocopherols, is homogenized with modified food starch and dried to a uniform powder. Silicon dioxide is added for flow at < 2%. E350MT/SD is intended for use as a natural vitamin E, mixed tocopherols in dietary supplements and foods.

**Item Number:** E119

**CAS-Number:** 58-95-7

**Country of Origin-** Manufactured in the USA

**Compendia Requirements-**

Provitas® E350MT/SD meets all requirements of the USP monograph *Vitamin E Preparation*. The d-alpha tocopherol 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® E350MT/SD 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® E350MT/SD 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. Protect from heat, light and oxygen. Do not expose to alkalis or strong oxidizing agents.

**GMP-**

Provitas LLC confirms that Provitas® E350MT/SD 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® E350MT/SD is manufactured by physical and chemical means and is therefore not an organic product. Provitas® E350MT/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® E350MT/SD E700SD contains some ingredients in this product may have been derived from a genetically modified source material but are free from both genetically modified DNA and the proteins derived from genetically modified DNA. The active raw ingredient, d- $\alpha$  tocopherol used to manufacture Provitas® E350MT/SD is derived from genetically modified soybeans according to EU regulations. Due to the manufacturing process of the active raw ingredient, Provitas® E350MT/SD will test negative for any soy DNA proteins.

TEST	METHOD	SPECIFICATIONS
<b>Organoleptic Properties</b> Description: Color: Odor:	Observation	Solid - powder Cream to beige Bland
<b>Identification:</b> Identity (A) Optical Rotation (B) GC Peak Retention Time (C)	USP monograph	Red to orange color develops $\geq +24^\circ$ 95.0% - 120.0%
<b>Assay:</b> d- $\alpha$ tocopherol, IU/g mg/g Non- $\alpha$ tocopherols, mg/g	J. Chromatogr. A870 (2000) 207-15 & Dionex Tech Note 89	$\geq 350$ $\geq 235$ $\geq 59$
<b>Microbial purity:</b> 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
<b>Heavy Metals:</b> 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
Moisture: %	USP<731>	$\leq 5$
<b>Residual Solvents (RS)</b>	USP <467>	Complies <sup>1</sup>
<b>Benzo (a) pyrene:</b> ppb	Calculated	$\leq 1.0^2$
1. Specification is informational and not part of release testing but is determined by the use of USP grade vitamin E that meets USP (RS) specifications and water is only solvent used in the production of E350MT/SD Natural Powder 2. Specification is informational and not part of release testing but is based on specification and lot specific analysis provided for d- tocopherols used in the production of E350MT/SD Natural Powder		

## Provitas® E350MT/SD

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

Per 100 g			
Nutrients	Result	Nutrients	Result
Calories (kcal)	204.3	Cholesterol (mg)	0
Calories from Fat (kcal)	102.6	Water (g)	2.8
Calories from SatFat (kcal)	16.2	Ash (g)	2.2
Protein (g)	0	Vitamin A (mg)	0
Carbohydrates (g)	49.8	Cholecalciferol (mg)	0
Dietary Fiber (g)	0	D-alpha tocopherol (mg)	2693.8
Total Sugars (g)	24.2	Mixed Tocopherols (mg)	580
Added Sugars (g)	0	Calcium (mg)	20
Other Carbs (g)	0	Iron (mg)	0.105
Fat (g)	11.5	Potassium (mg)	40
Saturated Fat (g)	1.8	Sodium (mg)	30
Trans Fatty Acid (g)	0.2		

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 Provitas® E350MT/SD. This includes but not limited to heavy metals, PAHs, PHOs, dioxins, propylene, melamine, mycotoxins, and solvents. Provitas® E350MT/SD is in compliance with the EU Commission regulation (EU) 1881/2006.

**Residual Solvent Statement-**

Provitas LLC certifies that Provitas® E350MT/SD fully complies with Chemical test <467> USP/NF: Residual Solvents Limits and EU directive 2009/32/EC. Water is the only solvent used in the Provitas® E350MT/SD manufacturing process.

**WADA-**

Provitas LLC certifies that Provitas® E350MT/SD 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® E350MT/SD is not considered a nanomaterial. Therefore, it does not require labeling as such.

**Prop 65-**

We certify that Provitas® E350MT/SD and all materials used to manufacture Provitas® E350MT/SD 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/BHA/BHT-**

Provitas, LLC guarantees that no BSE/TSE causing ingredients are present in Provitas® E350MT/SD. Provitas® E350MT/SD is free of any animal origin organisms/ingredients. Provitas® E350MT/SD tests PCR negative for any animal-based organisms.

We certify that Provitas® E350MT/SD is free of radiation. Irradiation is not used in the production, packaging and/or storage of Provitas® E350MT/SD.

We certify that Provitas® E350MT/SD is free of ethylene oxide. Ethylene oxide sterilization is not used in the production, packaging and/or storage of Provitas® E350MT/SD.

We certify that Provitas® E350MT/SD is free of BHA and BHT. BHA and BHT are not used in the production, packaging and/or storage of Provitas® E350MT/SD.

**Vegetarian Statement-**

Provitas® E350MT/SD 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® E350MT/SD has been produced, packaged and stored without the use of sewage sludge.

## Provitas® E350MT/SD

**Packaging Details-**

<b>100gm Sample E1197100</b>	<b>25 Kg carton E1197153</b>
Aluminum pouch  100 gram net weight each / 100gm 4" x 6" (10cm x 15cm)	Fiber carton w/plastic liner 25kg net weight 26kg gross weight 12"x12"x20" (31cm x 31cm x 51cm) 27kg gross weight (over pack) 22"X14"X14" (56cm x 36cm x 36cm)  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 Moran	----	July 22, 2021	Updated spec to 2020 template