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

FORM-06-14-01 (V00)

Page 1/10

ΕN

Publication: 05/03/2022 Revision: 02/08/2024

Version: 01



BALSAMUM PERUVIANUM

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

1.1 Product identifier

Product name: Peru balsam

Balsamum peruvianum

Perubalsem
Baume de Pérou
Perubalsam

N° CAS: 8007-00-9 N° EC: 232-352-8

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: Magis-Pharma NV

Neerlandweg 24 2610 Wilrijk 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

Acute Tox. 4 H302 Skin Sens. 1 H317 Aquatic Chronic 2 H411

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):





Signal word(s): Attention

Hazard statements:

H302 Harmful if swallowed.

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

FORM-06-14-01 (V00)

Page 2/10

ΕN

Publication: 05/03/2022 Revision: 02/08/2024

Version: 01



BALSAMUM PERUVIANUM

H317 May cause an allergic skin reaction.

H411 Toxic to aquatic life with long lasting effects.

Precautionary statements:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.

Additional applicable label

elements:

P391

Collect spillage. Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:

IUPAC name:

Synonyms:

N° CAS:

N° EC:

Molecular Formula:

Peru balsam

Not available.

Content: 45.0 per cent m/m to 70.0 per cent m/m of esters, mainly benzyl benzoate and

benzyl cinnamate.

3.2 Mixtures

Product name: Benzyl benzoate

IUPAC name: Benzyl benzoate

Synonyms: Benzoic acid, phenylmethyl ester

Phenylmethyl benzoate

 N° CAS:
 120-51-4

 N° EC:
 204-402-9

 Molecular Formula:
 $C_{14}H_{12}O_2$

 Content:
 30-50%

Product name: Benzyl cinnamate

IUPAC name: Benzyl (E)-3-phenylprop-2-enoate

Synonyms: Cinnamein

Benzyl alcohol, cinnamic ester

N° CAS: 103-41-3

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

BALSAMUM PERUVIANUM

FORM-06-14-01 (V00)

Page 3/10

ΕN

Publication: 05/03/2022 Revision: 02/08/2024

Version: 01



 $$N^{\circ}$$ EC: 203-109-3 Molecular Formula: $$C_{16}H_{14}O_{2}$$ Content: 20 - 25 %

Product name: trans-Nerolidol

IUPAC name: (6*E*)-3,7,11-trimethyldodeca-1,6,10-trien-3-ol Synonyms: (E)-3,7,11-trimethyldodeca-1,6,10-trien-3-ol

Nerolidol

 N° CAS:
 40716-66-3

 N° EC:
 255-053-4

 Molecular Formula:
 $C_{15}H_{26}O$

 Content:
 2.5-10%

Product name: Eugenol

IUPAC name: 2-methoxy-4-prop-2-enylphenol

Synonyms: Phenol, 2-methoxy-4-(2-propenyl)

Eugenic acid

 N° CAS:
 97-53-0

 N° EC:
 202-589-1

 Molecular Formula:
 $C_{10}H_{12}O_2$

 Content:
 0.1 - 1%

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

the 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

Harmful if swallowed.

May cause allergic skin reaction.

4.3 Indication of any immediate medical attention and special treatment needed

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

Publication: 05/03/2022 Revision: 02/08/2024

FORM-06-14-01 (V00)

01

Version:



ΕN

Page 4/10

BALSAMUM PERUVIANUM

In case of accident or if you feel unwell, consult a doctor immediately (if possible show him the instructions for use or the safety data sheet).

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Foam, dry powder, carbon dioxide, sand, water mist. Suitable extinguishing media:

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

May release toxic, irritating and/or corrosive gases.

Exposure to decomposition products may be hazardous to health. Do not allow extinguishing waters to enter sewers or watercourses.

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 a mask, solvent resistant protective gloves, safety goggles and protective clothing. See protective measures in sections 7 and 8.

For emergency responders

Wear a mask, solvent resistant protective gloves, safety goggles and protective clothing. See protective measures in sections 7 and 8.

6.2 Environmental precautions

In case of gas leakage or penetration into watercourses, soil or sewage system, inform the responsible authorities, if necessary.

6.3 Methods and material for containment and cleaning up

Suitable collection material: dry, inert absorbent material (vermiculite, sand, earth). Wash with plenty of water and quickly recover the product.

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

BALSAMUM PERUVIANUM

FORM-06-14-01 (V00)

Page 5/10

ΕN

Publication: 05/03/2022 Revision: 02/08/2024

Version: 01



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: No smoking, eating or drinking while working.

Personal protection: Personal protective equipment, see section 8.

Technical protective measures: Not available. Handling: Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Not available.

