

Provitas® EF1300

Product Description-

Provitas® EF1300 is a viscous, oily liquid that is clear yellowish to reddish brown in color and standardized in soybean oil. The active ingredient, d-α tocopherol is derived from natural sources, i.e. edible vegetable oils, and is produced by suitable physical and chemical means. Provitas® EF1300 is designed for use in oil dispersions, encapsulated products, fortified food and personal care products.

Item Number: E137

CAS-Number: 59-02-9

Country of Origin- Manufactured in the USA.

Harmonized Tariff Schedule Code- 2936.28.00

Compendia Requirements-

Provitas® EF1300 meets all requirements of the USP monograph *Vitamin E*. 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.

Solubility- Provitas® EF1300 is insoluble in water. It is soluble in ethanol, acetone, chloroform, ether, lipophilic solvents, oils & fats.

Generally Recognized as Safe-

Provitas® EF1300 is affirmed (GRAS) Generally Recognized as Safe by the US FDA as stated in the US FDA Code of Federal Regulations: 21CFR182.8890

Stability and Storage-

The shelf life in sealed, original containers under normal storage conditions is 36 months after the date of manufacture. Stable to acid, unstable to alkali and oxidizing agents. Avoid prolonged exposure to light and oxygen. Store in tightly closed containers in cool and dry conditions. Protect from heat, light, and oxygen. Avoid freezing temperatures.

GMP-

Provitas LLC confirms that Provitas® EF1300 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® EF1300 is manufactured by physical and chemical means and is therefore not an organic product. Provitas® EF1300 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® EF1300 contains ingredients that 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.

Vegetarian Statement-

Provitas® EF1300 is produced using raw materials derived from plant sources. This product is vegetarian and vegan since no animal source product is used in manufacturing.

TEST	METHOD	SPECIFICATIONS
Organoleptic: Description: Color: Odor:	Observation	Clear viscous oil Yellowish to Amber Typical faint
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%
Assay: d-α tocopherol, IU/g mg/g	AOAC 969.40	≥ 1,300 ≥ 872
Acid Value: mL/g	AOCS Cd 3d-63	< 2.0
Heavy Metals: Arsenic Cadmium Lead Mercury	AOAC 993.14 AOAC 993.14 AOAC 993.14 DMA	<1.5 ppm <0.3 ppm <2.0 ppm <0.2 ppm
Microbial purity: Aerobic Plate Count, cfu/gm in 50g Coliforms, cfu/g Yeast & Mold, cfu/g E. Coli, cfu/g Staphylococcus aureus, cfu/g Salmonella, in 10g	USP<2021> USP<2021> USP<2021> USP<2022> USP<2022> USP<2022>	≤1,000 <100 <100 Negative Negative Negative
Residual Solvents (RS):	USP <467>	Meets USP Requirements ¹
Benzo (a) pyrene:	Calculated	≤ 2 ppb 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 no additional solvents used in the production of Provitas® EF1300. 2. Specification is informational and not part of release testing but is based on lot specific analysis provided for d-alpha tocopherol used in the production of Provitas® EF1300		

Provitas® EF1300
Nutritional Data (per 100 grams)-

Item	Result	Item	Result
Calories (kcal)	113.152	Water (g)	0
Calories from Fat (kcal)	115.2	Ash (g)	0
Calories from SatFat (kcal)	16.128	Vitamin A	0
Protein (g)	0	Vitamin C (mg)	0
Carbohydrates (g)	0	Vitamin D	0
Dietary Fiber (g)	0	D-alpha tocopherol (mg)	87200
Total Sugars (g)	0	D-alpha tocopherol (IU)	129928
Added Sugars (g)	0	Calcium (mg)	0
Fat (g)	12.8	Iron (mg)	0
Saturated Fat (g)	1.792	Magnesium (mg)	0
Monounsaturated Fat (g)	3.328	Manganese (mg)	0
Polyunsaturated Fats (g)	7.616	Potassium (mg)	0
Trans Fatty Acid (g)	0.064	Sodium (mg)	0
Cholesterol (mg)	0		

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.

Residual Solvent Statement-

Provitas LLC certifies that Provitas® EF1300 fully complies with Chemical test <467> USP/NF: Residual Solvents Limits.

WADA-

Provitas LLC certifies that Provitas® EF1300 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® EF1300 is not considered a nanomaterial. Therefore, it does not require labeling as such.

Contaminants and Impurities Statement-

To our knowledge, there is no contamination by potentially harmful materials in Provitas® EF1300. This includes but not limited to heavy metals, pesticides, PAHs, PHO's, Propylene, dioxins, melamine, aflatoxins, mycotoxins, phthalates and solvents.

Sewage-

We certify that Provitas® EF1300 has been produced, packaged, and stored without the use of sewage sludge

Prop 65-

We certify that Provitas® EF1300 and all materials used to manufacture ESF450SD 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. Provitas® EF1300 does not contain Carcinogen, Mutagen, or toxic for the Reproduction substances according to the 1272/2008 (EC) Regulation, directive 67/548/EWG.

BSE/TSE/Irradiation/EtO Statements-

We certify that Provitas® EF1300 is free of radiation. Irradiation is not used in the production, packaging and/or storage of Provitas® EF1300.

We certify that Provitas® EF1300 is free of ethylene oxide. Ethylene oxide sterilization is not used in the production, packaging and/or storage of Provitas® EF1300.

We certify that Provitas® EF1300 is free of BHA and BHT. BHA and BHT are not used in the production, packaging and/or storage of Provitas® EF1300.

Provitas® EF1300
Packaging Details-

50gm Sample E1371300	10kg carton E1371355	190kg carton E1371323
Plastic bottle 50ml 50 gram net weight 1.77" x 2.68" (45mm x 68mm)	Fiber carton containing 2 x 5kg plastic bottles 10kg net weight 12kg gross weight 12"x8"x12" (31cm x 20cm x 31cm) Quantity per 40" x 48" pallet: 1 layer of 15 cartons (150kg) Maximum 4 layers / pallet (600kg)	Metal open-head drum 190kg net weight 212kg gross weight 24"x24"x34.5" (61cm x 61cm x 88cm) Quantity per 40" x 48" pallet 1 layer of 4 drums Maximum 1 layer / pallet

Revision History			
Revision	Modified by	Date of Change	Description of Change
1	Mac Weber	June 28, 2013	Created
2	Emily Moran	February 10 th , 2022	Updated PDS format