

# Material Safety Data Sheet

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

## CINNARIZINUM

EN

FORM-06-14-01 (V00)

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

#### 1.1 Product identifier

Product name: Cinnarizine  
Cinnarizinum  
Cinnarizine  
Cinnarizine  
Cinnarizin

N° CAS: 298-57-7

N° EC: 206-064-8

#### 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: 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

Skin Irrit. 2	H315
Repr. 1B	H360
Aquatic Acute 1	H400
Aquatic Chronic 1	H410
Aquatic Chronic 4	H413

#### 2.2 Label elements

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

Hazard pictogram(s):



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Signal word(s):	Danger
Hazard statements:	
H315	Causes skin irritation.
H360	May damage fertility or the unborn child.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long-lasting effects.
H413	May cause long-lasting harmful effects to aquatic life.
Precautionary statements:	
P273	Avoid release to the environment.
P501	Dispose of contents/container in accordance with national regulations.
Additional applicable label elements:	Not applicable.

### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Cinnarizine
IUPAC name:	1-benzhedryl-4-[(E)-3-phenylprop-2-enyl]piperazine
Synonyms:	Stugeron Dimitronal
N° CAS:	298-57-7
N° EC:	206-064-8
Molecular Formula:	C <sub>26</sub> H <sub>28</sub> N <sub>2</sub>
Content:	99.0 per cent to 101.0 per cent (dried substance)

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

After inhalation:	If breathed in, move person to fresh air. Allow the victim to rest in a well-ventilated area. Evacuate the victim to a safe area as soon as possible. Loosen tight clothing such as a collar, tie, belt or waistband. If breathing is difficult, administer oxygen. If the victim is not breathing, perform mouth-to-mouth resuscitation. In severe cases or if symptoms persist, seek medical attention.
After skin contact:	After contact with skin, wash immediately with plenty of water. Wash the contaminated skin gently and thoroughly with running water and non-abrasive soap. Be particularly careful to clean folds, crevices, creases and groin. Cover the

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After eye contact:

irritated skin with an emollient. If irritation persists, seek medical attention. Wash contaminated clothing before reusing.

After ingestion:

In case of contact with eyes, flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Seek medical advice.

If swallowed, wash out mouth with water provided person is conscious. Seek medical advice.

### 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:

Water spray, carbon dioxide, dry chemical powder or appropriate foam.

Unsuitable extinguishing media:

Not available.

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

Not available.

### 5.3 Advice for firefighters

Surrounding fires:

Not available.

Protection against fire:

Wear self-contained breathing apparatus and protective clothing to prevent.

Hazardous combustion products:

Not available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

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

#### For non-emergency personnel

Evacuate area. Wear self-contained breathing apparatus, rubber boots and heavy rubber gloves. Avoid breathing vapours, mist or gas. Ensure adequate ventilation.

#### For emergency responders

Evacuate area. Wear self-contained breathing apparatus, rubber boots and heavy rubber gloves

### 6.2 Environmental precautions

Avoid release to the environment.

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

Contain spill and collect, as appropriate. Transfer to a chemical waste container for disposal accordance with local regulations.

### 6.4 Reference to other sections

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Not available.

### SECTION 7: HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

Precautions for safe handling:	Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. It should always be handled in an efficient fume hood or equivalent system. Care should be taken to prevent the chemical from coming into contact with the skin or eyes and from contaminating personal clothing. This material should be handled per label instructions to ensure product integrity.
Personal protection:	If necessary, wear protective equipment.
Technical protective measures:	Not available.
Handling:	This product should be handled only by, or under the close supervision of, those properly qualified in the handling and use of potentially hazardous chemicals, who should take into account the fire, health and chemical hazard data given on this dossier.

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

Storage:	This material should be stored per label instructions to ensure product integrity.
Conditions for safe storage, including any incompatibilities:	Keep container tightly closed in a dry and well-ventilated place.
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

Safety shower and eye bath. Mechanical exhaust required. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

Wash thoroughly after handling.

##### Individual protection measures

Eye/face protection:	Chemical safety goggles.
Skin protection:	Not available.
Hand protection:	Compatible chemical resistant gloves.
Respiratory protection:	Government approved respirator.

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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:	White or almost white powder.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	118 °C to 122 °C
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:	Freely soluble in methylene chloride, soluble in acetone, slightly soluble in ethanol (96%) and in methanol.
Solubility in water:	Practically insoluble 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

Stable under recommended storage conditions.

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### 10.2 Chemical stability

Hazardous polymerization: Will not occur.

### 10.3 Possibility of hazardous reactions

Reacts with oxidising agents. Risk of dust explosion.

### 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:	Oral LD50 (mus): > 4 500 mg/kg Oral LD50 (rat): > 6 500 mg/kg
Skin corrosion/irritation:	Causes skin irritation.
Serious eye damage/irritation:	May have an irritating effect.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	May damage fertility or the unborn child.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Indication and symptoms after exposure: Drowsiness and tranquillisation, nausea, dizziness and headache.

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

Eye contact:	May have an irritating effect.
Skin contact:	Causes skin irritation.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

## SECTION 12: ECOLOGICAL INFORMATION

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### 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

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.  
Dispose of in accordance with national regulations.

## 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.

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### 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:



Risk phrases:

R38 Irritating to skin.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R60 May impair fertility.

R61 May cause harm to the unborn child.

Safety phrases:

S61 Avoid release to the environment. Refer to special instructions/safety data sheet.

### 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

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

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