

Provitas® E700NP

Product Description-

Provitas® E700NP is a uniform free-flowing, granular powder which is white to light cream in color with a bland odor and taste. The active ingredient, d-α tocopheryl acetate is derived from natural sources, i.e. soybean oil and traces of other edible vegetable oils and is produced by suitable physical and chemical means. The active ingredient, d-α tocopheryl acetate, is adsorbed onto a silicon dioxide carrier. E700NP is intended for use as natural vitamin E in dietary supplements and fortified foods. Provitas® E700NP is Kosher and Halal Certified.

Item Number: E103

CAS-Number: 58-95-7

Country of Origin-

Manufactured in the USA.

Compendia Requirements-

Provitas® E700NP meets all requirements of the USP monograph *Vitamin E Preparation*.

Generally Recognized as Safe-

E700NP 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® E700NP is not 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.

TEST	METHOD	SPECIFICATIONS
Description:	Observation	Solid - powder
Color:	Observation	White to off-white
Odor:	Observation	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: dl-α tocopheryl acetate, IU/g mg/g	J. Chromatogr. A870 (2000) 207-15 & Dionex Tech Note 89	≥ 700 IU/gm 515 mg/gm
Heavy Metals: Arsenic Cadmium Lead Mercury	AOAC 993.14 AOAC 993.14 AOAC 993.14 EPA 7473	<1.5 ppm <2.5 ppm <3.0 ppm <1.5 ppm
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
Residual Solvents (RS)³	USP <467>	Complies
Benzo (a) pyrene: ppb	calculated	≤ 1 ppb ²
<ol style="list-style-type: none"> 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 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 E700NP 		

GMP-

Provitas LLC confirms that Provitas® E700NP 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® E700NP is manufactured by physical and chemical means and is therefore not an organic product. Provitas® E700NP 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.

E700NP is PCR-negative.

The active raw ingredients used to manufacture E700NP are derived from GMO's according to EU regulations.

- d-α tocopheryl acetate

Vegetarian Statement-

Provitas® E700NP

Provitas® E700NP 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.

Nutritional Data (per 100 grams)-

Item	Result	Item	Result
Total Calories	0 Kcal	Water	< 3 grams
Calories from Fat	0 Kcal	Ash	< 41 grams
Calories from Saturated Fat	0 Kcal	Vitamin A (IU) / (RE)	00.00 gram
Protein	0 gram	Vitamin E (α-tocopherol)	70,000 IU
Fat	56 grams	Vitamin D	00.00 gram
Saturated Fat	56 grams	Vitamin C	00.00 gram
Carbohydrate	42.72 gram	Calcium	.004 gram
Dietary Fiber	0 gram	Iron	00.00 gram
Sugar - Total	0 gram	Sodium	.75 gram
Added sugar	0 gram	Potassium	00.00 gram
		Magnesium	00.00 gram
<small>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.</small>			

Sewage-

We certify that Provitas® E700NP has been produced, packaged and stored without the use of sewage sludge.

Residual Solvent Statement-

Provitas LLC certifies that Provitas® E700NP fully complies with Chemical test <467> USP/NF: Residual Solvents Limits. Water is the only solvent used in the Provitas® E700NP manufacturing process.

WADA-

Provitas LLC certifies that Provitas® E700NP 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® E700NP is not considered a nanomaterial. Therefore, it does not require labeling as such.

Prop 65-

We certify that Provitas® E700NP and all materials used to manufacture E700NP 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/BHA Statements-

We certify that Provitas® E700NP is free of radiation. Irradiation is not used in the production, packaging and/or storage of Provitas® E700NP.

We certify that Provitas® E700NP is free of ethylene oxide. Ethylene oxide sterilization is not used in the production, packaging and/or storage of E700NP.

We certify that Provitas® E700NP is free of BHA and BHT. BHA and BHT are not used in the production, packaging and/or storage of Provitas® E700NP.

Provitas, LLC guarantees that any BSE/TSE causing ingredients or animal originated ingredients are not present in Provitas® E700NP.

Provitas® E700NP

Packaging Details-

100gm Sample E1031300	25 Kg carton E1031353
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) 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	July 15, 2019	March 18 th , 2020	Added revision table and updated Part number, Updated to PDS 2020 Format, product number and footer
02	Emily Baird	March 18 th , 2020	June 5, 2020	Added BSE statement