

Material Safety Data Sheet

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

ZOLPIDEMI TARTRAS

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: Zolpidem tartrate
Zolpidemi tartras
Zolpidemtartraat
Zolpidem (tartrate de)
Zolpidemtartrat

N° CAS: 99294-93-6

N° EC: 629-694-9

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

The substance is not classified according to the CLP regulation.

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s): Not applicable.

Signal word(s): Not applicable.

Hazard statements: Not applicable.

Precautionary statements:

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

P314 Get medical advice/attention if you feel unwell.

P402+P404 Store in a dry place. Store in a closed container.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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Additional applicable label elements: Not applicable.

2.3 Other hazards

None. Additional information: This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Zolpidem tartrate
IUPAC name: 2,3-dihydroxybutanedioic acid;N,N-dimethyl-2-[6-methyl-2-(4-methylphenyl)imidazo[1,2-a]pyridin-3-yl]acetamide
Synonyms: N,N,6-Trimethyl-2-p-tolylimidazo(1,2-a)pyridine-3-acetamide L-(+)-tartrate (2:1)
Zolpidem hemitartrate
Zolpidem L-(+)-hemitartrate
N° CAS: 99294-93-6
N° EC: 629-694-9
Molecular Formula: $C_{42}H_{48}N_6O_8$
Content: 98.5 per cent to 101.0 per cent (anhydrous substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: When in doubt or if symptoms are observed, get medical advice.
After inhalation: No special measures are necessary.
After skin contact: Wash immediately with: Water and soap Change contaminated, saturated clothing. Wash contaminated clothing prior to re-use.
After eye contact: Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.
After ingestion: Call a physician in any case! Do NOT induce vomiting. If major quantity of dust is swallowed or inhaled, immediately drink: Water.

4.2 Most important symptoms and effects, both acute and delayed

The following symptoms may occur: No known symptoms to date. Repeated exposure may cause skin dryness or cracking.

4.3 Indication of any immediate medical attention and special treatment needed

None.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: None.

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Unsuitable extinguishing media: None.

5.2 Special hazards arising from the substance/mixture

None.

5.3 Advice for firefighters

Surrounding fires: Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

Protection against fire: None.

Hazardous combustion products: None.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid contact with skin, eyes and clothes. Use personal protection equipment.

For emergency responders

Not available.

6.2 Environmental precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains. Make sure spills can be contained, e.g. in sump pallets or kerbed areas. In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

6.3 Methods and material for containment and cleaning up

For containment: Collect in closed and suitable containers for disposal. Treat the recovered material as prescribed in the section on waste disposal.

For cleaning up: Suitable material for taking up: Sand. Absorbing material, organic.

6.4 Reference to other sections

See protective measures under section 7 and 8.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: None.

Personal protection: None.

Technical protective measures: None.

Handling: None.

7.2 Conditions for safe storage, including any incompatibilities

Storage: In an airtight container.

Conditions for safe storage, including any incompatibilities: Keep/Store only in original container.

Suitable container/equipment material: Stainless steel Polyethylene (PE). Unsuitable container/equipment material: Butyl caoutchouc (butyl rubber).

Storage class (TRGS 510) : 13

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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

None.

8.2 Exposure controls

Appropriate engineering control

General health and safety measures: Immediately remove any contaminated clothing, shoes or stockings. Wash contaminated clothing prior to re-use.

Individual protection measures

Eye/face protection: Eye glasses with side protection.

Skin protection: Not determined.

Hand protection: The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. DIN-/EN-Norms EN ISO 374 DIN EN 420. Suitable material: NBR (Nitrile rubber), PVA (Polyvinyl alcohol), PVC (polyvinyl chloride).

Breakthrough time (maximum wearing time): > 60 m.

Thickness of the glove material: > 0.5 mm

Respiratory protection: If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn. Suitable respiratory protection apparatus: Full-/half-/quarter-face masks (DIN EN 136/140), Filtering device (full mask or mouthpiece) with filter: ABEK-P3

Thermal hazards: Not determined.

Environmental exposure control

See section 7. No additional measures necessary.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: White or almost white, hygroscopic, crystalline powder.

Odour: Not available.

Odour threshold: Not available.

pH: Not available.

Melting/freezing point: Not available.

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: Not available.

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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:	Sparingly soluble in methanol, practically insoluble in methylene chloride.
Solubility in water:	Slightly soluble 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

None.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not applicable.

10.2 Chemical stability

Stable under normal conditions of use.

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Strong oxidizers.

10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Not available.
Skin corrosion/irritation:	Not an irritant.
Serious eye damage/irritation:	Not an irritant.

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Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	No indications of human germ cell mutagenicity exist.
Carcinogenicity:	This substance does not meet the criteria for classification as CMR category 1A or 1B according to CLP.
Reproductive toxicity:	This substance does not meet the criteria for classification as CMR category 1A or 1B according to CLP.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not applicable.
STOT-repeated exposure:	Prolonged or repeated contact with skin or mucous membrane result in irritation symptoms such as redness, blistering, dermatitis, etc.
Aspiration Hazard:	Not available.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Harmless to aquatic organisms up to the tested concentration.

12.2 Persistence and degradability

Biodegradable.

12.3 Bioaccumulative potential

No indication of bioaccumulation potential.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.

12.6 Other adverse effects

None.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Delivery to an approved waste disposal company.

Contaminated packages must be completely emptied and can be re-used following proper cleaning.

Handle contaminated packages in the same way as the substance itself.

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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) : UN 3077

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Land transport (ADR/RID)
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zolpidem tartrate)
Sea transport (IMDG)
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zolpidem tartrate)
Air transport (ICAO-TI/IATA-DGR)
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zolpidem tartrate)

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Land transport (ADR/RID)
Class(es): 9
Classification code: M7
Hazard identification number (Kemler No.): 90
Tunnel restriction code: -
Special provisions: LQ 5 kg · E 1 · ADR: - (SP 375 <= 5 l/kg)
Hazard label(s): 9 / N
Sea transport (IMDG)
Class(es): 9
EmS-No.: F-A / S-F
Special provisions: LQ 5 kg · E 1 · IMDG: - (SP 2.10.2.7 <= 5 l/kg)
Hazard label(s): 9 / N
Air transport (ICAO-TI/IATA-DGR)
Class(es): 9
Special provisions: E 1 · IATA: - (SP A197 <= 5 l/kg)
Hazard label(s): 9 / N

14.4 Packing group

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

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Land transport (ADR/RID): Yes
Sea transport (IMDG): Yes (P)
Air transport (ICAO-TI/IATA-DGR): Yes

14.6 Special precautions for user

None.

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

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Not applicable.

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: Not applicable.

Risk phrases: Not applicable.

Safety phrases: S7/8 Keep container tightly closed and dry.

S23 Do not breathe dust/fume/gas/mist/vapours/spray.

S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

15.2 Chemical safety assessment

Chemical safety assessments for substances in this preparation were not 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

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

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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

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