

Product Technical Data Sheet

Product name: Vitamin K2 oil 5%

AC code: AC01832d

1. Technical Data Sheet

Product Name	Vitamin K2 oil 5%	
Molecular formula	C46H64O2	
Molecular weight	649	
CAS number	2124-57-4	
Item	Standard	Analysis Method
Typical Analysis		
Appearance	Light yellow to yellow oil	
Identification	The principal peak in the chromatogram obtained with the test solution is similar in retention time to that of reference solution.	
Content of MK-7	NLT 50000 ppm	USP-HPLC
Isomeric Purity (<i>cis</i> -MK-7)	NMT 2% of MK-7	USP-HPLC
Impurity (Menaquinone-6)	NMT 5000 ppm	USP-HPLC
Loss on Drying	NMT 5.0% USP	USP<731>
Heavy metals		
Total Heavy Metals	≤10ppm	ICP-MS
Lead (Pb)	≤3ppm	ICP-MS
Arsenic (As)	≤2ppm	ICP-MS
Cadmium (Cd)	≤1ppm	ICP-MS
Mercury (Hg)	≤0.1ppm	ICP-MS
Microorganism		
Total Plate Count	≤1000 cfu/g	USP<2021>
Yeast & Mould	≤100 cfu/g	USP<2021>
E.Coli	Negative	USP<2022>
Salmonella	Negative	USP<2022>
Staphylococcus Aureus	Negative	USP<2022>
Storage & Shelf Life		
Package	5kg/drum , 10kg/carton	
Shelf life	The shelf life for the product is 24 months from date of production. Use it as soon as possible once it is opened.	
Storage	Store in a tightly closed container in a dry place, protected from light	

2. Origin & Ingredient

Country of origin of the product: China

Origin statement: available ☒

This product is a pure material ☒

This product is a compound material ☐

Animal origin

☐ bovine

Specific Source: /

	☐ porcine		Specific Source: /
	☐ avian		Specific Source: /
	☐ Others:		Specific Source: /
Synthetic	☐	Starting material:	origin: China
Biotechnological processing	☐ Catalysis By Enzymes		Name Of Enzyme: / Sources Of Enzymes: /
	☒ Fermentation		Source: Bacillus subtilis natto
Botanical Origin	Botanical Name:		/
	Part:		/
	Wild Or Cultivated:		/
	Country Of Origin:		/
	Solvent Used:		/

3.Nutrition Data		
Nutritional Composition	☒ Per 100g	☐ Per Serving
☒ Energy(Kj) ☐ Energy(Kcal)	3511.3 kJ	
Protein(G)	0	
Fat(G)	94.9	
Carbohydrates(G)	0	
Fibre	0	
K2	5.0	
Vitamin E	0.1	
Remarks: Nutrition Data Are Obtained By 3 rd Party Lab; Tested On A Yearly Basis		

4. GMO declaration	Conforms	Not Conforms
The product does not contain or consist of GMO	☒	☐
The product is not produced from GMO or not contain ingredients produced from GMO (irrespective of whether there is NDA or protein of GM origin in the final production)	☒	☐
This product is not produced by means of GM microorganism including precursor substances, e.g. with GMOs or Genetically Modified microorganisms processing aids(bacteria, yeast,...)	☒	☐
This product is not produced with the help of enzymes, which were obtained from GMOs	☒	☐
Does the product contain any ingredients from animal?	☒	☐
If yes, are genetically modified crops contained in the feed for the animal?	☒	☐
We confirm that this product complies with regulations EC/1829/2003 and EC1830/2003 and keep NON-GMO statement available	☒	

5.Allergen declaration
We have carefully reviewed this product according to EU Regulation 1169/2011 and modifications and confirm the following:

