Pharmaquinone
vitamin k2 revolution

Pharmaquinone®0.2 % MCC Powder

Vitamin K2 as MK-7

PIDS

Product Information Data Sheet

July 2023

Replacing February 2023

Document is subject to updates

Pharmaquinone
vitamin k2 revolution

Table of Contents

Section 1	Product Identity and Form
Product name	Pharmaquinone®0.2 % MCC Powder Vitamin K2 as MK-7
SKU code	020P
Chemical names	Menaquinone-7 (MK-7)
Common name	Vitamin K2
General product information	Synthetic Vitamin K2 as MK-7 in MCC 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	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 MCT oil in a prolonged process and controlled heating. The oil obtained in the process is combined with MCC. The powder concentrate is further mixed with MCC 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	Polyethylene Zip lock bag inside a silver, aluminum-based doypack with appropriate labelling
Storage conditions	The packaged product should be stored at 5-25°C / 41-77°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	020P2307-1 020P - 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
Vegan	Certified	Vegan Society	20.06.2024
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 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 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 Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006

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®0.2 % MCC powder, Vitamin K2 as MK-7		**Batch No.:** 020P2109-1	**Mfg. date:** 09.2021		**Exp. date:** 03.2024		**Packaging:** doypack with zipper bag	
Study: Long term **Time period:** 36 months	**Storage condition:** 25°C ± 2°C; 60% RH ± 5% RH	**Time period covered by data at submission: 18 months**						
TESTS	**REQUIREMENTS**	**METHOD**	**Result (0M)**	**Result (3M)**	**Result (6M)**	**Result (9M)**	**Result (12M)**	**Result (18M)**
1. Description	Light yellow to yellow powder	Visual assessment	Comply	Comply	Comply	Comply	Comply	Comply
2. Assay of vitamin K2 (MK7)	90.0%–120.0% of the labeled amount (2 000 ppm) on the as-is basis*	UPLC method (*Jedynak et al.*)	111.9 %	112.8 %	108.2 %	109.4 %	110.1 %	102.5 %
3. Assay of vitamin K2 (MK7)	90.0%–120.0% of the labeled amount (2 000 ppm) on the as-is basis*	USP method	109.2 %	109.1 %	107.7 %	106.9 %	103.3 %	105.0 %
4. Related substances Total impurities	Not more than 1.50%	UPLC method (*Jedynak et al.*)	0.12 %	0.20 %	0.18 %	0.51 %	0.71 %	1.14 %
5. Isomeric purity Content of cis-menaquinone-7	Not more than 1.50%	USP method	Not detected	Not detected	Not detected	Not detected	Not detected	Not detected

* according to USP Menaquinone-7 Preparation

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	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
Microcrystalline cellulose (MCC)	9004-34-6	98.0%	Vegetable origin	non-GMO

Section 9 Nutritional Profile*

Component	Typical value per 100 g
Total calories	12.2 Kcal
Total proteins	0.00 g
Total fat	1.8 g
Dietary fiber	98.0 g
Total sugars	0.00 g
Carbohydrates	0.00 g
Salt	0.00 g
Vitamin K2 as MK7	2 000 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[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,

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

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® 0.2% MCC Powder Vitamin K2 as MK-7
SKU codes:	020P
Vitamin K2 content	NLT 2000 mg K2 as MK-7/g
Packaging	1 kg or 5 kg of Product in unit doypack with zipper bag inside

