

Provitas® K₂ 1% MCC

Product Description-

Provitas® K₂ 1% MCC is a uniform free-flowing, powder which is light yellow in color with a bland odor and taste. The active ingredient, all-trans-menaquinone-7 is of USP grade and produced by suitable physical and chemical means. The active ingredient, menaquinone-7, is standardized in MCT oil and then plated onto a microcrystalline cellulose (MCC) carrier.

Item Number: K514

CAS-Number: 2124-57-4

Country of Origin-

Provitas® K₂ 1% MCC manufactured and guaranteed in the USA.

Compendia Requirements-

Menaquinone-7 preparation USP monograph

Harmonized Tariff Schedule Code-2936.29.5050

Solubility-

Provitas® K₂ 1% MCC is soluble in cold water

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. 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® K₂ 1% MCC 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 1% MCC 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 1% MCC not derived from genetically modified organisms. Provitas® K₂ 1% MCC does not contain ingredients, additives or processing aides derived from commodities that contain or are derived from genetically modified organisms.

Provitas® K₂ 1% MCC 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 1% MCC 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® K₂ 1% MCC has been produced, packaged, and stored without the use of sewage sludge.

TEST	METHODS	SPECIFICATIONS
Organoleptic: Description: Color: Odor:	Observation	Solid - powder Light yellow Bland
Identification: ¹ Chromatography (A) Assay (B)	USP Monograph	Corresponds to Standard Solution 90.0% - 120.0%
Assay: Menaquinone-7 (ppm) %	USP Monograph	≥ 10,000 ≥ 1.0%
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)	<2.0 <1.0 <1.0 <0.1
Microbial purity: APC, cfu/g Coliforms, cfu/g Yeast and mold, cfu/g E. Coli, cfu/g Staphylococcus aureus, cfu/g Salmonella sp., cfu/g	USP<61> USP<61> USP<62> USP<62> USP<62> USP<62>	≤1,000 ≤100 ≤100 Negative Negative Negative
Loss on Drying %	USP<731>	7
1. Specification is informational and not part of release testing but is based on lot specific analysis provided for menaquinone-7 used in the production of K ₂ 1% MCC		

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Nutritional Data (per 100g)-

Item	Result	Item	Result
Total Calories	420	Ash	0
Calories from Fat	72	Vitamin A (IU) / (RE)	0
Calories from Saturated Fat	72	Menaquinone (mg)	1000
Protein	0	Vitamin E (dl-α tocopherol)	0
Fat	8g	Vitamin D	0
Saturated Fat	8g	Calcium	<1mg
Carbohydrate	87g	Iron	<1mg
Dietary Fiber	87g	Sodium	<3mg
Sugar - Total	0	Potassium	<3mg
Added sugar	0	Magnesium	0
Water	<5g	Other	

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® K₂ 1% MCC 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® K₂ 1% MCC fully complies with Chemical test <467> USP/NF: Residual Solvents Limits. No solvents are used in the manufacturing of Provitas® K₂ 1500 MCT.

WADA-

Provitas LLC certifies that Provitas® K₂ 1% MCC 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 1% MCC 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 1% MCC. This includes but not limited to heavy metals, pesticides, propylene, PAHs, dioxins, melamine, mycotoxins, and solvents.

Prop 65-

We certify that Provitas® K₂ 1% MCC and all materials used to manufacture Provitas® K₂ 1% MCC 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 1% MCC. Provitas® K₂ 1% MCC is free of any animal origin organisms/ingredients. Provitas® K₂ 1% MCC tests PCR negative for any animal-based organisms.

Provitas LLC certifies that Provitas® K₂ 1% MCC is free of radiation. Irradiation is not used in the production, packaging and/or storage of Provitas® K₂ 1% MCC.

We certify that Provitas® K₂ 1% MCC is free of ethylene oxide. Ethylene oxide sterilization is not used in the production, packaging and/or storage of Provitas® K₂ 1% MCC.

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Packaging Details-

50 gm Sample K5141300	1 Kg K5141311
HDPE bottle, 50ml 25 gram net weight 1.97" x 3.66" (50mm x 93mm)	Aluminum bag in fiber carton 1 Kg net weight 1.5 Kg gross weight 12"x 9"x 3" (31cm x 23cm x 8cm)

Revision History				
Revision	Modified by	Date of Change	Description of Change	Approved By
01	Emily Baird	October 9, 2019	Created form	-
02	Emily Baird	October 11 th , 2019	Updated Specification	-
03	Emily Moran	November 10, 2021	Updated format to 2020 standard	-
04	Emily Moran	March 10, 2022	Updated spec table, packaging spec and nutritional table	MW