

## Provitas® EG360SD

**Product Description-**

Provitas® EG360SD is a uniform water-soluble powder that is tan to dark tan or orange in color with a bland odor and taste. The active ingredient, high- $\gamma$  (gamma) mixed tocopherols are derived from natural sources, i.e. edible vegetable oils, and are produced by suitable physical and chemical means. The active ingredient, high- $\gamma$  mixed tocopherols, is homogenized with modified food starch and dried to a uniform powder. Silicon dioxide is added for flow at < 2%. EG360SD is intended for use in foods and nutritional supplements.

**Item Number: T158**
**CAS-Number:**

$\alpha$  – 59-02-9  
 $\beta$  – 16698-35-4  
 $\gamma$  – 54-28-4  
 $\delta$  – 119-13-1

**Country of Origin-** Manufactured in the USA

**Compendia Requirements-**

Provitas® EG360SD meets all requirements of the FCC monograph *RRR-Tocopherols Concentrate, Mixed, Low-alpha type*

**Generally Recognized as Safe-**

Provitas® EG360SD 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-** EG360SD is dispersible in water

**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 in cool and dry conditions. Protect from heat, light and oxygen. Do not expose to alkalis or strong oxidizing agents.

**GMP-**

Provitas LLC confirms that Provitas® EG360SD 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 3<sup>rd</sup> party certified.

**Non-GMO and Organic compliant statement-**

Provitas® EG360SD is manufactured by physical and chemical means and is therefore not an organic product. Provitas® EG360SD 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® EG360SD contains some 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. The active raw ingredient, d- $\gamma$  tocopherol used to manufacture Provitas® EG360SD is derived from genetically modified soybeans according to EU regulations. Due to the manufacturing process of the active raw ingredient, Provitas® EG360SD will test negative for any soy DNA proteins

**Vegetarian Statement-**

Provitas® EG360SD 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
<b>Organoleptic Properties</b> <b>Description:</b> <b>Color:</b> <b>Odor:</b>	Observation	Solid - powder Tan to Orange Bland
<b>Identification:</b> Identity: color development, A GC Peak retention time, B Optical Rotation	USP monograph USP monograph USP monograph	Red to orange Assay >+20°
<b>Moisture:</b> %	USP<731>	≤ 5
<b>Assay:</b> Total mixed-tocopherols, mg/g $\gamma$ -tocopherol, mg/g $\alpha$ -tocopherol, mg/g $\beta$ -tocopherol, mg/g $\delta$ -tocopherol, mg/g	J. Chromatogr. A870 (2000) 207-15 & Dionex Tech Note 89	≥ 450 ≥ 360 as reported <sup>2</sup> as reported <sup>2</sup> as reported <sup>2</sup>
<b>Microbial purity:</b> 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
<b>Heavy Metals:</b> Arsenic Cadmium Lead Mercury	AOAC 993.14 AOAC 993.14 AOAC 993.14 DMA	<1.5 ppm <0.3 ppm <1.0 ppm <0.2 ppm
<b>Residual Solvents (RS)</b>	USP <467>	Complies <sup>1</sup>
<b>Benzo (a) pyrene:</b>	Calculated	≤ 1 ppb <sup>3</sup>
1. Specification is informational and not part of release testing but is determined by the use of raw ingredients that meets USP (RS) specifications and water is only solvent used in the production of EG360SD 2. Specifications, if listed, are typical but not guaranteed; actual results are reported on Certificate of Analysis.		

## Provitas® EG360SD

**Nutritional Data (per 100 grams)-**

Item	Result	Item	Result
Total Calories	200 Kcal	Total Fat	0 g
Calories from Fat	0 Kcal	Saturated Fat	0 g
Protein	0 g	Cholesterol	0 g
Carbohydrate	50 g	Sodium	100 mg
Total Fiber	>0.5 g	Calcium	12 mg
Soluble fiber	>0.5 g	Water	< 5 g
Insoluble fiber	0.00 g	Ash	< 3 g
Sugars	30 g	Potassium	0 g
Added Sugars	0 g	Mixed tocopherols	45 g
		Vitamin E (α-tocopherol)	6,000 IU

**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® EG360SD fully complies with Chemical test <467> USP/NF: Residual Solvents Limits and EU directive 2009/32/EC. Water is the only solvent used in the Provitas® EG360SD manufacturing process.

**NDA**

Provitas® EG360SD is a food/dietary ingredient that is a component of commercial food in the United States prior to DSHEA, October 15<sup>th</sup>, 1994

**WADA-**

Provitas LLC certifies that Provitas® EG360SD 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® EG360SD is not considered a nanomaterial. Therefore, it does not require labeling as such.

**Prop 65-**

We certify that Provitas® EG360SD and all materials used to manufacture Provitas® EG360SD 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.

**Sewage-**

We certify that Provitas® EG360SD has been produced, packaged and stored without the use of sewage sludge.

**BSE/TSE/Irradiation/EtO Statements-**

Provitas® EG360SD is free of any animal origin organisms/ingredients. Product is PCR negative for any or animal-based organisms. Provitas, LLC guarantees that no BSE causing ingredients are present in Provitas® EG360SD.

We certify that Provitas® EG360SD is free of radiation. Irradiation is not used in the production, packaging and/or storage of Provitas® EG360SD.

We certify that Provitas® EG360SD is free of ethylene oxide. Ethylene oxide sterilization is not used in the production, packaging and/or storage of Provitas® EG360SD.

We certify that Provitas® EG360SD is free of BHA and BHT. BHA and BHT are not used in the production, packaging and/or storage of Provitas® EG360SD.

**Contaminants and Impurities Statement-**

To our knowledge, there is no contamination by potentially harmful materials in Provitas® EG360SD. This includes but not limited to heavy metals, PAHs, PHOs, pesticides, dioxins, propylene, melamine, mycotoxins, sweeteners, flavoring, synthetic preservatives, and solvents. Provitas® EG360SD is in compliance with the EU Commission regulation (EU) 1881/2006.

## Provitas® EG360SD

**Packaging Details-**

<b>100gm Sample T1587100</b>	<b>25 Kg carton T1587153</b>
Aluminum pouch  100 gram net weight each / 100gm 4" x 6" (10cm x 15cm)	Fiber carton w/plastic liner 25kg net weight 26kg gross weight 11"x15"x20" (31cm x 31cm x 51cm) 26 kg gross weight (over pack) 12"X16"X22" (56cm x 36cm x 36cm)  Quantity per 40" x 48" pallet: 1 layer of 10 cartons (250kg) Maximum 3 layers / pallet (750kg)

Revision History				
Revision	Modified by	Previous Date	Date of Change	Description of Change
01	Emily Baird	April 29, 2019	August 17 <sup>th</sup> , 2020	Added revision table and updated Part number, updated to PDS 2020 Format, product number and footer
02	Emily Moran	August 17 <sup>th</sup> , 2020	November 12 <sup>th</sup> , 2020	Added NDA statement
03	Emily Moran	November 12 <sup>th</sup> , 2020	February 25 <sup>th</sup> , 2021	Updated the Contaminants and Impurities Statement
04	Emily Moran	February 25 <sup>th</sup> , 2021	November 17, 2021	Added compendia and corrected CAS numbers