Pharmaquinone
vitamin k2 revolution

Pharmaquinone®0.45% Olive Oil

Vitamin K2 as MK-7

PIDS

Product Information Data Sheet

February 2023

Replacing September 2022

Document is subject to updates

Pharmaquinone
vitamin k2 revolution

Table of Contents

Section 1	Product Identity and Form
Product name	Pharmaquinone®0.45% Olive Oil Vitamin K2 as MK-7
SKU code	045L
Chemical names	Menaquinone-7 (MK-7)
Common name	Vitamin K2
General product information	Synthetic Vitamin K2 as MK-7 in olive oil 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	2 Szałwiowa Street 03-167 Warsaw Poland
Telephone	+48 22 602 22 29
Info	sales@pharmaquinone.com
Web	www.pharmaquinone.com

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 olive oil in a prolonged process and controlled heating. The oil obtained in the process is further mixed with olive oil to a given concentration
Manufacturing flow chart	See section 14
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
SDS	See section 15
Last revision of QA/QC systems	2023

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, which is co-packed in the aluminum-based and appropriate labeled doypack packaging
Storage conditions	The packaged product should be stored at 15-25°C / 59-77°F and 30-50% humidity. Protect from light and excessive heat. The product is very light sensitive and exposure may deteriorate K2 activity considerably. Avoid excessive humidity.
Batch/lot numbering system	045L2206-1 045L - the product SKU code yy.mm - the date format 1st batch of the month
Label information	Product name and SKU code Batch no., manufacturing date & best before Handling precautions VitaSynth contact information Icons identifying certifications such as Kosher or Halal status
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	18.08.2023
Halal	Certified	HFCE	31.01.2024
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

* See section 16

Section 6 Regulatory Status and IPR

Compliance with Regulations

Pharmaquinone® Products are identical to already authorised under Regulation 258/1997/EC novel foods and these authorizations are not data protected according to the requirements of Article 26 of Regulation EU 20015/2283. 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 authorised specifications and conditions of use as set out in the Union list of authorised novel foods and/or the implementing Regulations authorizing these substances in accordance to COMMISSION 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 EU Regulation No 1829/2003, including amended EU Directive 2001/18/EC
Ionizing radiation	Complies with EU Directive 1999/2/EC. Product has not been sterilized
Contaminants/toxins	Complies with Regulation (EC) No. 1881/2006 setting maximum levels for certain contaminants in foodstuffs and amendments as per (EC) No 629/2008 of 2 July 2008

Pesticides	Complies with EU Regulations (EC) No 396/2005, including amended EU Directive 91/414/EEC
Residual Solvents	Complies with good manufacturing practice, EU Directive 2009/32/EC and Ph. Eur. p. 2.4.24 / USP <467> Residual Solvents requirements
BSE/TSE*	Complies with good manufacturing practice and EU Regulation (EC) No 999/2001.
Prop 65	Does not contain compounds listed in California Proposition 65
Nano material	No nanomaterial substances as per definition of EU REG.1169/2011
WADA	Do not contain any substances included in the prohibited list of the World Anti-Doping Agency (WADA)

* See section 16

Stability Protocol

Stability program follows ICH Guideline to meet market specific requirements.

Product name: Pharmaquinone®0.45 % Olive Oil, Vitamin K2 as MK-7			**Batch No.:** 020222DT	**Mfg. date:** 02.2022		**Exp. date:** 08.2023
Study: Accelerated Time period: 6 months	**Storage condition: 40°C ± 2°C/ 75% RH ± 5% RH**		**Time period covered by data at submission: 6 months**			
TESTS	**REQUIREMENTS**	**METHOD**	**Result (0M)**	**Result (1M)**	**Result (3M)**	**Result (6M)**
1. Description	Light yellow to dark yellow oil	Visual assessment	Comply	Comply	Comply	Comply
2. Assay of vitamin K2 (MK7)	90.0%–120.0% of the labeled amount (ppm)	HPLC method	99.4 %	99.1 %	100.4 %	94.5 %
3. Isomeric purity Content of cis-menaquinone-7	≤ 2.0 %	HPLC method	Not detected	Not detected	Not detected	Not detected
4. Microbiological parameters						
TAMC in 1g	≤ 1 x 10^3 CFU	Ph. Eur. / USP	< 1 x 10^1 CFU	Not applicable	Not applicable	< 1 x 10^1 CFU
TYMC in 1g	≤ 1 x 10^2 CFU		< 1 x 10^1 CFU			< 1 x 10^1 CFU
E. Coli in 1g	Absent		Absent			Absent
Salmonella in 25 g	Absent		Absent			Absent
Staphylococcus aureus in 1g	Absent		Absent			Absent
Bile tolerant gram negative bacteria** in 1g	≤ 1 x 10^2 CFU		< 1 x 10^1 CFU			< 1 x 10^1 CFU

