SAFETY DATA SHEET

1. Identification

Product identifier **Zolpidem Impurities Mixture**

Other means of identification

Catalog number 1724951

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

Physical hazards Not classified.

Health hazards

Acute toxicity, oral	Category 4
Specific target organ toxicity, single exposure	Category 3 narcotic effects

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Signal word Warning

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

Precautionary statement

Prevention Wash thoroughly after handling. Use only outdoors or in a well-ventilated area.

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.

Other hazards which do not result in classification None known.

3. Composition/information on ingredients

Mixture

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Zolpidem Tartrate	Zolpidem hemitartrate	99294-93-6	>99

Non-hazardous components

Chemical name	Common name and synonyms	CAS number	%
Related Impurities		No Data	<1

4. First-aid measures

Inhalation If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. 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.

Most important symptoms/effects, acute and delayed Narcotic effects.

Indication of immediate medical attention and special treatment needed Treatment of zolpidem overdose should be symptomatic and supportive and 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). [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 No unusual fire or explosion hazards noted.

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.

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. 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.

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

Components	Type	Value
Zolpidem Tartrate (CAS 99294-93-6)	TWA	0.006 mg/m3

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.
Other	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing 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).
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	White powder.
Physical state	Solid.
Form	Powder.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
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.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	Not available.
Chemical stability	Material is stable under 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	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	Component: Dizziness. Drowsiness. Headache. Vertigo. Weakness. Unsteadiness. Anxiety. Confusion. Depression. Memory loss. Visual disturbances. Abnormal thoughts or dreams. Sleepwalking . Nausea. Indigestion. Diarrhea. Constipation. Hiccups. Dry mouth. Muscle pain. Back pain. Palpitations. Skin rash. Flu symptoms. Upper respiratory tract infection. Sore throat. Stuffy nose.
Delayed and immediate effects of exposure	Component: Dependence. Withdrawal.
Medical conditions aggravated by exposure	Component: Mental depression. Psychosis. History of drug or alcohol abuse or addiction. Sleep apnea. Myasthenia gravis. Respiratory impairment. Liver impairment. Porphyria.
Acute toxicity	Harmful if swallowed.

Components	**Species**	**Test Results**
Zolpidem Tartrate (CAS 99294-93-6)		
Acute		
Oral		
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

Zolpidem Tartrate

Eye irritancy test
Result: Not irritating.
Species: Rabbit
Skin irritancy test
Result: Not irritating.
Species: Rabbit

Respiratory or skin sensitization

Respiratory sensitization Due to lack of data the classification is not possible.

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

Skin sensitization

Zolpidem Tartrate

Guinea pig maximization test
Result: Not sensitizing.

Germ cell mutagenicity Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.

Mutagenicity

Zolpidem Tartrate

Ames test
Result: Negative.
In vitro chromosomal aberration assay in human lymphocyte s 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 product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Zolpidem Tartrate

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.

Reproductivity

Zolpidem Tartrate

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

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

Persistence and degradability No data is available on the degradability of this product.

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 regulated.

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, n.o.s. (Zolpidem Tartrate Mixture)

Transport hazard class(es)

Class 9

Subsidiary risk -

Packing group III

IATA

UN number	UN3077
UN proper shipping name	Environmentally hazardous substance, n.o.s. (Zolpidem Tartrate Mixture)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Other information	
Passenger and cargo aircraft	Allowed.
Cargo aircraft only	Allowed.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not 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 - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

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

US. California Proposition 65

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

Country(s) or region	Inventory name	On inventory (yes/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
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
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

Issue date 02-19-2009

Revision date 10-06-2015

Version # 03

Further information Not available.

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Revision Information Hazard(s) identification: Hazard statement
Hazard(s) identification: Response
Physical & Chemical Properties: Multiple Properties
Physical and chemical properties: Appearance
Transport Information: Material Transportation Information
Regulatory Information: United States
Regulatory information: California Prop 65
Regulatory information: US state regulations
GHS: Classification