

## 1. Identification

<b>Product identifier</b>	<b>Temazepam</b>	
<b>Other means of identification</b>		
<b>Catalog number</b>	1643408	
<b>Chemical name</b>	2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-3-hydroxy-1-methyl-5-phenyl-	
<b>Recommended use</b>	Specified quality tests and assay use only.	
<b>Recommended restrictions</b>	Not for use as a drug. Not for administration to humans or animals.	
<b>Manufacturer/Importer/Supplier/Distributor information</b>		
<b>Company name</b>	U. S. Pharmacopeia	
<b>Address</b>	12601 Twinbrook Parkway Rockville MD 20852-1790 US	
<b>Telephone</b>	RS Technical Services	301-816-8129
<b>Website</b>	www.usp.org	
<b>E-mail</b>	RSTECH@usp.org	
<b>Emergency phone number</b>	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
	Reproductive toxicity	Category 2
	Specific target organ toxicity, single exposure	Category 3 narcotic effects
<b>OSHA hazard(s)</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Warning
<b>Hazard statement</b>	Harmful if swallowed. Suspected of damaging fertility or the unborn child. May cause drowsiness or dizziness.
<b>Precautionary statement</b>	
<b>Prevention</b>	Wash thoroughly after handling. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection. 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. If exposed or concerned: Get medical advice/attention.
<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>	Not classified.

## 3. Composition/information on ingredients

**Substance**

## Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Temazepam		846-50-4	100

## 4. First-aid measures

<b>Inhalation</b>	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.
<b>Skin contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
<b>Most important symptoms/effects, acute and delayed</b>	Narcotic effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Treatment of benzodiazepine overdose should be symptomatic and supportive and may include the following: Do NOT induce vomiting. Administer activated charcoal as a slurry. If patient is unconscious, perform gastric lavage with cuffed endotracheal tube. Monitor respiration, pulse, and blood pressure, and maintain an adequate airway. Give intravenous fluids to control blood pressure. Forced diuresis is ineffective. For hypotension, administer intravenous isotonic fluid or vasopressors such as dopamine or norepinephrine. For respiratory depression, administer oxygen. Maintain adequate pulmonary ventilation. After airway, ventilation, and intravenous access have been secured, administer flumazenil, a specific benzodiazepine receptor antagonist, to reverse sedative effects. Monitor patient for return of sedation. Do NOT use barbiturates to control excitation. Dialysis is of no known value. (Meditext)
<b>General information</b>	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

<b>Suitable extinguishing media</b>	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO <sub>2</sub> .
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	No unusual fire or explosion hazards noted.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire-fighting equipment/instructions</b>	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.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	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.
<b>Methods and materials for containment and cleaning up</b>	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

<b>Precautions for safe handling</b>	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.
<b>Conditions for safe storage, including any incompatibilities</b>	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

Material	Type	Value
Temazepam (CAS 846-50-4)	TWA	120 micrograms/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).

#### Thermal hazards

Not available.

### General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

### Appearance

White or almost white crystalline powder.

#### Physical state

Solid.

#### Form

Powder.

### Odor

Odorless.

### Odor threshold

Not available.

### pH

Not available.

### Melting point/freezing point

246.2 - 249.8 °F (119 - 121 °C) ; also reported as 157 - 163 °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

< 0.0000001 kPa at 25 °C

### Vapor density

Not available.

### Relative density

Not available.

### Solubility in water

Very slightly soluble.

### Partition coefficient (n-octanol/water)

Not available.

<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Benzodiazepine.
<b>Molecular formula</b>	C <sub>16</sub> H <sub>13</sub> CIN <sub>2</sub> O <sub>2</sub>
<b>Molecular weight</b>	300.74
<b>Solubility (other)</b>	Sparingly soluble in ethanol; freely soluble in methylene chloride.

