Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

VITAMINI A SYNTHETICI DENSATI PULVIS

Publication: 26/04/2022
Revision: XX/XX/XXXX
Version: 00

MAGIS PHARMA

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

1.1 Product identifier

Product name:	Vitamin A concentrate (powder form), synthetic Vitamini A synthetici densati pulvis Viamine A concentraat (poeder), synthetisch Vitamine A synthétique (concentrat de), forme pulvérulente Vitamin-A-Pulver
N° CAS:	Not available.
N° EC:	Not available.

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

Identified uses:	Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company:	FAC SECUNDUM ARTEM NV Oostmalsebaan 1c (unit 5) 2960 Sint-Lenaarts Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

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

Repr. 1B	H360D
Aquatic Chronic 3	H412

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):

Signal word(s): Danger

Hazard statements:

H360D	May damage the unborn child.
H412	Harmful to aquatic life with long lasting effects.

Precautionary statements:

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P273	Avoid release to the environment.
P202	Do not handle until all safety precautions have been read and understood.
P308+P311	IF exposed or concerned: Call a POISON CENTER/doctor.
P405	Store locked up.
P501	Dispose of contents/container to special or hazardous waste collection point.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

The product may cause a dust explosion under certain conditions. The product does not contain any substance meeting the PBT criteria (persistent/bioaccumulative/toxic) or the vPvB criteria (very persistent/very bioaccumulative).

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

Hazardous substances (GHS)

In accordance with Regulation (EC) No 1272/2008

Product name:	Retinyl acetate
IUPAC name:	[(2*E*,4*E*,6*E*,8*E*)-3,7-dimethyl-9-(2,6,6-trimethylcyclohexen-1-yl)nona-2,4,6,8-tetraenyl] acetate
Synonyms:	Vitamin A acetate
	All-trans-Retinyl acetate
	All-trans-Retynol acetate
	Retinol acetate
N° CAS:	127-47-9
N° EC:	204-844-2
Molecular Formula:	$C_{22}H_{32}O_2$
Content:	(W/W): ≥ 20 % - < 25 %

Product name:	2,6-di-tert-butyl-p-kresol
IUPAC name:	2,6-di*tert*-butyl-4-methylphenol
Synonyms:	Butylated hydroxytoluene
	Ionol
	BHT
N° CAS:	128-37-0
N° EC:	204-881-4
Molecular Formula:	$C_{15}H_{24}O$

Content:	(W/W): ≥ 1 % - < 2.4 %

Chemical description

Preparation on the basis of: retinyl acetate
500 000 I.U./g

Embedded in: carbohydrates, gelatins

Stabilised with: 2,6-di-tert-butyl-p-cresol

The product contains 95.0 per cent to 115.0 per cent of the vitamin A content stated on the label.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Emergency workers must think of their own protection. In case of danger of unconsciousness, position and transport in the stable side position. Remove contaminated clothing immediately.
After inhalation:	Rest, fresh air, seek medical advice.
After skin contact:	Wash thoroughly immediately with plenty of water and soap, seek medical advice.
After eye contact:	Rinse thoroughly with running water for at least 15 minutes with eyelids open.
After ingestion:	Immediately rinse mouth and drink plenty of water, induce vomiting, seek medical advice.

4.2 Most important symptoms and effects, both acute and delayed

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

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: treatment of symptoms (removal of contaminant, control of vital functions), no specific antidote known.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Water spray, carbon dioxide, extinguishing powder, foam.
Unsuitable extinguishing media:	Full water jet.

5.2 Special hazards arising from the substance/mixture

Vapours harmful to health, carbon dioxide.

The listed substances/dust groups may be released in a fire. Development of smoke/mist.

Risk of dust explosion. Avoid dust/product agitation due to dust explosion hazard.

5.3 Advice for firefighters

Surrounding fires:	Cool endangered packages with water spray. Dispose of fire debris and contaminated fire fighting water in accordance with local authority regulations. Collect contaminated fire fighting water separately, do not allow it to reach sewage system or waste water stream.

Protection against fire:	Wear self-contained breathing apparatus with compressed air cylinder and protective clothing.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Use personal protective equipment. For information on personal protective equipment, see section 8. Avoid formation of dust. Ensure adequate ventilation. Do not breathe dust. Avoid contact with skin, eyes and clothing.

For emergency responders

Use personal protective equipment. For information on personal protective equipment, see section 8. Avoid formation of dust. Ensure adequate ventilation. Do not breathe dust. Avoid contact with skin, eyes and clothing.

6.2 Environmental precautions

Do not allow to enter drains/surface water/groundwater. In the event of penetration into water bodies and sewage systems, the competent authority must be notified.

6.3 Methods and material for containment and cleaning up

For large quantities: Take up using mechanical equipment. Collect waste separately in suitable, labelled and closable containers.

Residues: Pick up with dust binding agent and dispose of as waste. Dispose of the material collected according to regulations. Avoid formation of dust. Clean-up work must be carried out using respiratory protection.

