Vitaquinone® 0.2% Maltodextrin Powder

Vitamin K2 as MK-7

PDS

Product Data Sheet

17.04.2025

Document is subject to updates

VITASYNTH sp. z o. o. 4G Macieja Rataja St., Koprki (05-850), Poland

Content

Section 1 Product Identity and Form

Product name	Vitaquinone® 0.2% Maltodextrin Powder, Vitamin K2 as MK-7
SKU code	V020PM
Chemical names	Menaquinone-7 (MK-7)
Common name	Vitamin K2
General product information	Synthetic Vitamin K2 as all-trans MK-7 in Maltodextrin powder for use in food and dietary supplements
Country of origin	Poland

Section 2 Responsible for Product Development, Research and Regulatory Affairs

Product developer, marketing responsible, IPR holder and regulatory affairs	Vitasynth sp. z o. o.
Office and postal address	4G Macieja Rataja Street 05-850 Koprki Poland
Telephone	+1 720 841 8837 - Americas +48 734 475 296 - Europe
Info	sales@vitaquione.eu
Web	www.vitaquinone.eu

Section 3 Manufacturing and Quality Assurance/Quality Control Information

QA/QC and control	Vitasynth is responsible for Vitamin K2 quality and control
Manufacturer	EuroPharma Alliance, ul. Al. LED 1, 55-020 Rzeplin, Poland (sister company of Vitasynth, CMO facility)
Manufacturing process	Pure K2 (as all-trans MK-7) vitamin is mixed with MCT oil in a prolonged process and controlled heating. The oil obtained in the process is combined with Maltodextrin. The powder concentrate is further mixed with Maltodextrin to a given concentration.
Manufacturing flow chart	See section 14
Quality Assurance Systems	See section 5 for details.
Certificates available upon request	
Irradiation or chemical sterilization	No irradiation or chemical sterilization is used during production. See section 6 Regulatory Status
Traceability system for product identity	In place
Last revision of QA/QC systems	2024

Section 4 Lot Number System, Product Storage, Packaging and Labelling Information

Packaging and labelling	Polyethylene Zip lock bag inside a silver, aluminum-based doypack with appropriate labelling
Storage conditions	The packaged product should be stored at 15-25°C / 59-77°F. Protect from light and excessive heat. The product is light sensitive, and exposure may deteriorate K2 activity considerably. Avoid excessive humidity.
Batch/lot numbering system	nYY n - production number in a given year starting from 0001 YY - given year
Label information	Product name and SKU code Batch no., manufacturing date & best before Handling precautions Vitasynth contact information
Recommended restriction / limitation on finished product label	Market specific labelling is implemented where required Vitamin K2 may counteract the effects of anticoagulation therapy, and therefore is not recommended for patients on blood-thinning medications. The maximal daily dose in food supplement of 0.2 mg should not be exceeded.

Section 5 Certifications and Compliance

Certification	Status	Third Party	Expiry
Kosher	Certified	EarthKosher	19.08.2025
Halal	Certified	Polish Institute of Halal	26.02.2026
Vegan	Certified	Vegan Society	19.06.2027
FDA	Statement	NA	NA
cGMP	Statement	NA	NA
HACCP	Certified	TÜV Rheinland	03.01.2026
ISO (FSSC22000)	Certified	TÜV Rheinland	03.01.2026
Non-GMO	Statement	NA	NA

Section 6 Regulatory Status and IPR

Compliance with Regulations

Vitaquinone® products are identical to already authorized under Regulation (EC) 258/97 novel foods and these authorizations are not data protected according to the requirements of Article 26 of Regulation (EU) 2015/2283. Therefore Vitaquinone® products have been placed in the EU market without a dedicated application. The specifications and conditions of use of Vitaquinone® products are in line with the authorized specifications and conditions of use as set out in the Union list of authorized novel foods and/or the implementing Regulations authorizing these substances in accordance with Implementing Regulation (EU) 2018/1023 of 23 July 2018 correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods.

