

Provitas® E700IP/SD

Product Description-

E700IP/SD is a uniform water-soluble powder which is white to light cream in color with a bland odor and taste. The active ingredient, non-GMO d-alpha 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 modified food starch and dried to a uniform powder. Silicon dioxide is added for flow at < 2%. E700IP/SD is intended for use as a natural-sourced vitamin E in foods, beverages and powdered nutritional supplements.

Item Number: E140

CAS-Number: 58-95-7

Country of Origin-

Manufactured in the USA

Compendia Requirements-

Provitas® E700IP/SD 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® E700IP/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® E700IP/SD is soluble in cold water

TEST	METHOD	SPECIFICATIONS
Organoleptic Properties Description: Color: Odor:	Observation	Solid - powder White to cream Bland
Identification: Identity (A) Optical Rotation (B) GC Peak Retention Time (C)	USP monograph USP monograph USP monograph	Red to orange color develops ≥ +24° 95.0% - 120.0%
Moisture:	% USP<731>	≤ 5
Assay: d-alpha tocopheryl acetate IU mg/g	J. Chromatogr. A870 (2000) 207-15 & Dionex Tech Note 89	≥ 700 IU/g 514.7 mg/g
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)	USP <467>	Complies

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® E700IP/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 3rd party certified.

Non-GMO and Organic compliant statement-

Provitas® E700IP/SD is manufactured by physical and chemical means and is therefore not an organic product. Provitas® E700IP/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® E700IP/SD 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.

Provitas® E700IP/SD 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.

Provitas® E700IP/SD

Nutritional Data (per 100 grams)-

Item	Result	Item	Result
Total Calories	137 Kcal	Water	< 5 grams
Calories from Fat	0 Kcal	Ash	< 3 grams
Protein	< .225 gram	Vitamin A (IU) / (RE)	0 grams
Fat	< .067 grams	Vitamin E	70,000 IU
Saturated Fat	< .036 grams	Vitamin D	0 grams
Carbohydrate	34 gram	Vitamin C	0 grams
Dietary Fiber	< .45 gram	Calcium	< .0112 gram
Sugar - Total	0.19 gram	Iron	0 grams
Added sugar	0 grams	Sodium	< .046 gram
Other	60 grams	Potassium	0 grams
		Magnesium	0 grams

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® E700IP/SD. This includes but not limited to heavy metals, PAHs, PHOs, dioxins, propylene, melamine, mycotoxins, and solvents. Provitas® E700IP/SD is in compliance with the EU Commission regulation (EU) 1881/2006.

Residual Solvent Statement-

Provitas LLC certifies that Provitas® E700IP/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® E700IP/SD manufacturing process.

WADA-

Provitas LLC certifies that Provitas® E700IP/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® E700IP/SD is not considered a nanomaterial. Therefore, it does not require labeling as such.

Vegetarian Statement-

Provitas® E700IP/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.

Prop 65-

We certify that Provitas® E700IP/SD and all materials used to manufacture Provitas® E700IP/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-

Provitas® E700IP/SD 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® E700IP/SD.

We certify that Provitas® E700IP/SD is free of radiation. Irradiation is not used in the production, packaging and/or storage of Provitas® E700IP/SD.

We certify that Provitas® E700IP/SD is free of ethylene oxide. Ethylene oxide sterilization is not used in the production, packaging and/or storage of Provitas® E700IP/SD.

We certify that Provitas® E700IP/SD is free of BHA and BHT. BHA and BHT are not used in the production, packaging and/or storage of Provitas® E700IP/SD.

Sewage-

We certify that Provitas® E700IP/SD has been produced, packaged and stored without the use of sewage sludge.

Provitas® E700IP/SD

Packaging Details-

100gm Sample E1407100	25 Kg carton E1407153
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	September 27 th 2019	April 3, 2020	Added revision table and updated Part number, updated to PDS 2020 Format, product number and footer
02	Emily Baird	April 3 rd , 2020	June 11, 2020	Added EU compliance statements
03	Emily Baird	June 11, 2020	June 15, 2020	Updated contaminates statement