** Bile tolerant gram negative bacteria inclide enterobacteriaceae, pseudomonas and aeromonas

Intellectual Property Rights/Patents Granted/Patent Pending

To whom it may concern,

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.

Yours faithfully,

Vitasynth Sp. z o.o.
ul. Szałwiowa 2
03-167 Warszawa
NIP 6772335293, REGON 121072974

Name: Elżbieta Filutowska

Designation: Quality Department

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

To whom it may concern,

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.

Yours faithfully,

Vitasynth Sp. z o.o.
ul. Szałwiowa 2
03-167 Warszawa
NIP 6772335293, REGON 121072974

Name: Elżbieta Filutowska

Designation: Quality Department

Section 8	Origin and Composition			
Name ingredient	CAS	4 500 ppm	Origin	GMO status
Menaquinone-7	2124-57-4	0.45%	Chemical synthesis	non-GMO
Olive oil extra virgin	8001-25-0	~98.5%	Vegetable origin	non-GMO
Natural vitamin E	59-02-9	~0.8%	Vegetable origin	non-GMO
Rosemary extract	84604-14-8	~0.2%	Vegetable origin	non-GMO

Section 9 Nutritional Profile*

To whom it may concern,

VitaSynth does not test for nutritional data. Products Pharmaquinone®, Vitamin K2 as MK-7 typically do not contribute to the nutritional value of food and dietary supplements due to their extremely low usage levels and therefore fall under the nutritional labeling exemption defined in Section 101.9(a) and (j) of Title 21 of the Code of Federal Regulations, and Annex V of Regulation (EU) No 1169/2011.

Yours faithfully,

Vitasynth Sp. z o.o.
ul. Szałwiowa 2
03-167 Warszawa
NIP 6772335293, REGON 121072974

Name: Elżbieta Filutowska

Designation: Quality Department

*Based on theoretical calculations

Component	Typical value per 100 g
Total calories	739,95 Kcal
Total proteins	0 g
Total fat	89.8 g
Dietary fiber	0 g
Total sugars	0 g
Carbohydrates	0 g
Salt	0 g
Vitamin E	0 g
Vitamin K2 as MK7	4 500 ppm

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	Yes
Crustaceans and products thereof	No	Yes
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	Yes
Lupin and products thereof	No	No
Molluscs and products thereof	No	Yes

Your faithfully,

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Name: Elżbieta Filutowska

Designation: Quality Department

[1] namely: wheat, rye, barley, oats, spelt, kamut or their hybridised 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 Free from Allergen Statement

To whom it may concern,

In compliance with EU Directive 1169/2011 Annex II

1. Cereals containing gluten
2. Crustaceans and products thereof
3. Eggs and products thereof
4. Fish and products thereof
5. Peanuts and products thereof
6. Soybeans and products thereof
7. Milk and products thereof (including lactose)
8. Nuts and products thereof
9. Celery and products thereof
10. Mustard and products thereof
11. Sesame seeds and products thereof
12. Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO2
13. Lupin and products thereof
14. Molluscs and products thereof

Your faithfully,

Vitasynth Sp. z o.o.
ul. Szałwiowa 2
03-167 Warszawa
NIP 6772335293, REGON 121072974