	Direct incorporation as a base raw material or in a derivative form (don't forget the carriers, the additives and the processing aids)		CROSS CONTAMINATION					
			Presence on the production line		Presence on the production workshop		Presence on the production factory	
	Yes (precise nature)	No	Yes (precise the nature)	No	Yes (precise the nature)	No	Yes (precise the nature)	No
Cereals containing gluten(1) and products thereof		N		N		N		N
Crustaceans and products thereof		N		N		N		N
Eggs and products thereof		N		N		N		N
Fish and products thereof (2)		N		N		N		N
Peanuts and products thereof		N		N		N		N
Soybeans and products thereof (3)		N		N		N		N
Milk and products thereof (including lactose)(4)		N		N		N		N
Nuts (5) or products thereof		N		N		N		N
Celery and products thereof		N		N		N		N
Mustard and products thereof		N		N		N		N
Sesame seeds and product thereof		N		N		N		N
Sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10 mg/l expressed as SO ₂		N		N		N		N
Lupines and products thereof		N		N		N		N
Mollusc and product thereof		N		N		N		N

- (1) Cereals which contain gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) except: wheat-based glucose syrups including dextrose, wheat-based maltodextrins, glucose syrups based on barley, cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;
- (2) Except: fish gelatine used as carrier for vitamin or carotenoid preparations, fish gelatine or Isinglass used as fining agent in beer and wine;
- (3) Except fully refined soybean oil and fat, natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources; vegetable oils derived phytosterols and phytosterol esters from soybean sources; plant stanol ester produced from vegetable oil sterols from soybean sources;
- (4) Except when used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages, lactitol;
- (5) almond (*Amygdalus communis* L.) hazelnuts (*Corylus avellana*), walnut (*Juglans regia*), cashew (*Anacardium occidentale*), pecan nuts (*Carya illinoensis*), brazil nut (*Bertholletia excelsa*), pistachio nut (*Pistacia vera*), macadamia nut and queensland nut (*Macadamia terniflora*) and products thereof, except nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;

6. NON IRRADIATION

(According to EU directive 1999/2/EC & 1999/3/EC)

This product has not been treated with ionising radiation	☒ Conforms	☐ Not Conforms
None of the raw materials we used for this product have been treated with ionising radiation.	☒ Conforms	☐ Not Conforms
We confirm above Non-Irradiation statement is available	☒	

7. NANOMATERIAL

(according to EU Regulation (EU) No. 1169/2011)

This product does not contain any nanomaterials as defined in EU food legislation	☒ Conforms	☐ Not Conforms
This product has not been made with nanotechnology	☒ Conforms	☐ Not Conforms
We confirm above Non-Nanomaterial statement is available	☒	

8. Residual solvents	
(according to UE Directive 2009/32 modified by(UE)2010/59; EP5.4;USP476;ICH Q3C(R7))	
For this product following solvents are used during production process: Solvent A: Ethanol Max residual level: Ethanol < 0.5%	☒ solvent used ☐ solvent not used
We confirm solvent residual of this product complies with:	☒ EP5.4 ☒ USP <476> ☒ ICH Q3C(R7) ☒ Directive 2010/59/EU ☐ NA
We confirm Solvent residual statement is available	☒

9. Pesticide residual	
(according to EC 396/2005; EP07; USP <561>)	
This product is of vegetable origin	☒ Conforms ☐ Not Conforms
We confirm pesticide residual of this product complies with:	☒ EC 396/2005 ☒ EP 07/2008 ☒ USP<561> ☐ N/A
Pesticide residual statement available	☒

