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

## RHEI EXTRACTUM SICCUM NORMATUM

FORM-06-14-01 (V00)

Page 1/8

Publication: 05/05/2022 Revision: 05/05/2022

Version: 00



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

#### 1.1 Product identifier

Product name: Rhubarb dry extract, standardised

Rhei extractum siccum normatum

Rabarber droogextract, gestandaardiseerd Rhubarbe, extrait sec titré de (standardisé) Rhabarber-Trockenextrakt, standardisiert

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

The product is not considered as dangerous regarding Article 31 and Annex II of Regulation N° 1907/2006 (REACH).

#### 2.2 Label elements

#### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):

Signal word(s):

Hazard statements:

Precautionary statements:

Additional applicable label

Not applicable.

Not applicable.

Not applicable.

elements:

#### 2.3 Other hazards

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

## RHEI EXTRACTUM SICCUM NORMATUM

FORM-06-14-01 (V00)

Page 2/8

ΕN

Publication: 05/05/2022 Revision: 05/05/2022

Version: 00



Not available.

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

#### 3.1 Substances

Product name: Rhubarb dry extract, standardised.

IUPAC name:

Synonyms:

Not available.

N° CAS:

Not available.

N° EC:

Not available.

Molecular Formula: Not available.

Content: Adjusted dry rhubarb extract contains not less than 4,0 and not more than 6,0 per

cent hydroxyanthracene derivatives, calculated as rhein (C<sub>15</sub>H<sub>8</sub>O<sub>6</sub>; M<sub>r</sub> 284,2) and

based on the dried extract.

Used plant material: Rheum palmatum L.

Part of plant used: Root

Extraction solvent: Water/Ethanol (70/30 V/V)

Excipients: Maltodextrin and colloidal anhydrous silica (max. 0,5%)

Ratio plant/extract: 4/1 (indicative)

#### 3.2 Mixtures

Not applicable.

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

#### 4.1 Description of first aid measures

Not available.

#### 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: Not available.
Unsuitable extinguishing media: Not available.

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

Not available.

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

FORM-06-14-01 (V00)

Page 3/8

ΕN

Publication: 05/05/2022 Revision: 05/05/2022

Version: 00



## RHEI EXTRACTUM SICCUM NORMATUM

5.3 Advice for firefighters

Not available. Surrounding fires: Protection against fire: Not available. Hazardous combustion products: Not available.

#### **SECTION 6: ACCIDENTAL RELEASE MEASURES**

#### 6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Not available.

For emergency responders

Not available.

#### **6.2 Environmental precautions**

Not available.

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

Not available.

#### 6.4 Reference to other sections

Not available.

#### **SECTION 7: HANDLING AND STORAGE**

#### 7.1 Precautions for safe handling

Precautions for safe handling: Not available. Personal protection: Not available. Technical protective measures: Not available. Handling: Not available.

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

Storage: In a well-closed container.

Packaging: LDPE double bag in cardboard box of 25kg.

Store in cool, dark and dry place.

Conditions for safe storage, including any

incompatibilities: Shelf-life: 3 years.

Storage - away from: Store protected from humidity and 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

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

FORM-06-14-01 (V00)

Page 4/8

Publication: 05/05/2022 Revision: 05/05/2022

Version: 00



## RHEI EXTRACTUM SICCUM NORMATUM

Appropriate engineering control

Not available.

Individual protection measures

Eye/face protection: Not determined. Not determined. Skin protection: Not determined. Hand protection: Respiratory protection: Not determined. 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: Brown, powdery or pulverisable mass. Hygroscopic.

Odour: Peculiar.

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

explosive limits:

Not available.

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

Solubility: Soluble in ethanol (70 per cent).

Solubility in water: Slightly soluble in water.

Partition coefficient Not available.

(n-octanol/water):

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

9.2 Other information

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

FORM-06-14-01 (V00)

Page 5/8

Publication: 05/05/2022 Revision: 05/05/2022

Version: 00



RHEI EXTRACTUM SICCUM NORMATUM

Loss on drying (3 hours – 105 °C):  $\leq$  5% Residual solvents:  $\leq$  0.5 % ethanol

Heavy metals (Atomic absorption): ≤ 10 ppm (Pb < 3 ppm – Cd < 1ppm – Hg < 0.1 ppm)

Tapped density: about 0,5 g/mL

Particle size: ≥90% goes through sieve nr. 500 (sieve method Eur, Ph.)

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

#### 10.1 Reactivity

Not available.

#### 10.2 Chemical stability

Not available.

## 10.3 Possibility of hazardous reactions

Not available.

#### 10.4 Conditions to avoid

Not available.

#### 10.5 Incompatible materials

Not available.

#### 10.6 Hazardous decomposition products

Not available.

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

#### 11.1 Information on toxicological effects

Not available. Acute toxicity: Skin corrosion/irritation: Not available. Serious eye damage/irritation: Not available. Respiratory/skin sensitisation: Not available. Not available. Germ cell mutagenicity: Not available. Carcinogenicity: Not available. Reproductive toxicity: Summary of evaluation of the Not available.

CMR properties:

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

Other: Not available.

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

Eye contact: Not available.

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

FORM-06-14-01 (V00)

Page 6/8

ΕN

Publication: 05/05/2022 Revision: 05/05/2022

Version: 00



## RHEI EXTRACTUM SICCUM NORMATUM

Skin contact: Not available.

Inhalation: Not available.

Ingestion: Not available.

Aspiration: 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

Not available.

#### **SECTION 13: DISPOSAL CONSIDERATIONS**

#### 13.1 Waste treatment methods

Not available.

#### **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), IATA/ICAO (Air):

Not classified.

#### 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):

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

FORM-06-14-01 (V00)

Page 7/8

Publication: 05/05/2022 Revision: 05/05/2022

Version: 00



## RHEI EXTRACTUM SICCUM NORMATUM

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

Not available.

#### **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

Not available.

#### **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.

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

## RHEI EXTRACTUM SICCUM NORMATUM

FORM-06-14-01 (V00)

Page 8/8

Publication: 05/05/2022 Revision: 05/05/2022

Version: 00



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.

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