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PHYTOMENADIONUM

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name: Phytomenadione

> Phytomenadionum **Fytomenadion** Phytoménadione Phytomenadion

N° CAS: 84-80-0 N° EC: 201-564-2

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient.

1.3 Details of the supplier of the safety data sheet

Company: Magis-Pharma NV

> Neerlandweg 24 2610 Wilrijk Belgium

Telephone: (+32) (0)3 457 11 76 Email: info@magis-pharma.be www.magis-pharma.be Web page:

1.4 Emergency telephone number

Public utility foundation: Belgisch Antigifcentrum Centre Antipoisons Belge

Telephone: (+32) (0)70 245 245 (Service 24/7)

Web page: www.antigifcentrum.be www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

The substance is not classified according to Regulation (EC) 1272/2008 (CLP).

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Warning

Hazard statements:

H317 May cause an allergic skin reaction.

H413 May cause long lasting harmful effects to aquatic life.

Precautionary statements:

P261 Avoid breathing dust/fume/gas/mist/vapors/spray.



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P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing

protection/...

If on skin: wash with plenty of water. P302+P352

Specific treatment (see section 4 on this label). P321

If skin irritation or rash occurs: Get emergency medical help. P333+P317 Take off contaminated clothing and wash it before reuse. P362+P364

Dispose of contents/container to local/regional/national/international regulations. P501

Additional applicable label

elements:

Not applicable.

2.3 Other hazards

None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Phytomenadione

IUPAC name: 2-methyl-3-[(2E,7R,11R)-3,7,11,15-tetramethylhexadec-2-en-1-yl]-1,4-

dihydronaphthalene-1,4-dione

Vitamin K1 Synonyms:

> Phylloquinone Phytonadione

N° CAS: 84-80-0 N° EC: 201-564-2 Molecular Formula: $C_{31}H_{46}O_{2}$

Content: 97.0 % to 103.0 %

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: Consult a physician. Show the safety data sheet to the doctor on duty.

After inhalation: Remove to fresh air. If breathing is irregular, call a physician immediately. Only

apply artificial respiration if breathing stops or under medical supervision.

After skin contact: Wash immediately with plenty of soap and water for at least 15 minutes. Remove all

contaminated clothing immediately. Get medical attention if irritation develops and

persists.

Remove contact lenses and rinse immediately with plenty of water, including under After eye contact:

eyelids, for at least 15 minutes. Get medical attention.

After ingestion:



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If conscious, give victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

Dangerous in case of contact with eyes (irritant), ingestion, inhalation.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Foam, dry powder, carbon dioxide, sand, water mist water fog.

Neighboring fires (containers exposed to fire): Water spray or water

fog.

Unsuitable extinguishing media: Direct water jet.

5.2 Special hazards arising from the substance/mixture

Avoid breathing combustion products (carbon dioxide, nitrous gases, cyanides).

5.3 Advice for firefighters

Surrounding fires: Cool containers with water to avoid product decomposition and the

> development of potential health hazards. Always use full fire protection. Collect water from entering sewage system. Dispose of contaminated water used to extinguish and the remains of the

second in accordance with current regulations.

Protection against fire: Helmet with visor, fireproof clothing (jacket and pants with straps

> around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the entire face of the operator or self (self protective) in the case of large amounts of

smoke, a self-contained breathing apparatus (EN 137).

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Do not breathe vapours, aerosols. Evacuate the danger area, follow emergency procedures, consult experts.

For emergency responders

See section 8.

6.2 Environmental precautions

Prevent the product from entering sewers, surface and/or ground water.

6.3 Methods and material for containment and cleaning up

Contain spill with soil or inert material. Collect most of the material and remove the residue with water jets. Disposal of contaminated material should be carried out in accordance with section 13.

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6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Handle the product after consulting all other sections of this safety

data sheet. Avoid dispersing product into the environment. Do not

eat, drink or smoke during use.

Personal protection: Not available. Technical protective measures: Not available. Not available. Handling:

7.2 Conditions for safe storage, including any incompatibilities

Not available. Storage:

Conditions for safe storage, including any

incompatibilities:

Keep container tightly closed and in a well-ventilated place.

Storage – away from: Not available.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must bear the CE marking attesting to compliance with applicable regulations. Provide an emergency shower with a visco-elastic tray.

Hygiene measures: Handle with proper industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after the end of the workday.