Name: Elżbieta Filutowska

Designation: Quality Department

Section 12 Product Specification

Product name	Pharmaquinone® 0.45% Olive Oil Vitamin K2 as MK-7
SKU codes:	045L
Vitamin K2 content	NLT 4.500 mcg K2 as MK-7/g
Packaging	1 kg or 5 kg of Product in aluminium bottle with tamper evident PP screw cap closure with foam/aluminium liner and LDPE plug

Tests	Requirements	Method
Appearance	Light yellow to yellow oil	Visual assessment
Identification	Corresponds to the standard HPLC profile	UPLC method* / USP <621>
Total Vitamin K2 as MK-7	> 0.45% or > 4 500 ppm	UPLC method*
Related substances **Single unknown impurity** **Total impurities**	 ≤ 1.0% ≤ 1.5%	UPLC method*
Isomeric purity **Content of cis-menaquinone-7**	 ≤ 1.0%	 USP <621>
Density (in 20˚C)	0.915 +/- 5% g/ml	PN-EN ISO 6883:2017-03
Weight tolerance limit	Not less than 100% of the declared weight	Each unit container is weighed Sampling/emptying allowance is added to each unit container
Uniformity of mix	All samples must pass assay test	$\sqrt{n}+1$ unit containers are drawn from each production batch
Heavy metals Arsenic*** Cadmium*** Lead*** Mercury***	 ≤ 0.5 ppm ≤ 0.3 ppm ≤ 0.5 ppm ≤ 0.1 ppm	 Ph. Eur. <2.2.58> / USP <233> Ph. Eur. <2.2.58> / USP <233> Ph. Eur. <2.2.58> / USP <233> Ph. Eur. <2.2.58> / USP <233>
Microbiological parameters TAMC in 1g TYMC in 1g E. Coli in 1g Salmonella in 25 g Staphylococcus aureus in 1g Bile tolerant gram negative bacteria**in 1g	 ≤ 1 x 10^3 CFU ≤ 1 x 10^2 CFU Absent Absent Absent ≤ 1 x 10^2 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>

* <A novel method for the determination of chemical purity and assay of menaquinone-7. Comparison with the methods from the official USP monograph> *by Jedynak et al.*