Conditions for safe storage, including any

incompatibilities:

Store in a cool, well-ventilated place.

Storage – away from: Store protected from light. Store away from heat, flames, sparks and

other sources of ignition.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Appropriate engineering control

Since the use of appropriate technical measures should 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.

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

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.

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).

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

BALSAMUM PERUVIANUM

FORM-06-14-01 (V00)

Page 6/10

ΕN

Publication: 05/03/2022 Revision: 02/08/2024

Version: 01



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: Dark brown, viscous liquid which is transparent and yellowish-brown when viewed

in a thin layer; it is not sticky, non-drying and does not form threads.

Odour: Sweet, balsamic, vanilla

Odour threshold: Not available.

pH: 4.3

Melting/freezing point: Not available. > 100 °C Initial boiling point:

Boiling range: Not available. Flash point: Not available. Not available. Evaporation rate: Not available. Flammability (solid/gas): Upper/lower flammability or Not available.

explosive limits:

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

Relative density: 1.140 - 1.170 g/mL

Solubility: Freely soluble in anhydrous ethanol, not miscible with fatty oils, except for castor

Solubility in water: Practically insoluble in water.

Partition coefficient

Not available.

(n-octanol/water):

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

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No decomposition if stored and applied as directed.

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

BALSAMUM PERUVIANUM

FORM-06-14-01 (V00)

Page 7/10

ΕN

Publication: 05/03/2022 Revision: 02/08/2024

Version: 01



10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

Stable under recommended storage conditions.

10.4 Conditions to avoid

Keep away from open flames, sparks and heat sources. Avoid direct sun exposure. Avoid accumulation of electrostatic charges.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

No decomposition if used according to instructions. No decomposition if stored under normal conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Acute oral toxicity (LD₅₀, rat): 500 mg/kg (benzyl benzoate)

Acute oral toxicity (LD₅₀, rat): 1930 mg/kg (eugenol) Acute Oral Toxicity (LC₅₀, rat): 2.58 mg/L (eugenol) Acute dermal toxicity (rabbit): 100 mg (eugenol)

Skin corrosion/irritation:

Serious eye damage/irritation:

Respiratory/skin sensitisation:

Germ cell mutagenicity:

Carcinogenicity:

Reproductive toxicity:

Not available.

Not available.

Not available.

Not available.

Not available.

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.

Skin contact: May cause an allergic skin reaction.

Inhalation: Not available.

Ingestion: Harmful if swallowed.

Aspiration: Not available.

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

FORM-06-14-01 (V00) Page 8/10

05/03/2022

Publication: Revision: 02/08/2024

Version: 01



BALSAMUM PERUVIANUM

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Fish toxicity (LC₅₀): 2.7 - 3.9 mg/L, 96 h

Invertebrate toxicity (EC₅₀): 3.09 mg/L (Daphnia magna)

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

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),

3082

IATA/ICAO (Air):

14.2 UN proper shipping name

ADR/RID(Land),IMDG(Sea), IATA/ICAO (Air):

ADR/RID: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (TRANS-NEROLIDOL, BENZYL BENZOATE, TRANS-NEROLIDOL, BENZYL BENZOATE)

IMDG: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (TRANS-NEROLIDOL, BENZYL BENZOATE, BENZYL BENZOATE, TRANS-NEROLIDOL, BENZYL

BENZOATE)

IATA: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (TRANS-NEROLIDOL, BENZYL BENZOATE, TRANS-NEROLIDOL, BENZYL BENZOATE)

14.3 Transport hazard class(es)

ΕN

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

BALSAMUM PERUVIANUM

FORM-06-14-01 (V00) Page 9/10

05/03/2022

ΕN

Publication: Revision: 02/08/2024

Version: 01



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

IATA/ICAO (Air):

14.4 Packing group

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

Ш

IATA/ICAO (Air):

14.5 Environmental hazards

ADR/RID(Land), IMDG(Sea), ADR/RID: Environmentally Hazardous

IATA/ICAO (Air): IMDG: Marine Pollutant IATA: Marine Pollutant

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:

Harmful to the environment

Irritant

R22 Harmful if swallowed. Risk phrases:

R43 May cause sensitisation by skin contact.

R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the

aquatic environment.

Safety phrases: S27 Take off immediately all contaminated clothing.

> S36/37/39 Wear suitable protective clothing, gloves and eye/face protection. S61 Avoid release to the environment. Refer to special instructions/safety data

sheet.

15.2 Chemical safety assessment

A chemical safety assessment of the product has not been carried out.

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

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

FORM-06-14-01 (V00)

Page 10/10

ΕN

Publication: 05/03/2022 Revision: 02/08/2024

Version: 01



BALSAMUM PERUVIANUM

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