

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

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Version: 00



CAPSICI OLEORESINA RAFFINATA ET NORMATA

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

1.1 Product identifier

Product name:	Capsicum oleoresin, refined and standardised Capsici oleoresina raffinata et normata Geraffineerd en gestandaardiseerd oliehart van cayennepeper Piment de Cayenne (oléorésine raffiné et titrée de) Capsicum Oleoresin, raffiniert und standardisiert
N° CAS:	84625-29-6
N° EC:	283-403-6

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

Acute Tox. 4	H302
Skin Irrit. 2	H315
Skin Sens. 1	H317
Eye Effects 2	H319
Resp. Sens. 1	H334

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



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Signal word(s):	Danger
Hazard statements:	
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Precautionary statements:	
P261	Avoid breathing vapours.
P304+P340	If INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P342+P311	If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
P301+P312	If SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

This mixture is not classifiable as PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 based on an assessment of the constituent ingredients.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

General compositional description

A hydro-alcoholic extract of Capsicum Ph. Eur. standardised by the addition of Castor Oil (CAS 8001-79-4). Contains capsaicinoids, maximum 13.2 %w/w.

Hazardous components according to Regulation (EC) No. 1272/2008

Product name:	Castor oil
IUPAC name:	2,3-bis[[(Z)-12-hydroxyoctadec-9-enoyl]oxy]propyl (Z)-12-hydroxyoctadec-9-enoate
Synonyms:	Ricinus oil Cosmetol
N° CAS:	8001-79-4
N° EC:	232-293-8
Molecular Formula:	C ₅₇ H ₁₀₄ O ₉
Content:	17 – 57 %w/w

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Product name: Capsaicin
IUPAC name: (E)-N-(4-Hydroxy-3-methoxybenzyl)-8-methylnon-6-enamid
Synonyms: Zostrix
Qutenza
N° CAS: 404-86-4
N° EC: 206-969-8
Molecular Formula: $C_{18}H_{27}NO_3$
Content: 7.4 %w/w

Product name: Dihydrocapsaicin
IUPAC name: N-[(4-hydroxy-3-methoxyphenyl)methyl]-8-methylnonanamide
Synonyms: 6,7-Dihydrocapsaicin
8-Methyl-N-vanillylnonanamide
N° CAS: 19408-84-5
N° EC: 606-308-7
Molecular Formula: $C_{18}H_{29}NO_3$
Content: 4.6 %w/w

Product name: N-Vanillylnonanamide (Nonivamide)
IUPAC name: N-[(4-hydroxy-3-methoxyphenyl)methyl]nonanamide
Synonyms: Pseudocapsaicin
Pelargonic acid vanillylamide
N° CAS: 2444-46-4
N° EC: 219-484-1
Molecular Formula: $C_{17}H_{27}NO_3$
Content: 0.3 %w/w

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: Avoid contact with skin and eyes. If vapour is likely to be present, wear a suitable organic vapour respirator or self-contained breathing apparatus.

After inhalation: Remove to fresh air, keep warm and at rest. If there are any difficulties with breathing, give oxygen if available and safe to do so, and seek medical assistance immediately. If breathing stops or gives signs of failing, apply artificial respiration.

After skin contact: Remove contaminated clothing; this should not be worn again until it has been laundered. Wash the affected area thoroughly with copious amounts of soap and water. If pain or discomfort persists, seek medical advice.

After eye contact: Rinse eyes with water or eye wash solution and remove contact lenses if possible. Irrigate eyes with water or eye wash solution for at least fifteen minutes. Seek medical assistance if discomfort persists.

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After ingestion:

Wash mouth out with water if conscious. Seek medical advice. If there are any difficulties with breathing give oxygen if available and safe to do so, and seek medical assistance immediately.

4.2 Most important symptoms and effects, both acute and delayed

Capsicum extracts cause a severe burning sensation in contact with the skin and mucous membranes. They are used to desensitise the pain response in certain chronic pain conditions, and so loss of sensation after exposure is likely.

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: Water spray, AFFF foam, chemical dry powder or carbon dioxide.
Unsuitable extinguishing media: None.

5.2 Special hazards arising from the substance/mixture

Burning will produce acrid smoke, irritating fumes, carbon monoxide, carbon dioxide, and oxides of nitrogen.

5.3 Advice for firefighters

Surrounding fires: Not available.
Protection against fire: Wear full protective clothing and 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

Wear respiratory protection - avoid breathing vapour or fumes; evacuate area; ventilate area.

For emergency responders

Wear respiratory protection - avoid breathing vapour or fumes; evacuate area; ventilate area.

6.2 Environmental precautions

Do not allow product to enter drains and watercourses. Inform local authority if preparation enters drains or watercourses.