** BILE TOLERANT GRAM NEGATIVE BACTERIA INCLIDE ENTEROBACTERIACEAE, PSEUDOMONAS AND AEROMONAS

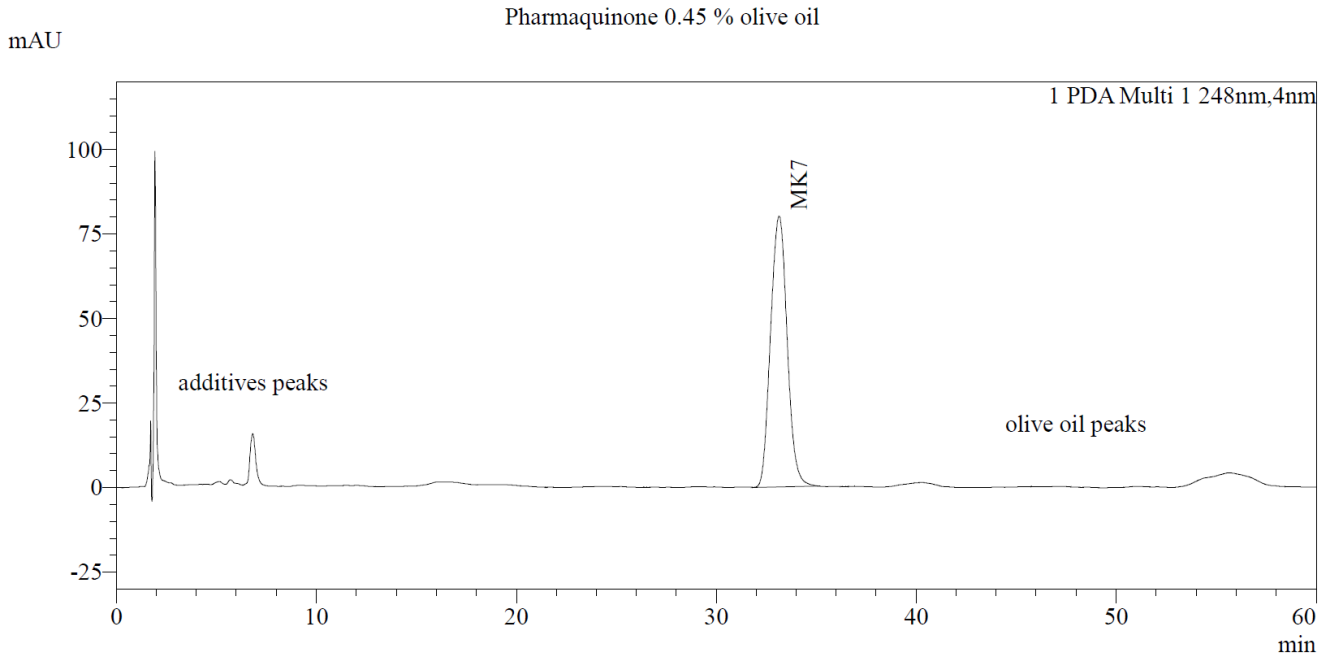
*** EVERY THIRD BATCH IS TESTED

Shelf life, storage and handling

18 months of date of production. The packed Product should be stored in temperature 15-25 °C and humidity 30-50%. Protect from the light.

The product is very light sensitive and exposure may deteriorate K2 activity.

The only „Single peak" vitamin K2



Section 13 Certificate of Analysis

Pharmaquinone
vitamin k2 revolution

CERTIFICATE OF ANALYSIS

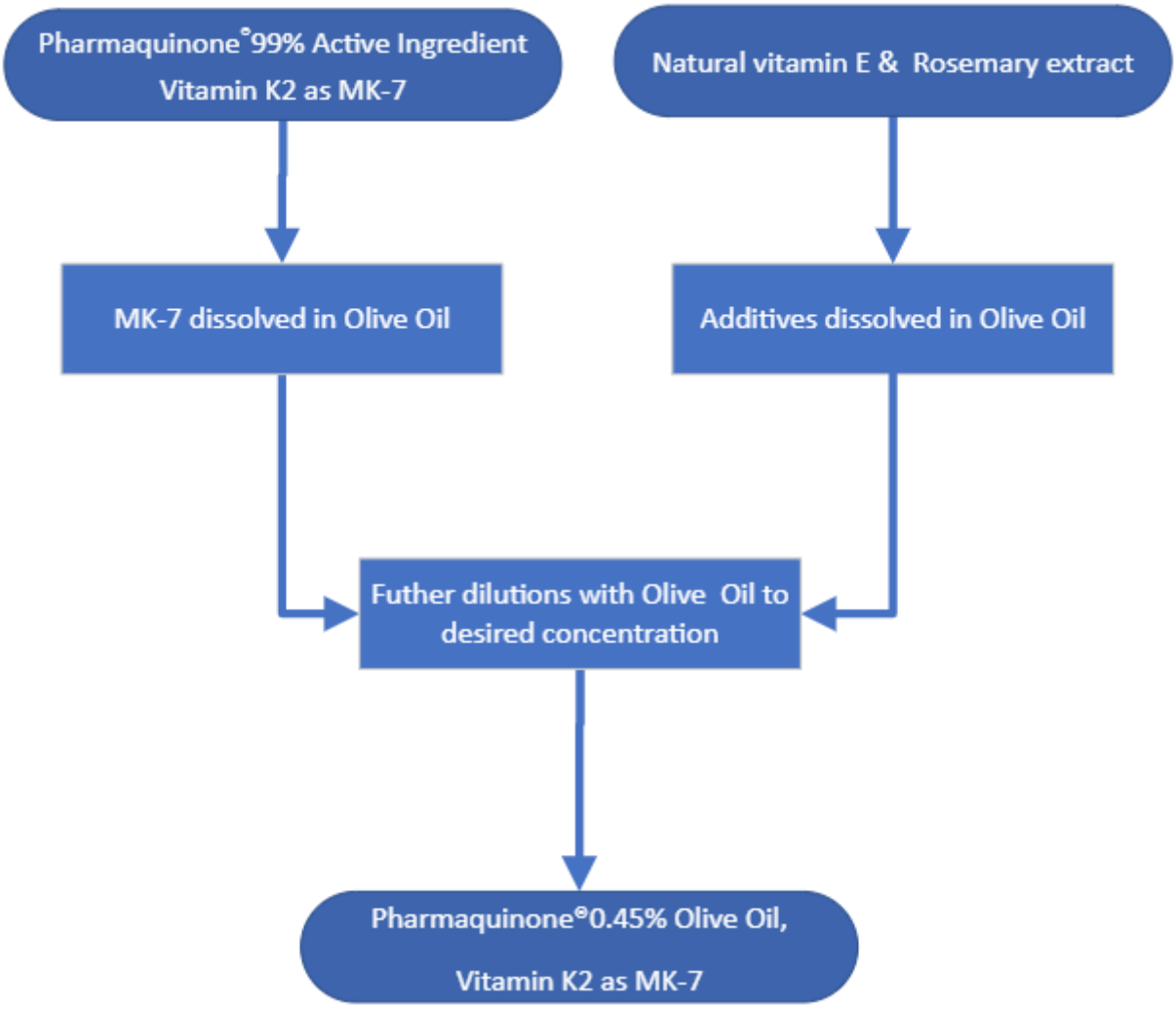
Product name	Pharmaquinone®0.45% Olive Oil Vitamin K2 as MK-7
SKU code	045L
Batch number	
Retest period	18 months from manufacture
Manufacturing date	
Retest date	
Storage	The packed Product should be stored in temperature 15-25 °C. Protect from the light.
Packaging	aluminium bottle