Individual protection measures

Protective face shields and safety goggles in accordance with EN166. Eye/face protection:

Skin protection: Choose body protection according to the amount and concentration of the

hazardous substance in the workplace.

Hand protection: Handle with gloves.

The selected protective gloves must comply with the specifications of EU Directive

89/686/EEC and the derived EN 374 standard.



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Respiratory protection: Where risk assessment shows that air purifying respirators are appropriate, use dust

> mask type N95 (USA) or type P1 (EN 143). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (USA) or

CEN (EU).

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Yellow liquid. Odour: Odourless.

Odour threshold: Not available. Not available. pH:

Melting/freezing point: -20 °C Initial boiling point: 140 °C

Boiling range: 140 - 145 °C Flash point: Not available. Evaporation rate: Not available. Flammability (solid/gas): Not available. Upper/lower flammability or Not available.

explosive limits:

Vapour pressure: Not available. Vapour density: Not available. Relative density: Not available.

Solubility: Sparingly soluble in ethanol (96 %), miscible with fatty oils.

Solubility in water: Practically insoluble in water.

Partition coefficient

(n-octanol/water):

Not available.

Auto-ignition temperature: Not available. Decomposition temperature: Not available. Not available. Viscosity: **Explosive properties:** Not available. Oxidising properties: Not available.

9.2 Other information

Molecular weight: 450.70 g/mol Density (20 °C): 0.970 g/ml



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SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

The product is stable if used properly. No special conditions.

10.2 Chemical stability

Sensitive to light and air.

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Strong reducing agents and strong bases.

10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Acute oral toxicity (LD₅₀, rat): > 33.49 mg/kg

Skin corrosion/irritation: Not available. Serious eye damage/irritation: Not available. Not available. Respiratory/skin sensitisation: Germ cell mutagenicity: Not available.

No component of this product is identified as a probable, possible or confirmed Carcinogenicity:

human carcinogen at levels greater than or equal to 0.1%.

Not available. Reproductive toxicity: Not available. Summary of evaluation of the

CMR properties:

Not available. STOT-single exposure: STOT-repeated exposure: Not available. **Aspiration Hazard:** Not available.

Other: Signs and Symptoms of Exposure

Exposure may cause nausea, vomiting, diarrhea and skin rash.

RTECS QY5800000

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact: Not available.

Skin contact: May be harmful by skin contact. Inhalation: May be harmful by inhalation. May be harmful if swallowed. Ingestion:



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Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish (LC₅₀): > 100 mg/L/96 h (Oncorhynchus mykiss)

12.2 Persistence and degradability

Easily biodegradable.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment is not available as chemical safety assessment is not required/not performed.

12.6 Other adverse effects

Use in accordance with good work practices, avoiding dispersal of the product in the environment.

Notify the competent authorities if the product reaches watercourses, sewers, soil or vegetation.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated container: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air):

It is not dangerous in transport.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),

It is not dangerous in transport.

IATA/ICAO (Air):

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),

It is not dangerous in transport.

IATA/ICAO (Air):

14.4 Packing group

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ADR/RID(Land),IMDG(Sea),

It is not dangerous in transport.

IATA/ICAO (Air):

14.5 Environmental hazards

ADR/RID(Land),IMDG(Sea), It is not dangerous in transport.

IATA/ICAO (Air):

14.6 Special precautions for user

It is not dangerous in transport.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

The product should not be considered hazardous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not applicable. Risk phrases: Not applicable. Safety phrases: Not applicable.

15.2 Chemical safety assessment

A chemical safety assessment of the product has not been carried out.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

UN (number):

16.2 Abbreviations and acronyms used

European Agreement concerning the International Carriage of Dangerous Goods by ADR:

Road

CAS: Chemical Abstracts Service (division of the American Chemical Society)

EC (number): European Community (number)

IATA: **International Air Transport Association** ICAO: International Civil Aviation Organization

IMDG: International Maritime Code for Dangerous Goods **IUPAC:** International Union of Pure and Applied Chemistry PBT: Persistent, Bioaccumulative and Toxic substance

United Nations (number)

RID: Regulations Concerning the International Transport of Dangerous Goods by Rail

Specific Target Organ Toxicity STOT:



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vPvB:

very Persistent and very Bioaccumalative

16.3 Key literature references/sources for data

European Chemicals Agency.

https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

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