6.4 Reference to other sections

Information on exposure monitoring, personal protection and handling conditions can be found in sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Use explosion-proof apparatus/fittings.
Personal protection:	Not available.
Technical protective measures:	Avoid dust formation. Provide extraction if dust is generated. Fire and explosion protection: Avoid dust formation. Product is dust-explosive. Take precautions against electrostatic charge - keep away from ignition sources - have fire extinguishers ready.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	In an airtight container.
Conditions for safe storage, including any incompatibilities:	Once the container has been opened, its contents are to be used as soon as possible; any part of the contents not used at once should be protected by an atmosphere of inert gas. Suitable materials: high density polyethylene (HDPE), low density polyethylene (LDPE). Further information about storage conditions:

	Keep container tightly closed and dry; store in a cool place. Protect against the effects of air. Protect from light.
Storage – away from:	Store protected from light.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Substances with workplace exposure limits :

57-50-1: sucrose	TGG value (8 hours) 10 mg/m^3 (TLV (BE))
128-37-0: 2,6-di-tert-butyl-p-kresol	TGG value (8 hours) 2 mg/m^3 (TLV (BE)), Vapour and spray mist

8.2 Exposure controls

Appropriate engineering control

Avoid inhalation and skin contact by pregnant women at all times. Observe usual precautionary measures when handling chemicals. In addition to the information on personal protection equipment, it is compulsory to wear closed working clothes. Avoid contact with skin, eyes and clothing. Do not inhale dust. Do not eat, drink, smoke or sniff while working. Wash hands and/or face before breaks and at end of work. Store working clothes separately.

Individual protection measures

Eye/face protection:	Safety glasses with side shields (spectacles with frames) (e.g. EN 166).
Skin protection:	Chemical-resistant coveralls (e.g. according to EN ISO 13982) in case of dust generation.
Hand protection:	Chemical-resistant gloves (EN 374).
Respiratory protection:	Suitable respiratory protection for low concentrations or short duration exposure: high capacity particulate filter for solid and liquid particles (e.g. EN 143 or 149, type P3 or FFP3).
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:	Yellowish powder usually in the form of particles of almost uniform size.
Odour:	Mild, pleasant.
Odour threshold:	Not determined due to the potential health hazard by inhalation.
pH:	Not determined.
Melting/freezing point:	Not determinable. Substance/product decomposes.
Initial boiling point:	Not applicable.
Boiling range:	Not available.

Flash point:	Not applicable, the product is a solid.
Evaporation rate:	Negligible.
Flammability (solid/gas):	Not determined.
Upper/lower flammability or explosive limits:	For solids not relevant for classification and labelling.
Vapour pressure:	Negligible.
Vapour density:	Not available.
Relative density:	Not applicable.
Solubility:	Swells or forms an emulsion, depending on the formulation.
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	Not applicable for mixtures.
Auto-ignition temperature:	Not available.
Decomposition temperature:	No decomposition if instructions for storage and use are observed.
Viscosity:	Not applicable, the product is a solid.
Explosive properties:	The product is not explosive but a dust explosion can occur from an air/dust mixture.
Oxidising properties:	Due to its structure, the product is classified as non-oxidising.

9.2 Other information

Bulk density: approx. 600 kg/m^3

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No dangerous reaction if the regulations/instructions for storage and use are observed.

10.2 Chemical stability

The product is stable if the regulations/directives for storage and use are observed.

10.3 Possibility of hazardous reactions

Dust explosion hazard.

10.4 Conditions to avoid

See section 7 - Handling and storage.

Avoid dust formation. Avoid moisture. Avoid heat. Avoid light.

10.5 Incompatible materials

Substances to avoid: Airborne oxygen content.

10.6 Hazardous decomposition products

No hazardous decomposition products, if regulations/indications for storage and handling are observed.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Acute toxicity evaluation: After a single oral intake practically non-toxic. *Information on: retinyl acetate* *Experimental/calculated data: LD_{50} rat (oral): > 2,000 mg/kg (BASF test)* *No mortality was observed. The product has not been tested. Statement is derived from substance/products with similar structure or composition.*
Skin corrosion/irritation:	Evaluation irritation: Slightly irritating by skin contact. Not irritating to the eyes Inhalation of dust causes slight irritation of the respiratory tract. *Information on: retinyl acetate* *Evaluation irritation: May cause slight irritation to skin. Not irritating to the eyes.* *Information on: Gelatins* *Evaluation irritation: Not irritating to eyes and skin. Inhalation of dust causes slight irritation to respiratory system.*
Serious eye damage/irritation:	See above (Skin corrosion/irritation).
Respiratory/skin sensitisation:	Sensitisation evaluation: A sensitising effect on particularly sensitive persons cannot be excluded. *Information on: Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-* *Sensitisation evaluation: A sensitising effect on particularly sensitive persons cannot be excluded.*
Germ cell mutagenicity:	Assessment of mutagenicity: Based on the ingredients, there is no suspicion of a mutagenic effect.
Carcinogenicity:	*Information on: 2,6-di-tert-butyl-p-cresol* *Carcinogenicity assessment: All available information gives no indication of carcinogenic effects.*
Reproductive toxicity:	Reproductive toxicity assessment: Not classified, due to lack of data. <u>Developmental toxicity</u> Assessment of teratogenicity: May cause harm to the unborn child. *Information on: retinyl acetate* *Assessment teratogenicity: May cause harm to the unborn child.*
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	STOT assessment single exposure: The available information is insufficient for an assessment of the specific target organ toxicity.
STOT-repeated exposure:	*Information on: retinyl acetate* *Repeated dose toxicity evaluation: Large amounts may cause specific organ damage on repeated exposure.* *Information on: 2,6-di-tert-butyl-p-cresol* *Repeated dose toxicity evaluation: The substance may cause damage to the liver on the basis of experimental studies on animals with repeated oral intake of large amounts.*
Aspiration Hazard:	No aspiration hazard expected.