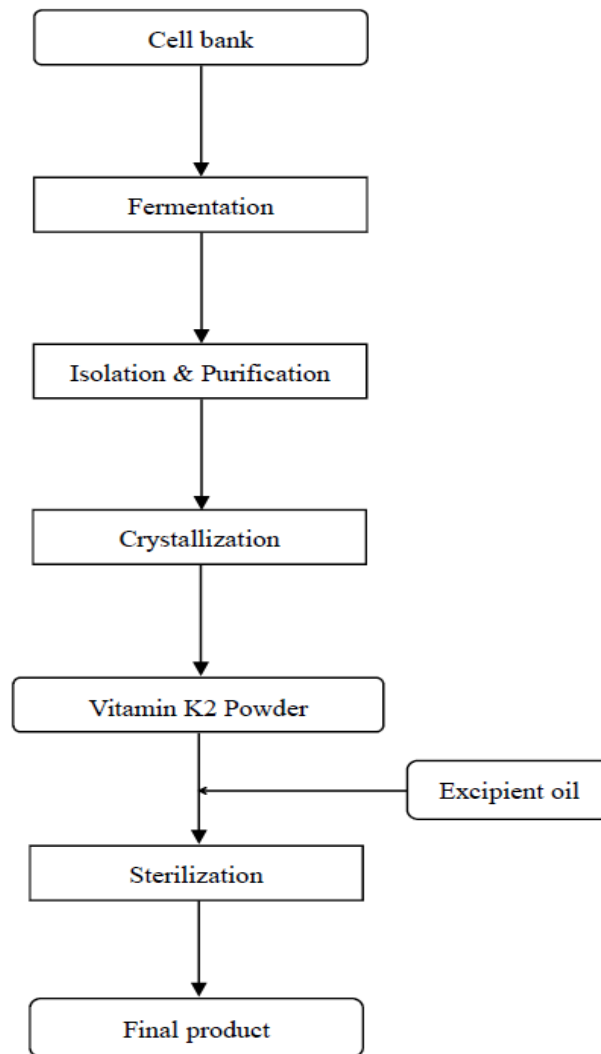
10. BSE/TSE information	
(according to EU legislation 999/2001; EP general chapter 5.2.8)	
Cattle, sheep, goats and animals that are naturally susceptible to infect with transmissible spongiform encephalopathy agents or susceptible to infection through the oral route other than humans and non-human primates are defined as “ESE-relevant animal species Pigs and birds are not naturally susceptible to infection via the oral route; therefore, they are not TSE-relevant animal species. Dogs, rabbits and fish are not TSE-relevant animal species.”	
the product contains no ingredients of ruminant origin and no materials derived from, or exposed to ruminants affected by or under quarantine for Transmitting Transmissible Spongiform Encephalopathy (TSE) / Bovine Spongiform Encephalopathy (BSE)	☒ Conforms ☐ Not Conforms ☐ NA
In the manufacturing of this product, there is no any raw or source material and /or reagent used that is of animal origin i.e. bovine, serum-albumin, enzymes, culture broths including those used to prepare working or master cell tanks	☒ Conforms ☐ Not Conforms
Equipment/systems/tools use for processing or storage of the material do not come into contact at any time with materials of animal origin (e.g., components of media filler used to check such system)	☒ Conforms ☐ Not Conforms

The material is not purified by using solvents, chromatographic media or buffers that contain components of animal origin	☒ Conforms ☐ Not Conforms
We confirm this product complies with:	☒ EU legislation 999/2001 & ☒ EP general chapter 5.2.8
We confirm BSE/TSE statement is available	☒ Conforms

11. Contaminants information (according to EU Regulation No 915/2023 and NO.629/2008 as regards maximum levels for certain contaminants in foodstuff)	
- Food supplements containing $\geq 80\%$ peanuts or oilseeds - Aflatoxins B1 ≤ 2.0 ppb - Aflatoxins B1+B2+G1+G2 ≤ 4.0 ppb - Other food supplements - Aflatoxins B1 ≤ 5.0 ppb - Aflatoxins B1+B2+G1+G2 ≤ 10.0 ppb - Food supplements, cocoa fibre, banana chips, dried herbs and dried spices - Ochratoxin A ≤ 5.0 ppb	☒ Conforms ☐ Not Conforms ☐ NA
Melamine	☒ Conforms
Applicable to: food supplements, cocoa fibre, banana chips, dried herbs and dried spices - Benzo(a)pyrene ≤ 1.0 ppb - The sum of PAH4 (PAH4; benzo[a]pyrene, chrysene, benz[a]anthracene and benzo[b]fluoranthene) ≤ 10.0 ppb	☒ Conforms ☐ Not Conforms ☐ NA
We confirm this product complies with Regulation (EU) 915/2023 and NO.629/2008 and keep compliance statement available	☒ Conforms

12. Others
We confirm we could meet with the requirement on hygiene of foodstuffs according to Reg 852/2004. We confirm we could meet with the requirement on general principles and requirements of food law according to REGULATION (EC) No 178/2002

FLOW CHART





Material Safety Data Sheet (MSDS)

