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

#### 1.1 Product identifier

Product name: Horse-chestnut dry extract, standardised

Hippocastani seminis extractum siccum normatum

Witte paardenkastanje zaad droog extract, gestandaardiseerd

Marron d'inde (extrait sec titré de)

Rosskastanien-Trockenextrakt, standardisiert

N° CAS: 8053-39-2 N° EC: 232-497-7

#### 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

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):

Not applicable.

Not applicable.

Not applicable.

Precautionary statements:

Additional applicable label

Not applicable.

Not applicable.

elements:

#### 2.3 Other hazards

Not available.

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#### **SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

#### 3.1 Substances

Product name: Horse-chestnut dry extract, standardised

IUPAC name: Aesculus hippocastanum bark extract

Synonyms: Horse chestnut, aesculus hippocastanum, ext.

N° CAS: 8053-39-2
N° EC: 232-497-7
Molecular Formula: Not available.

Content: 6.5 per cent to 10.0 per cent of total triterpene glycosides, expressed as

protoaescigenin (C<sub>30</sub>H<sub>50</sub>O<sub>6</sub>; Mr 506.7) (dried extract).

#### 3.2 Mixtures

Not applicable.

#### **SECTION 4: FIRST AID MEASURES**

#### 4.1 Description of first aid measures

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

After inhalation: Take to fresh air. If breathing is irregular, call a doctor immediately. Only give

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.

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

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

After ingestion: If conscious, give the 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

Not available.

#### 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.

Neighbouring fires (containers exposed to fire): Water spray or fog.

Unsuitable extinguishing media: Direct water jet.

#### 5.2 Special hazards arising from the substance/mixture

Not available.

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#### 5.3 Advice for firefighters

Surrounding fires: Cool containers with water to prevent decomposition of product

and development of potential health hazards. Always use full fire protection. Collect water from entering sewage system. Dispose of contaminated water used for extinguishing and residues in

accordance with current regulations.

Protection against fire: Helmet with visor, flame retardant clothing (jacket and trousers with

straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the whole face of the operator or the car (self protective) in 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

Wear self-contained breathing apparatus, chemical safety goggles, boots and strong rubber gloves.

#### For emergency responders

If vapours from breathing or dust are released into the air, wear respiratory protection. These guidelines are only valid for emergency workers and emergency actions.

Wear self-contained breathing apparatus, chemical safety goggles, boots and strong rubber gloves.

#### 6.2 Environmental precautions

Avoid penetration of products into sewers, surface water, groundwater.

#### 6.3 Methods and material for containment and cleaning up

Collect dry, place in a closed container and dispose of waste.

Ventilate the room, wash and rinse the place where the product has been spilled, once it has been completely removed.

Avoid raising dust.

#### 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: Avoid contact with skin, eyes and mucous membranes, and avoid

breathing dust. Take care to avoid generation of dust.

Personal protection:

Technical protective measures:

Handling:

Not available.

Not available.

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#### 7.2 Conditions for safe storage, including any incompatibilities

Storage: In an airtight container.

The product does not require special storage measures.

Conditions for safe storage, including any

incompatibilities:

Store tightly closed containers in a cool, dry 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

Not available.

#### 8.2 Exposure controls

#### Appropriate engineering control

Since the use of appropriate technical measures must 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 be CE-marked for compliance with applicable regulations.

Provide an emergency shower with a viscoelastic tray.

#### **Individual protection measures**

Eye/face protection: Protective face shields and safety goggles according to EN166.

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

hazardous substance in the workplace.

Hygiene measures: Handle with appropriate industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after finishing work.

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.

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 (US) 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: Yellowish or yellowish-brown, hygroscopic powder or agglomerate.

Odour: Not available.

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Odour threshold: Not available. Not available. pH: Melting/freezing point: Not available. Initial boiling point: Not available. Boiling range: Not available. Not available. Flash point: Not available. Evaporation rate: Flammability (solid/gas): Not available. Upper/lower flammability or Not available. explosive limits: Not available.

Vapour pressure: Vapour density: Not available. Relative density: Not available. Solubility: Not available. Solubility in water: Not available. Partition coefficient Not available.

(n-octanol/water):

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

#### 9.2 Other information

Not available.

#### **SECTION 10: STABILITY AND REACTIVITY**

#### 10.1 Reactivity

No special conditions.

#### 10.2 Chemical stability

Stable under recommended handling and storage conditions (see section 7).

#### 10.3 Possibility of hazardous reactions

The product does not present the possibility of dangerous reactions.

#### 10.4 Conditions to avoid

None in particular.

#### 10.5 Incompatible materials

Alkali and alkaline earth metals, alkaline oxides, strong oxidants.

#### 10.6 Hazardous decomposition products

Combustion may generate CO,  $CO_2$  as well as unidentified organic and inorganic compounds.

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#### **SECTION 11: TOXICOLOGICAL INFORMATION**

#### 11.1 Information on toxicological effects

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

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/irritation: Based on available data, the classification criteria are not met.

Respiratory/skin sensitisation: Based on available data, the classification criteria are not met.

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

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

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

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

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

CMR properties:

STOT-single exposure: Based on available data, the classification criteria are not met.

STOT-repeated exposure: Based on available data, the classification criteria are not met.

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

Other: Not available.

#### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:

Skin contact:

Inhalation:

Ingestion:

Aspiration:

Not available.

Not available.

Not available.

Not available.

#### **SECTION 12: ECOLOGICAL INFORMATION**

#### 12.1 Toxicity

Not available.

#### 12.2 Persistence and degradability

Not available.

#### 12.3 Bioaccumulative potential

Not available.

#### 12.4 Mobility in soil

Not available.

#### 12.5 Results of PBT and vPvB assessment

Not available.

#### 12.6 Other adverse effects

Use in accordance with good laboratory practice, avoid dispersal into the environment. Inform the competent authorities if the product contaminates ground water, sewage, soil or vegetation.

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#### **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 for disposal 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),

Not classified.

IATA/ICAO (Air):

#### 14.2 UN proper shipping name

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

Not classified.

IATA/ICAO (Air):

#### 14.3 Transport hazard class(es)

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

Not classified.

IATA/ICAO (Air):

#### 14.4 Packing group

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

Not classified.

IATA/ICAO (Air):

#### 14.5 Environmental hazards

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

Not classified.

IATA/ICAO (Air):

#### 14.6 Special precautions for user

Not available.

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

Not available.

#### 14.8 Additional transport information

The product is not to be considered dangerous 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 has not been carried out.

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#### **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

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

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