Other:	The product has not been investigated. The information on toxicology was derived from the properties of the individual components.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity evaluation: Harmful to aquatic organisms with long lasting effects.

Information on: 2,6-di-tert-butyl-p-cresol

Aquatic toxicity evaluation: Acutely very toxic to aquatic organisms. When low concentrations are introduced into biological wastewater treatment plants in an appropriate manner, disturbances in the degradability of activated sludge are not to be expected.

Information on: 2,6-di-tert-butyl-p-cresol

Toxicity to fish: LC_0 (96 h) ≥ 0,57 mg/l, Brachydanio rerio (OECD 203; ISO 7364; 84/449/EEC, C.1, weakly flowing) The toxicity data refer to the analytical concentration. Only one limit concentration was investigated (LIMIT test).

Information on: 2,6-di-tert-butyl-p-cresol

Aquatic invertebrates: ECO (48 h) 0.48 mg/l, Daphnia magna (OECD Guideline 202, Part 1, static). The toxicity data refer to the analytical concentration.

I*nformation on: 2,6-di-tert-butyl-p-cresol*

Aquatic plants:

EC_{50} (72 h) > 0.40 mg/l (growth rate), Scenedesmus subspicatus (Directive 92/69/EEC, C.3, static). The toxicity data refer to the analytically determined concentration.

Information on: 2,6-di-tert-butyl-p-cresol

Micro-organisms/effects on activated (organic) sludge: ECO (3 h) 1,000 mg/l, activated sludge (DIN EN ISO 8192-OECD 209-88/302/EEC,D.C, aerobic).

12.2 Persistence and degradability

Assessment of biodegradability and elimination (H20): Product is not expected to be readily biodegradable.

Information about: retinyl acetate

Assessment of biodegradability and elimination (H20): Not readily biodegradable (according to OECD criteria). Moderately/partly biodegradable.

Information on: 2,6-di-tert-butyl-p-cresol

Assessment of biodegradability and elimination (H20): Not readily biodegradable (according to OECD criteria). Readily biodegradable.

Information on: retinyl acetate

Elimination data: 42,2 % CO2 formation of the theoretical value (28 d) (OECD 301B; ISO 9439; 92/69/EEC, C.4- C) (aerobic activated sludge, municipal)

Information on: 2,6-di-tert-butyl-p-cresol

Elimination data: 4.5 % BOD of ThOD (28 d) (OECD 301C; ISO 9408; 92/69/EEC, C.4-F) (aerobic activated sludge)

12.3 Bioaccumulative potential

Information on: 2,6-di-tert-butyl-p-cresol

Assessment of bioaccumulation potential: May be enriched in organisms.

Information on: retinyl acetate

Assessment bioaccumulation potential: No significant accumulation in organisms is expected.

12.4 Mobility in soil

Information on: 2,6-di-tert-butyl-p-cresol

Assessment of transport between environmental compartments: Volatility: From the surface of water the substance does not evaporate into the atmosphere. Adsorption into soil: Adsorption into the solid state soil is expected.

Information on: retinyl acetate

Assessment of transport between environmental compartments: Volatility: No data available. Soil adsorption: Adsorption to soil solids is expected.

12.5 Results of PBT and vPvB assessment

In accordance with Annex XIII of the REACH Regulation (EC) No 1907/2006 (Registration, Evaluation, Authorisation and Restriction of Chemicals): The product does not contain any substance meeting the PBT criteria (persistent/bioaccumulative/toxic) or the vPvB criteria (very persistent/very bioaccumulative).

12.6 Other adverse effects

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

Additional information: Other ecotoxicological information The product has not been investigated. The information on ecotoxicology is derived from the properties of the individual components.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

The national and local legal requirements must be observed.

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) :	Not a hazardous material within the meaning of the transport regulations.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not applicable.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not applicable.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not applicable.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not applicable.

14.6 Special precautions for user

Not known.

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

Not evaluated.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:

Harmful

Risk phrases: R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R61 May cause harm to the unborn child.

Safety phrases: S1 Keep locked up.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

S56 Dispose of this material and its container at hazardous or special waste collection point.

S61 Avoid release to the environment. Refer to special instructions/safety data sheet.

15.2 Chemical safety assessment

Chemical Safety Assessment (CSA) not required.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by 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
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
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

Classification based on the main component.

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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