Tests	Requirements	Method
Appearance	Light yellow to yellow powder	Visual assessment
Identification	Corresponds to the standard HPLC profile	UPLC method* / USP <621>
Total Vitamin K2 as MK-7	> 0.20% or > 2000 ppm	UPLC method*
Related substances Total impurities	Not more than 1.50%	UPLC method*
Total Vitamin K2 as MK-7	> 0.20% or > 2000 ppm	USP <621>
Isomeric purity Content of cis-menaquinone-7	≤ 1.50%	USP <621>
Particle size***	100% passes through 40 mesh	USP <786>
Bulk density	0.3 – 0.55 g/ml	Ph. Eur. <2.9.34> / USP <616>
Water solubility	Insoluble	Ph. Eur. <General Notices> / USP <General Notices>
Loss of drying (105˚C/ 4h)	≤ 8.0%	Ph. Eur. <2.2.32>
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***	≤ 0.5 ppm	Ph. Eur. <2.2.58> / USP <233>
Cadmium***	≤ 0.3 ppm	Ph. Eur. <2.2.58> / USP <233>
Lead***	≤ 0.5 ppm	Ph. Eur. <2.2.58> / USP <233>
Mercury***	≤ 0.1 ppm	Ph. Eur. <2.2.58> / USP <233>
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>

