

## Provitas® E700IP

**Product Description-**

Provitas® E700IP 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-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 conventional gum acacia and dried to a uniform powder. Silicon dioxide is added for flow at < 2%. E700IP is intended for use as a natural-sourced vitamin E in foods, beverages and powdered nutritional supplements.

**Item Number:** E132

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

**Country of Origin-**

Manufactured in the USA

**Compendia Requirements-**

Provitas® E700IP 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 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 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® E700IP 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® E700IP is manufactured by physical and chemical means and is therefore not an organic product. Provitas® E700IP 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 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® E700IP 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   |
|---|--|--|
| <b>Organoleptic Properties</b><br>Description:<br>Color:<br>Odor:   | Observation  | Solid - powder<br>White to cream<br>Bland                    |
| <b>Identification:</b><br><br>Identity (A)<br><br>Optical Rotation (B)<br>GC Peak Retention Time (C)  | USP monograph<br><br>USP monograph<br>USP monograph                              | Red to orange color develops<br>≥ +24°<br>Meets requirements |
| <b>Moisture:</b><br><br>%   | USP<731>   | ≤ 5  |
| <b>Assay:</b><br>d-alpha tocopheryl acetate<br>IU<br>mg/g   | J. Chromatogr.<br>A870<br>(2000) 207-15 &<br>Dionex Tech Note<br>89              | ≥ 700<br>≥ 515   |
| <b>Microbial purity:</b><br>Aerobic Plate Count, cfu/g<br>Coliforms, cfu/g<br>Yeasts & molds, cfu/g<br>E. coli, cfu/g<br>Salmonella, cfu/g<br>Staphylococcus aureus, cfu/g  | USP <2021><br>USP <2021><br>USP <2021><br>USP <2022><br>USP <2022><br>USP <2022> | <1,000<br><100<br><100<br>Negative<br>Negative<br>Negative   |
| <b>Heavy Metals:</b><br>Arsenic, ppm<br>Cadmium, ppm<br>Lead, ppm<br>Mercury, ppm   | AOAC 993.14<br>AOAC 993.14<br>AOAC 993.14<br>DMA                                 | <1.5<br><0.3 ppm<br><1.0 ppm<br><0.1 ppm                     |
| <b>Residual Solvents (RS)</b>   | USP <467>  | Complies <sup>1</sup>  |
| <b>Benzo (a) pyrene:</b><br><br>ppb   |  | ≤ 1.0 <sup>2</sup>   |
| 1. Specification is informational and not part of release testing but is determined using USP grade vitamin E that meets USP (RS) specifications and water is only solvent used in the production of E700IP<br>2. Specification is informational and not part of release testing but is based on lot specific analysis provided for d-α tocopheryl acetate used in the production of E700IP |  |  |

## Provitas® E700IP

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

| Item              | Result  | Item                  | Result    |
|-------------------|---------|-----------------------|-----------|
| Total Calories    | 93 kcal | Water                 | <5 g      |
| Calories from Fat | 0       | Ash                   | 3 g       |
| Protein           | 1 g     | Vitamin A (IU) / (RE) | 0         |
| Fat               | 0       | Vitamin E             | 96,000 mg |
| Saturated Fat     |         | Vitamin D             | 0         |
| Carbohydrate      | 43 g    | Vitamin C             | 0         |
| Dietary Fiber     | 0       | Calcium               | 418 mg    |
| Sugar - Total     | 0       | Iron                  | 0         |
| Added sugar       | 0       | Sodium                | 46 mg     |
| Other             |         | Potassium             | 140 mg    |
|                   |         | Magnesium             | 93 mg     |

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

**Residual Solvent Statement-**

Provitas LLC certifies that Provitas® E700IP 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 manufacturing process.

**WADA-**

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

**Prop 65-**

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

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

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

**Sewage-**

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

## Provitas® E700IP

**Packaging Details-**

| <b>100gm Sample<br/>E1327100</b>  | <b>25 Kg carton<br/>E1327153</b>  |
|---|---|
| Aluminum pouch<br><br><p style="text-align: center;">100 gram net weight<br/>each / 100gm<br/>4" x 6" (10cm x 15cm)</p> | Fiber carton w/plastic liner<br><p style="text-align: center;">25kg net weight<br/>26kg gross weight<br/>12"x12"x20" (31cm x 31cm x 51cm)<br/>27kg gross weight (over pack)<br/>22"x14"x14" (56cm x 36cm x 36cm)</p> <p>Quantity per 40" x 48" pallet:<br/>                     1 layer of 9 cartons (225kg)<br/>                     Maximum 3 layers / pallet (675kg)</p> |

| Revision History |             |                             |                             |   |
|------------------|-------------|-----------------------------|-----------------------------|---|
| Revision         | Modified by | Previous Date               | Date of Change              | Description of Change   |
| 01               | Emily Baird | November 30, 2018           | July 1 <sup>st</sup> . 2020 | Added revision table and updated Part number, updated to PDS 2020 Format, product number and footer |
| 01               | Emily Baird | July 1 <sup>st</sup> . 2020 | October 11, 2021            | Added hydroquinone to contaminants statement  |