

# Provitas® MT300IP

#### **Product Description-**

Provitas® MT300IP is a non-GMO uniform water-soluble powder that is light cream to tan or beige in color with a bland odor and taste. The active ingredient, non-GMO mixed tocopherols are derived from natural sources, i.e. edible vegetable oils, and are produced by suitable physical and chemical means. The active ingredient, non-GMO mixed tocopherols, is homogenized with non-GMO modified food starch and dried to a uniform powder. Synthetic silicon dioxide is added for flow at < 2%. Provitas® MT300IP is intended for use as a natural tocopherol preservative in foods and nutritional supplements.

**Item Number:** T141

**CAS-Number:** 

 $\alpha - 59-02-9$ 

 $\beta - 16698-35-4$ 

 $\gamma - 54-28-4$ 

**δ** – 119-13-1

Country of Origin- Manufactured in the USA

#### Compendia Requirements-

Provitas® MT300IP meets all requirements of FCC monograph "Tocopherols Concentrate, Mixed".

# Generally Recognized as Safe-

Provitas® MT300IP 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® MT300IP is soluble in cold 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.

TEST	METHODS	SPECIFICATIONS	
Organoleptic:			
Description:		Solid - powder	
Color:	Observation	Cream to beige	
Odor:		Bland	
Assay:			
Total tocopherols	J Chromatogr A. > 300		
d- $\alpha$ tocopherol, mg/g	2012	<u>&lt;</u> 60	
β-tocopherol, mg/g <sup>3</sup>	Jun 22; 1243:39-	+/- 10	
γ-tocopherol, mg/g <sup>3</sup>	46	+/- 165	
δ-tocopherol, mg/g <sup>3</sup>		+/- 75	
Acid Value:	AOCS CA 5A-40		
Mg KOH/gm	AOAC 983.23	< 2.0ml/gm	
Heavy Metals:			
Arsenic, mg/kg	AOAC 993.14	<1.5	
Cadmium, mg/kg	AOAC 993.14	<0.3	
Lead, mg/kg	AOAC 993.14	<1.0	
Mercury, mg/kg	DMA	<0.2	
Microbial purity:			
APC, cfu/gm in 50gm	USP <2021>	<u>≤</u> 1,000	
Coliforms, cfu/gm	USP<2021>	<100	
Yeast & Mold, cfu/gm	USP <2021>	<100	
E. Coli, cfu/gm	USP <2022>	Negative	
Staphylococcus aureus	USP <2022>	Negative	
Salmonella, in 10gm	USP <2022>	Negative	
Moisture	USP <731>	<u>&lt;</u> 5%	
Residual Solvents (RS) <sup>1</sup>	USP <467>	Meets USP requirements <sup>1</sup>	
Benzo (a) pyrene:			
ppb	calculated	≤ 1 ppb²	

- 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
- 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
- Specifications listed are typical but not guaranteed; actual results are reported on Certificate of Analysis.

#### GMP-

Provitas LLC confirms that Provitas® MT300IP 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® MT300IP is manufactured by physical and chemical means and is therefore not an organic product. Provitas® MT300IP 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® MT300IP 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.

#### Sewage-

We certify that Provitas® MT300IP has been produced, packaged and stored without the use of sewage sludge.



# Provitas® MT300IP

# Nutritional Data (per 100 grams)-

Item	Result	Item	Result
Total Calories	212 Kcal	Water	5 gram
Calories from Fat	0 Kcal	Ash	2 gram
Calories from Saturated Fat	0 Kcal	Cholesterol	0.00 gram
Kilojoules	880	Mixed tocopherols	30,000 mg
Protein	0.00 gram	Vitamin E	8,940 IU
Fat	0 gram	Vitamin A	0.00 gram
Saturated Fat	0 gram	Vitamin C	0.00 gram
Trans Fat	0.00 gram	Calcium	15 milligram
Carbohydrate	53 grams	Sodium	59 milligram
Total Sugars	0.00 gram	Iron	0.00 milligram
Dietary Fiber	0.00 gram		

#### 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® MT300IP is free of radiation. Irradiation is not used in the production, packaging and/or storage of Provitas® MT300IP.

We certify that Provitas® MT300IP is free of ethylene oxide. Ethylene oxide sterilization is not used in the production, packaging and/or storage of Provitas® MT300IP.

We certify that Provitas® MT300IP is free of BHA and BHT. BHA and BHT are not used in the production, packaging and/or storage of Provitas® MT700IP.

### **Residual Solvent Statement-**

Provitas LLC certifies that Provitas® MT300IP fully complies with Chemical test <467> USP/NF: Residual Solvents Limits. Water is the only solvent used in the Provitas® MT300IP manufacturing process.

#### WADA-

Provitas LLC certifies that Provitas® MT300IP 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® MT300IP is not considered a nanomaterial. Therefore, it does not require labeling as such.

# Prop 65-

We certify that Provitas® MT300IP and all materials used to manufacture Provitas® MT300IP 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® MT300IP. This includes but not limited to aspartame, heavy metals, PAHs, dioxins, propylene, melamine, mycotoxins, and solvents.

# Vegetarian Statement-

Provitas® MT300IP is produced using raw materials derived from plant or synthetic sources. This product is vegetarian and vegan since no animal source product is used in manufacturing.



# Provitas® MT300IP

Packaging Details-

100g Sample	25 Kg carton		
T1417100	T1417153		
Aluminum pouch	Fiber carton w/plastic liner		
	25kg net weight		
100-gram net weight	26kg gross weight		
1.77" x 2.68" (45mm x 68mm)	15"x11"x22" (38cm x 28cm x 56cm)		
	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	02/27/2018	April 30, 2020	Updated to PDS 2020 Format	
02	Emily Moran	April 30, 2020	February 25,2021	Added to the contaminates statement	
03	Emily Moran	February 25.2021	May 28, 2021	Updated specification table	