

Material Safety Data Sheet

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

EN

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RHAMNI PURSHIANAE EXTRACTUM SICCCUM NORMATUM

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

1.1 Product identifier

Product name:	Cascara dry extract, standardised Rhamni purshianae extractum sicccum normatum Cascara droog extract, gestandaardiseerd Cascara (extrait sec titré de) Cascara-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.
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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):	Not applicable.
Signal word(s):	Not applicable.
Hazard statements:	Not applicable.
Precautionary statements:	Not applicable.

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Additional applicable label
elements:

Not applicable.

2.3 Other hazards

Potential Acute Health Effects: Hazardous in case of eye contact (irritant), of ingestion, of inhalation. Slightly hazardous in case of skin contact (irritant).

Potential Chronic Health Effects: Repeated or prolonged exposure is not known to aggravate medical condition.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Standardised dry extract obtained from *Cascara (0105)*.

Product name: Cascara dry extract, standardised

IUPAC name: Not available.

Synonyms: Cascara bark powdered extract
Rhamnus purshiana, ext.

N° CAS: Not available.

N° EC: Not available.

Molecular Formula: Not available.

Content: Hydroxyanthracene glycosides expressed as cascarioside A ($C_{27}H_{32}O_{14}$; M_r 580.5): 8.0 per cent to 25.0 per cent m/m (dried extract) and 90 per cent to 110 per cent of the nominal content stated on the label;
Cascariosides expressed as cascarioside A ($C_{27}H_{32}O_{14}$; M_r 580.5): minimum 60 per cent of the hydroxyanthracene glycosiders.
Production: The extract is produced from the herbal drug by an appropriate procedure using either boiling water or a hydroalcoholic solvent at least equivalent in strength to ethanol (60 per cent V/V).

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

After skin contact: Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops.

After eye contact: Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention.

After ingestion: Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.

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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: SMALL FIRE: Use DRY chemical powder.
LARGE FIRE: Use water spray, fog or foam.

Unsuitable extinguishing media: Water jet.

5.2 Special hazards arising from the substance/mixture

Flammability of the product: May be combustible at high temperature.

5.3 Advice for firefighters

Surrounding fires: Not available.

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

Small Spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill: Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Keep away from heat.
Keep away from sources of ignition.
Ground all equipment containing material.

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Personal protection:	Do not breathe dust. Avoid contact with eyes. Wear suitable protective clothing.
Technical protective measures:	Wear suitable protective clothing.
Handling:	Ground all equipment containing material. Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	In an airtight container.
Conditions for safe storage, including any incompatibilities:	Keep container tightly closed. Keep container in a cool, well-ventilated area. Do not store above 35°C.
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

Not available.

8.2 Exposure controls

Appropriate engineering control

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures

Eye/face protection:	Splash goggles. In case of a large spill: Splash goggles.
Skin protection:	Lab coat. In case of a large spill: Full suit. Boots. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.
Hand protection:	Use gloves while handling powder. In case of a large spill: Gloves.
Respiratory protection:	Dust respirator. In case of a large spill: Dust respirator. A self contained breathing apparatus should be used to avoid inhalation of the product.
Thermal hazards:	Not determined.

Environmental exposure control

Not available.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	Brown, free-flowing powder.
Odour:	Characteristic.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	Not available.
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Not available.
Solubility in water:	Soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

The product is stable.
Conditions of instability: Excess heat, incompatible materials.
Polymerisation: Will not occur.

10.3 Possibility of hazardous reactions

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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

Acute toxicity:	Not available.
Skin corrosion/irritation:	Slightly hazardous in case of skin contact (irritant). Unlikely to cause skin irritation.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Chronic potential health effects: No information found at this time. The toxicological properties of this substance have not been fully investigated

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Dust may cause eye irritation.
Skin contact:	Slightly hazardous in case of skin contact (irritant).
Inhalation:	Hazardous in case of inhalation. This material may produce dust. Dust may cause respiratory tract irritation. Breathing small amounts of this material is not likely to be harmful.
Ingestion:	Hazardous in case of ingestion. May cause gastrointestinal tract irritation. Swallowing small amounts is not likely to be harmful.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

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12.1 Toxicity

Not available.

12.2 Persistence and degradability

Products of Biodegradation: Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

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

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

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 applicable.

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 available.

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

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Not applicable.

14.8 Additional transport information

DOT Classification: Not a DOT controlled material (United States).

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 Bioaccumulative

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.

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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