

## 1. Identification

Product identifier	Zolpidem Tartrate CIV	
Other means of identification		
Catalog number	1724907	
CAS number	99294-93-6	
Synonyms	Zolpidem hemitartrate	
Chemical name	N,N-Dimethyl-2-(6-methyl-2-p-tolylimidazo[1,2-a]pyridin-3-yl)acetamide hemitartrate	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Acute toxicity, oral	Category 4
	Specific target organ toxicity, single exposure	Category 3 narcotic effects
<b>Environmental hazards</b>	Not classified.	
<b>OSHA defined hazards</b>	Not classified.	

### Label elements



<b>Signal word</b>	Warning
<b>Hazard statement</b>	Harmful if swallowed. May cause drowsiness or dizziness.
<b>Precautionary statement</b>	
<b>Prevention</b>	Avoid breathing dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Use only outdoors or in a well-ventilated area.
<b>Response</b>	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell.
<b>Storage</b>	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Hazard(s) not otherwise classified (HNOC)</b>	This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.
<b>Supplemental information</b>	Potent pharmacologically active material.

### 3. Composition/information on ingredients

#### Substance

Chemical name	Common name and synonyms	CAS number	%
Zolpidem Tartrate CIV	Zolpidem hemitartrate	99294-93-6	100

### 4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
Most important symptoms/effects, acute and delayed	Narcotic effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Treatment of overdose may include the following: Do NOT induce vomiting. Administer activated charcoal as a slurry. Administer oxygen and manage airway as needed. Monitor pulse oximetry and/or ABGs as indicated. Monitor blood pressure following severe exposures. Zolpidem is NOT dialyzable. Administration of flumazenil may be useful, but may contribute to the appearance of neurological symptoms (convulsions).
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

### 5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

### 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. For personal protection, see section 8 of the SDS. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Methods and materials for containment and cleaning up	For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

### Precautions for safe handling

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

### Conditions for safe storage, including any incompatibilities

Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

### Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

### Exposure limit values

Industrial Use Material	Type	Value
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Zolpidem Tartrate CIV (CAS 99294-93-6)	TWA	0.006 mg/m3
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### Biological limit values

No biological exposure limits noted for the ingredient(s).

### Appropriate engineering controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

#### Skin protection

##### Hand protection

Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

##### Other

Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

#### Respiratory protection

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

#### Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

### General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

## 9. Physical and chemical properties

### Appearance

Appearance descriptions are general information and not specific to any USP lot.

#### Physical state

Solid.

#### Form

Crystalline powder.

#### Color

White. Off-white.

### Odor

Not available.

### Odor threshold

Not available.

### pH

Not available.

### Melting point/freezing point

384.8 °F (196 °C)

### Initial boiling point and boiling range

Not available.

### Flash point

Not available.

<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Slightly soluble.
<b>Solubility (other)</b>	Propylene glycol: Sparingly soluble. Dichloromethane: Practically insoluble. Methanol: Sparingly soluble.
<b>Partition coefficient (n-octanol/water)</b>	2.42
<b>Auto-ignition temperature</b>	950 °F (510 °C)
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Imidazopyridine.
<b>Dust explosion properties</b>	
<b>Kst</b>	206 bar.m/s
<b>St class</b>	2
<b>Minimum ignition energy (MIE) - dust cloud</b>	< 10 mJ
<b>Molecular formula</b>	(C19-H21-N3-O)2.C4-H6-O6
<b>Molecular weight</b>	764.86 g/mol
<b>pH in aqueous solution</b>	4 - 5.5 Solution: 1%

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	May cause drowsiness and dizziness.
<b>Skin contact</b>	Knowledge about health hazard is incomplete.
<b>Eye contact</b>	Knowledge about health hazard is incomplete.
<b>Ingestion</b>	Harmful if swallowed. Based on information from therapeutic use, this material may cause: Narcotic effects.

**Symptoms related to the physical, chemical, and toxicological characteristics**

Dizziness. Drowsiness. Headache. Vertigo. Weakness. Unsteadiness. Anxiety. Confusion. Depression. Memory loss. Visual disturbances. Abnormal thoughts or dreams. Muscle pain. Back pain. Palpitations. Skin rash. Flu-like symptoms. Gastrointestinal disturbances.

