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# **MEPHENESINUM**

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

#### 1.1 Product identifier

Product name: Mephenesin

Mephenesinum Mefenesine Méphénésine Mefenesin

N° CAS: 59-47-2 N° EC: 200-427-4

# 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

 Acute Tox. 4
 H302

 Skin Irrit. 2
 H315

 Eye Irrit. 2B
 H320

# 2.2 Label elements

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

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H302 Harmful if swallowed.

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H320 Causes eye irritation.

Precautionary statements:

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

Causes skin irritation.

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

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

Additional applicable label

elements:

H315

Not applicable.

#### 2.3 Other hazards

Not available.

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

#### 3.1 Substances

Product name: Mephenesin

IUPAC name: 3-(2-methylphenoxy)propane-1,2-diol

Synonyms: Cresoxydiol

Decontractyl Mephedan Anatensin

 $N^{\circ}$  CAS: 59-47-2  $N^{\circ}$  EC: 200-427-4 Molecular Formula:  $C_{10}H_{14}O_{3}$ 

Content: Not less than 99.0 per cent and not more than 101.0 per cent (dried substance).

# 3.2 Mixtures

Not applicable.

# **SECTION 4: FIRST AID MEASURES**

# 4.1 Description of first aid measures

General notes: Consult a physician. Show this safety data sheet to the doctor in attendance.

After inhalation: If breathed in, move person into fresh air. If not breathing, give artificial respiration.

Consult a physician.

After skin contact: Wash off with soap and plenty of water. Consult a physician.

After eye contact: Rinse thoroughly with plenty of water for at least 15 minutes and consult a

physician.

After ingestion: Never give anything by mouth to an unconscious person. Rinse mouth with water.

Consult a physician.

# 4.2 Most important symptoms and effects, both acute and delayed

Nausea, headache, vomiting, central nervous system depression.

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# **MEPHENESINUM**

### 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: Use water spray, alcohol-resistant foam, dry chemical or carbon

dioxide.

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 for fire fighting if

necessary.

Hazardous combustion products: Hazardous decomposition products formed under fire conditions:

carbon oxides.

# **SECTION 6: ACCIDENTAL RELEASE MEASURES**

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

#### For non-emergency personnel

Use personal protective equipment. Avoid breathing dust. Ensure adequate ventilation. Evacuate personnel to safe areas.

#### For emergency responders

Use personal protective equipment. Avoid breathing dust. Ensure adequate ventilation. Evacuate personnel to safe areas.

# **6.2 Environmental precautions**

Do not let product enter drains.

# 6.3 Methods and material for containment and cleaning up

Soak up with inert absorbent material, vacuum or sweep up material and keep in suitable, closed containers for disposal. Avoid generating dusty conditions.

#### 6.4 Reference to other sections

Not available.

# **SECTION 7: HANDLING AND STORAGE**

# 7.1 Precautions for safe handling

Precautions for safe handling: Normal measures for preventive fire protection.

Personal protection: Avoid contact with skin and eyes. Avoid inhalation of dust, vapour or

mist.

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

# 7.2 Conditions for safe storage, including any incompatibilities

Storage: In a well-closed container.

Conditions for safe storage, including any

Keep container tightly closed in a dry and well-ventilated place.

Conditions for safe storage, including any incompatibilities:

Contained

Contained

Containers which are opened must be carefully resealed and kept

upright to prevent leakage.

Storage – away from: Not available.

#### 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

Hygiene measures: Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of the working day.

#### Individual protection measures

Eye/face protection: Tightly fitting safety goggles. Face shield (8-inch minimum).

Use equipment for eye protection tested and approved under appropriate

government standards such as NIOSH (US) or EN 166(EU).

Skin protection: Complete suit protecting against chemicals, the type of protective equipment must

be selected according to the concentration and amount of the dangerous substance

at the specific workplace.

Hand protection: Handle with gloves.

Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good

laboratory practices. Wash and dry hands.

Respiratory protection: Where risk assessment shows air-purifying respirators are appropriate, use a

full-face respirator with multipurpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as

NIOSH (US) or CEN (EU).

Thermal hazards: Not determined.

# **Environmental exposure control**

Not available.

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# **MEPHENESINUM**

# **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

# 9.1 Information on basic physical and chemical properties

Appearance: White crystalline powder or colourless crystals.

Odour: Not available.
Odour threshold: Not available.

pH: The pH of the saturated aqueous solution is around 6.0.

Melting/freezing point: Between 70 °C and 73 °C

Initial boiling point:

Boiling range:

Not available.

Flash point:

Evaporation rate:

Flammability (solid/gas):

Upper/lower flammability or

Not available.

Not available.

explosive limits:

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

Solubility: Very soluble in alcohol, chloroform and ether.

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

Molecular weight: 182,2 g/mol

# **SECTION 10: STABILITY AND REACTIVITY**

### 10.1 Reactivity

Not available.

# 10.2 Chemical stability

Stable under recommended storage conditions.

#### 10.3 Possibility of hazardous reactions

Not available.

# 10.4 Conditions to avoid

Not available.

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# 10.5 Incompatible materials

Oxidising agents.

# 10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions: carbon oxides, nitrogen oxides (NO<sub>v</sub>), hydrogen chloride gas.

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

#### 11.1 Information on toxicological effects

Oral LD50 (rat): 625 mg/kg Acute toxicity:

Remarks: Behavioural: Somnolence (general depressed activity). Behavioural:

Antipsychotic. Lungs, thorax, or respiration: Other changes.

Skin corrosion/irritation: Not available. Serious eye damage/irritation: Not available. Respiratory/skin sensitisation: Not available. Germ cell mutagenicity: Not available.

Carcinogenicity: IARC: No component of this product present at levels greater than or equal to 0.1%

is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1%

is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1%

is identified as a carcinogen or potential carcinogen by OSHA.

Not available. Reproductive toxicity: Summary of evaluation of the

CMR properties:

Not available.

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

Other: Signs and symptoms of exposure: Nausea, headache, vomiting, central nervous

system depression.

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

Eye contact: Causes eye irritation.

Skin contact: May be harmful if absorbed through skin. Causes skin irritation. Inhalation: May be harmful if inhaled. Causes respiratory tract irritation.

May be harmful if swallowed. Ingestion:

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

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Very toxic to aquatic life.

# **SECTION 13: DISPOSAL CONSIDERATIONS**

# 13.1 Waste treatment methods

Product: Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.

Contaminated packaging: 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),

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

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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 hazardous material as defined by the transport regulations.

#### **SECTION 15: REGULATORY INFORMATION**

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

Hazard symbol:

×

Risk phrases: R22 Harmful if swallowed.

R36 Irritating to eyes R38 Irritating to skin.

Safety phrases: S23 Do not breathe dust/fumes/gas/mist/vapours/spray.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek

medical advice.

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

# 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 GoodsIUPAC: International Union of Pure and Applied ChemistryPBT: 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

#### ΕN

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# 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.

#### 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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