

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 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
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Pharma Active ingredients
- **1.3 Details of the supplier of the safety data sheet**
Fagron UK Ltd
4B Coquet St
Newcastle upon Tyne
England NE1 2QB
Tel. 0845 6522525
- **Further information obtainable from:**
Emergency response telephone number:
+44 (0) 845 652 2525
- **1.4 Emergency telephone number:**
Emergency response telephone number:
+44 (0) 845 652 2525

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Acute Tox. 4 H302 Harmful if swallowed.
Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The substance is classified and labelled according to the GB CLP regulation.
- **Hazard pictograms**

GHS07 GHS09
- **Signal word** Warning
- **Hazard statements**
H302 Harmful if swallowed.
H411 Toxic to aquatic life with long lasting effects.
- **Precautionary statements**
P264 Wash thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

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P273 Avoid release to the environment.
P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P330 Rinse mouth.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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

SECTION 3: Composition/information on ingredients

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

SECTION 4: First aid measures

- **4.1 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:** Call for a doctor immediately.
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
Water spray
Carbon dioxide
Fire-extinguishing powder
Foam
Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 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)

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- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:**
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 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.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special precautions are necessary if used correctly.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Additional information about design of technical facilities:** No further data; see item 7.
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
- **Respiratory protection:** 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.
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.

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- **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

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

· Form:	Crystalline
· Colour:	Whitish
· Odour:	Odourless
· Odour threshold:	Not determined.

· **pH-value:** Not applicable.

· Change in condition

· Melting point/freezing point:	191–196°C
· Initial boiling point and boiling range:	Undetermined.

· **Flash point:** Not applicable.

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

· **Decomposition temperature:** Not determined.

· **Auto-ignition temperature:** Not determined.

· **Explosive properties:** Product does not present an explosion hazard.

· Explosion limits:

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapour pressure:** Not applicable.

· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.

· **Solubility in / Miscibility with water at 20°C:** 21.1 g/l

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

· Viscosity:

· Dynamic:	Not applicable.
· Kinematic:	Not applicable.

· **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.

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

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

- **Acute toxicity**
Harmful if swallowed.

· LD/LC50 values relevant for classification:

Oral	LD50	695 mg/kg (rat)
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- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Toxic for fish
- **Additional ecological information:**
- **General notes:**
Water hazard class 2 (German Regulation) (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.
Also poisonous for fish and plankton in water bodies.
Toxic for aquatic organisms
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

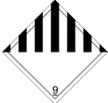
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SECTION 13: Disposal considerations

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

SECTION 14: Transport information

· 14.1 UN-Number · ADR, IMDG, IATA	UN3077
· 14.2 UN proper shipping name · ADR	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))
· 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))
· 14.3 Transport hazard class(es) · ADR, IMDG, IATA	
 	
· Class	9 Miscellaneous dangerous substances and articles.
· Label	9
· 14.4 Packing group · ADR, IMDG, IATA	III
· 14.5 Environmental hazards:	
· Marine pollutant:	Symbol (fish and tree)
· Special marking (ADR):	Symbol (fish and tree)

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· Special marking (IATA):	Symbol (fish and tree)
· 14.6 Special precautions for user	Warning: Miscellaneous dangerous substances and articles.
· 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.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	

· ADR	
· 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
· Transport category	3
· Tunnel restriction code	(-)

· 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

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** Substance is not listed.
- **Seveso category E2** Hazardous to the Aquatic Environment
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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SECTION 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.

· **Department issuing SDS:**

Fagron UK
Quality Assurance

· **Contact:** quality@fagron.co.uk

· **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

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

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

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 4: Acute toxicity – Category 4

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

· * **Data compared to the previous version altered.**

GB