

## Provitas® K<sub>1</sub> 300 MCT Oil

**Product Description-**

K<sub>1</sub> Oil-USP is standardized in MCT Oil. Provitas® K<sub>1</sub> 300 MCT is designed for use in oil dispersions, encapsulated products, and fortified foods.

**Item Number:** -K503

**CAS-Number:** 84-80-0

**Country of Origin-**

Provitas® K<sub>1</sub> 300 MCT Oil is manufactured and guaranteed in the USA.

**Compendia Requirements-** A specific USP or FCC monograph does not exist for vitamin K<sub>1</sub> preparations. USP grade phytonadione and USP/NF and/or FCC grade excipients are used to manufacture Provitas® K<sub>1</sub> 300 MCT Oil.

**Harmonized Tariff Schedule Code-**2936.2920

**Solubility-**

Provitas® K<sub>1</sub> 300 MCT Oil is miscible in fats and oils.

**Stability and Storage-**

The shelf life in sealed, original containers stored at <25°C/77°F and well protected from light and excessive heat exposure is 24 months after the date of manufacture. Store in tightly closed containers at <25°C/77°F. Vitamin K is especially sensitive to light; protect from light, heat and oxygen. If opened container and partial contents are to be stored, flush contain of oxygen with an inert gas and tightly reseal.

**GMP-**

Provitas LLC confirms that Provitas® K<sub>1</sub> 300 MCT Oil is manufactured in a facility that adheres to Good Manufacturing Practices as defined by the U.S. FDA, CFR Title 117. Provitas and the facility are FDA registered, and 3<sup>rd</sup> party certified.

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

Provitas® K<sub>1</sub> 300 MCT Oil is manufactured by physical and chemical means and is therefore not an organic product.

Provitas® K<sub>1</sub> 300 MCT Oil 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® K<sub>1</sub> 300 MCT 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.

Provitas® K<sub>1</sub> 300 MCT 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.

**Vegetarian/Vegan Statement-**

Provitas® K<sub>1</sub> 300 MCT Oil is produced using raw materials derived from plant and synthetic sources. This product is vegetarian and vegan since no animal source product is used in manufacturing.

**Sewage-**

We certify that Provitas® K<sub>1</sub> 300 MCT Oil has been produced, packaged, and stored without the use of sewage sludge.

TESTS	METHODS	SPECIFICATIONS
<b>Organoleptic</b> Description: Color: Odor:	Observation	Clear oily Oil Yellow to Dark Yellow Typically Faint
Assay: Phytonadione (vitamin K <sub>1</sub> ), mg/g	USP	≥ 300
<b>Acid Value:</b> Mg KOH/g	AOCS CD 3D-63	< 2.0
<b>Peroxide Value:</b> meq/kg	AOCS CD 88-90	< 5.0
<b>Heavy Metals:</b> Arsenic, ppm Cadmium, ppm Lead, ppm Mercury, ppm	JAOAC 2016 99(3) JAOAC 2016 99(3) JAOAC 2016 99(3) JAOAC 2016 99(3)	<1.5 <0.3 <1.0 <0.2
<b>Microbial purity:</b> APC, cfu/g Coliforms, cfu/g Yeast and molds, cfu/g E. Coli, cfu/g S. aureus, cfu/g Salmonella sp., cfu/g P. Aeruginosa, cfu/g	USP<61> USP<61> USP<61> USP<62> USP<62> USP<62> USP<62>	≤1,000 <100 <100 Negative Negative Negative Negative

## Provitas® K<sub>1</sub> 300 MCT Oil

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

Nutrient	Quantity	Nutrient	Quantity
Calories (kcal)	630	Vitamin A	0
Calories from Fat (kcal)	630	Vitamin C	0
Calories from SatFat (kcal)	0	Vitamin D	0
Protein (g)	0	Vitamin E	0
Carbohydrates (g)	0	Phytonadione, K <sub>1</sub> (mg)	30000
Dietary Fiber (g)	0	Calcium (mg)	0
Total Sugars (g)	0	Chromium (mcg)	0
Added Sugars (g)	0	Iron (mg)	0
Other Carbs (g)	0	Magnesium (mg)	0
Fat (g)	70	Manganese (mg)	0
Saturated Fat (g)	0	Potassium (mg)	0
Trans Fatty Acid (g)	0.07	Sodium (mg)	0
Cholesterol (mg)	0	Zinc (mg)	0
Water (g)	0		
Ash (g)	0		

**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 Provitas® K<sub>1</sub> 300 MCT Oil 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® K<sub>1</sub> 300 MCT Oil fully complies with Chemical test <467> USP/NF: Residual Solvents Limits. No solvents are used in the manufacturing of Provitas® K<sub>1</sub> 300 MCT Oil.

**WADA-**

Provitas LLC certifies that Provitas® K<sub>1</sub> 300 MCT Oil 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® K<sub>1</sub> 300 MCT Oil is not considered a nanomaterial. Therefore, it does not require labeling as such.

**Prop 65-**

We certify that Provitas® K<sub>1</sub> 300 MCT Oil and all materials used to manufacture Provitas® K<sub>1</sub> 300 MCT Oil 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® K<sub>1</sub> 300 MCT Oil does not contain Carcinogen, Mutagen, or toxic for the Reproduction substances according to the 1272/2008 (EC) Regulation, directive 67/548/EWG.

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

Provitas, LLC guarantees that no BSE causing ingredients are present in Provitas® K<sub>1</sub> 300 MCT Oil. Provitas® K<sub>1</sub> 300 MCT Oil is free of any animal origin organisms/ingredients. Provitas® K<sub>1</sub> 300 MCT Oil tests PCR negative for any animal-based organisms.

Provitas LLC certifies that Provitas® K<sub>1</sub> 300 MCT Oil is free of radiation. Irradiation is not used in the production, packaging and/or storage of Provitas® K<sub>1</sub> 300 MCT Oil.

We certify that Provitas® K<sub>1</sub> 300 MCT Oil is free of ethylene oxide. Ethylene oxide sterilization is not used in the production, packaging and/or storage of Provitas® K<sub>1</sub> 300 MCT Oil.

We certify that Provitas® K<sub>1</sub> 300 MCT Oil is free of BHA and BHT. BHA and BHT are not used in the production, packaging and/or storage of Provitas® K<sub>1</sub> 300 MCT Oil.

**Contaminants and Impurities Statement-**

To our knowledge, there is no contamination by potentially harmful materials in Provitas® K<sub>1</sub> 300 MCT Oil. This includes but not limited to heavy metals, pesticides, propylene, PAHs, dioxins, melamine, mycotoxins, and solvents.

### Provitas® K<sub>1</sub> 300 MCT Oil

**Packaging Details-**

<b>50 gm Sample K5031300</b>	<b>1kg carton K5031311</b>	<b>10kg carton K5031355</b>
HDPE bottle, 50ml  50-gram net weight 1.97" x 3.66" (50mm x 93mm)	Fiber carton containing 1 x 1kg Aluminum bottles  1kg net weight 2kg gross weight 4"x4"x11" (10cm x 10cm x 280cm)	Fiber carton containing 2 x 5kg plastic bottles  10kg net weight 11kg 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 (600 kg)

Revision History				
Revision	Modified by	Previous Date	Date of Change	Description of Change
01	Emily Moran	October 2, 2014	January 14, 2022	Updated to 2020 Product sheet template