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# **LEVOMENTHOLUM**

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

#### 1.1 Product identifier

Product name: Levomenthol

Levomentholum Levomenthol Levomenthol

N° CAS: 2216-51-5 N° EC: 218-690-9

### 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 Eye Irrit. 2 H319

### 2.2 Label elements

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

Hazard pictogram(s):



Signal word(s): Attention

Irritant

Hazard statements:

H315 Causes skin irritation.

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Precautionary statements:

P264 Wash skin thoroughly after handling.

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

Causes serious eye irritation.

P302+P352 IF ON SKIN: Wash with plenty of water.

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

if present and easy to do. Continue rinsing.

P332+P313 If skin irritation 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

None.

H319

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

#### 3.1 Substances

Product name: Levomenthol

IUPAC name: (1R,2S,5R)-2-isopropyl-5-methyl-cyclohexanol

Synonyms: L-Menthol

Menthacamphor Menthomenthol

 N° CAS:
 2216-51-5

 N° EC:
 218-690-9

 Molecular Formula:
  $C_{10}H_{20}O$  

 Content:
 100 %

## 3.2 Mixtures

It contains no other components or impurities that may influence the classification of the product.

#### **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.

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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: Foam, dry powder, carbon dioxide, sand, water mist.

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

Do not use a compact stream of water as it may scatter and spread the fire.

#### 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 which must not enter 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

For exposure control and personal protective measures, see section 8. Ensure adequate ventilation.

#### For emergency responders

For exposure control and personal protective measures, see section 8. Ensure adequate ventilation.

## **6.2 Environmental precautions**

No special environmental precautions are required.

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

Store away from other materials.

If on the ground, sweep or scoop (shovel or similar) into suitable containers.

Limit dust production.

Local authorities should be informed if major spills cannot be contained.

#### 6.4 Reference to other sections

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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: Do not eat, drink or smoke while handling this product.

Personal protection:

Technical protective measures:

Handling:

Not available.

Not available.

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

Storage: Not available.

Conditions for safe storage, including any

incompatibilities:

Keep only in the original container. Keep container tightly closed in a

dry, well-ventilated place.

Storage – away from: To maintain the quality of the product, do not store in heat or direct

sunlight.

#### 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

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).

Thermal hazards: Not determined.

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#### **Environmental exposure control**

Not available.

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

## 9.1 Information on basic physical and chemical properties

Appearance: Prismatic or acicular, colourless, shiny crystals.

Odour: Characteristic. Odour threshold: Not available. Not available. about 43 °C Melting/freezing point: 218.94 °C Initial boiling point: Boiling range: Not available.

94 °C Flash point:

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

explosive limits:

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

Solubility: Very soluble in ethanol (96 per cent) and in light petroleum.

> Freely soluble in fatty oils. Freely soluble in liquid paraffin. Very slightly soluble in glycerol.

Solubility in water: Practically insoluble in water.

0.397 g/l (20 °C)

Partition coefficient (n-octanol/water):

Explosive properties:

Oxidising properties:

Log(P) ow 3.15

Auto-ignition temperature:

Not available. Decomposition temperature: Not available. Not available. Not available. Not available.

# 9.2 Other information

Viscosity:

Molecular weight: 156.27 g/mol Density (25 °C): 0.890 g/ml

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## 10.1 Reactivity

Not available.

### 10.2 Chemical stability

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

## 10.3 Possibility of hazardous reactions

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: Acute oral toxicity (LD50, rat): 2615 mg/kg

Acute oral toxicity (LD50, rabbit): > 5000 mg/kg

Skin corrosion/irritation: Irritating to skin. Slight eye irritation. Serious eye damage/irritation:

Respiratory/skin sensitisation: Not available. Germ cell mutagenicity: Not available.

Carcinogenicity: No component of this product is identified as a probable, possible or confirmed

human carcinogen at levels greater than or equal to 0.1%.

Not available. Reproductive toxicity: Summary of evaluation of the

CMR properties:

Not available.

STOT-single exposure: May cause respiratory irritation.

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: Causes serious eye irritation.

Skin contact: Causes skin irritation.

Inhalation: Not available. Ingestion: Not available. Aspiration: Not available.

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### **SECTION 12: ECOLOGICAL INFORMATION**

## 12.1 Toxicity

Acute toxicity (LC<sub>50</sub>, fish): 5.6 mg/L/96 h (*Danio zebra*)

Acute toxicity (EC<sub>50</sub>, invertebrates): 26.6 mg/L/48 h (*Daphnia magna*)

Acute toxicity (EC<sub>50</sub>, aquatic plants): 21.4 mg/L/72 h (*Desmodesmus subspicatus*)

Acute toxicity (EC<sub>50</sub>, micro-organisms): 237 mg/L

## 12.2 Persistence and degradability

Readily biodegradable.

#### 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), IATA/ICAO (Air):

It is not dangerous in transport.

# 14.2 UN proper shipping name

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

It is not dangerous in transport.

# 14.3 Transport hazard class(es)

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

It is not dangerous in transport.

IATA/ICAO (Air) :

## 14.4 Packing group

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

It is not dangerous in transport.

14.5 Environmental hazards

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

It is not dangerous in transport.

IATA/ICAO (Air):

#### 14.6 Special precautions for user

It is not dangerous in transport.

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

Not available.

#### 14.8 Additional transport information

The product is not to be considered dangerous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

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

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

Hazard symbol:

×

Irritant

Risk phrases: R36/38 Irritating to eyes and skin.

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

medical advice.

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

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

#### 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

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

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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

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 info@magis-pharma.be