



Material Safety Data Sheet

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Rockville, MD 20852 USA

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

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MIRTAZAPINE

Catalog Number: 1444279

Revision Date:

April 30, 2008

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Mirtazapine

Manufacturer: U. S. Pharmacopeia

Responsible Party: Reference Standards Technical Services

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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 - Toxic

Adverse Effects: Adverse effects may include shortness of breath, swelling, flu-like symptoms, limited movement, mood or mental changes, skin rash, constipation, dizziness, drowsiness, dry mouth, increased appetite, weight gain, abdominal pain, abnormal dreams, weakness, back pain, increased sensitivity to touch, low or high blood pressure, thirst, muscle pain, nausea, trembling or shaking, increased urination, vertigo, and vomiting. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: Overdose effects may include disorientation, drowsiness, impaired memory, and fast heartbeat.

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

Chronic: Possible hypersensitization.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, active alcoholism, epilepsy or history of seizures, cardiovascular or cerebrovascular disease, hypotension, diabetes mellitus, history of bipolar disorder or psychoses, suicidal thoughts or major depressive disorder, and impaired liver or kidney function.

Cross Sensitivity: n/f

Target Organs: n/f

For additional information on toxicity, see Section 11.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

MIRTAZAPINE

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Common Name: Mirtazapine

Formula: C17H19N3

Synonym: n/f

Chemical Name: Pyrazino[2,1-alpha]pyrido[2,3- c][2]benzazepine,1,2,3,4,10,14b-hexahydro-2-methyl-

CAS: 61337-67-5

RTECS Number: UQ4410250

Chemical Family: Piperazinoazepine

Therapeutic Category: Antidepressant

Composition: Pure Material

SECTION 4 - FIRST AID MEASURES

Inhalation: May cause 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. Mirtazapine is well absorbed from the gastrointestinal tract.

General First Aid Procedures: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Note to Physicians

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

1. Do NOT induce vomiting.
2. Perform gastric lavage with a large-bore orogastric tube with protect airway for recent ingestion, if needed.
3. Administer activated charcoal.
4. Ensure adequate airway, oxygenation, and ventilation.
6. Monitor cardiac rhythm and vital signs. [PDR 2006]

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-labelled 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. Wash thoroughly after handling.

Storage: Store in tight, light-resistant 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: Engineering controls such as exhaust ventilation are recommended.

Respiratory Protection: Use a NIOSH approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Gloves: Chemically compatible

Eye Protection: Safety glasses or goggles

Protective Clothing: Protect exposed skin.

Exposure Limits: Industry: 125 micrograms/day (target limit); 250 micrograms/day (action limit)

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 creamy-white crystalline powder; odorless.

Odor Threshold: n/f

pH: 7 (0.3 grams/L aqueous solution; 25° C)

Melting Range: 112 - 124° 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: 1.23 at 20° C

Solubility in Water: Practically insoluble

Fat Solubility: n/f

Other Solubility: Freely soluble in methanol, in anhydrous ethanol, and in toluene; soluble in ethyl ether; sparingly soluble in n-hexane

Partition Coefficient: n-octanol/water: 3.09

Percent Volatile: n/f

Reactivity in Water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

Formula: C17H19N3

Molecular Weight: 265.35

SECTION 10 - STABILITY AND REACTIVITY

Conditions to Avoid: Avoid exposure to light and moisture.

Incompatibilities: Strong oxidizing agents

Decomposition Products: When heated to decomposition material emits toxic fumes of NOx. Emits toxic fumes under fire conditions.

Stable? Yes **Hazardous Polymerization?** No

SECTION 11 - TOXICOLOGICAL PROPERTIES

Oral Rat: LD50: 320 mg/kg (female); 490 mg/kg (male)

Oral Mouse: LD50: n/f

Other Toxicity Data: n/f

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: Carcinogenicity studies were conducted with mirtazapine given in the diet at doses of 2, 20, and 200 mg/kg/day to mice and 2, 20, and 60 mg/kg/day to rats. There was an increased incidence of hepatocellular adenoma and carcinoma in male mice at the high dose. In rats, there was an increase in hepatocellular adenoma in females at the mid and high doses and an increase in hepatocellular tumors and thyroid follicular adenoma/cystadenoma and carcinoma in males at the high dose. The data suggest that the above effects could possibly be mediated by non-genotoxic mechanisms, the relevance of which to humans is not known.

Mutagenicity Data: Mirtazapine was not mutagenic or clastogenic and did not induce general DNA damage in the following tests: Ames test, in vitro gene mutation assay in Chinese hamster V 79 cells, in vitro sister-chromatid exchange assay in cultured rabbit lymphocytes, in vivo bone marrow micronucleus test in rats, and unscheduled DNA synthesis assay in HeLa cells.

Reproductive and Developmental Effects: In fertility studies with rats given mirtazapine at doses up to 100 mg/kg, mating and conception were not affected, but estrous cycling was disrupted and pre-implantation losses occurred.

Reproduction studies in pregnant rats and rabbits at doses up to 100 mg/kg and 40 mg/kg, respectively, revealed no evidence of birth defects. However, in rats, there were an increase in post-implantation losses, a decrease in pup birth weights, and an increase in pup deaths during the first 3 days of lactation.

In one study of 104 pregnancies where there were exposures to mirtazapine, the rate of major malformations was not higher than the baseline rate.

SECTION 12 - ECOLOGICAL INFORMATION

Ecological Information: Mirtazapine does not biodegrade within 112 days.

SECTION 13 - DISPOSAL CONSIDERATIONS

Disposal: Dispose of waste in accordance with all applicable Federal, State and local laws.

SECTION 14 - TRANSPORT INFORMATION

Shipping Name: n/f

Class: n/f

UN Number: n/f

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Packing Group: n/f**Additional Transport Information:** n/f

SECTION 15 - REGULATORY INFORMATION

U.S. Regulatory Information: n/f**International Regulatory Information:** EINECS # 288-060-6

Hazard code: Xn

Risk phrases: R20/21/22

Safety phrases: S22, S24/25

SECTION 16 - OTHER INFORMATION

Revision: 30-Apr-08**Previous Revision Date:** 05-Jul-06