* <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

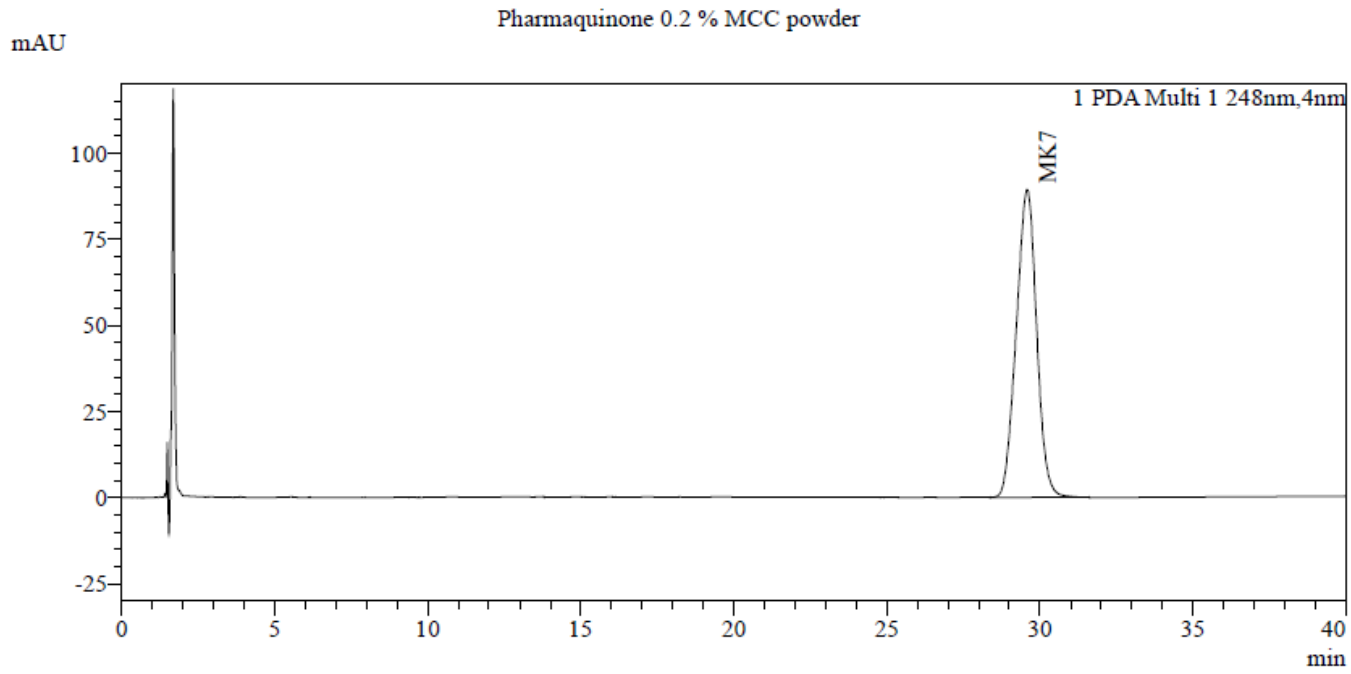
*** EVERY THIRD BATCH IS TESTED

Shelf life, storage and handling

30 months of date of production. The packed Product should be stored in temperature 5-25 °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
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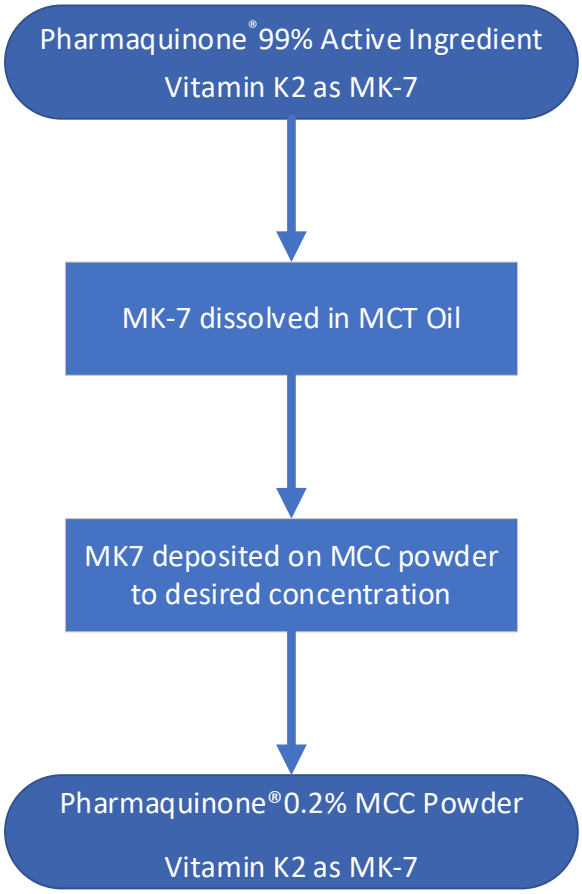
CERTIFICATE OF ANALYSIS

Product name	Pharmaquinone® 0.2% MCC Powder Vitamin K2 as MK-7
SKU code	020P
Batch number	
Best before	30 months from manufacture
Manufacturing date	
Expiry date	
Storage	The packed Product should be stored in temperature 5-25 °C and humidity 30-50%. Protect from the light.
Packaging	in unit doypack with zipper bag inside

TESTS	REQUIREMENTS	RESULTS
Appearance	Light yellow to yellow powder	Complies
Identification	Corresponds to the standard HPLC profile	Complies
Total Vitamin K2 as MK-7 (UPLC method*)	> 0.20 % or > 2 000 ppm	
Related substances (UPLC method*) **Total impurities**	≤ 1.50 %	
Total Vitamin K2 as MK-7 (USP method)	> 0.20 % or > 2 000 ppm	
Isomeric purity (USP method) **Content of cis-menaquinone-7**	≤ 1.50 %	
Particle size	100% passes through 40 mesh	
Bulk density	0.3 – 0.55 g/ml	
Water solubility	Insoluble	
Loss of drying (105°C/ 4h)	≤ 8.0 %	
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

Section 14 Flowchart



Section 15 Safety Data Sheet

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

1.1. Product identifiers

Product name: Pharmaquinone®0.2% MCC Powder
Vitamin K2 as MK-7

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses: food, dietary supplements

1.3. 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

1.4. Emergency telephone

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

2. Hazards identification

2.1. Classification of the substance or mixture

For the classification of the mixture the following methods have been applied: extrapolation on the concentration levels of the hazardous substances, on basis of test results and after evaluation of experts. The methodologies used are mentioned at the respective test results.

According to Regulation (EC) No 1272/2008 [CLP]

No need for classification according to GHS criteria for this product.

2.2. Label elements

According to Regulation (EC) No 1272/2008 [CLP]

The product does not require a hazard warning label in accordance with GHS criteria.

2.3. Other hazards

According to Regulation (EC) No 1272/2008 [CLP]

The product is under certain conditions capable of dust explosion.

