Material Safety Data Sheet

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

ALPHA-TOCOPHERYLIS ACETATIS PULVIS

Publication: 01/02/2022
Revision: 01/02/2022
Version: 00

MAGIS PHARMA

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

1.1 Product identifier

Product name:	Alpha-Tocopheryl acetate concentrate (powder form) Alpha-Tocopherylis acetatis pulvis Alfa-Tocoferylacetaat concentraat (poeder) Alpha-Tocophéryle (concentrate d'acétate d'), forme pulvérulente Alpha-Tocopherolacetat-Trockenkonzentrat
N° CAS:	58-95-7
N° EC:	200-405-4

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

Not a hazardous substance or mixture.

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):	Not applicable.
Signal word(s):	Not applicable.
Hazard statements:	Not applicable.
Precautionary statements:	Not applicable.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

The product is under certain conditions capable of dust explosion. The product does not contain a substance fulfilling the PBT (persistent/bioaccumulative/toxic) criteria or the vPvB (very persistent/very bioaccumulative) criteria.

Material Safety Data Sheet

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

ALPHA-TOCOPHERYLIS ACETATIS PULVIS

MAGIS PHARMA

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Alpha-Tocopheryl acetate concentrate (powder form)
IUPAC name:	[(2*R*)-2,5,7,8-tetramethyl-2-[(4*R*,8*R*)-4,8,12-trimethyltridecyl]-3,4-dihydrochromen-6-yl] acetate
Synonyms:	Vitamin E Alpha-Tocopherol acetate
N° CAS:	58-95-7
N° EC:	200-405-4
Molecular Formula:	$C_{31}H_{52}O_3$
Content:	90.0 per cent to 115.0 per cent of the α-tocopheryl acetate content stated on the label, which is not less than 25 g per 100 g of concentrate.

3.2 Mixtures

Alpha- Tocopheryl acetate is a matrix of starch, gelatins.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	No risks requiring special first aid measures.
After inhalation:	Move to fresh air. If symptoms persist, consult a doctor.
After skin contact:	Remove contaminated clothing and shoes immediately. Wash with soap and plenty of water.
After eye contact:	Rinse eyes with water as a precautionary measure for at least 15 minutes. Remove contact lenses. Protect undamaged eye. Keep eyes open while rinsing.
After ingestion:	Clean mouth with water and then drink plenty of water. Do not give milk or alcoholic drinks. Never let an unconscious person drink (or eat).

4.2 Most important symptoms and effects, both acute and delayed

Symptoms: No significant reaction of the human body to the product known.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Symptomatic treatment (decontamination, vital functions).

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Water spray, carbon dioxide, dry powder, foam.
Unsuitable extinguishing media:	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/mixture

Carbon oxides, harmful vapours.

The substances/groups of substances mentioned can be released in case of fire. Evolution of fumes/fog. Dust explosion hazard.

5.3 Advice for firefighters

Surrounding fires:	Dispose of fire debris and contaminated extinguishing water in accordance with official regulations. Cool endangered containers with water-spray.
Protection against fire:	Wear a self-contained breathing apparatus.
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 clothing. Information regarding personal protective measures see, section 8. Avoid dust formation.

For emergency responders

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

6.2 Environmental precautions

Do not discharge into drains/surface waters/groundwater.

6.3 Methods and material for containment and cleaning up

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

For large amounts: Sweep/shovel up.

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.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	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.
Personal protection:	Not available.
Technical protective measures:	Avoid dust formation. Provide exhaust ventilation if dust is formed.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	In an airtight, well-filled container. Suitable materials for containers: High density polyethylene (HDPE), Low density polyethylene (LDPE).
Conditions for safe storage, including any incompatibilities:	Keep container tightly closed and dry; store in a cool place.

Storage – away from:	Protected from light.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with occupational exposure limits:

57-50-1: Sucrose

STEL value 20 mg/m^3 (WEL/EH 40 (UK))

TWA value 10 mg/m^3 (WEL/EH 40 (UK))

9005-25-8: Starch

TWA value 10 mg/m^3 (WEL/EH 40 (UK)), Inhalable

TWA value 4 mg/m^3 (WEL/EH 40 (UK)), Respirable

8.2 Exposure controls

Appropriate engineering control

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.

Individual protection measures

Eye/face protection:	Safety glasses with side-shields (frame goggles) (e.g. EN 166).
Skin protection:	Chemical protection overall (f.e. according to EN 13982) if dust is formed.
Hand protection:	Chemical resistant protective gloves (EN 374).
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).
Thermal hazards:	Not determined.

Environmental exposure control

For information regarding environmental exposure controls, see section 6.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	Almost white, yellowish or light brown, small particles.
Odour:	Almost odourless.
Odour threshold:	Not applicable, odour not perceivable.
pH:	Not applicable.
Melting/freezing point:	The substance/product decomposes, therefore not determined.

Initial boiling point:	Not applicable.
Boiling range:	Not applicable.
Flash point:	Not applicable, the product is a solid.
Evaporation rate:	Not applicable.
Flammability (solid/gas):	May form flammable dust concentrations in air.
Upper/lower flammability or explosive limits:	For solids not relevant for classification and labelling.
Vapour pressure:	Not applicable.
Vapour density:	Not applicable.
Relative density:	Not applicable.
Solubility:	Not available.
Solubility in water:	Practically insoluble or swells or forms a dispersion in water, depending on the formulation.
Partition coefficient (n-octanol/water):	Not applicable for mixtures.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Decomposes when heated. Potential exothermic hazard.
Viscosity:	Not applicable, the product is a solid.
Explosive properties:	Product is not explosive, however a dust explosion could result from an air/dust mixture.
Oxidising properties:	Based on its structural properties, the product is not classified as oxidising.

