

Provitas® K₁ 10SD

Product Description-

K₁ 10SD 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 gum acacia and glucose syrup and then dried to a uniform powder. Tricalcium phosphate is added for flow. K₁ 10SD is intended for the fortification of vitamin K₁ in foods and pharmaceutical preparations.

Item Number: K506

CAS- 84-80-0

Country of Origin-

Provitas® K₁ 10SD 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 10SD.

Harmonized Tariff Schedule Code-2936.29.5050

Solubility- Provitas® K₁ 10SD 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 10SD decomposes on exposure to light.

GMP-

Provitas LLC confirms that Provitas® K₁ 10SD 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 10SD is manufactured by physical and chemical means and is therefore not an organic product.

Provitas® K₁ 10SD 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 10SD 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® K₁ 10SD 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® K₁ 10SD 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 ¹ | J. Chrom. A 870 (2000) 207-15 & Dionex Tech Note 89 | ≥ 10 mg/g < 2.1 mg/g |
| 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 | <1.0 <0.3 <1.0 <0.1 |
| 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 |
| Particle Size Distribution²: Through Sieve No. 100 Through Sieve No. 170 Through Sieve No. 325 | USP <786> | > 90% >75% < 40% |
| Residual Solvents (RS)³: | USP <467> | Meets USP Requirements |
| 1. Specification is not part of release testing but is determined by the use of USP grade phytonadione that meets USP specifications. 2. Specification is tested randomly and not reported on Certificate of Analysis. 3. Specification is informational and not part of release testing but is determined by the use of USP grade vitamin K ₁ that meets USP (RS) specifications. Water is the only solvent used in the production of K ₁ 10SD powder. | | |

Provitas® K₁ 10SD

Nutritional Data (per 100g)-

| Item | Result | Item | Result |
|-----------------------------|----------|---------------------------------------|---------------|
| Total Calories | 293 Kcal | Sugar - Total | 8 gram |
| Calories from Fat | 0 Kcal | Vitamin K ₁ (phytonadione) | 1 gram |
| Calories from Saturated Fat | 0 Kcal | Vitamin D | 0 Microgram |
| Kilojoules | 1226 KJ | Calcium | 215 milligram |
| Protein | 1 gram | Potassium | 846 milligram |
| Fat | 0 gram | Iron | 0 milligram |
| Saturated Fat | 0 gram | Sodium | 430 milligram |
| Carbohydrate | 92 gram | Water | 4 gram |
| Soluble Fiber | 34 gram | Ash | 2 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 10SD 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 10SD fully complies with Chemical test <467> USP/NF: Residual Solvents Limits. No solvents are used in the manufacturing of Provitas® K₁ 10SD.

WADA-

Provitas LLC certifies that Provitas® K₁ 10SD 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 10SD 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 10SD. This includes but not limited to heavy metals, pesticides, propylene, PAHs, dioxins, melamine, mycotoxins, and solvents.

Prop 65-

We certify that Provitas® K₁ 10SD and all materials used to manufacture Provitas® K₁ 10SD 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/TSE causing ingredients are present in Provitas® K₁ 10SD. Provitas® K₁ 10SD is free of any animal origin organisms/ingredients. Provitas® K₁ 10SD tests PCR negative for any animal-based organisms.

Provitas LLC certifies that Provitas® K₁ 10SD is free of radiation. Irradiation is not used in the production, packaging and/or storage of Provitas® K₁ 10SD.

We certify that Provitas® K₁ 10SD is free of ethylene oxide. Ethylene oxide sterilization is not used in the production, packaging and/or storage of Provitas® K₁ 10SD.

Sewage-

We certify that Provitas® K₁ 10SD has been produced, packaged, and stored without the use of sewage sludge.

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Packaging Details-

| 50 gm Sample K5067100 | 25 kg carton K5067153 |
|--|---|
| Aluminum pouch 100 gram net weight 4" x 6" (10cm x 15cm) | Fiber carton w/plastic liner 25kg net weight 26kg gross weight 12"x12"x20" (31cm x 31cm x 51cm) 27kg gross weight (over pack) 22"X14"X14" (56cm x 36cm x 36cm) Quantity Per Pallet 1 layer of 9 cartons (225 Kg) Maximum 3 layers / pallet (675 Kg) |

| Revision History | | | | |
|------------------|-------------|----------------------------------|--|-------------|
| Revision | Modified by | Date of Change | Description of Change | Approved By |
| 00 | - | June 29, 2016 | - | - |
| 01 | Emily Baird | February 11 th , 2019 | Added Revision table | - |
| 02 | Emily Baird | July 23 rd , 2020 | Updated to 2020 Product sheet template | - |
| 03 | Emily Moran | April 27, 2022 | Updated GMO statement and added BE statement | EM |