

Safety Data Sheet

acc. to OSHA HCS

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Printing date 09/12/2022

Reviewed on 09/12/2022

1 Identification

- **Product identifier**
- **Trade name:** Zolpidem tartrate
Zolpidemi tartras
Imidazo(1,2-a)pyridine-3-acetamide, N,N,6-trimethyl-2-(4-methylphenyl)-, (2R,3R)-2,3-dihydroxybutanedioate (2:1)
- **Article number:** 101841
- **CAS Number:** 99294-93-6
- **EC number:** 629-694-9
- **Application of the substance / the mixture** Pharma Active ingredients
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Fagron Inc
2400 Pilot Knob Road
St. Paul, MN 55120
www.fagron.us
QA@fagron.us
- **Information department:**
Tel.: 800-423-6967
Fax: 800-339-1596
- **Emergency telephone number:**
Emergency Telephone:
US: 1-800-535-5053
International: 1-352-323-3500

2 Hazard(s) identification

- **Classification of the substance or mixture**
Acute Toxicity - Oral 4 H302 Harmful if swallowed.

- **Label elements**
- **GHS label elements**
The substance is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard statements**
Harmful if swallowed.
- **Precautionary statements**
Wash thoroughly after handling.
Do not eat, drink or smoke when using this product.
If swallowed: Call a poison center/doctor if you feel unwell.
Rinse mouth.
Dispose of contents/container in accordance with local/regional/national/international regulations.

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USA

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- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**



- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Substances**
- **CAS No. Description**
CAS: 99294-93-6 Zolpidem tartrate
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- **Identification number(s)**
- **EC number:** 629-694-9

4 First-aid measures

- **Description of first aid measures**
- **General information:**
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** If skin irritation continues, consult a doctor.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** Immediately call a doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
Water spray
Carbon dioxide
Fire-extinguishing powder
Foam

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- Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
In case of fire, the following can be released:
Nitrogen oxides (NOx)
- **Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
- **Protective Action Criteria for Chemicals**
- **PAC-1:** Substance is not listed.
- **PAC-2:** Substance is not listed.
- **PAC-3:** Substance is not listed.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** No special precautions are necessary if used correctly.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
- **Breathing equipment:** Not required.
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

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Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

Nitrile rubber, NBR
 Butyl rubber, BR
 PVC gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:** Not required.

· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

| | |
|--------------------------|-----------------|
| · Form: | Crystalline |
| · Color: | Whitish |
| · Odor: | Odorless |
| · Odor threshold: | Not determined. |

· **pH-value:** Not applicable.

· **Change in condition**

| | |
|---------------------------------------|---------------------------|
| · Melting point/Melting range: | 191–196°C (375.8–384.8°F) |
| · Boiling point/Boiling range: | Undetermined. |

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Product is not flammable.

· **Decomposition temperature:** Not determined.

· **Auto igniting:** Not determined.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

| | |
|-----------------|-----------------|
| · Lower: | Not determined. |
| · Upper: | Not determined. |

· **Vapor pressure:** Not applicable.

· **Density:** Not determined.

· **Relative density** Not determined.

· **Vapor density** Not applicable.

· **Evaporation rate** Not applicable.

· **Solubility in / Miscibility with**

| | |
|--------------------------------|----------|
| · Water at 20°C (68°F): | 21.1 g/l |
|--------------------------------|----------|

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

| | |
|-------------------|-----------------|
| · Dynamic: | Not applicable. |
|-------------------|-----------------|



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Kinematic: Not applicable.

Other information No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
 No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** Nitrogen oxides (NOx)

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

| | | |
|------|------|-----------------|
| Oral | LD50 | 695 mg/kg (rat) |
|------|------|-----------------|

- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
- **Carcinogenic categories**
- **IARC (International Agency for Research on Cancer)** Substance is not listed.
- **NTP (National Toxicology Program)** Substance is not listed.
- **OSHA-Ca (Occupational Safety & Health Administration)** Substance is not listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**

Water hazard class 2 (Self-assessment): hazardous for water
 Do not allow product to reach ground water, water course or sewage system.
 Danger to drinking water if even small quantities leak into the ground.

- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

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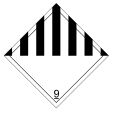
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13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

| | |
|---|--|
| · UN-Number | |
| · DOT | not regulated |
| · IMDG, IATA | UN3077 |
| · UN proper shipping name | |
| · DOT | not regulated |
| · IMDG | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zolpidem tartrate Zolpidemi tartras Imidazo(1,2-a)pyridine-3-acetamide, N,N,6- trimethyl-2-(4-methylphenyl)-, (2R,3R)-2,3- dihydroxybutanedioate (2:1)) |
| · IATA | Environmentally hazardous substance, solid, n.o.s. (Zolpidem tartrate Zolpidemi tartras Imidazo(1,2-a)pyridine-3-acetamide, N,N,6- trimethyl-2-(4-methylphenyl)-, (2R,3R)-2,3- dihydroxybutanedioate (2:1)) |
| · Transport hazard class(es) | |
| · DOT | |
| · Class | not regulated |
| · IMDG, IATA | |
|   | |
| · Class | 9 Miscellaneous dangerous substances and articles |
| · Label | 9 |
| · Packing group | |
| · DOT | not regulated |
| · IMDG, IATA | III |
| · Environmental hazards: | |
| · Marine pollutant: | Symbol (fish and tree) |
| · Special marking (IATA): | Symbol (fish and tree) |
| · Special precautions for user | Warning: Miscellaneous dangerous substances and articles |

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USA

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- | | |
|---|---|
| · Hazard identification number (Kemler code): 90 | |
| · EMS Number: | F-A,S-F |
| · Stowage Category | A |
| · Stowage Code | SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · Transport/Additional information: | |
| · IMDG | |
| · Limited quantities (LQ) | 5 kg |
| · Excepted quantities (EQ) | Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g |
| · UN "Model Regulation": | UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ZOLPIDEM TARTRATE ZOLPIDEMI TARTRAS IMIDAZO(1,2-A)PYRIDINE-3-ACETAMIDE, N,N,6-TRIMETHYL-2-(4-METHYLPHENYL)-, (2R,3R)-2,3-DIHYDROXYBUTANEDIOATE (2:1)), 9, III |

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
No further relevant information available.
- Sara
- Section 355 (extremely hazardous substances): Substance is not listed.
- Section 313 (Specific toxic chemical listings): Substance is not listed.
- TSCA (Toxic Substances Control Act): Substance is not listed.
- Hazardous Air Pollutants Substance is not listed.
- Proposition 65
- Chemicals known to cause cancer: Substance is not listed.
- Chemicals known to cause reproductive toxicity for females: Substance is not listed.
- Chemicals known to cause reproductive toxicity for males: Substance is not listed.
- Chemicals known to cause developmental toxicity: Substance is not listed.
- Carcinogenic categories
- EPA (Environmental Protection Agency) Substance is not listed.
- TLV (Threshold Limit Value) Substance is not listed.
- NIOSH-Ca (National Institute for Occupational Safety and Health) Substance is not listed.
- Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.


personlizing
medicine
USA

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· **Department issuing SDS:**

Fagron US

Quality Assurance

· **Contact:** QA@fagron.us

· **Date of preparation / last revision** 09/12/2022 / -

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Acute Toxicity - Oral 4: Acute toxicity – Category 4

USA