Pharmaquinone
vitamin k2 revolution

Pharmaquinone® 99% Active Ingredient

Vitamin K2 as MK-7

PDS

Product Data Sheet

14.01.2026
Document is subject to updates

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

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Content

Section 1 Product Identity and Form

Product name	Pharmaquinone® 99% Active Ingredient, Vitamin K2 as MK-7
SKU code	K2MK7
CAS number	2124-57-4
Chemical names	Menaquinone-7 (MK-7)
Common name	Vitamin K2
General product information	Synthetic Vitamin K2 as all-trans MK-7 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	+48 734 475 296
Info	sales@pharmaquinone.com
Web	www.pharmaquinone.com

Section 3 Manufacturing and Quality Assurance/Quality Control Information

QA/QC and control	Vitasynth Sp. z o.o.
Manufacturer	Vitasynth Sp. z o.o.
Manufacturing process	Multi-stage organic synthesis of vitamin MK7 from menadione, geraniol and farnesol
Manufacturing flow chart	See section 13
Quality Assurance Systems	See section 5 for details
Certificates available upon request	
Residual solvent in accordance	See section 6 for details
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	2025

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

Packaging and labelling	HDPE bottles (high density polyethylene) intended for contact with food, protecting light-sensitive contents.
Storage conditions	The packaged product should be stored at 5-25°C/ 41-77°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	APIyymm-n API – the Active Powder Ingredient yymm - the date format (year, month) n -production number of the month
Label information	Product name and SKU code. Batch no., manufacturing date & retest date. 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
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 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)

Stability Protocol

Stability program follows ICH Guideline to meet market specific requirements.

Product name: Pharmaquinone 99% Active Ingredient Vitamin K2 as MK-7	**Batch number:** RD-S01-MK7-2020.05.08	**Mfg. date:** 05.2020	**Retest date:** 05.2023	**Packaging:** HDPE containers

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 (36M)**
Description	Yellow crystalline powder	Visual assessment	Comply	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Assay of vitamin K2 (MK7)	Not less than 99.0 % - not more than 101.0 %	UPLC method	100.75 %	100.48 %	100.65 %	100.33 %	100.61 %	100.25 %	99.96 %	99.84 %
Assay of vitamin K2 (MK7)	Not less than 99.0 % - not more than 101.0 %	USP method	100.49 %	100.72 %	100.72 %	100.46 %	100.34 %	100.37 %	99.65 %	99.50 %
Related substances Total impurities	Not more than 1.00 %	UPLC method	0.21 %	0.17 %	0.19 %	0.22 %	0.21 %	0.22 %	0.28 %	0.27 %
Isomeric purity Content of cis-menaquinone-7	Not more than 1.00 %	USP method	Not detected	Not detected	Not detected	Not detected	Not detected	Not detected	Not detected	Not detected
Loss on drying	Not more than 0.50 %	Ph. Eur.<2.2.32>	0.09 %	0.11 %	0.00 %	0.00 %	0.05 %	0.12 %	0.29 %	0.11 %

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.	25446420
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	Origin	CAS	Concentration	Manufacturer	GMO status
Menaquinone-7	Chemical synthesis	2124-57-4	NLT 99%	Vitasynth	non-GMO

Section 9 Nutritional Profile

Component	Typical value per 100 g
Total calories	NA
Total fat	NA
whereof saturated fatty acids	NA
whereof monounsaturated fatty acids	NA
whereof polyunsaturated fatty acids	NA
Carbohydrates	NA
Sugar	NA
Fiber	NA
Protein	NA
Salt	NA
Vitamin K2 as MK7	NLD 99%

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[1] and products thereof	No	No
Crustaceans and products thereof	No	No
Eggs and products thereof	No	No
Fish and products thereof	No	No
Peanuts and products thereof	No	No
Soybeans and products thereof	No	No
Milk and products thereof (including lactose)	No	No
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
Molluscs 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