Product does not contain a substance above legal limits included in the list established in accordance with Article 59(1) of Regulation (EC) No 1907/2006 for having endocrine disrupting properties or is identified to have endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. The product does not fulfill the criteria for PBT (Persistent/bioaccumulative/toxic) and vPvB (very persistent/very bioaccumulative).

3. Composition/information on ingredients

Name ingredient	CAS	Concentration
Menaquinone-7	2124-57-4	0.2%
Medium chain triglyceride oil (MCT)	73398-61-5	1.8%
Microcrystalline cellulose (MCC)	9004-34-6	98%

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

4. First aid measures

4.1. Description of first-aid measures

Remove contaminated clothing.

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:	Wash affected eyes for at least 15 minutes under running water with eyelids held open. Get medical attention if irritation develops and persists.
Ingestion:	Rinse mouth and then drink 200-300 ml of water.
General information:	In all cases of doubt, or when symptoms persist, seek medical advice.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms: (Further) symptoms and / or effects are not known so far.

4.3. Indication of any immediate medical attention and special treatment needed

Treatment: Symptomatic treatment (decontamination, vital functions).

5. Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: water spray, carbon dioxide, dry powder, foam.

Unsuitable extinguishing media for safety reasons: water jet .

Additional information: Avoid whirling up the material/product because of the danger of dust explosion.

5.2. Special hazards arising from the substance or mixture

Endangering substances: carbon oxides, harmful vapours.

Advice: The substances/groups of substances mentioned can be released in case of fire. Burning produces harmful and toxic fumes. Dust explosion hazard.

5.3. Advice for firefighters

Special protective equipment:

Wear a self-contained breathing apparatus.

Further information

Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

Cool endangered containers with water-spray.

6. Accidental release measures

Dust can form an explosive mixture with air.

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective clothing. Information regarding personal protective measures, see section 8.

Ensure adequate ventilation. Avoid dust formation.

6.2. Environmental precautions

Do not discharge into drains/surface waters/groundwater.

6.3. Methods and materials for containment and cleaning up

For small amounts: Pick up with suitable appliance and dispose of.

For large amounts: Contain with dust binding material and dispose of.

Dispose of absorbed material in accordance with regulations. Avoid raising dust.

6.4. Reference to other sections

Information regarding exposure controls/personal protection and disposal considerations can be found in section 8 and 13.

7. Handling and storage

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice. Avoid dust formation. Provide exhaust ventilation if dust is formed.

Protection against fire and explosion:

The product is capable of dust explosion. Avoid dust formation. Prevent electrostatic charge - sources of ignition should be kept well clear - fire extinguishers should be kept handy. Use explosion-proof apparatus and fittings.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed, may be stored in temperatures between 5 °C and 25 °C (RH: 30-50%). Further information on storage conditions: Protect from the effects of light.

Storage class:

Storage class (TRGS 510): 11: Combustible Solids

7.3. Specific end use(s)

For the relevant identified use(s) listed in Section 1 the advice mentioned in this section 7 is to be observed.

8. Exposure controls/personal protection

8.1. Control parameters

Components with occupational exposure limits.

9004-34-6: cellulose: TWA value 10 mg/m3 (OEL (ES))

8.2. Exposure controls

Personal protective equipment:

Respiratory protection:	Breathing protection if breathable aerosols/dust are formed. Particle filter with low efficiency for solid particles (e.g. EN 143 or 149, Type P1or FFP1).
Hand protection:	Chemical resistant protective gloves (EN ISO 374-1).
Eye protection:	Safety glasses with side-shields (frame goggles) (e.g. EN 166).
Body protection:	Chemical protection overall (f.e. according to EN 13982) if dust is formed.

General safety and hygiene measures

Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. No eating, drinking, smoking or tobacco use at the place of work. Hands and/or face should be washed before breaks and at the end of the shift. Store work clothing separately.

