Material Safety Data Sheet

12601 Twinbrook Parkway,
Rockville, MD 20852 USA

Phone Calls: 301-816-8129
8 a.m. to 5 p.m. EST Mon. - Fri.

QUAZEPAM

Catalog Number: 1592205 **Revision Date:** December 16, 2009

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Quazepam

Manufacturer: U. S. Pharmacopeia

Responsible Party: Reference Standards Technical Services

Mailing Address: 12601 Twinbrook Parkway, Rockville, MD 20852 USA

Phone: 301-816-8129

Hours: 8 a.m. to 5 p.m. EST Mon. - Fri.

Product Use: USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

SECTION 2 - HAZARD INFORMATION

EMERGENCY OVERVIEW : Reproductive Hazard.

Adverse Effects: Adverse effects of benzodiazepines may include memory loss, confusion, false sense of well-being, drowsiness, dizziness, weakness, unsteadiness, headache, blurred or double vision, slurred speech, nausea, dry mouth, diarrhea, and constipation. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

Overdose Effects: Overdose effects include the adverse effects listed above and fast or slow heartbeat; low blood pressure; troubled breathing; cold, clammy skin; coma; and death.

Acute: Possible eye, skin, gastrointestinal, and/or respiratory tract irritation.

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

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, alcohol or drug abuse, glaucoma, myasthenia gravis, lung disease, sleep apnea, kidney or liver impairment, seizure disorders, and mental disorders such as depression.

Cross Sensitivity: Persons sensitive to other benzodiazepines may be sensitive to this material also.

Target Organs: Central nervous system

For additional information on toxicity, see Section 11.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Common Name: Quazepam

n/f = not found

Formula: C17H11ClF4N2S

Synonym: n/f

Chemical Name: 2H-1,4-Benzodiazepine-2-thione, 7-chloro-5-(2-fluorophenyl)-1,3-dihydro-1-(2,2,2-trifluoroethyl)-

CAS: 36735-22-5

RTECS Number: DE9710000

Chemical Family: Benzodiazepine

Therapeutic Category: Sedative-hypnotic

Composition: Pure material

SECTION 4 - FIRST AID MEASURES

Inhalation: Causes irritation. Remove to fresh air.

Eye: May cause irritation. Flush with copious quantities of water.

Skin: May cause irritation. Flush with copious quantities of water.

Ingestion: May cause irritation. Flush out mouth with water. This material is rapidly and well absorbed from the gastrointestinal tract and has a rapid onset of action.

General First Aid Procedures: 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.

Note to Physicians

Overdose Treatment: Treatment of benzodiazepine overdose should be symptomatic and supportive and may include the following:

1. Do not induce vomiting.
2. Administer activated charcoal as a slurry.
3. Monitor vital signs, manage airway, and provide assisted ventilation if needed.
4. Infuse 10 - 20 mL/kg isotonic fluid to control hypotension. If persistent, treat with intravenous administration of a vasopressor such as dopamine or norepinephrine.
5. Flumazenil, a benzodiazepine agonist/antagonist, has been administered intravenously to reverse coma and respiratory depression in cases of severe poisoning. Flumazenil use is not recommended in cases where seizures are likely or there is serious cyclic antidepressant poisoning.
6. Forced diuresis and hemodialysis are ineffective.
7. Manage withdrawal symptoms initially with phenobarbital or the benzodiazepine, then decrease dose by about 10% per day for ten days. [Meditext 2009]

SECTION 5 - FIREFIGHTING MEASURES

Extinguisher Media: Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

Fire and Explosion Hazards: This material is assumed to be combustible. As with all dry powders, it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Spill Response: Wear approved respiratory protection, chemically compatible gloves, and protective clothing. Wipe up spillage or collect spillage using a high-efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labeled container for disposal. Wash spill site.

SECTION 7 - HANDLING AND STORAGE

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.

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

SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION

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.

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).

Gloves: Chemically compatible. 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.

Eye 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.

Protective Clothing: 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.

Exposure Limits: n/f

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

Appearance and Odor: White to light-cream crystalline powder.

Odor Threshold: n/f

pH: n/f

Melting Range: 137 - 139° C; 146 - 151° C

Boiling Point: n/f

Flash Point: n/f

Autoignition Temperature: n/f

Evaporation Rate: n/f

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Vapor Pressure: n/f

Vapor Density: n/f

Specific Gravity: n/f

Solubility in Water: Insoluble

n/f = not found

Fat Solubility: Lipophilic

Other Solubility: Soluble in ethanol.

Partition Coefficient: n-octanol/water: logP = 4.03

Percent Volatile: n/f

Reactivity in Water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

Formula: C17H11ClF4N2S

Molecular Weight: 386.80

n/f = not found

SECTION 10 - STABILITY AND REACTIVITY

Conditions to Avoid: n/f

Incompatibilities: Oxidizing agents

Decomposition Products: When heated to decomposition, material emits toxic fumes of HCl, F-, NOx and SOx. Emits toxic fumes under fire conditions.

Stable? Yes **Hazardous Polymerization?** No

SECTION 11 - TOXICOLOGICAL PROPERTIES

Oral Rat: LD50: >5 grams/kg

Oral Mouse: LD50: >5 grams/kg

Other Toxicity Data: Oral Dog LD50: >1000 mg/kg

Irritancy Data: n/f

Corrosivity: n/f

Sensitization Data: n/f

Listed as a Carcinogen by: **NTP:** No **IARC:** No **OSHA:** No

Other Carcinogenicity Data: Quazepam was not carcinogenic in oral oncogenicity studies in mice and hamsters.

Mutagenicity Data: Results of the mouse lymphoma mutagenicity assay with quazepam were equivocal and Ames test results were negative.

Reproductive and Developmental Effects: Results were mixed in a meta-analysis of studies that tracked the occurrence of major malformations in infants of mothers who used a benzodiazepine in early pregnancy. There have been reports of newborns exhibiting flaccidity, breathing and feeding problems, and hypothermia after maternal use of benzodiazepines in late pregnancy, and withdrawal symptoms, e.g. tremor and irritability, have been seen in newborns exposed to benzodiazepines in utero.
Quazepam did not increase the incidence of major drug-related malformations in the offspring of mice given high doses (66 to 400 times the human dose), but minor developmental variations occurred. In rabbits, doses up to 134 times the human dose did not affect fetal morphology or development of the offspring.

SECTION 12 - ECOLOGICAL INFORMATION

Ecological Information: n/f

SECTION 13 - DISPOSAL CONSIDERATIONS

Disposal: Dispose of waste in accordance with all applicable Federal, State, and local laws. Additionally, because this is a controlled substance, notify local DEA office for appropriate disposal procedures.

SECTION 14 -TRANSPORT INFORMATION

Shipping Name: n/f

Class: n/f

UN Number: n/f

Packing Group: n/f

Additional Transport Information: n/f

SECTION 15 - REGULATORY INFORMATION

U.S. Regulatory Information: DEA Schedule IV Controlled Substance
California Proposition 65: Developmental Toxicity

International Regulatory Information: EINECS # 253-179-4

SECTION 16 - OTHER INFORMATION

Revision: 16-Dec-09

Previous Revision Date: 21-Jun-04

n/f = not found