9.2 Other information

Bulk density: approx. 600 kg/m^3

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

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

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

Avoid dust formation. See MSDS section 7 - Handling and storage.

Avoid heat.

10.5 Incompatible materials

Strong acids and strong bases, strong oxidising agents.

10.6 Hazardous decomposition products

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

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Virtually nontoxic after a single ingestion. Virtually nontoxic after a single skin contact. The product has not been tested. The statement has been derived from the properties of the individual components. Information on: 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-yl acetate: Oral LD_{50} (rat): > 10 000 mg/kg (BASF-Test) Dermal LD_{50} (rat): > 3 000 mg/kg
Skin corrosion/irritation:	Not irritating to the skin. The product has not been tested. The statement has been derived from the properties of the individual components. Information on: 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-yl acetate: Experimental/calculated data: rabbit: non-irritant (OECD Guideline 404)
Serious eye damage/irritation:	Not irritating to the eyes. The product has not been tested. The statement has been derived from the properties of the individual components. Information on: 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-yl acetate: Experimental/calculated data: rabbit: non-irritant (OECD Guideline 405)
Respiratory/skin sensitisation:	Based on the ingredients, there is no suspicion of a skin-sensitising potential. Information on: 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-yl acetate: Experimental/calculated data: photo-allergy test guinea pig: Non-sensitizing.
Germ cell mutagenicity:	Based on available data, the classification criteria are not met. Information on: 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-yl acetate: No mutagenic effect was found in various tests with bacteria and mammals.
Carcinogenicity:	Based on available data, the classification criteria are not met. Information on: 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-yl acetate: In long-term animal studies in which the substance was given in high doses by feed, a carcinogenic effect was not observed.
Reproductive toxicity:	Based on available Data, the classification criteria are not met. Information on: 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-yl acetate: The results of animal studies gave no indication of a fertility impairing effect.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Based on available Data, the classification criteria are not met.
STOT-repeated exposure:	Information on: 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-yl acetate: Repeated oral uptake of the substance did not cause substance-related effects.
Aspiration Hazard:	Not available.
Other:	Developmental toxicity: Based on available data, the classification criteria are not met.

Information on: 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-yl acetate: Assessment of teratogenicity: No indications of a developmental toxic/teratogenic effect were seen in animal studies.

Other relevant toxicity information: Based on our experience and the information available, no adverse health effects are expected if handled as recommended with suitable precautions for designated uses.

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

There is a high probability that the product is not acutely harmful to aquatic organisms. The product has not been tested. The statement has been derived from the properties of the individual components.

Information on: 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-yl acetate:

Toxicity to fish: LC50 (96 h) > 11 mg/l, *Oncorhynchus mykiss* (OECD Guideline 203, static). The statement of the toxic effect relates to the analytically determined concentration. No toxic effects occur within the range of solubility.

Aquatic invertebrates: EC50 (48 h) > 20.6 mg/l, *Daphnia magna* (OECD Guideline 202, part 1, static). The statement of the toxic effect relates to the analytically determined concentration. No toxic effects occur within the range of solubility.

Aquatic plants: EC50 (72 h) > 27.8 mg/l (growth rate), *Pseudokirchneriella subcapitata* (OECD Guideline 201, static). The statement of the toxic effect relates to the analytically determined concentration. No toxic effects occur within the range of solubility.

Microorganisms/Effect on activated sludge: EC20 (30 min) > 927 mg/l, activated sludge, domestic (DIN EN ISO 8192, aquatic). The details of the toxic effect relate to the nominal concentration.

Chronic toxicity to fish: No observed effect concentration (28 d) > 100 mg/l, *Oncorhynchus mykiss* (OECD Guideline 215, semistatic). No data available regarding toxicity to fish.

12.2 Persistence and degradability

Assessment biodegradation and elimination (H_2O): Not readily biodegradable (by OECD criteria).

The product has not been tested. The statement has been derived from the properties of the individual components.

Information on: 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-yl acetate:

Assessment biodegradation and elimination (H_2O): Moderately/partially biodegradable. Not readily biodegradable (by OECD criteria). The product is virtually insoluble in water and can thus be separated from water mechanically in suitable effluent treatment plants.

12.3 Bioaccumulative potential

Accumulation in organisms is not to be expected. The product has not been tested. The statement has been derived from the properties of the individual components.

Information on: 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-yl acetate:

Assessment bioaccumulation potential: Accumulation in organisms is not to be expected.

12.4 Mobility in soil

Assessment transport between environmental compartments:

Volatility: The substance will slowly evaporate into the atmosphere from the water surface. The ecological data given are those of the active ingredient.

Adsorption in soil: Adsorption to solid soil phase is expected. The ecological data given are those of the active ingredient.

12.5 Results of PBT and vPvB assessment

According to Annex XIII of Regulation (EC) No.1907/2006 concerning the Registration, Evaluation, Authorisation 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 Other adverse effects

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

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Residues and non-reusable solutions should be taken to a licensed disposal company.

Contaminated packaging: Empty containers should be taken to an authorised waste disposal centre for reuse or disposal.

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 classified.

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

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

14.4 Packing group

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

14.5 Environmental hazards

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

14.6 Special precautions for user

Not classified as a dangerous good under transport regulations

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

Not applicable.

15.2 Chemical safety assessment

A chemical safety assessment is 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.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FSA NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. FSA NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

16.8 Department issuing MSDS

Quality Department
FAC SECUNDUM ARTEM NV
info@magis-pharma.be