**Information on toxicological effects**

**Acute toxicity** Harmful if swallowed.

Product	Species	Test Results
Zolpidem Tartrate CIV (CAS 99294-93-6)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Mouse	695 mg/kg
	Rat	695 - 1030 mg/kg
		2700 mg/kg

**Skin corrosion/irritation** Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation** Based on available data, the classification criteria are not met.

**Local effects**

Eye irritation  
Result: Negative.  
Species: Rabbit  
Skin irritation  
Result: Negative.  
Species: Rabbit

**Respiratory or skin sensitization**

**Respiratory sensitization** Knowledge about health hazard is incomplete.

**Skin sensitization** Based on available data, the classification criteria are not met.

Guinea pig maximization test  
Result: Negative.

**Germ cell mutagenicity** Knowledge about mutagenicity is incomplete.

**Mutagenicity**

Ames test  
Result: Negative.  
Chromosome aberration  
Result: Negative.  
Micronucleus test  
Result: Negative.  
Species: Mouse  
Mouse lymphoma assay  
Result: Negative.  
Unscheduled DNA synthesis  
Result: Negative.

**Carcinogenicity** Based on available data, the classification criteria are not met.

4 - 80 mg/kg/day Carcinogenicity, administered as base.  
Result: Negative.  
Species: Mouse  
4 - 80 mg/kg/day Carcinogenicity, administered as base.  
Result: Renal tumors occurred at the middle and high doses.  
Species: Rat

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Not listed.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not regulated.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

**Reproductive toxicity** Based on available data, the classification criteria are not met.  
Epidemiological studies have not shown an association between therapeutic use of this material during pregnancy and an increased incidence of birth defects.

## Reproductivity

1 - 16 mg/kg/day Reproductivity / developmental, administered orally as base during organogenesis.

Result: Embryofetal toxicity at high dose.

Species: Rabbit

4 - 100 mg/kg/day Reproductivity / developmental, administered orally as base during late pregnancy and lactation.

Result: Decreased offspring growth and survival.

Species: Rat

4 - 100 mg/kg/day Reproductivity / developmental, administered orally as base during organogenesis.

Result: Dose-related decreased fetal skull ossification.

Species: Rat

4 - 100 mg/kg/day Reproductivity / developmental, administered orally as base prior to and during mating.

Result: No impairment of fertility.

Species: Rat

5 mg/kg/day Reproductivity / developmental, administered orally for 11 days.

Result: Fetotoxicity.

Species: Rat

**Specific target organ toxicity - single exposure** May cause drowsiness and dizziness.

**Specific target organ toxicity - repeated exposure** Knowledge about health hazard is incomplete.

**Aspiration hazard** Based on available data, the classification criteria are not met.

**Further information** Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

## 12. Ecological information

### Ecotoxicity

Product		Species	Test Results
Zolpidem Tartrate CIV (CAS 99294-93-6)			
<i>Acute</i>			
Other	IC50	Pseudokirchnerella subcapitata	2.2 mg/l, 96 hours
<b>Aquatic</b>			
<i>Acute</i>			
Crustacea	EC50	Daphnia magna	120 mg/l, 48 hours
Fish	LC50	Oncorhynchus mykiss	22 mg/l, 96 hours

**Persistence and degradability** Not readily biodegradable.

### Bioaccumulative potential

**Octanol/water partition coefficient log Kow**  
2.42

**Mobility in soil** No data available.

**Other adverse effects** No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. Disposal considerations

**Disposal instructions** Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

**Local disposal regulations** Dispose in accordance with all applicable regulations.

**Hazardous waste code** The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

**Waste from residues / unused products** Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging** Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

### DOT

Not regulated as dangerous goods.

### IATA

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

**General information** It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

## 15. Regulatory information

**US federal regulations** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

### SARA 304 Emergency release notification

Not regulated.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

**Hazard categories** Immediate Hazard - Yes  
Delayed Hazard - No  
Fire Hazard - Yes  
Pressure Hazard - No  
Reactivity Hazard - No

### SARA 302 Extremely hazardous substance

Not listed.

**SARA 311/312 Hazardous chemical** Yes

**SARA 313 (TRI reporting)**  
Not regulated.

### Other federal regulations

#### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

#### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

**Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)** Schedule IV - 2783

**US state regulations** California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

<b>Issue date</b>	12-10-2008
<b>Revision date</b>	10-22-2018
<b>Version #</b>	02
<b>Further information</b>	Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.
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