

Provitas® Vitamin E Acetate Oil USP

Product Description-

Vitamin E Acetate Oil USP is designed for use in oil dispersions, encapsulated products, food fortification and personal care products. Chemical Names:

- dl-alpha tocopheryl acetate
- dl-alpha tocopherol acetate
- all-rac-alpha-tocopherol acetic acid ester

Item Number: E111

CAS-Number: 7695-91-2

Country of Origin-

Packaged in the USA with active ingredient of Western European origin.

Compendia Requirements-

Provitas® Vitamin E Acetate meets all requirements of the USP monograph *Vitamin E Preparation*. The dl-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® Vitamin E Acetate 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® Vitamin E Acetate is soluble in Fats and oils.

Stability and Storage-

The shelf life in sealed, original containers and stored at under 25°C is 36 months after the date of manufacture. Store in tightly closed containers in cool and dry conditions. Protect from heat, light and oxygen. Avoid freezing temperatures. Avoid strong oxidizing agents or alkalis.

GMP-

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

Provitas® Vitamin E Acetate 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® Vitamin E Acetate 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
Organoleptic: Description: Color: Odor:	Observation	Clear viscous oil Pale yellow to yellow Typical faint
Assay: dl-alpha tocopheryl acetate, mg/g IU/g %	AOAC 969.40	≥ 960 ≥ 960 ≥ 96
Acid Value: mL/g	AOCS Cd 3b-63	< 1.0
Peroxide Value: meq/g	AOCS Cd 88-90	< 5
Microbial purity¹: Aerobic Plate Count, cfu/g Coliforms, cfu/g Yeasts & molds, cfu/g E. Coli, cfu/g P. aeruginosa, cfu/g S. aureus, cfu/g Salmonella, cfu/g	USP<61> USP<61> USP<61> USP<62> USP<62> USP<62> USP<62>	<1,000 <100 <100 Absent Absent Absent Absent
Heavy Metals: Arsenic, ppm Cadmium, ppm Lead, ppm Mercury, ppm	AOAC 993.14 AOAC 993.14 AOAC 993.14 DMA	<1.0 <1.0 <2.0 <0.1
Residual Solvents (RS)²	USP <467>	Complies
1. Indicates an estimate due to low plate counts 2. Specification is informational and not part of release testing but is determined by the use of USP grade d-α tocopheryl acetate that meets USP (RS) specifications.		

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Nutritional Data (per 100 grams)-

Item	Result	Item	Result
Total Calories	0 kcal	Water	0 g
Calories from Fat	0 kcal	Ash	0 g
Calories from Saturated Fat	0 kcal	Vitamin A (IU) / (RE)	0 g
Kilojoules	0 g	Vitamin E (α-tocopherol)	96,000 mg
Protein	0 g	Vitamin D	0 g
Fat	0 g	Vitamin C	0 g
Saturated Fat	0 g	Calcium	0 g
Carbohydrate	0 g	Iron	0 g
Dietary Fiber	0 g	Sodium	0 g
Sugar - Total	0 g	Potassium	0 g
Added sugar	0 g	Magnesium	0 g
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.			

Sewage-

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

Residual Solvent Statement-

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

WADA-

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

Prop 65-

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

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

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

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Packaging Details-

100gm Sample E1111300	10 Kg carton E1111355	190kg carton E1111323
Aluminum pouch 100 gram net weight each / 100gm 4" x 6" (10cm x 15cm)	Fiber carton containing 2 x 5kg plastic bottles 10kg net weight 11kg gross weight 11.5" x 7.5" x 12" (29cm x 19cm x 31cm) Quantity per pallet: 1 layer of 15 cartons Maximum 4 layers / pallet	Metal open-head drum 190kg net weight 211kg gross weight 24"x24"x34.5" (61cm x 61cm x 88cm) Quantity per pallet: 1 layer of 4 drums Maximum 1 layer / pallet

Revision History				
Revision	Modified by	Previous Date	Date of Change	Description of Change
01	Emily Baird	No date listed	February 6 th , 2020	Updated Test/Method/Standard table to reflect USP requirements and methods of testing, added product number, and revision table, added packaging table
02	Emily Moran	February 6 th , 2020	July 28 th , 2020	Updated to 2020 PDS template