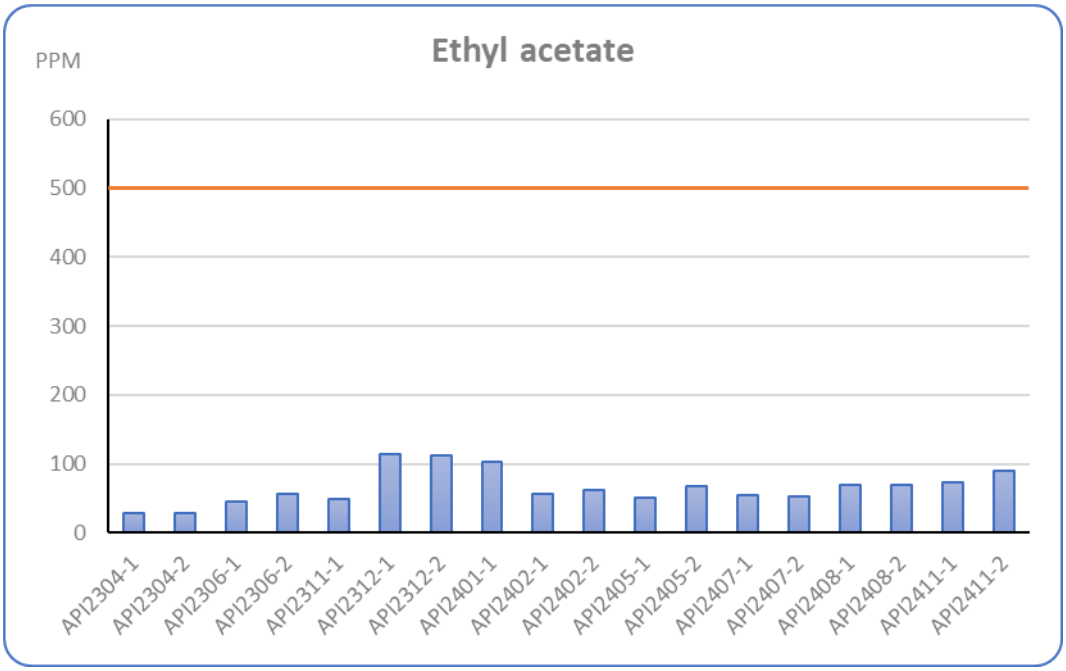
Section 11 Product Specification

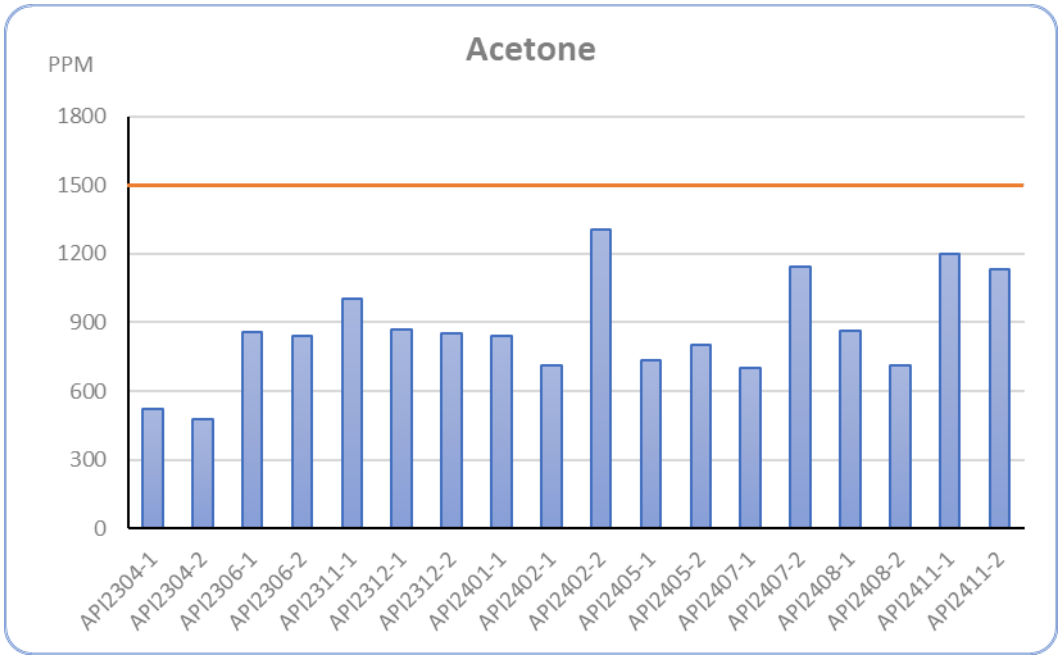
Product name	Pharmaquinone®99% Active Ingredient. Vitamin K2 as MK-7
SKU codes	K2MK7
Vitamin K2 content	NLT 99.0% K2 as all-trans MK-7
Packaging	HDPE bottles intended for contact with food, protecting light-sensitive contents
Specification code	SPK/KJ/001 Rev. 09