Compliance to Regulations in Europe and the US

GMO	Complies with Regulation (EC) 1829/2003, including amended Directive 2001/18/EC
Ionizing radiation	Complies with Directive 1999/2/EC product has not been sterilized
Contaminants/toxins	Complies with Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food
Pesticides	Complies with Regulations (EC) 396/2005
Residual Solvents	Complies with good manufacturing practice, Directive 2009/32/EC and Ph. Eur. <2.4.24>/ USP <467> Residual Solvents requirements.
Palm, Soy	Free of palm and soy
Lactose, Gluten	Free of lactose or gluten
BSE/TSE*	Complies with good manufacturing practice and Regulation (EC) 999/2001.
Prop 65	Does not contain compounds listed in California Proposition 65
Nano material	No nanomaterial substances as per definition of Regulation (EU) 1169/2011
WADA	Do not contain any substances included in the prohibited list of the World Anti-Doping Agency (WADA)

Intellectual Property Rights/Patents Granted/Patent Pending

To the best of our knowledge, the product Vitaquinone®, Vitamin K2 as MK-7 does not infringe any patent rights, rights in inventions, copyright and related rights in information (including protected know-how, confidentiality and trade secrets) ("IPRs"), belonging to a third party based on the comprehensive overview of the patents' situation (granted and pending) in Europe.

Tariff Code, FDA Registration and Compendial Standard

EU export tariff code	2936 29 00 00
US import tariff code	2936 29 50 50
U.S. FDA Registration Vitasynth No.	18752137180
DUNS Vitasynth No.	425446420
Compendial standard	USP monograph for menaquinone-7 and in-house methods

Section 7 Food Safety System

Vitaquinone® Product, Vitamin K2 as MK-7 is a generic of the well-established and safe for human consumption original active ingredient, which has achieved GRAS in USA and novel food status in EU. The product is intended for use in the manufacturing of food products, including food supplements. Our process ensures the best quality and accordance to European novel food specification, being accepted by the Health Authorities as a reference for the manufacturers.

Section 8 Origin and Composition

Name ingredient	CAS	2000 ppm	Origin	GMO status
Menaquinone-7	2124-57-4	0.2%	Chemical synthesis	non-GMO
Medium chain triglyceride oil (MCT)	73398-61-5	1.8%	Vegetable origin	non-GMO
Maltodextrin	9050-36-6	98.0%	Vegetable origin	non-GMO

Section 9 Nutritional Profile

Component	Typical value per 100 g*
Total calories	388.7 Kcal
Total fat	1.8 g
whereof saturated fatty acids	1.8 g
whereof monounsaturated fatty acids	0.0 g
whereof polyunsaturated fatty acids	0.0 g
Carbohydrates	93.0 g
Sugar	7.0 g
Fiber	0.0 g
Protein	0.0 g
Salt	0.0 mg
Vitamin K2 as MK7	2000 ppm

* Based on theoretical calculations

Section 10 Allergens on Production Line

Free from allergens in compliance with EU Directive 1169/2011 Annex II

Raw material/allergen	Presence in Vitaquinone® Product	Presence in production line for other products
Cereals containing gluten[1] and products thereof	No	No
Crustaceans and products thereof	No	No
Eggs and products thereof	No	No
Fish and products thereof	No	Yes
Peanuts and products thereof	No	No
Soybeans and products thereof	No	Yes
Milk and products thereof (including lactose)	No	Yes
Nuts[2] and products thereof	No	No
Celery and products thereof	No	No
Mustard and products thereof	No	No
Sesame seeds and products thereof	No	No
Sulphur dioxide and sulphites[3]	No	No
Lupin and products thereof	No	No
Mollusks and products thereof	No	No

[1] namely: wheat, rye, barley, oats, spelt, kamut or their hybridized strains.
[2] namely: almonds (Amygdalus communis L.), hazelnuts (Corylus avellana), walnuts (Juglans regia), cashews (Anacardium occidentale), pecan nuts (Carya illinoinensis (Wangenh.) K. Koch), Brazil nuts (Bertholletia excelsa), pistachio nuts (Pistacia vera), macadamia or Queensland nuts (Macadamia ternifolia)
[3] at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO_2 which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers

Section 12 Product Specification

Product name	Vitaquinone® 0.2% Maltodextrin Powder, Vitamin K2 as MK-7
SKU codes:	V020PM
Vitamin K2 content	NLT 2mg K2 (as all-trans MK-7)/g
Packaging	1kg or 5kg of Product in doypack pouches
Specification code	SPK/KJ/024 Rev. 01

