

Provitas® EA1360

Product Description-

Provitas®EA1360 is a viscous, oily liquid that is clear to yellow in color. The active ingredient, d-α tocopheryl acetate is derived from natural sources, i.e. edible vegetable oils, and is produced by suitable physical and chemical means. Provitas® EA1360 is intended for use as a natural vitamin E for the fortification of dietary supplements, foods and personal care products.

Item Number: E151

CAS-Number: 58-95-7

Country of Origin- Packaged in the USA

Compendia Requirements-

Provitas® EA1360 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® EA1360 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® EA1360 is miscible in fats and oils

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. The esterified form of vitamin E is stable to light and oxygen however, exposure should be limited. 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® EA1360 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® EA1360 is manufactured by physical and chemical means and is therefore not an organic product. Provitas® EA1360 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® EA1360 natural vitamin E oil (d-α tocopheryl acetate) tests PCR negative for genetically modified organisms due to the manufacturing processes for natural vitamin E. The raw material used in the manufacturing of d-α tocopheryl acetate oil is Deodorizer Distillate, a by-product from the refining of soybean oil. Deodorizer Distillate used to manufacture Provitas® EA1360 does come from soybean oil refined from genetically modified soybeans.

Vegetarian Statement-

Provitas® EA1360 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 Properties Description: Color: Odor:	Observation	Clear viscous oil Yellow 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° 96.0% - 102.0%
Assay: d-alpha tocopheryl acetate IU mg/g	J. Chromatogr. A870 (2000) 207-15 & Dionex Tech Note 89	≥ 1,305 ≥ 960
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, ppm Cadmium, ppm Lead, ppm Mercury, ppm	AOAC 993.14 AOAC 993.14 AOAC 993.14 DMA	<1.5 <0.3 <1.0 <0.2
Acid Value: mL/g	AOCS CD 3D-63	< 2.0
Residual Solvents (RS)	USP <467>	Complies ¹
Benzo (a) pyrene: ppb	Calculated	≤ 1.0 ²
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 EA1360 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 EA1360		

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Nutritional Data (per 100 grams)-

Item	Result	Item	Result
Total Calories	0 Kcal	Water	0.5 grams
Calories from Fat	0 Kcal	Ash	0 grams
Protein	0 grams	Vitamin A (IU) / (RE)	0 gram
Fat	0 grams	Vitamin E IU/mg	≥130,500 / 96,000
Saturated Fat	0 gram	Vitamin D	0 grams
Carbohydrate	0 grams	Vitamin C	0 grams
Dietary Fiber	0 grams	Calcium	0 gram
Sugar - Total	0 grams	Iron	0 grams
Added sugar	0 gram	Sodium	0 grams
Other	0 grams	Potassium	0 gram
		Magnesium	0 grams
<p>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.</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>			

Contaminants and Impurities Statement-

To our knowledge, there is no contamination by potentially harmful materials in Provitas® EA1360. This includes but not limited to heavy metals, PAHs, phthalate, PHOs, dioxins, propylene, melamine, mycotoxins, and solvents. Provitas® EA1360 is in compliance with the EU Commission regulation (EU) 1881/2006.

WADA-

Provitas LLC certifies that Provitas® EA1360 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® EA1360 is not considered a nanomaterial. Therefore, it does not require labeling as such.

Prop 65-

We certify that Provitas® EA1360 and all materials used to manufacture Provitas® EA1360 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.

Residual Solvent Statement-

Provitas LLC certifies that Provitas® EA1360 fully complies with Chemical test <467> USP/NF: Residual Solvents Limits and EU directive 2009/32/EC.

BSE/TSE/Irradiation/EtO Statements-

Provitas® EA1360 is free of any animal origin organisms/ingredients. Product is PCR negative for any or animal-based organisms. Provitas, LLC guarantees that no BSE/TSE causing ingredients are present in Provitas® EA1360.

We certify that Provitas® EA1360 is free of radiation. Irradiation is not used in the production, packaging and/or storage of Provitas® EA1360.

We certify that Provitas® EA1360 is free of ethylene oxide. Ethylene oxide sterilization is not used in the production, packaging and/or storage of Provitas® EA1360.

We certify that Provitas® EA1360 is free of BHA and BHT. BHA and BHT are not used in the production, packaging and/or storage of Provitas® EA1360.

Sewage-

We certify that Provitas® EA1360 has been produced, packaged and stored without the use of sewage sludge.

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Packaging Details-

100gm Sample E1511300	10kg carton E1511353	190kg carton E1511323
Aluminum bottle, 50mL 50 gram net weight 1.77" x 2.68" (45mm x 68mm)	Fiber carton w/plastic liner 10kg net weight 11kg 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 211kg gross weight 24"x24"x34.5" (61cm x 61cm x 88cm) Quantity per 40" x 48" pallet: 1 layer of 4 drums (760kg) Maximum 1 layer / pallet (760kg)

Revision History				
Revision	Modified by	Previous Date	Date of Change	Description of Change
01	Emily Moran	February 6 th , 2020	September 23, 2020	Added revision table, updated to PDS 2020 Format