1. Identification

Product identifier: Zolpidem Tartrate

Other means of identification:
- Catalog number: 1724907
- Chemical name: N,N-Dimethyl-2-(6-methyl-2-p-tolylimidazo[1,2-a]pyridin-3-yl)acetamide hemitartrate
- Synonym(s): Zolpidem 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:
- Company name: U. S. Pharmacopeia
- Address: 12601 Twinbrook Parkway, Rockville, MD 20852-1790, US
- 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

Note: 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.

Physical hazards: Not classified.

Health hazards:
- Acute toxicity, oral: Category 4
- Specific target organ toxicity, single exposure: Category 3 narcotic effects

OSHA hazard(s): Not classified.

Label elements:

Signal word: Warning

Hazard statement: Harmful if swallowed. May cause drowsiness or dizziness.

Precautionary statement:
- Prevention: Use only outdoors or in a well-ventilated area. Wash thoroughly after handling.
- Response: 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.
- Storage: Store in a well-ventilated place. Keep container tightly closed. Store locked up.
- Disposal: Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC): Not classified.

3. Composition/information on ingredients

Substance
### Hazardous components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zolpidem Tartrate</td>
<td>Zolpidem hemitartrate</td>
<td>99294-93-6</td>
<td>100</td>
</tr>
</tbody>
</table>

### 4. First-aid measures

**Inhalation**
Move to fresh air. Call a POISON CENTER or doctor/physician if you feel unwell.

**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**
IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth.

**Most important symptoms/effects, acute and delayed**
Dizziness. Drowsiness.

**Indication of immediate medical attention and special treatment needed**
Treatment of overdose should be symptomatic and supportive and may include the following:
1. Do NOT induce vomiting.
2. Administer activated charcoal as a slurry.
3. Administer oxygen and manage airway as needed.
4. Monitor pulse oximetry and/or ABGs as indicated. Monitor blood pressure following severe exposures.
5. Zolpidem is NOT dialyzable.
6. Administration of flumazenil may be useful, but may contribute to the appearance of neurological symptoms (convulsions). [Meditext 2008 and PDR 2008]

**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**
Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.

**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.

**Specific methods**
Use standard firefighting procedures and consider the hazards of other involved materials.

### 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**
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.
Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

**Methods and materials for containment and cleaning up**
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

### 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. Use of a designated area is recommended for handling of potent materials. Combustible dust clouds may be created where operations produce fine material (dust). Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions.

**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

Exposure limit values

Industrial Use

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zolpidem Tartrate (CAS 99294-93-6)</td>
<td>TWA</td>
<td>0.006 mg/m³</td>
</tr>
</tbody>
</table>

Biological limit values

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

Appropriate engineering controls

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin protection

Hand protection

Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.

Other

For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.

Respiratory protection

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Thermal hazards

Not available.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance

White to off-white crystalline powder.

Physical state

Solid.

Form

Powder.

Odor

Not available.

Odor threshold

Not available.

pH

4 - 5.5 (1% solution)

Melting point/freezing point

384.8 °F (196 °C)

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

Not available.

Flammability limit - upper (%)

Not available.

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Vapor pressure

Not available.

Vapor density

Not available.

Relative density

Not available.
Solubility in water
Slightly soluble.
Partition coefficient (n-octanol/water)
2.42
Auto-ignition temperature
950 °F (510 °C)
Decomposition temperature
Not available.
Viscosity
Not available.
Other information
Chemical family
Imidazopyridine.
Dust explosion properties
Kst 206 bar.m/s
St class 2
Minimum ignition energy (MIE) - dust cloud < 10 mJ
Molecular formula (C19-H21-N3-O)2.C4-H6-O6
Molecular weight 764.86 g/mol
Solubility (other)
Sparingly soluble in methanol and in propylene glycol; practically insoluble in dichloromethane.

10. Stability and reactivity
Reactivity
No reactivity hazards known.
Chemical stability
Stable at normal conditions.
Possibility of hazardous reactions
No dangerous reaction known under conditions of normal use.
Conditions to avoid
None known.
Incompatible materials
Strong oxidizing agents
Hazardous decomposition products
NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information
Information on likely routes of exposure
Ingestion
Harmful if swallowed.
Inhalation
Due to lack of data the classification is not possible.
Skin contact
Due to lack of data the classification is not possible.
Eye contact
Based on available data, the classification criteria are not met.
Symptoms related to the physical, chemical, and toxicological characteristics
Delayed and immediate effects of exposure
Dependence. Withdrawal. Behavior, mood, or mental changes.
Medical conditions aggravated by exposure
Acute toxicity
Harmful if swallowed.