6.3 Methods and material for containment and cleaning up

Absorb spillage using a proprietary absorbent or sand, scoop up and place in a suitable container; remove to a safe place and dispose of through a licensed waste disposal contractor. Ventilate area thoroughly. Wash contaminated area thoroughly with water and detergent. Any residues may be removed with Industrial Methylated Spirit or Isopropyl Alcohol.

6.4 Reference to other sections

For personal protective equipment, see section 8.
For disposal information, see section 13.

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SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Avoid contact with skin and eyes. Use in a well-ventilated area. Avoid production of fumes or vapours. Wash contaminated clothing before reuse.
Personal protection:	Wear suitable respirators if fumes or vapours are produced.
Technical protective measures:	Not available.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Store in well closed containers.
Conditions for safe storage, including any incompatibilities:	Not available.
Storage – away from:	Store protected from light. Store away from sources of heat.

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

Local exhaust ventilation if vapour is likely to be produced in use.

Individual protection measures

Eye/face protection:	Wear goggles or face-shield meeting the requirements of EN166.
Skin protection:	Overalls and protective footwear are recommended.
Hand protection:	Wear protective gloves; nitrile rubber or PVC are suitable. Wash hands thoroughly with soap and water after use.
Respiratory protection:	Use an appropriate CEN approved organic vapour mask (e.g. meeting EN14387) or full face supplied air respirator if vapour is likely to be present.
Thermal hazards:	Not determined.

Environmental exposure control

Prevent further leakage or spillage if safe to do so.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	Red or brown mobile extract.
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Odour:	Characteristic odour.
Odour threshold:	Not available.
pH:	Typically 5 – 8.
Melting/freezing point:	Not available.
Initial boiling point:	> 100 °C
Boiling range:	Not available.
Flash point:	> 60 °C
Evaporation rate:	Not available.
Flammability (solid/gas):	Not applicable.
Upper/lower flammability or explosive limits:	Not applicable.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Approximately 0.96
Solubility:	Soluble in ethanol.
Solubility in water:	Not available.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not expected to pose an explosion hazard.
Oxidising properties:	None.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No reactivity hazards have been identified.

10.2 Chemical stability

The mixture is stable under normal ambient temperatures and expected handling conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions have been identified.

10.4 Conditions to avoid

None applicable.

10.5 Incompatible materials

Avoid mixing with strong oxidisers.

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10.6 Hazardous decomposition products

Hazardous decomposition products will not be produced in normal use of the mixture.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Classified for acute toxicity by ingestion, based on the toxicity of the hazardous components Capsaicin, Dihydrocapsaicin, and Nonivamide.
Skin corrosion/irritation:	Based on available data on the hazardous constituents identified in section 3, the classification criteria are not met.
Serious eye damage/irritation:	Classified as irritating to eyes, based on the classification of the hazardous components Castor Oil, Capsaicin, Dihydrocapsaicin, and Nonivamide.
Respiratory/skin sensitisation:	Classified as a sensitiser by inhalation and skin contact based on the classification of the hazardous components Capsaicin, Dihydrocapsaicin, and Nonivamide.
Germ cell mutagenicity:	Based on available data on the hazardous constituents identified in section 3, the classification criteria are not met.
Carcinogenicity:	Based on available data on the hazardous constituents identified in section 3, the classification criteria are not met.
Reproductive toxicity:	Based on available data on the hazardous constituents identified in section 3, the classification criteria are not met.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Based on available data on the hazardous constituents identified in section 3, the classification criteria are not met.
Aspiration Hazard:	Not available.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Causes serious eye irritation.
Skin contact:	Causes skin irritation. May cause an allergic skin reaction.
Inhalation:	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Ingestion:	Harmful if swallowed.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

No data available. No constituents are classified with respect to toxicity to fish, aquatic invertebrates and algae.

12.2 Persistence and degradability

Based on available data on the hazardous constituents identified in section 3, the product is expected to biodegrade.

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12.3 Bioaccumulative potential

Based on available data on the hazardous constituents identified in section 3, the product is expected to have a moderate bioconcentration potential.

12.4 Mobility in soil

Based on available data on the hazardous constituents identified in section 3, the product is expected to have a low mobility in soil.

12.5 Results of PBT and vPvB assessment

The mixture contains no constituents which are classified as PBT or vPvB.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Dispose of product through a suitable licenced waste disposal contractor.

Contaminated packaging: Dispose of containers as for waste product through a suitable licenced waste disposal contractor.

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

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Not classified as hazardous for all modes of transportation.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Hazard symbol:



Irritant
Harmful

Risk phrases:

R22 Harmful if swallowed.

R38 Irritating to skin.

R36 Irritating to eyes.

R43 May cause sensitization by skin contact.

Safety phrases:

S23 Do not breathe vapours.

S28 After contact with skin, wash immediately with plenty of soap and water.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

S63 In case of accident by inhalation: remove casualty to fresh air and keep at rest.

15.2 Chemical safety assessment

A chemical safety assessment 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
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

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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.

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16.8 Department issuing MSDS

Quality Department

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