

Provitas® K₂ 5% MCT Oil

Product Description-

All-trans K₂-MK7 crystals are standardized in MCT (capric/caprylic triglycerides) Oil. Provitas® K₂ 5% MCT Oil is kosher, and halal certified and produced in a 3rd party audited and certified FDA cGMP facility. Provitas® K₂ 5% MCT Oil is designed for use in oil dispersions, encapsulated products and fortified foods.

Item Number: K515

CAS-Number: 2124-57-4

Country of Origin-

Provitas® K₂ 5% MCT Oil Manufactured and guaranteed in the USA.

Compendia Requirements-

Menaquinone-7 preparation USP monograph

Harmonized Tariff Schedule Code-2936.29.5050

Solubility-

Provitas® K₂ 5% 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.

TESTS	METHODS	SPECIFICATIONS
Organoleptic: Description: Color: Odor:	Observation	Clear oily solution Yellow Almost odorless
Assay: Menaquinone (MK7), ppm %	USP	≥ 50,000 ≥5.0%
Acid Value: Mg KOH/g	AOCS CD 3D-63	< 2.0
Peroxide Value: meq/kg	AOCS CD 88-90	< 10.0
Heavy Metals: 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 <1.0 <1.0 <0.2
Microbial purity: 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

GMP-

Provitas LLC confirms that Provitas® K₂ 5% 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 3rd party certified.

Non-GMO and Organic compliant statement-

Provitas® K₂ 5% MCT Oil is manufactured by physical and chemical means and is therefore not an organic product.

Provitas® K₂ 5% 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® K₂ 5% MCT Oil 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.

Vegetarian/Vegan Statement-

Provitas® K₂ 5% 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.

Residual Solvent Statement-

Provitas LLC certifies that Provitas® K₂ 5% MCT Oil fully complies with Chemical test <467> USP/NF: Residual Solvents Limits. No solvents are used in the manufacturing of Provitas® K₂ 5% MCT.

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Nutritional Data (per 100g)-

Nutrients	Result	Nutrients	Result
Calories (kcal)	854.541	Vitamin A - IU	0
Calories from Fat (kcal)	854.541	Vitamin A - RAE	0
Calories from SatFat (kcal)	0	Vitamin C (mg)	0
Protein (g)	0	Ergocalciferol	0
Carbohydrates (g)	0	Cholecalciferol	0
Dietary Fiber (g)	0	D-L-alpha tocopherol	0
Added Sugars (g)	0	D-L-alpha tocopheryl acetate	0
Other Carbs (g)	0	D-alpha tocopherol	0
Fat (g)	94.949	Phytonadione (mcg)	0
Saturated Fat (g)	94.949	Menaquinone (mg)	5000.49
Trans Fatty Acid (g)	0	Iron (mg)	0
Cholesterol (mg)	0	Magnesium (mg)	0
Water (g)	0	Sodium (mg)	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 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.

WADA-

Provitas LLC certifies that Provitas® K₂ 5% 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® K₂ 5% MCT Oil is not considered a nanomaterial. Therefore, it does not require labeling as such.

Contaminants and Impurities Statement-

To our knowledge, there is no contamination by potentially harmful materials in Provitas® K₂ 5% MCT Oil. This includes but not limited to heavy metals, pesticides, propylene, PAHs, dioxins, melamine, mycotoxins, and solvents.

Sewage-

We certify that Provitas® K₂ 5% MCT Oil has been produced, packaged, and stored without the use of sewage sludge.

Prop 65-

We certify that Provitas® K₂ 5% MCT Oil and all materials used to manufacture Provitas® K₂ 5% MCT 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.

BSE/TSE/Irradiation/EtO Statements-

Provitas, LLC guarantees that no BSE causing ingredients are present in Provitas® K₂ 5% MCT Oil. Provitas® K₂ 5% MCT Oil is free of any animal origin organisms/ingredients. Provitas® K₂ 5% MCT tests PCR negative for any animal-based organisms.

Provitas LLC certifies that Provitas® K₂ 5% MCT Oil is free of radiation. Irradiation is not used in the production, packaging and/or storage of Provitas® K₂ 5% MCT Oil.

We certify that Provitas® K₂ 5% MCT Oil is free of ethylene oxide. Ethylene oxide sterilization is not used in the production, packaging and/or storage of Provitas® K₂ 5% MCT Oil.

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Packaging Details-

50 gm Sample K5151300	1kg carton K5151311	10kg carton K5151355
HDPE bottle, 50ml 25 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 Maximum 4 layers / pallet

Revision History				
Revision	Modified by	Previous Date	Date of Change	Description of Change
01	Emily Baird	----	October 9, 2019	Created form
02	Emily Baird	October 9, 2019	October 11 th , 2019	Updated Specification
03	Emily Moran	October 11 th , 2019	August 27, 2021	Updated form to 2020 update