1.	IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY	
	COMMON NAME	Vitamin K2 oil 5%
	COMPANY NAME	Confidential
2.	INFORMATION ON SUBSTANCE	
	PRINCIPAL-HAZARDOUS COMPONENT (S)	Non
	CAS No	2124-57-4
	APPEARANCE	Light yellow to yellow powder
3.	HAZARDS INFORMATION ON SUBSTANCE	
	HEALTH HAZARDS	No data available yet
	FIRE AND EXPLOSION HAZARDS	No data available yet
	ENVIRONMENTAL HAZARDS	No environmental hazards as far as to our knowledge.
4.	FIRST-AID MEASURES	
	INHALATION	Remove to well-ventilated area. Seek medical attention.
	SKIN CONTACT	Washed by soap water or clear water if it comes into contact with skin.
	EYE CONTACT	Washed by clear water if contacting with eyes. Sent to hospital if having excessive intake by mistake.
	INGESTION	Wash out mouth with water if conscious. Seek medical attention.
	PROTECT MEASURES	Wearing protective clothes and safety gloves when operating.
5.	FIRE-FIGHTING MEASURES	
	EXTINGUISHER MEDIA	Water Spray, Carbon Dioxide, Dry Chemical Powder or other appropriate form.
	SPECIAL FIRE FIGHTING PROCEDURES	Wear self-containing breathing apparatus against toxic fumes and protective clothing.
	FIRE & EXPLOSION	Not combustible, flammable or explosive. Emits toxic

HAZARDS	fumes under fire conditions.
6. ACCIDENTAL RELEASE MEASURES STEPS TO BE TAKEN IN CASE MATERIAL IS SPILLED OR RELEASED CLEANING METHODS WASTE DISPOSALS METHODS	Wear protective equipment. Sweep up, place in proper container for waste disposal, do not get water inside container. Avoid raising dust. Ventilate area & wash site after material pickup is complete. Wash premises, equipment and working surfaces with water. Dispose of as solid organic waste in accordance with national and local regulations
7. HANDLING & STORAGE HANDLING&STORAGE	Keep far away from kindled material, heat source and direct light. Keep the container airtight. Should be separately stored from oxidant and edible chemical compound.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION OCCUPATIONAL EXPOSURE LIMITS GB TWA: Not established D TWA: Not established USA TWA/TLV: Not established USA TWA/STEL: Not established VENTILATION PERSONAL PROTECTIVE EQUIPMENT	Local exhaust may be needed. Protective goggles, gloves. Coveralls, apron, boots. Respiratory protection with dust-filter may be needed.
9. PHYSICAL AND CHEMICAL PROPERTIES APPEARANCE BOILING POINT MELTING POINT AUTO-IGNITION TEMP. WATER SOLUBILITY FLASH POINT EXPLOSIVE LIMITS IN AIR	Off-white fine powder n.a. n.a. n.a. Part of water soluble n.a. n.a.
10. STABILITY & REACTIVITY STABILITY & REACTIVITY CONDITIONS TO AVOID	The compound is stable at room temperature in closed containers. Incompatible materials, light, dust generation, moisture, excess heat, strong oxidants.

	MATERIALS TO AVOID Oxidizing agents HAZARDOUS Carbon monoxide, carbon dioxide. DECOMPOSITION PRODUCTS
11.	TOXICOLOGICAL INFORMATION ACUTE ORAL LD50 Not known (MICE/RATS) IRRITATION TESTS (EYES) Not known INHALATION Not known
12.	ECOLOGICAL INFORMATION No Data available yet.
13.	DISPOSAL CONSIDERATIONS
14.	TRANSPORT INFORMATION UN UN No. Not classified as dangerous goods ADR Not restricted DGR Not restricted IMDG Not restricted
15.	REGULATORY INFORMATION Data not available
16.	OTHER INFORMATION Vitamin K2 OIL 5% has been proved no offensive smell, no infective danger or any other danger when transported. The information (including data and statements) in this Material Safety Data Sheet (MSDS) is based on experimental data and believed to be true and accurate as of the date issued. But all recommendations or suggestions are made without guarantee, since the conditions and methods of using the product and information referred to herein beyond the control of us. It is our policy, to assist our customers and to help solve particular problems, which may arise in applying our products.