THALIDOMIDE
Catalog Number: 1652500
Revision Date: April 24, 2007

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Thalidomide
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: Toxic. Reproductive Hazard.

Adverse Effects: Adverse effects may include chest pain; cough; fainting; fast or slow heartbeat; troubled breathing; tingling, burning, numbness, or pain in extremities; muscle weakness; dizziness; drowsiness; constipation; diarrhea; nausea; stomach pain; dry mouth; skin dryness or rash; headache; increased appetite; mood changes; swelling of legs; and seizures. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: Overdose effects include lowered blood pressure, fever, and sedation.

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

Chronic: Possible hypersensitization, decreased white blood cell count, and nerve damage.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, active alcoholism, multiple myeloma, neutropenia, peripheral neuropathy, and epilepsy or other factors predisposing to seizures.

Cross Sensitivity: n/f

Target Organs: Central nervous system; immune system.

For additional information on toxicity, see Section 11.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Common Name: Thalidomide
Formula: C13H10N2O4
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Synonym: alpha-(N-Phthalimido)glutarimide

Chemical Name: 1H-Isindole-1,3(2H)-dione, 2-(2,6-dioxo-3-piperidinyl)-, (+/-)

CAS: 50-35-1

RTECS Number: TI4375000

Chemical Family: Glutamic acid derivative

Therapeutic Category: Immunomodulator; sedative-hypnotic

Composition: Pure Material

SECTION 4 - FIRST AID MEASURES

Inhalation: May cause irritation. Remove to fresh air. Significant inhalation can cause systemic effects.

Eye: May cause irritation. Avoid contact. Flush with copious quantities of water for at least 15 minutes. Seek medical attention.

Skin: May cause irritation. Avoid contact. Flush with copious quantities of soap and water for at least 15 minutes. This material can be absorbed through the skin.

Ingestion: May cause irritation and toxicity. Avoid ingestion. Flush out mouth with water. This material is slowly 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: Overdose treatment should be symptomatic and supportive and may include the following:
1. Do NOT induce vomiting.
2. Consider gastric lavage within 1 hour of ingestion of a very large amount.
3. Administer charcoal slurry.
4. Treat hypotension with infusion of isotonic fluid. Place patient in Trendelenburg position. If hypotension persists, administer dopamine or norepinephrine.
5. Monitor patient for central nervous system depression and peripheral neuropathies.
6. For bradycardia, administer intravenous atropine. [Meditext 2007]

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: 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 off-white crystalline powder; nearly odorless or odorless

Odor Threshold: n/f

pH: n/f

Melting Range: 269 - 271° C; also reported as 239 - 241° 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: Sparingly soluble

Fat Solubility: n/f

Other Solubility: Very soluble in dimethylformamide, in dioxane, and in pyridine; sparingly soluble in acetone, in butyl acetate, in ethanol, in ethyl acetate, in glacial acetic acid, and in methanol; practically insoluble in benzene, in chloroform, and in ether

Partition Coefficient: n-octanol/water: 0.33

Percent Volatile: n/f

Reactivity in Water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

Formula: C13H10N2O4

Molecular Weight: 258.23
SECTION 10 - STABILITY AND REACTIVITY

Conditions to Avoid: Avoid exposure to light.

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: 113 mg/kg
Oral Mouse: LD50: 2 grams/kg

Other Toxicity Data: Skin Rat LD50: 1550 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: There was no evidence for compound-related tumorigenic effects of thalidomide in two-year studies of male and female mice administered 3000 mg/kg/day, female rats administered 3000 mg/kg/day, and male rats administered 300 mg/kg/day.

Mutagenicity Data: Thalidomide was not mutagenic in S. typhimurium Ames or E. coli gene mutation assay, in L5178YTK +/- mouse lymphoma cell assays, or in AS52/XPRT mammalian cell forward gene mutation assays, with or without activation. It was not clastogenic in chromosomal aberration assays using Chinese hamster ovary cells, human lymphocytes, grasshopper neuroblasts, or Drosophila melanogaster somatic cells; in human lymphocyte micronucleus assays; or in biome marrow micronucleus assays using male and female rabbits.

Reproductive and Developmental Effects: The window of embryolethality for thalidomide is small (approximately from day 21 to day 56 after conception). A single therapeutic dose of thalidomide during this time can cause severe birth defects including digit and limb anomalies; intestinal, heart, and kidney abnormalities; eye, ear, and cranial nerve defects; and many other malformations. Fetal and newborn death has also occurred. Death at or shortly after birth has been reported at about 40%. The effects outside this window are unknown. Males receiving thalidomide therapy are advised to use barrier contraception during sexual contact with women of childbearing potential because thalidomide may be present in semen.

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.

SECTION 14 - TRANSPORT INFORMATION

Shipping Name: Toxic solid, organic, n.o.s. (Thalidomide)

Class: 6.1
UN Number: UN2811
Packing Group: III

Additional Transport Information: n/f
SECTION 15 - REGULATORY INFORMATION

U.S. Regulatory Information: California Proposition 65: Developmental Toxicity

International Regulatory Information: EINECS # 200-031-1
Hazard Code: T
Risk Phrases: R61, R46, R62, R25, R21
Safety Phrases: S45, S36/37/39, S26, S22
Canada: WHMIS Classification D1B, D2A

SECTION 16 - OTHER INFORMATION

Revision: 24-Apr-07
Previous Revision Date: 02-Apr-03