TESTS	REQUIREMENTS	RESULTS
Appearance	Light yellow to dark yellow oil	Complies
Identification	Corresponds to the standard HPLC profile	Complies
Total Vitamin K2 (all-trans MK-7) assay*	> 0.45% or > 4 500 ppm	
Related substances (UPLC method*) **Single unknown impurity** **Total impurities**	 ≤ 1.0 % ≤ 1.5 %	
Isomeric purity (USP method) **Content of cis-menaquinone-7**	 ≤ 1.0 %	
Density (in 20°C)	0.915 +/- 5% g/ml	
Heavy metals **Arsenic** **Cadmium** **Lead** **Mercury**	 ≤ 0.5 ppm ≤ 0.3 ppm ≤ 0.5 ppm ≤ 0.1 ppm	
Microbiological parameters **TAMC in 1g** **TYMC in 1g** **E. Coli in 1g** **Salmonella in 25 g** **Staphylococcus aureus in 1g** **Bile tolerant gram negative bacteria"in 1g**	 ≤ 1 x 10^3 CFU ≤ 1 x 10^2 CFU Absent Absent Absent ≤ 1 x 10^2 CFU	

* Jedynak et al.
" Bile tolerant gram negative bacteria inclide enterobacteriaceae, pseudomonas and aeromonas

Note:
The revised CoA will be issued after the retest date for a further 12 months, as appropriate.

Section 14 Flow chart



Section 15 Safety Data Sheet

1. Identification of the substance/mixture and of the company/undertaking

Product identifiers

Product name:	Pharmaquinone®0.45% Olive Oil Vitamin K2 as MK-7
Product Number:	045L
Brand:	VitaSynth Sp. z o. o.
Recommended use:	Food, dietary supplements
Identified uses:	The manufacturing of food products, including food supplements, have been Generally Recognized as Safe (self-affirmed GRAS), meaning that they are safe for human consumption. In the European Union Pharmaquinone products are recognized as Generic Novel Foods.

Details of the supplier of the safety data sheet

Company:	VitaSynth Sp. z o. o. 2 Szałwiowa Street PL- 03-167 Warsaw
Telephone:	+48 22 602 22 29
E-mail address:	sales@pharmaquinone.com

Emergency telephone

Emergency Phone:	+(48)-223988029 (CHEMTREC) 998 (fire department) 112 (emergency call center)

2. Hazards identification

Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.

