

## Provitas® E700SD

**Product Description-**

E700SD is a uniform water-soluble powder which is white to light cream in color with a bland odor and taste. The active ingredient, PCR-Negative d-α tocopheryl acetate is derived from natural sources, i.e. edible vegetable oils, and is produced by suitable physical and chemical means. The active ingredient is homogenized with a combination of modified food starch and maltodextrin and then dried to a uniform powder. Silicon dioxide is added for flow at < 2%.

**Item Number: E108**
**CAS-Number: 58-95-7**
**Country of Origin-** Manufactured in the USA

**Compendia Requirements-**

Provitas® E700SD meets all requirements of the USP monograph *Vitamin E Preparation*. The d-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® E700SD 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-**2939.28.0000

**Solubility-** Provitas® E700SD is soluble in 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® E700SD 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® E700SD is manufactured by physical and chemical means and is therefore not an organic product. Provitas® E700SD 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® 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-α tocopheryl acetate used to manufacture Provitas® E700SD is derived from genetically modified soybeans according to EU regulations. Due to the manufacturing process of the active raw ingredient, Provitas® E700SD will test negative for any soy DNA proteins

Provitas® E700SD 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.

TEST	METHOD	SPECIFICATIONS
<b>Organoleptic Properties</b> Description: Color: Odor:	Observation	Solid - powder White to off White Bland
Identification: Identity (A) Optical Rotation (B) GC Peak Retention Time (C)	USP monograph USP monograph USP monograph	Red to orange color develops ≥ +24° The retention time of the major peak of the sample solution corresponds to that of the standard solution.
<b>Moisture:</b> %	USP<731>	≤ 5
<b>Assay:</b> d-alpha tocopheryl acetate IU mg/g	J. Chromatogr. A870 (2000) 207-15 & Dionex Tech Note 89	≥ 700 IU/g 514.7 mg/g
<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 Cadmium Lead Mercury	AOAC 993.14 AOAC 993.14 AOAC 993.14 DMA	<1.5 ppm <0.3 ppm <1.0 ppm <0.2 ppm
<b>Residual Solvents (RS)</b>	USP <467>	Complies <sup>1</sup>
Benzo (a) pyrene:	Calculated	≤ 1 ppb <sup>2</sup>
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 E700SD Natural Powder 2. Specification is informational and not part of release testing but is based on lot specific analysis provided for d-alpha tocopheryl acetate used in the production of E700SD Natural Powder		

## Provitas® E700SD

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

Item	Result	Item	Result
Total Calories	176.67 Kcal	Sodium	< .046 gram
Calories from Fat	.45 Kcal	Calcium	< .0112 gram
Protein	< .225 gram	Other	52 grams
Carbohydrate	40.22 gram	Vitamin E	70,000 IU
Total Fiber	< .45 gram	Water	< 5 grams
Soluble fiber	< .45 gram	Ash	< 3 grams
Insoluble fiber	0.00 gram	Potassium	0 grams
Sugars	.225 gram		
Cholesterol	0 grams		
Total Fat	< .067 grams		
Saturated Fat	< .036 grams		
<p><b>Accuracy Disclaimer-</b>            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.</p> <p>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.</p>			

**Residual Solvent Statement-**

Provitas LLC certifies that Provitas® E700SD 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® E700SD manufacturing process.

**WADA-**

Provitas LLC certifies that Provitas® E700SD 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® E700SD is not considered a nanomaterial. Therefore, it does not require labeling as such.

**Prop 65-**

We certify that Provitas® E700SD and all materials used to manufacture Provitas® E700SD 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.

**Sewage-**

We certify that Provitas® E700SD has been produced, packaged and stored without the use of sewage sludge.

**BSE/TSE/Irradiation/EtO Statements-**

Provitas® E700SD is free of any animal origin organisms/ingredients. Product is PCR negative for any or animal-based organisms. Provitas, LLC guarantees that no BSE causing ingredients are present in Provitas® E700SD.

We certify that Provitas® E700SD is free of radiation. Irradiation is not used in the production, packaging and/or storage of Provitas® E700SD.

We certify that Provitas® E700SD is free of ethylene oxide. Ethylene oxide sterilization is not used in the production, packaging and/or storage of Provitas® E700SD.

We certify that Provitas® E700SD is free of BHA and BHT. BHA and BHT are not used in the production, packaging and/or storage of Provitas® E700SD.

**Contaminants and Impurities Statement-**

To our knowledge, there is no contamination by potentially harmful materials in Provitas® E700SD. This includes but not limited to heavy metals, PAHs, PHOs, dioxins, propylene, melamine, mycotoxins, and solvents. Provitas® E700SD is in compliance with the EU Commission regulation (EU) 1881/2006.

**Vegetarian Statement-**

Provitas® E700SD 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.

## Provitas® E700SD

**Packaging Details-**

<b>100gm Sample E1087100</b>	<b>25 Kg carton E1087153</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 Baird	April 29, 2019	August 17 <sup>th</sup> , 2020	Added revision table and updated Part number, updated to PDS 2020 Format, product number and footer
02	Emily Moran	August 17 <sup>th</sup> , 2020	October 11, 2021	Added BE statement