

Provitas® EF96

Product Description-

Provitas® EF96 is a viscous, oily liquid that is clear to yellow in color. The active ingredient, dl- α tocopherol is produced by suitable physical and chemical means. Provitas® EF96 is designed for use in oil dispersions, encapsulated products, fortified food, and personal care products.

Item Number: E112

CAS-Number: 10191-41-0

Country of Origin- Packaged in the USA.

Compendia Requirements-

Provitas® EF96 meets all requirements of the USP monograph *Vitamin E*. The dl- α -Tocopherol (all-rac- α -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.

Harmonized Tariff Schedule Code-

Solubility- Provitas® EF96 is soluble in fats and oils

Generally Recognized as Safe-

Provitas® EF96 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 24 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® EF96 is packaged 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® EF96 is manufactured by physical and chemical means and is therefore not an organic product. Provitas® EF96 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® EF96 contains 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® EF96 is produced using raw materials derived from synthetic 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 Pale to yellow Characteristic
Identification: Identity Optical Rotation GC Peak Retention Time (C)	USP monograph/NF	Must Comply Must Comply Must Comply
Assay: dl-alpha-Tocopherol , IU/g mg/g	AOAC 969.40	1,056 960
Microbial purity: APC, cfu/g Coliforms, cfu/g Yeast & mold, cfu/g E. Coli, cfu/g Staphylococcus aureus, cfu/g Salmonella spp., 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 ≤2.5 ≤1.0 ≤1.5
Residual Solvents (RS)	USP <467>	Complies ¹
Acid Value mg KOH/g	AOCS Cd 3d-63	<2.0
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® EF96		

Provitas® EF96
Nutritional Data (per 100 grams)-

Item	Result	Item	Result
Total Calories	0 Kcal	Vitamin A (IU) / (RE)	0 grams
Protein	0 grams	Vitamin E (all- <i>rac</i> - α -tocopherol I)	50,000 IU ¹
Fat	0 grams	Vitamin D	0 grams
Saturated Fat	0 grams	Vitamin C	0 grams
Carbohydrate	0 grams	Calcium	0 grams
Dietary Fiber	0 grams	Iron	0 grams
Sugar - Total	0 grams	Sodium	0 grams
Added sugar	0 grams	Potassium	0 grams
Cholesterol	0 grams	Magnesium	0 grams
Water	0 grams	Other	
Ash	0 grams		
1. 1 mg vitamin E (label claim) = 1mg RRR- α -tocopherol = 2 mg all- <i>rac</i> - α -tocopherol as according to 21 CFR 101.9 (101.9(c)(8)(iv))			
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® EF96 has been produced, packaged and stored without the use of sewage sludge.

Residual Solvent Statement-

Provitas LLC certifies that Provitas® EF96 fully complies with Chemical test <467> USP/NF: Residual Solvents Limits. Water is the only solvent used in the Provitas® EF96 manufacturing process.

WADA-

Provitas LLC certifies that Provitas® EF96 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.

Prop 65-

We certify that Provitas® EF96 and all materials used to manufacture Provitas® EF96 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® EF96 does not contain Carcinogen, Mutagen, or toxic for the Reproduction substances according to the 1272/2008 (EC) Regulation, directive 67/548/EWG.

Nanomaterial Statement-

Based on our current understanding of nanomaterial regulation EU No 1169/2011, Provitas® EF96 is not considered a nanomaterial. Therefore, it does not require labeling as such.

BSE/TSE/Irradiation/EtO Statements-

We certify that Provitas® EF96 is free of BHA and BHT. BHA and BHT are not used in the production, packaging and/or storage of Provitas® EF96.

We certify that Provitas® EF96 is free of radiation. Irradiation is not used in the production, packaging and/or storage of Provitas® EF96.

We certify that Provitas® EF96 is free of ethylene oxide. Ethylene oxide sterilization is not used in the production, packaging and/or storage of Provitas® EF96.

Contaminants and Impurities Statement-

To our knowledge, there is no contamination by potentially harmful materials in Provitas® EF96. This includes but not limited to heavy metals, pesticides, PAHs, PHO's, Propylene, dioxins, melamine, aflatoxins, mycotoxins, phthalates and solvents.

Provitas® EF96
Packaging Details-

50gm Sample E0961300	10kg carton E0961355	190kg carton E0961323
Aluminum bottle, 50ml 50 gram net weight 1.77" x 2.68" (45mm x 68mm)	Fiber carton containing 2 x 5kg aluminum bottles 10kg net weight 11kg gross weight 7"x14"x7" (18cm x 36cm x 18cm) Quantity Per Pallet: 1 layer of 15 cartons (150kg) Maximum 4 layers / pallet (600kg)	Metal open-head drum 190kg net weight 210kg gross weight 24"x24"x34.5" (61cm x 61cm x 88cm) Quantity Per Pallet: 1 layer of 4 drums (760kg) Maximum 1 layer / pallet

Revision History			
Revision	Modified by	Date of Change	Description of Change
1	Emily Moran	February 10 th , 2022	PDS created
2	Mac Weber	May 31, 2022	Revise Item Number