

## Provitas® MT300SD

**Product Description-**

Provitas® MT300SD is a uniform water-soluble powder that is light cream to tan or beige in color with a bland odor and taste. The active ingredient, mixed tocopherols are derived from natural sources, i.e. edible vegetable oils, and are produced by suitable physical and chemical means. The active ingredient, mixed tocopherols, is homogenized with modified food starch and dried to a uniform powder. Silicon dioxide is added for flow at < 2%. Provitas® MT300SD is intended for use as a natural tocopherol preservative in foods and nutritional supplements.

**Item Number:** T120

**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-**

Provitas® MT300SD meets all requirements of FCC monograph "Tocopherols Concentrate, Mixed".

**Harmonized Tariff Schedule Code-** 2939.28.0000

**Solubility-** Provitas® MT300SD is soluble in water

**Generally Recognized as Safe-**

Provitas® MT300SD 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 12 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. Do not expose to alkalis or strong oxidizing agents.

**GMP-**

Provitas LLC confirms that Provitas® MT300SD 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® MT300SD is manufactured by physical and chemical means and is therefore not an organic product. Provitas® MT300SD 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® MT300SD 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.

Provitas® MT300SD does not contain detectable modified genetic materials, as according to the USDA National Bioengineered Food Disclosure Standard (NBFDS), 7 CFR Part 66. This product does not require disclosure as a BE substance.

**Sewage-**

We certify that Provitas® MT300SD has been produced, packaged and stored without the use of sewage sludge.

TEST	METHODS	SPECIFICATIONS
<b>Organoleptic</b> Description: Color: Odor:	Observation	Solid - powder Cream to beige Bland
<b>Identification:</b> Identity: color development, A GC Peak retention time, B Optical Rotation	USP monograph USP monograph	Red to orange Assay >+20°
<b>Assay:</b> Total tocopherols d-α tocopherol, mg/g β-tocopherol, mg/g <sup>3</sup> γ-tocopherol, mg/g <sup>3</sup> δ-tocopherol, mg/g <sup>3</sup>	J Chromatogr A. 2012 Jun 22; 1243:39-46	≥ 300 ≤60 +/- 10 +/- 165 +/- 75
<b>Heavy Metals:</b> Arsenic, mg/kg Cadmium, mg/kg Lead, mg/kg Mercury, mg/kg	AOAC 993.14 AOAC 993.14 AOAC 993.14 DMA	<1.5 <0.3 <1.0 <0.2
<b>Microbial purity:</b> APC, cfu/10g Coliforms, cfu/10g Yeast & Mold, cfu/10g E. Coli, cfu/10g Staphylococcus aureus, cfu/10g Salmonella, cfu/10g	USP <2021> USP<2021> USP <2021> USP <2022> USP <2022> USP <2022>	≤1,000 <100 <100 Negative Negative Negative
<b>Residual Solvents (RS)<sup>1</sup></b>	USP <467>	Meets USP requirements <sup>1</sup>
<b>Benzo (a) pyrene:</b> ppb	calculated	≤ 1 ppb <sup>2</sup>
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 MT300SD Natural Powder 2. Specification is informational and not part of release testing but is based on specification and lot specific analysis provided for d-mixed tocopherols used in the production of MT300SD Natural Powder 3. Specifications listed are typical but not guaranteed; actual results are reported on Certificate of Analysis.		

## Provitas® MT300SD

<b>Nutritional Data (per 100 grams)-</b>			
<b>Nutrients</b>	<b>Result</b>	<b>Nutrients</b>	<b>Result</b>
Calories (kcal)	55.4928	Cholesterol (mg)	0
Calories from Fat (kcal)	47.9128	Water (g)	4.27216
Calories from SatFat (kcal)	7.63407	Ash (g)	0.494316
Protein (g)	0.0061	Vitamin A - IU	0
Carbohydrates (g)	57.828	Vitamin C (mg)	0
Dietary Fiber (g)	0	Ergocalciferol (mg)	0
Total Sugars (g)	28.06	Cholecalciferol (mg)	0
Added Sugars (g)	0	Mixed Tocopherols	30.001
Other Carbs (g)	29.768	d-alpha-tocopherol, mg/g	6.0002
Fat (g)	5.481	Calcium (mg)	53.07
Saturated Fat (g)	0.7588	Potassium (mg)	11.59
Monounsaturated Fat (g)	1.4092	Sodium (mg)	0.549
Polyunsaturated Fats (g)	3.2249		
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.			

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

We certify that Provitas® MT300SD is free of radiation. Irradiation is not used in the production, packaging and/or storage of Provitas® MT300SD.

We certify that Provitas® MT300SD is free of ethylene oxide. Ethylene oxide sterilization is not used in the production, packaging and/or storage of Provitas® MT300SD.

We certify that Provitas® MT300SD is free of BHA, BHT and sodium nitrate. BHA, BHT and sodium nitrate are not used in the production, packaging and/or storage of Provitas® MT300SD.

### **Residual Solvent Statement-**

Provitas LLC certifies that Provitas® MT300SD fully complies with Chemical test <467> USP/NF: Residual Solvents Limits. Water is the only solvent used in the Provitas® MT300SD manufacturing process.

### **WADA-**

Provitas LLC certifies that Provitas® MT300SD 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® MT300SD is not considered a nanomaterial. Therefore, it does not require labeling as such.

### **Prop 65-**

We certify that Provitas® MT300SD and all materials used to manufacture PROVITAS® MT300SD 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 outside US/EU legal limits by potentially harmful materials in Provitas® MT300SD. This includes but not limited to heavy metals, pesticides, PAHs, dioxins, organochlorines, propylene, melamine, mycotoxins, and solvents.

### **Vegetarian Statement-**

Provitas® MT300SD 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.

## Provitas® MT300SD

**Packaging Details-**

100gm Sample E1207100	25 Kg carton E1207153
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 12"x12"x20" (31cm x 31cm x 51cm) 27kg gross weight (over pack) 22"x14"x14" (56cm x 36cm x 36cm)  Quantity per 40" x 48" pallet: 1 layer of 9 cartons (225kg) Maximum 3 layers / pallet (675kg)

Revision History				
Revision	Modified by	Previous Date	Date of Change	Description of Change
03	Emily Moran	April 22 <sup>nd</sup> , 2016	April 26, 2021	Updated to 2020 format
04	Emily Moran	February 25, 2021	May 28, 2021	Updated specification table