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zolpidem Tartrate (CAS 99294-93-6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Mouse</td>
<td>695 mg/kg</td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>695 - 1030 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2700 mg/kg</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>Based on available data, the classification criteria are not met.</td>
<td></td>
</tr>
<tr>
<td>Serious eye damage/eye irritation</td>
<td>Based on available data, the classification criteria are not met.</td>
<td></td>
</tr>
<tr>
<td>Local effects</td>
<td>Eye irritancy test</td>
<td>Result: Not irritating.</td>
</tr>
<tr>
<td></td>
<td>Species: Rabbit</td>
<td></td>
</tr>
</tbody>
</table>
Local effects
Skin irritancy test
Result: Not irritating.
Species: Rabbit
Respiratory sensitization
Due to lack of data the classification is not possible.
Skin sensitization
Based on available data, the classification criteria are not met.
Sensitization
Guinea pig maximization test
Result: Not sensitizing.
Sensitization
Rare cases of angioedema and anaphylaxis following therapeutic use of zolpidem have been reported.
Germ cell mutagenicity
Due to lack of data the classification is not possible.
Data from germ cell mutagenicity tests were not found.
Mutagenicity
Ames test
Result: Negative.
In vitro chromosomal aberration assay in human lymphocytes
Result: Negative.
In vitro mouse lymphoma assay
Result: Negative.
In vivo mouse micronucleus test
Result: Negative.
Unscheduled DNA synthesis assay in rat hepatocytes
Result: Negative.
Carcinogenicity
Based on available data, the classification criteria are not met.
This material is not considered to be a carcinogen by IARC, NTP, or OSHA.
4 - 80 mg/kg/day Carcinogenicity test, administered as base.
Result: No evidence of carcinogenic potential noted.
Species: Mouse
4 - 80 mg/kg/day Carcinogenicity test, administered as base.
Result: Renal tumors occurred at the middle and high doses.
Species: Rat
Reproductive toxicity
Based on available data, the classification criteria are not met.
Flaccidity, hypothermia, respiratory depression, and withdrawal symptoms have been reported in newborns of mothers receiving sedative-hypnotics during pregnancy.
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 and development study, administered orally as base during organogenesis.
Result: Embryofetal toxicity at high dose.
Species: Rabbit
4 - 100 mg/kg/day Reproductivity and development study, administered orally as base during late pregnancy and lactation.
Result: Decreased offspring growth and survival.
Species: Rat
4 - 100 mg/kg/day Reproductivity and development study, administered orally as base during organogenesis.
Result: Dose-related decreased fetal skull ossification.
Species: Rat
4 - 100 mg/kg/day Reproductivity and development study, administered orally as base prior to and during mating.
Result: No impairment of fertility.
Species: Rat
5 mg/kg/day Reproductivity and development study, administered orally for 11 days.
Result: Fetotoxicity.
Species: Rat
Specific target organ toxicity - single exposure
Narcotic effects.
Specific target organ toxicity - repeated exposure
Based on available data, the classification criteria are not met.
Aspiration hazard
Based on available data, the classification criteria are not met.
12. Ecological information

Ecotoxicity

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zolpidem Tartrate (CAS 99294-93-6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crustacea</td>
<td>EC50</td>
<td>120 mg/l, 48 hours</td>
</tr>
<tr>
<td>Fish</td>
<td>LC50</td>
<td>22 mg/l, 96 hours</td>
</tr>
<tr>
<td>Other</td>
<td>IC50</td>
<td>2.2 mg/l, 96 hours</td>
</tr>
</tbody>
</table>

**Persistence and degradability**  Not readily biodegradable.

**Bioaccumulative potential**  Not available.

**Mobility in soil**  Not available.

**Other adverse effects**  Not available.

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**  Not available.

**Hazardous waste code**  Not available.

**Waste from residues / unused products**  Dispose of in accordance with local regulations. 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**  Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

**DOT**

- **UN number**  UN3077
- **UN proper shipping name**  Environmentally hazardous substance, solid, n.o.s. (Zolpidem Tartrate)
- **Transport hazard class(es)**  9
- **Subsidiary class(es)**  Not available.
- **Packing group**  III

**IATA**

- **UN number**  UN3077
- **UN proper shipping name**  Environmentally hazardous substance, solid, n.o.s. (Zolpidem Tartrate)
- **Transport hazard class(es)**  9
- **Subsidiary class(es)**  -
- **Packing group**  III

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**  No information available.

**DOT; IATA**

15. Regulatory information

**US federal regulations**  CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.
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
No

SARA 311/312 Hazardous chemical
No

Other federal regulations
- Safe Drinking Water Act (SDWA)
  Not regulated.
- Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)
  Schedule IV - 2783
- Food and Drug Administration (FDA)
  Not regulated.

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

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>Yes</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

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

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

Issue date: 12-10-2008
Revision date: 02-25-2014
Version #: 02

Further information
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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Revision Information
This document has undergone significant changes and should be reviewed in its entirety.