

Provitas® EG70

Product Description-

Provitas® EG70 oil is a PCR-negative natural high-gamma mixed tocopherol oil standardized in a suitable edible grade vegetable oil. The active ingredient, mixed tocopherols is derived from natural sources, i.e. edible vegetable oil distillate, and is produced by suitable physical and chemical means. Provitas® EG70 oil is intended for use as a source of natural gamma-rich mixed tocopherols in fortified foods and nutritional supplements. Provitas® EG70 oil is designed for use in oil dispersions, encapsulated products, and fortified foods. Provitas® EG70 is certified kosher.

Item Number: T154

CAS-Number:

α – 59-02-9
 β – 16698-35-4
 γ – 54-28-4
 δ – 119-13-1

Country of Origin- Manufactured in the USA

Compendia Requirements-

EG70 oil meets all requirements of the FCC monograph *RRR-Tocopherols Concentrate, Mixed, Low-alpha type*

Generally Recognized as Safe-

Provitas® EG70 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® EG70 is soluble in Fats and oils.

Stability and Storage-

The shelf life in sealed, original containers under normal storage conditions is 12 months after the date of manufacture. Store in tightly closed containers blanketed by inert gas, in cool and dry conditions. Protect from heat, light and oxygen. Avoid freezing temperatures.

GMP-

Provitas LLC confirms that Provitas® EG70 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® EG70 is manufactured by physical and chemical means and is therefore not an organic product. Provitas® EG70 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® EG70 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® EG70 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	METHODS	SPECIFICATIONS
Description:	Observation	Clear viscous oil
Color:	Observation	Amber
Odor:	Observation	Typical, faint
Assay: Total tocopherols, mg/g d- γ tocopherol, mg/g d- α tocopherol, mg/g d- β tocopherol, mg/g d- δ tocopherol, mg/g	J Chromatogr A. 2012 Jun 22; 1243:39-46	≥ 900 ≥ 700 As reported As reported As reported
Heavy Metals: Arsenic, mg/kg Cadmium, mg/kg Lead, mg/kg Mercury, mg/kg	AOAC 993.14 AOAC 993.14 AOAC 993.14 DMA	<1.0 <0.3 <2.0 <0.2
Microbial purity: APC, cfu/gm in 50gm Coliforms, cfu/gm Yeast & Mold, cfu/gm E. Coli, cfu/gm Staphylococcus aureus Salmonella, in 10gm	USP <2021> USP<2021> USP <2021> USP <2022> USP <2022> USP <2022>	≤1,000 <100 <100 Negative Negative Negative

Provitas® EG70

Nutritional Data (per 100 grams)-

Item	Result	Item	Result
Total Calories	0	Vitamin A (IU) / (RE)	0
Calories from Fat	0	Vitamin E (α-tocopherol)	<20 grams
Calories from Saturated Fat	0	Vitamin D	0
Protein	0	Vitamin C	0
Fat	0	Calcium	0
Saturated Fat	0	Iron	0
Polyunsaturated Fatty Acids	0	Sodium	0
Monounsaturated Fatty Acids	0	Potassium	0
Carbohydrate	0	Magnesium	0
Dietary Fiber	0	Potassium	0
Sugar - Total	0	Water	0
Added sugar	0	Ash	0
		Other (β,γ,δ tocopherols)	> 80 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>			

BSE/TSE/Irradiation/EtO Statements-

We certify that Provitas® EG70 is free of radiation. Irradiation is not used in the production, packaging and/or storage of Provitas® EG70.

We certify that Provitas® EG70 is free of ethylene oxide. Ethylene oxide sterilization is not used in the production, packaging and/or storage of Provitas® EG70.

We certify that Provitas® EG70 is free of BHA and BHT. BHA and BHT are not used in the production, packaging and/or storage of Provitas® EG70.

Residual Solvent Statement-

Provitas LLC certifies that Provitas® EG70 fully complies with Chemical test <467> USP/NF: Residual Solvents Limits. Water is the only solvent used in the Provitas® EG70 manufacturing process.

WADA-

Provitas LLC certifies that Provitas® EG70 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® EG70 is not considered a nanomaterial. Therefore, it does not require labeling as such.

Sewage-

We certify that Provitas® EG70 has been produced, packaged, and stored without the use of sewage sludge.

Prop 65-

We certify that Provitas® EG70 and all materials used to manufacture Provitas® EG70 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.

Contaminants and Impurities Statement-

To our knowledge, there is no contamination by potentially harmful materials in Provitas® EG70. This includes but not limited to heavy metals, PAHs, dioxins, propylene, pesticides, melamine, mycotoxins, and solvents.

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Packaging Details-

50g Sample T1541300	10kg carton T1541355	190kg carton T1541323
Aluminum 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 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 Baird	07/05/2019	5/5/2020	Added revision table and updated Part number, updated to PDS 2020 Format, product number and footer