TESTS	REQUIREMENTS	METHOD
Description	Light yellow powder	Visual assessment
Identification		
HPLC	Corresponds to the standard HPLC profile	UPLC method*/USP method** ANL/KJ/010
Vitamin K2 (as all-trans MK7) assay	> 0.20 % or > 2 000 ppm	UPLC method*/USP method** ANL/KJ/010
Limit of Menaquinone-6	Absent	UPLC method*/USP method** ANL/KJ/010
Related substances		
Single unknown impurity	≤ 1.0 %	UPLC method* ANL/KJ/010
Total impurities	≤ 1.5 %	
Isomeric purity		
Content of cis-menaquinone-7	≤ 1.0 %	USP method** ANL/KJ/010
Particle size	> 90 % passes through 30 mesh	PB-264 rev.1*
Bulk density	0.30–0.50 g/ml	Ph. Eur. <2.9.34> / USP <616>
Loss on drying	≤ 6.0 %	Ph. Eur. <2.2.32> / USP<713>
Metal content		
Arsenic	≤ 0.5 ppm	PN-EN-15763:2010
Cadmium	≤ 0.3 ppm	
Lead	≤ 0.5 ppm	
Mercury	≤ 0.1 ppm	
Microbiological parameters		
TAMC in 1g	≤ 1 x 10^3 CFU	Ph. Eur. <2.6.12>/USP <2021>
TYMC in 1g	≤ 1 x 10^2 CFU	Ph. Eur. <2.6.12>/USP<2021>
E. Coli in 1g	Absent	Ph. Eur. <2.6.13>/USP <2022>
Salmonella in 25 g	Absent	Ph. Eur. <2.6.13>/USP <2022>
Staphylococcus aureus in 1g	Absent	Ph. Eur. <2.6.13>/USP <2022>
Bile tolerant gram-negative bacteria in 1g ***	≤ 1 x 10^2 CFU	Ph. Eur. <2.6.13>/USP <2021>

* in-house method

** in accordance with Dietary Supplement Monograph, Menaquinone-7 Preparation, USP-NF

*** bile tolerant gram-negative bacteria include *Enterobacteriaceae*, *Pseudomonas* and *Aeromonas*

Shelf life, storage and handling

30 months from manufacture. The product should be stored at temperature 15-25°C / 59-77°F, in a dry place. Protect from light.

Section 13 Certificate of Analysis

Vitaquinone

CERTIFICATE OF ANALYSIS

Product name	Vitaquinone® 0.2% Maltodextrin Powder, Vitamin K2 as MK-7
SKU code	V020PM
Batch number	
Best before	30 months from manufacture
Manufacturing date	
Expiry date	
Storage	The product should be stored at temperature 15-25°C /59-77°F, in a dry place. Protect from light.
Product specification code	SPK/KJ/024 Rev.01

TESTS	REQUIREMENTS	METHOD	RESULTS
Description	Light yellow powder	Visual	
Identification	Corresponds to the standard HPLC profile	UPLC method* / USP method** ANL/KJ/010	
Vitamin K2 (as all-trans MK-7) assay	> 0.20 % or > 2 000 ppm	UPLC method* / USP method** ANL/KJ/010	
Limit of Menaquinone-6	Absent	UPLC method* / USP method** ANL/KJ/010	
Related substances			
Single unknown impurity	≤ 1.0 %	UPLC method* ANL/KJ/010	
Total impurities	≤ 1.5 %		
Isomeric purity			
Content of cis-menaquinone-7	≤ 1.0 %	USP method** ANL/KJ/010	
Particle size	> 90% passes through 30 mesh	PB-264 rev.1*	
Bulk density	0.30 – 0.55 g/ml	Ph.Eur<2.9.34>/USP<616>	
Loss on drying (105°C/ 4h)	≤ 6.0 %	Ph.Eur.<2.2.32>/USP<731>	
Metal content			
Arsenic	≤ 0.5 ppm		
Cadmium	≤ 0.3 ppm	PN-EN 15763:2010	
Lead	≤ 0.5 ppm		
Mercury	≤ 0.1 ppm		
Microbiological parameters			
TAMC in 1g	≤ 1 x 10^3 CFU	Ph. Eur. <2.6.12> / USP <2021>	
TYMC in 1g	≤ 1 x 10^2 CFU	Ph. Eur. <2.6.12> / USP <2021>	
E. Coli in 1g	Absent	Ph. Eur. <2.6.13> / USP <2022>	
Salmonella in 25 g	Absent	Ph. Eur. <2.6.13> / USP <2022>	
Staphylococcus aureus in 1g	Absent	Ph. Eur. <2.6.13> / USP <2022>	
Bile tolerant G(-) bacteria* in 1g**	≤ 1 x 10^2 CFU	Ph. Eur. <2.6.13> / USP <2021>	

* in-house method
** in accordance with Dietary Supplement Monograph, Menaquinone-7 Preparation, USP-NF
*** bile tolerant gram negative bacteria include *Enterobacteriaceae, Pseudomonas* and *Aeromonas*

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Section 14 Flowchart