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

1.1 Product identifier

Product name: Ergotamine tartrate

Ergotamini tartras Ergotaminetartraat Ergotamine (tartrate d')

Ergotamintartrat

N° CAS: 379-79-3 N° EC: 206-835-9

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

Acute Tox. 3 H301+H311
Acute Tox. 2 H330
Repr. 2 H361

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):





Signal word(s): Danger

Hazard statements:

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H301+H311 Toxic if swallowed or in contact with skin.

H330 Fatal if inhaled.

H361 Suspected of damaging fertility or the unborn child.

Precautionary statements:

P260 Do not breathe dust/fumes/gas/mist/vapours/spray.

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.

P310 Immediately call a POISON CENTER/doctor.
P320 Specific treatment is urgent (see on this label).

P322 Specific measures (see on this label).

P361 Take off immediately all contaminated clothing.

Additional applicable label

elements:



2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Ergotamine tartrate

IUPAC name: 5'-benzyl-12'-hydroxy-2'-methyl-3',6',18-trioxoergotaman 2,3-dihydroxysuccinate

(salt)

Synonyms: Ergotamine D-tartrate

Ergostat Rigetamin

 N° CAS: 379-79-3 N° EC: 206-835-9 Molecular Formula: $C_{70}H_{76}N_{10}O_{16}$

Content: 98.0 per cent to 101.0 per cent (dried substance).

It may contain two molecules of methanol of crystallisation.

3.2 Mixtures

Not applicable.

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:

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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

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

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

water mist.

Unsuitable extinguishing media: Direct water jet.

5.2 Special hazards arising from the substance/mixture

Possible formation of toxic gases in case of heating or fire: carbon oxides (CO_x) and azo oxides (NO_x).

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 that should not enter the 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), gloves (fireproof and dielectric), a mask with face mask covering the whole face of the operator or the car (self shield) in the case of large amounts of

smoke.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid dust formation and breathing of vapours/mists/gases. For exposure control and personal protective measures, see section 8.

For emergency responders

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Avoid dust formation and breathing of vapours/mists/gases. For exposure control and personal protective measures, see section 8.

6.2 Environmental precautions

Prevent product from entering sewers, surface water, groundwater and/or neighbouring areas.

6.3 Methods and material for containment and cleaning up

Collect spillage by mechanical spraying and place in containers for recovery or disposal.

Eliminate waste water jets if there are no contraindications.

Ensure sufficient ventilation of the site affected by the leak.

Check for incompatibilities for container material in section 7.

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: Handle the product after consulting all other sections of this safety

data sheet. Avoid dispersing product into the environment. Do not eat, drink or smoke during use. Remove contaminated clothing and

protective equipment before entering eating areas.

Personal protection:

Technical protective measures:

Handling:

Not available.

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Store in an airtight container.

Hygroscopic product.

Conditions for safe storage, including any

incompatibilities:

Store in tightly closed containers in a cool, dry place.

Store at a temperature of 2 °C to 8 °C.

Storage – away from: Protected from light.

Store containers away from incompatible materials, see section 10.

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

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Since the use of appropriate technical measures must 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.

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.

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

Handle with gloves. The selected protective gloves must comply with the Hand protection:

specifications of EU Directive 89/686/EEC and the derived EN 374 standard.

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

> 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.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

White or almost white, crystalline powder or colourless crystals, slightly Appearance:

hygroscopic.

Odour: Perceptible. Odour threshold: Not available. pH: Not available.

Melting/freezing point: 203°C

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

explosive limits:

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

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Solubility: Slightly soluble in ethanol 96 per cent.

Aqueous solutions slowly become cloudy owing to hydrolysis; this may be prevented

by the addition of tartaric acid.

Solubility in water: Slightly soluble.

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

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No special conditions. Stable under recommended handling and storage conditions (see section 7).

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

The product has no possibility of hazardous polymerisation.

10.4 Conditions to avoid

Sensitive to light.

10.5 Incompatible materials

Strong oxidising agents.

10.6 Hazardous decomposition products

Decomposition by heat can produce toxic fumes of CO, CO₂ and NO_x.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Toxic if swallowed or in contact with skin.

Fatal if inhaled.

Skin corrosion/irritation: Causes skin irritation.

Serious eye damage/irritation: Not available.

Respiratory/skin sensitisation: Causes irritation of mucous membranes.

Germ cell mutagenicity: Not available.

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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%.

Reproductive toxicity:

Summary of evaluation of the

Not available.

Not available.

CMR properties:

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

Other: N° RTECS: KE8225000

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact: Not available.

Skin contact: Toxic in contact with skin.

Inhalation: Fatal if inhaled.
Ingestion: Toxic if swallowed.
Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

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

Use in accordance with good working practices, avoiding dispersal of the product into the environment. Notify the competent authorities if the product reaches watercourses, sewers, soil or vegetation.

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.

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Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

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

1544

IATA/ICAO (Air):

14.2 UN proper shipping name

ADR/RID(Land),IMDG(Sea), ADR/RID: SOLID ALKALOID SALTS, (ERGOTAMINE TARTRATE)

IATA/ICAO (Air): IMDG: ALKALOID SALTS, SOLID, (ERGOTAMINE TARTRATE, ERGOTAMINI TARTRAS)

IATA: ALKALOID SALTS, SOLID, (ERGOTAMINE TARTRATE, ERGOTAMINI TARTRAS)

14.3 Transport hazard class(es)

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

IATA/ICAO (Air):

6.1

14.4 Packing group

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

IATA/ICAO (Air):

14.5 Environmental hazards

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

Not available.

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

Not available.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:





Toxic Harmful

Risk phrases: R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

R62 Possible risk of impaired fertility.

R63 Possible risk of harm to the unborn child.

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

S27 Take off immediately all contaminated clothing.

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S46 If swallowed, seek medical advice immediately and show this container or label.

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 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

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(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

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