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance Form	Light yellow to yellow powder
Odor	Odorless
Odor Threshold	No data available
pH	5 - 7
Melting point/freezing point	Not applicable
Initial boiling point and boiling range	Not applicable
Flash point	Not determined
Evaporation rate	Not applicable
Flammability (solid, gas)	Not applicable
Upper/lower explosive limit	Approx. 30 g/m^3 / Approx. 11 g/m^3
Oxidizing characteristics	Not oxidizing
Vapor pressure	Not applicable
Vapor density	Not applicable
Density (in 20˚C)	0.3 – 0.55 g/ml
Water solubility	Insoluble
Organic solvents	0%
Partition coefficient n-octanol/water	Not determined
Auto-ignition temperature	Not applicable
Decomposition temperature	Approx. 200°C
Viscosity	Not applicable
Explosive properties	Potential dust explosive
Auto-ignition temperature	Not determined

Bulk density: Typical bulk density is 0.3 - 0.55 g/cm3

Particle size: Typical particle size is 100 % through 40 mesh

9.2. Other information

Information with regard to physical hazard classes

Explosives

Explosion hazard: Product is not explosive, however a dust explosion could result from an air / dust mixture.

Oxidizing properties

Fire promoting properties: Based on its structural properties the product is not classified as oxidizing.

Self-heating substances and mixtures

Self-heating ability: It is not a substance capable of spontaneous heating according to UN transport regulations class 4.2.

Corrosion to metals

No corrosive effect on metal.

Other safety characteristics

SAPT-Temperature: Study scientifically not justified.

Evaporation rate: The product is a non-volatile solid.

10. Stability and reactivity

10.1. Reactivity

No hazardous reactions if stored and handled as prescribed/indicated.

Corrosion to metals: Corrosive effects to metal are not anticipated.

10.2. Chemical stability

The product is stable if stored and handled as prescribed/indicated.

10.3. Possibility of hazardous reactions

Dust explosion hazard.

10.4. Conditions to avoid

Protect from light. Avoid electro-static charge. Avoid all sources of ignition: heat, sparks, open flame. Avoid dust formation.

10.5. Incompatible materials

Substances to avoid:

strong alkalies, strong oxidizing agents.

10.6. Hazardous decomposition products

At Hazardous decomposition products:

No hazardous decomposition products if stored and handled as prescribed/indicated.

11. Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Assessment of acute toxicity: Virtually nontoxic after a single ingestion.

Irritation

Assessment of irritating effects:

Not irritating to the skin. Not irritating to the eyes.

Respiratory/Skin sensitization

Assessment of sensitization:
Based on available data, the classification criteria are not met.

Germ cell mutagenicity

Assessment of mutagenicity:

Based on the ingredients, the classification criteria are not met.

Carcinogenicity

Assessment of carcinogenicity:

Based on available data, the classification criteria are not met.

Reproductive toxicity

Assessment of reproduction toxicity:

Based on the ingredients, the classification criteria are not met.

Developmental toxicity

Assessment of teratogenicity:

Based on the ingredients, the classification criteria are not met.

Specific target organ toxicity (single exposure)

Assessment of STOT single:

Based on the ingredients, the classification criteria are not met.

Repeated dose toxicity and Specific target organ toxicity (repeated exposure)

Assessment of repeated dose toxicity:

Based on available data, the classification criteria are not met.

Aspiration hazard

No aspiration hazard expected.

Interactive effects

No data available.

11.2. Information on other hazards

Endocrine disrupting properties

Product does not contain a substance above legal limits included in the list established in accordance with Article 59(1) of Regulation (EC) No 1907/2006 for having endocrine disrupting properties or is identified to have endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

Other information

Other relevant toxicity information

The product has not been tested. The statements on toxicology have been derived from the properties of the individual components.

12. Ecological information

12.1. Toxicity

Assessment of aquatic toxicity:

There is a high probability that the product is not acutely harmful to aquatic organisms.

12.2. Persistence and degradability

Assessment biodegradation and elimination (H2O):

Biodegradable.

12.3. Bioaccumulative potential

Assessment bioaccumulation potential:

No data available.

