

Provitas® K₁ 50SD

Product Description-

Provitas® K₁ 50SD is a uniform water-soluble powder, which is cream to light yellow in color with a bland odor and taste. The active ingredient, phytonadione is homogenized with non-GMO modified gum acacia and maltodextrin and then dried to a uniform powder. Provitas® K₁ 50SD is intended for the fortification of vitamin K₁ in foods and pharmaceutical preparations.

Item Number: K502

CAS-Number: 84-80-0

Country of Origin-

Provitas® K₁ 50SD Manufactured and guaranteed in the USA.

Compendia Requirements-

A specific USP or FCC monograph does not exist for vitamin K₁ preparations. USP grade phytonadione and USP/NF and/or FCC grade excipients are used to manufacture Provitas® K₁ 50SD.

Harmonized Tariff Schedule Code-
2936.29.5050

Solubility-

Provitas® K₁ 50SD is soluble in cold water

Stability and Storage-

The shelf life in sealed, original containers under normal storage conditions is 24 months after the date of manufacture. Store in tightly closed containers in cool and dry conditions. Protect from moisture, heat, light, and oxygen. Provitas® K₁ 50SD decomposes on exposure to light.

GMP-

Provitas LLC confirms that Provitas® K₁ 50SD 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® K₁ 50SD is manufactured by physical and chemical means and is therefore not an organic product.

Provitas® K₁ 50SD 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® K₁ 50SD is not derived from genetically modified organisms. Provitas® K₁ 50SD does not contain ingredients, additives or processing aides derived from commodities that contain or are derived from genetically modified organisms.

Vegetarian/Vegan Statement-

Provitas® K₁ 50SD 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.

TESTS	METHODS	SPECIFICATIONS
Organoleptic: Description: Color: Odor:	Observation	Solid - powder Cream to light yellow Bland
Assay: Vitamin K ₁ (phytonadione) Z Isomer Content	J. Chrom. A 870 (2000) 207-15 & Dionex Tech Note 89	≥ 50 mg/g < 10.5 mg/g ¹
Moisture: Karl Fischer Moisture	USP<731>	≤ 5%
Heavy Metals: Arsenic, ppm Cadmium, ppm Lead, ppm Mercury, ppm	AOAC 993.14 AOAC 993.14 AOAC 993.14 DMA	<1.5 <0.3 <1.0 <0.2
Microbial purity: APC, cfu/g Coliforms, cfu/g Yeast & Mold, cfu/g E. Coli, cfu/g Staphylococcus aureus, cfu/g Salmonella, cfu/g	USP <2021> USP <2021> USP <2021> USP <2022> USP <2022> USP <2022>	≤1,000 <100 <100 Absent Absent Absent
Residual Solvents (RS)¹:	USP <467>	Meets USP Requirements
1. Specification is informational and not part of release testing but is determined using USP grade vitamin K.		

Provitas® K₁ 50SD

Nutritional Data (per 100g)-

Item	Result	Item	Result
Total Calories	197.6 Kcal	Vitamin K ₁ (phytonadione)	5 gram
Calories from Fat	0 Kcal	Vitamin D	0 gram
Calories from Saturated Fat	0 Kcal	Calcium	648 milligram
Protein	1.44 gram	Potassium	1602 milligram
Fat	14 gram	Sodium	954 milligram
Saturated Fat	14 gram	Iron	0 Milligram
Carbohydrate	83.7 gram	Water	4 gram
Soluble Fiber	65 gram	Ash	4 gram
Sugar - Total	1 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 Provitas® K₁ 50SD 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® K₁ 50SD fully complies with Chemical test <467> USP/NF: Residual Solvents Limits. No solvents are used in the manufacturing of Provitas® K₁ 50SD.

WADA-

Provitas LLC certifies that Provitas® K₁ 50SD 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® K₁ 50SD 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® K₁ 50SD. This includes but not limited to antibiotics, Bisphenol-A, hormones/steroids, pesticides, propylene, PAHs, Phthalates, dioxins, melamine, mycotoxins, nitrosamines and solvents.

Prop 65-

We certify that Provitas® K₁ 50SD and all materials used to manufacture Provitas® K₁ 50SD 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® K₁ 50SD. Provitas® K₁ 50SD is free of any animal origin organisms/ingredients Provitas® K₁ 50SD tests PCR negative for any animal-based organisms.

Provitas LLC certifies that Provitas® K₁ 50SD is free of radiation. Irradiation is not used in the production, packaging and/or storage of Provitas® K₁ 50SD.

We certify that Provitas® K₁ 50SD is free of ethylene oxide. Ethylene oxide sterilization is not used in the production, packaging and/or storage of Provitas® K₁ 50SD.

Sewage-

We certify that Provitas® K₁ 50SD has been produced, packaged, and stored without the use of sewage sludge.

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Packaging Details-

50 gm Sample K5027100	25 kg carton K5027153
Aluminum pouch 100 gram net weight 4" x 6" (10cm x 15cm)	Fiber carton w/ aluminum liner: 25kg net weight 26kg gross weight 15"x11"x20" (38cm x 28cm x 51cm) 27kg gross weight (over pack) 16"x 12"x 21" (41cm x 31cm x 56cm) Quantity Per Pallet 1 layer of 9 cartons Maximum 3 layers / pallet

Revision	Modified by	Date of Change	Description of Change
-	-	August 15 th , 2019	---
01	Emily Baird	May 26 th , 2020	Updated to 2020 Product sheet template
02	Emily Moran	July 15, 2021	Updated GMO statement
03	Emily Moran	July 16, 2021	Corrected CAS number
04	Emily Moran	March 10, 2022	Updated the packaging
05	Emily Moran	May 19 th , 2022	Updated contaminants statement