Label elements

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.

Other hazards

None known

3. Composition/information on ingredients

Name ingredient	CAS	Concentration
Menaquinone-7	2124-57-4	0.45%
Olive oil extra virgin	8001-25-0	~98.5%
Natural vitamin E	59-02-9	~0.8%
Rosemary extract	84604-14-8	~0.2%

No components need to be disclosed according to the applicable regulations.

4. First aid measures

Description of first-aid measures

Inhalation: Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact: Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact: Rinse with water. Get medical attention if irritation develops and persists.

Ingestion: Persons receiving anticoagulant therapy, like warfarin or coumarins, should notify their physician. Product contains vitamin K which interferes with the biological activity of some anticoagulants.

General information: In all cases of doubt, or when symptoms persist, seek medical advice.

Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2) and/or in section 11

Indication of any immediate medical attention and special treatment needed

Treat symptoms. Product has low, dermal, inhalation toxicity and is non-irritating to eye and skin.

5. Firefighting measures

Extinguishing media

Carbon dioxide (CO_2). Foam. Dry extinguishing powder. Do not use water.

Special hazards arising from the substance or mixture

During fire, gases hazardous to health may be formed.

Advice for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Further information

Use standard firefighting procedures and consider the hazards of other involved materials.

No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. For personal protection see section 8.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up

Sweep up using spill control material, collect and dispose appropriately.

Reference to other sections

For disposal see section 13.

7. Handling and storage

Precautions for safe handling

Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Keep container tightly closed, may be stored in temperatures between 15 °C and 25 °C (RH: 30-50%). After opening the container, use as soon as possible or tightly close the container and store in refrigerator.

Store in dark. Store away from incompatible materials such as oxidizing agents and materials with high alkaline levels.

Specific end use(s)

Apart from the uses mentioned in section 1 no other specific uses are stipulated.

8. Exposure controls/personal protection

Exposure controls

Occupational exposure limits:	No exposure limits noted for ingredient(s).
Biological limit values:	No biological exposure limits noted for the ingredient(s).
Engineering controls:	Good general ventilation should be used. Ventilation rates should be matched to conditions. Ensure adequate ventilation, especially in confined areas.

Individual protection measures, such as personal protective equipment

Eye/face protection: If contact is likely, safety glasses with side shields are recommended.

Hand and skin protection: For prolonged or repeated skin contact use suitable protective gloves. Other Wear suitable protective clothing.

Respiratory protection: In case of insufficient ventilation, wear suitable respiratory equipment.

Thermal hazards: Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance Form	Light yellow to dark yellow oil
Odor	No data available
Odor Threshold	No data available
pH	No data available
Melting point/freezing point	-9-0 °C
Initial boiling point and boiling range	> 350 °C
Flash point	113 °F Closed Cup
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Upper/lower flammability or explosive limit	No data available
Vapor pressure	No data available
Vapor density	No data available
Density (in 20˚C)	0.915 +/- 5% g/ml
Water solubility	Insoluble
Partition coefficient n-octanol/water	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity	No data available
Explosive properties	No data available
Auto-ignition temperature	No data available

10. Stability and reactivity

Reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability

This product is stable under normal conditions.

Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid

Protect from light. Keep away from sources of heat.

Incompatible materials

Strong oxidizing agents. This product may react with strong alkalies.

Hazardous decomposition products

At high temperatures acrolein may be formed. Other decomposition products - No data available

In the event of fire: see section 5

11. Toxicological information

Information on toxicological effects

Most likely routes of exposure: Skin.

Symptoms: Direct contact with eyes may cause temporary irritation. No adverse effects due to skin contact are expected.

Method: Risk assessment based on values and information of ingredients found in literature.

Skin irritation	None known
Eye irritation	None known
Acute dermal	No
Acute oral	No
Inhalation	No data available
Sensitization	No data available
Mutagenicity	No data available
Target organ effects	No indication
Carcinogenicity	No indication
Teratogenicity	No indication

12. Ecological information

Toxicity

Not expected to have significant environmental effects

Persistence and degradability

Readily biodegradable

Bioaccumulative potential

No data available

Mobility in soil

No data available

Results of PBT and vPvB assessment

No data available

Other adverse effects

Negative ecological effects are not expected.