TESTS	REQUIREMENTS	METHOD
Description	Yellow crystalline powder	Visual assessment
Identification		
IR	Corresponds to the standard IR spectrum	IR method*** ANL/KJ/007
HPLC	Corresponds to the standard HPLC profile	UPLC method*/USP method** ANL/KJ/007
Vitamin K2 (as all-trans MK7) assay (calculated on the as-is basis)	99.0 % - 101.0 %	UPLC method*/USP method** ANL/KJ/007
Limit of Menaquinone-6	Absent	UPLC method*/USP method** ANL/KJ/007
Related substances		
Single unknown impurity	≤ 0.5 %	UPLC method* ANL/KJ/007
Total impurities	≤ 1.0 %	
Isomeric purity		
Content of cis-menaquinone-7	≤ 1.0 %	USP method** ANL/KJ/007
Loss on drying	≤ 0.5 %	TGA method*** ANL/KJ/007
Sulphated ash	≤ 0.1 %	Ph. Eur. <2.4.14>
Residual solvents		
Acetone	≤ 1500 ppm	GC method**** ANL/KJ/007
Ethyl acetate	≤ 500 ppm	
Metal content		
Arsenic	≤ 0.5 ppm	ICP-MS method*** ANL/KJ/007
Cadmium	≤ 1 ppm	
Lead	≤ 3 ppm	
Mercury	≤ 0.1 ppm	

* in-house UPLC method based on *J. Pharm. Biomed. Anal. 135, 116-125*
** in accordance with Dietary Supplement Monograph, Menaquinone-7, USP-NF
*** in-house method
**** in-house method, validated according to ICH Guideline Q3C(R9) and Q2(R2)

Typical profile of residual solvents





Shelf life. storage and handling

36 months from manufacture. The product should be stored at temperature 5-25°C / 41-77°F, in a dry place. Protect from light.

Section 12 Certificate of Analysis

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Certificate of analysis

Product name	Pharmaquinone® 99% Active Ingredient, Vitamin K2 as MK-7
SKU code	K2MK7
Batch number	
Retest date	36 months from manufacture
Manufacturing date	
Expiry date	
Storage	The product should be stored at temperature 5-25°C / 41-77°F, in a dry place. Protect from light.
Product specification code	SPK/KJ/001 rev.09

TESTS	REQUIREMENTS	METHOD	RESULTS
Description	Yellow crystalline powder	Visual assessment	
Identification **IR**	Corresponds to the standard IR spectrum	IR method*** ANL/KJ/007	
HPLC	Corresponds to the standard HPLC profile	UPLC method* / USP method** ANL/KJ/007	
Vitamin K2 (as all-trans MK-7) assay (calculated on the as-is basis)	99.0 % - 101.0 %	UPLC method* / USP method** ANL/KJ/007	
Limit of Menaquinone-6	Absent	UPLC method* / USP method** ANL/KJ/007	
Related substances Single unknown impurity	≤ 0.5 %	UPLC method* ANL/KJ/007	
Total impurities	≤ 1.0 %		
Isomeric purity Content of cis-menaquinone-7	≤ 1.0 %	USP method** ANL/KJ/007	
Loss on drying	≤ 0.5 %	TGA method*** ANL/KJ/007	
Sulphated ash	≤ 0.1 %	Ph. Eur. <2.4.14>	
Residual solvents Acetone Ethyl acetate	≤ 1500 ppm ≤ 500 ppm	GC method**** ANL/KJ/007	
Heavy metals Arsenic Cadmium Lead Mercury	≤ 0.5 ppm ≤ 1 ppm ≤ 3 ppm ≤ 0.1 ppm	ICP-MS method*** ANL/KJ/007	

* in-house method based on J. Pharm. Biomed. Anal. 135, 116–125
** in accordance with Dietary Supplement Monograph, Menaquinone-7. USP-NF
*** in-house method
**** in-house method, validated according to ICH Guideline Q3C(R9) and Q2(R2)

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Section 13 Flow chart

1. Starting materials: Farnesol, Geraniol Acetate, Menadione
2. Multi-stage organic synthesis (c.a. 25 unit process), comprising multiple purification process like chromatography, crystalization or destillation
3. Final synthetic step - oxidation of intermediate product to MK7
4. Chromatography - initial purification of raw MK7
5. Crystalization - final purificartion of MK7
6. Filtration of MK7 and washing filtration cake
7. Drying of MK7
8. Shredding and sieving of MK7 crystal
9. Analysis and certification of MK7
10. Packing
11. Warehousing and distribution