12.4. Mobility in soil

Assessment transport between environmental compartments:

Adsorption in soil: No data available.

12.5. Results of PBT and vPvB assessment

According to Annex XIII of Regulation (EC) No.1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH): The product does not contain a substance fulfilling the PBT (persistent/bioaccumulative/toxic) criteria or the vPvB (very persistent/very bioaccumulative) criteria. Self-classification.

12.6. Endocrine disrupting properties

Product does not contain a substance above legal limits included in the list established in accordance with Article 59(1) of Regulation (EC) No 1907/2006 for having endocrine disrupting properties or is identified to have endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

12.7. Other adverse effects

The product does not contain substances that are listed in Regulation (EC) 1005/2009 on substances that deplete the ozone layer.

12.8. Additional information

Other ecotoxicological advice:

The product has not been tested. The statements on ecotoxicology have been derived from the properties of the individual components.

13. Disposal considerations

13.1. Waste treatment methods

Observe national and local legal requirements.

Contaminated packaging:

Uncontaminated packaging can be re-used.

Packs that cannot be cleaned should be disposed of in the same manner as the contents.

14. Transport information

14.1. UN number

ADR/RID: - IMDG: - IATA: -

14.2. UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

14.3. Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

14.4. Packaging group

ADR/RID: - IMDG: - IATA: -

14.5. Environmental hazards

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

14.6. Special precautions for user

No data available

14.7. Further information

Not classified as dangerous in the meaning of transport regulations.

15. Regulatory information

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

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2. Chemical Safety Assessment

Chemical Safety Assessment not required.

16. Other information

Any other intended applications should be discussed with the manufacturer.

Abbreviations

ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road. ADN = The European Agreement concerning the International Carriage of Dangerous Goods by Inland waterways. ATE = Acute Toxicity Estimates. CAO = Cargo Aircraft Only. CAS = Chemical Abstract Service. CLP = Classification, Labelling and Packaging of substances and mixtures. DIN = German national organization for standardization. DNEL = Derived No Effect Level. EC50 = Effective concentration median for 50% of the population. EC = European Community. EN = European Standards. IARC = International Agency for Research on Cancer. IATA = International Air Transport Association. IBC-Code = Intermediate Bulk Container code. IMDG = International Maritime Dangerous Goods Code. ISO = International Organization for Standardization. STEL = Short-Term Exposure Limit. LC50 = Lethal concentration median for 50% of the population. LD50 = Lethal dose median for 50% of the population. TLV = Threshold Limit Value. MARPOL = The International Convention for the Prevention of Pollution from Ships. NEN = Dutch Norm. NOEC = No Observed Effect Concentration. OEL = Occupational Exposure Limit. OECD = Organization for Economic Cooperation and Development. PBT = Persistent, Bioaccumulative and Toxic. PNEC = Predicted No Effect Level. PPM = Parts per million. RID = The European Agreement concerning the International Carriage of Dangerous Goods by Rail. TWA = Time Weight Average. UN-number = UN number at transport. vPvB = very Persistent and very Bioaccumulative.

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 data contained in this safety data sheet are based on our current knowledge and experience and describe the product only with regard to safety requirements. This safety data sheet is neither a Certificate of Analysis (CoA) nor technical data sheet and shall not be mistaken for a specification agreement. Identified uses in this safety data sheet do neither represent an agreement on the corresponding contractual quality of the substance/mixture nor a contractually designated use. It is the responsibility of the recipient of the product to ensure any proprietary rights and existing laws and legislation are observed.

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 product listed above is not derived from genetically modified starting raw materials, or additives that are derived from genetically modified organisms, and do not contain detectable levels of genetically modified materials (known as PCR negative) in compliance with EU Regulation No 1829/2003, including amended EU Directive 2001/18/EC.

Yours faithfully,

Vitasynth Sp. z o.o.
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,

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

Name: Elżbieta Filutowska

Designation: Quality Department