## 10. Stability and reactivity

<b>Reactivity</b>	No reactivity hazards known.
<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>	None known.
<b>Incompatible materials</b>	Oxidizing agents. Acids.
<b>Hazardous decomposition products</b>	Cl <sup>-</sup> . NO <sub>x</sub> . Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Ingestion</b>	Harmful if swallowed.
<b>Inhalation</b>	Due to lack of data the classification is not possible.
<b>Skin contact</b>	Due to lack of data the classification is not possible.
<b>Eye contact</b>	Due to lack of data the classification is not possible.

**Symptoms related to the physical, chemical, and toxicological characteristics** Benzodiazepines: Nausea. Diarrhea. Constipation. Cold, clammy skin. Headache. Weakness. Unsteadiness. Drowsiness. Dizziness. Fast or slow heartbeat. Difficulty breathing. Blurred or double vision. Slurred speech. Memory loss. Confusion. False sense of well-being. Hallucinations. Delirium. Seizures.

**Delayed and immediate effects of exposure** Benzodiazepines: Tolerance. Dependence. Withdrawal. Change in blood pressure. Coma. Death.

**Chronic effects** Possible hypersensitization, tolerance, and dependence. Withdrawal symptoms may include restlessness, hallucinations, delirium, seizures, fast heartbeat, high blood pressure, flu-like aches, nausea, vomiting, and unsteadiness.

**Cross sensitivity** Persons sensitive to one benzodiazepine may be sensitive to this material also.

**Medical conditions aggravated by exposure** Benzodiazepines: Alcohol or drug abuse. Glaucoma. Myasthenia gravis. Lung disease. Sleep apnea. Liver impairment. Kidney impairment. Seizure disorders, or history of. Mental disorders. Porphyria.

**Acute toxicity** Harmful if swallowed.

<b>Product</b>	<b>Species</b>	<b>Test Results</b>
Temazepam (CAS 846-50-4)		
<i>Oral</i>		
LD50	Rat	2000 mg/kg 1833 mg/kg

**Skin corrosion/irritation** Due to lack of data the classification is not possible.

**Serious eye damage/eye irritation** Due to lack of data the classification is not possible.

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

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

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

### Mutagenicity

DNA strand breaks in rat livers  
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. IARC: Group 3; this material is not classifiable as to its carcinogenicity in humans.

>= 160 mg/kg/day Carcinogenicity study (dietary)  
Result: No evidence of carcinogenicity was observed, although hyperplastic liver nodules were seen in female mice at the highest dose.  
Species: Mouse  
Test Duration: 18 months  
>= 160 mg/kg/day Carcinogenicity study (dietary)  
Result: No evidence of carcinogenicity was observed, although hyperplastic liver nodules were seen in female mice at the highest dose.  
Species: Rat  
Test Duration: 24 months

**Reproductive toxicity** Suspected of damaging fertility or the unborn child. Most studies do not show a strong association between maternal therapeutic use of benzodiazepines and malformations in the offspring, although the risk of malformations may be increased. Withdrawal effects have been observed in newborns following maternal benzodiazepine use.

#### Reproductivity

30 mg/kg/day Reproductivity study  
Result: Increased fetal resorptions.  
Species: Rat  
60 mg/kg/day Reproductivity study  
Result: Increased nursling mortality.  
Species: Rat  
>= 240 mg/kg/day Reproductivity study  
Result: Increased skeletal variants.  
Species: Rat

**Specific target organ toxicity - single exposure** Narcotic effects.

**Specific target organ toxicity - repeated exposure** Due to lack of data the classification is not possible.

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

## 12. Ecological information

**Ecotoxicity** No ecotoxicity data noted for the ingredient(s).  
**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 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

Not regulated as a hazardous material by DOT.

### IATA

Not regulated as a dangerous good.

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

## 15. Regulatory information

**US federal regulations** California Proposition 65: Developmental Toxicity  
DEA Schedule IV Controlled Substance  
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 - Yes  
Fire Hazard - No  
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 - 2925

**Food and Drug Administration (FDA)** Not regulated.

**US state regulations** WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
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)	Yes
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	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)

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

**Issue date** 12-18-2009

**Revision date** 04-11-2014

**Version #** 02

**Further information** Not available.

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