

# **Pharmaquinone® 0.15% MCT Oil**

## **Vitamin K2 as MK-7**

Made with 100% Organic Coconut oil (MCT)

# **PDS**

## **Product Data Sheet**

14.01.2026

Document is subject to updates

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## Section 1 Product Identity and Form

Product name	Pharmaquinone® 0.15% MCT Oil, Vitamin K2 as MK-7
SKU code	015L
Chemical names	Menaquinone-7 (MK-7)
Common name	Vitamin K2
General product information	Synthetic Vitamin K2 as MK-7 in medium chain triglyceride oil from coconuts 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,	Vitasynth sp. z o. o.
IPR holder and regulatory affairs	
Office and postal address	4G Macieja Rataja Street 05-850 Koprki Poland
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Info	<a href="mailto:sales@pharmaquinone.com">sales@pharmaquinone.com</a>
Web	<a href="http://www.pharmaquinone.com">www.pharmaquinone.com</a>

## 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 vitamin is mixed with MCT oil in a prolonged process and controlled heating. The oil obtained in the process is further mixed with MCT oil to a given concentration.
Manufacturing flow chart	See section 13.
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 system	2025

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

Packaging and labelling	Aluminum, silver bottle, with white closure with warranty ring and LDPE/ALU/LDPE wad with appropriate labeled.
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 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
Kosher	Certified	EarthKosher
Halal	Certified	Polish Institute of Halal
Vegan	Certified	Vegan Society
FDA	Statement	NA
cGMP	Statement	NA
HACCP	Certified	TÜV Rheinland
ISO (FSSC22000)	Certified	TÜV Rheinland
Non-GMO	Statement	NA

## Section 6 Regulatory Status and IPR

### Compliance with Regulations

Pharmaquinone® 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 Pharmaquinone® products have been placed in the EU market without a dedicated application. The specifications and conditions of use of Pharmaquinone® 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 Regulation (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)

## Stability Protocol

Stability program follows ICH Guideline to meet market specific requirements.

Product name: Pharmaquinone® 0.15% MCT Oil Vitamin K2 as MK-7			Batch no.: 015L2101-1	Mfg. date: 09.2021	Expiry date: 09.2024	Packaging: aluminum bottles					
Study: Long term Time period: 36 months	Storage condition: 25 ± 2°C 60 ± 5% RH	Time period covered by data at submission: 36 months									
TESTS	REQUIREMENTS	METHOD	Result (0M)	Result (3M)	Result (6M)	Result (9M)	Result (12M)	Result (18M)	Result (24M)	Result (30M)	Result (36M)
Description	Light yellow to yellow oil	Visual assessment	Comply	Comply	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Assay of vitamin K2 (MK7)	Not less than 90.0 % of the labelled amount (1500 ppm)	UPLC method	106.1 %	105.4 %	105.8 %	105.9 %	108.3 %	104.0 %	106.1 %	106.6 %	105.5 %
Assay of vitamin K2 (MK7)	Not less than 90.0 % of the labelled amount (1500 ppm)	USP method	104.3 %	105.7 %	105.2 %	108.5 %	105.5 %	106.2 %	105.8 %	105.6 %	106.6 %
Related substances Total impurities	Not more than 1.5 %	UPLC method	0.13 %	0.47 %	0.46 %	0.40 %	0.37 %	0.45 %	0.40 %	0.38 %	0.42 %
Isomeric purity Content of cis-menaquinone-7	Not more than 1.0 %	USP method	Not detected	Not detected	Not detected	Not detected	Not detected	Not detected	Not detected	Not detected	Not detected

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## Intellectual Property Rights/Patents Granted/Patent Pending

To the best of our knowledge, the Product Pharmaquinone®, 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

Pharmaquinone® 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	1500ppm	Origin	GMO status
Menaquinone-7	2124-57-4	0.15%**	Chemical synthesis	non-GMO
Medium chain triglyceride oil (MCT)*	73398-61-5	99.85%**	Vegetable origin	non-GMO

\* 100% MCT Oil coconut based, organic.

\*\*The actual values may vary slightly due to the applied technological coverage of MK-7.

## Section 9 Nutritional Profile

Component	Typical value per 100 g *
Total calories	898.5 Kcal
Total fat	99.8 g
whereof saturated fatty acids	99.8 g
whereof monounsaturated fatty acids	0.0 g
whereof polyunsaturated fatty acids	0.0 g
Carbohydrates	0.0 g
Sugar	0.0 g
Fiber	0.0 g
Protein	0.0 g
Salt	0.0 mg
Vitamin K2 as MK7	1500 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 Pharmaquinone® Product	Presence on production line for other products
Cereals containing gluten <sup>1</sup> 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	No
Milk and products thereof (including lactose)	No	No
Nuts <sup>2</sup> 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 <sup>3</sup>	No	No
Lupin and products thereof	No	No
Mollusks and products thereof	No	No

<sup>1</sup> namely: wheat, rye, barley, oats, spelt, kamut or their hybridized strains.