13. Disposal considerations

Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging

Contaminated packaging convey the established processors of waste.

14. Transport information

UN number

ADR/RID: - IMDG: - IATA: -

UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

Packaging group

ADR/RID: - IMDG: - IATA: -

Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

Special precautions for user

No data available

15. Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

Generic authorizations of Novel Foods:

Authorizations are no longer individual. Instead, authorized novel foods are added to the EU list, which serves as a so-called 'positive list'. Every food business operator that complies with the conditions of the authorization can place the respective novel food on the market. Also the applicant-specific novel food authorizations under the old Regulation have been included in the European Union list. This led to an initial list containing 125 entries (numbers as mentioned on the website of the European Commission).

Regulatory Statement:

To the best of our knowledge, this product was not adulterated or misbranded as defined by the Federal Food, Drug, and Cosmetic Act, state, or municipal ordinances in which the definition of adulteration and misbranding is substantially the same as defined by the Act. This product is allowed under the provision of Section 404 or 505 of the Act, to be introduced into interstate commerce.

16. Other information

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide.

The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions.

It does not represent any guarantee of the properties of other product. VitaSynth shall not be held liable for any damage resulting from handling or from contact with the above product.

Section 16 Attachments

FDA/ CGMP STATEMENT

To whom it may concern,

We hereby confirm our various Menaquinone-7 products has been shipped to USA market under FDA supervision for several years. As a result, our Menaquinone-7 dilutions preparation site (sister company):

Europharma Alliance sp. z o. o.

AL. LED 1, 55-020 Rzeplin, Poland

has been audited by FDA on 9th and 10th of October, 2019. It was a comprehensive surveillance inspection of foreign dietary supplement raw material manufacturer conducted in accordance with PAC 0314, CGMP/Limited Scope PCHF Inspections, with Operation ID 126761. This inspection covered manufacturing of Vitamin K2 bulk premix as dietary ingredient requiring further processing. Inspection of raw ingredient/material receiving, quarantine, batch production, master manufacturing records, sanitation, quality and complaints produced 0 FDA 483 Inspectional
Observations. No complaints regarding the firm were found in FACTS. FDA "closed" inspection under 21 CFR 20.64(d)(3).

Yours faithfully,

Vitasynth Sp. z o.o.
ul. Szałwiowa 2
03-167 Warszawa
NIP 6772335293, REGON 121072974

Name: Elżbieta Filutowska

Designation: Quality Department

NON-GMO STATEMENT

To whom it may concern,

VitaSynth sp. z o. o. takes every precaution to manufacture and provide safe and functional product range under the trademark: Pharmaquinone®, Vitamin K2 as MK-7 used in the food and chemical industry.

To the best of our knowledge, the above VitaSynth material has not been derived from or produced using bioengineering, genetically modified organisms, or their derivatives. This product does not contain RNA, DNA and/or protein from genetic modification.

Based on this information, the product stated above, will not on their own, require labeling of the foodstuffs and food ingredients as indicated in 7 CFR Part 66, Regulation (EC) No 1829/2003, and (EC) No 1830/2003.

Yours faithfully,

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ul. Szałwiowa 2
03-167 Warszawa
NIP 6772335293, REGON 121072974

Name: Elżbieta Filutowska

Designation: Quality Department

BST/BSE FREE STATEMENT

To whom it may concern,

VitaSynth sp. z o. o. takes every precaution to manufacture and provide safe and functional product range under the trademark: Pharmaquinone®, Vitamin K2 as MK-7 used in the food and chemical industry.

The manufacturing process does not use any ingredient of animal origin nor do our products come in contact with animal products during storage and transportation.

To the best of our knowledge, the product listed above is free from Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE) in compliance with good manufacturing practice and EU Regulation (EC) No 999/2001.

Yours faithfully,

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NIP 6772335293, REGON 121072974

Name: Elżbieta Filutowska

Designation: Quality Department