<sup>2</sup> 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*)

<sup>3</sup> at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO<sub>2</sub> which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers

## Section 11 Product Specification

Product name	Pharmaquinone® 0.15% MCT Oil, Vitamin K2 as MK-7
SKU codes	015L
Vitamin K2 content	NLT 1.5mg (K2 as MK-7)/g
Packaging	1kg or 5 kg of Product in aluminum bottle
Specification code	SPK/KJ/002 Rev. 07

TESTS	REQUIREMENTS	METHOD
<b>Description</b>	Light yellow oil	Visual assessment
<b>Identification</b>		
HPLC	Corresponds to the standard HPLC profile	UPLC method*/USP method** ANL/KJ/009
Vitamin K2 (as all-trans MK7) assay	> 0.15 % or > 1500 ppm	UPLC method*/USP method** ANL/KJ/009
<b>Limit of Menaquinone-6</b>	Absent	UPLC method*/USP method** ANL/KJ/009
<b>Related substances</b>		
Single unknown impurity	≤ 1.0 %	UPLC method* ANL/KJ/009
Total impurities	≤ 1.5 %	
<b>Isomeric purity</b>		
Content of cis-menaquinone-7	≤ 1.0 %	USP method** ANL/KJ/009
<b>Density (in 20°C)</b>	0.930-0.960 g/ml	PN-EN ISO 6883:2017-03
<b>Metal content</b>		
Arsenic	≤ 0.5 ppm	
Cadmium	≤ 0.3 ppm	PN-EN 15763:2010
Lead	≤ 0.5 ppm	
Mercury	≤ 0.1 ppm	
<b>Microbiological parameters</b>		
TAMC in 1g	≤ 1 x 10 <sup>3</sup> CFU	Ph. Eur. <2.6.12> / USP <2021>
TYMC in 1g	≤ 1 x 10 <sup>2</sup> 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 <sup>2</sup> 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

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

## Section 12 Certificate of Analysis



### CERTIFICATE OF ANALYSIS

<b>Product name</b>	Pharmaquinone® 0.15% MCT Oil, Vitamin K2 as MK-7		
<b>SKU code</b>	015L		
<b>Batch number</b>			
<b>Best before</b>	36 months from manufacture		
<b>Manufacturing date</b>			
<b>Expiry date</b>			
<b>Storage</b>	The product should be stored at temperature 15-25°C / 59-77°F, in a dry place. Protect from light.		
<b>Product specification code</b>	SPK/KJ/002 Rev.07		
TESTS	REQUIREMENTS	METHOD	RESULTS
<b>Description</b>	Light yellow to yellow oil	Visual	
<b>Identification</b>	Corresponds to the standard HPLC profile	UPLC method* / USP method** ANL/KJ/009	
<b>Vitamin K2 (as all-trans MK-7) assay</b>	> 0.15 % or > 1500 ppm	UPLC method* / USP method** ANL/KJ/009	
<b>Limit of Menaquinone-6</b>	Absent	UPLC method* / USP method** ANL/KJ/009	
<b>Related substances</b> <b>Single unknown impurity</b>	≤ 1.0 %	UPLC method* ANL/KJ/009	
<b>Total impurities</b>	≤ 15 %		
<b>Isomeric purity</b> <b>Content of cis-menaquinone-7</b>	≤ 1.0 %	USP method* ANL/KJ/009	
<b>Density (in 20°C)</b>	0.930 – 0.960 g/ml	PN-EN ISO 6883:2017-03	
<b>Metal content</b> <b>Arsenic</b> <b>Cadmium</b> <b>Lead</b> <b>Mercury</b>	≤ 0.5 ppm ≤ 0.3 ppm ≤ 0.5 ppm ≤ 0.1 ppm	PN-EN 15763:2010	
<b>Microbiological parameters</b> <b>TAMC in 1g</b> <b>TYMC in 1g</b> <b>E. Coli in 1g</b> <b>Salmonella in 25 g</b> <b>Staphylococcus aureus in 1g</b> <b>Bile tolerant G(-) bacteria** in 1g</b>	≤ 1 x 10 <sup>3</sup> CFU ≤ 1 x 10 <sup>3</sup> CFU Absent Absent Absent ≤ 1 x 10 <sup>3</sup> CFU	Ph. Eur. <2.6.12> / USP <2021> Ph. Eur. <2.6.12> / USP <2021> Ph. Eur. <2.6.13> / USP <2022> Ph. Eur. <2.6.13> / USP <2022> Ph. Eur. <2.6.13> / USP <2022> Ph. Eur. <2.6.13> / USP <2021>	

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



## Section 13 Flowchart

