



# Material Safety Data Sheet

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## THALIDOMIDE

Catalog Number: 1652500

Package Size: 200 mg

Revision Date:

April 2, 2003

EMERGENCY OVERVIEW: Toxic. Reproductive Hazard. CAUTION: Thalidomide causes severe birth defects.

### SECTION 1 - IDENTIFICATION

**Common Name:** Thalidomide

**Formula:** C<sub>13</sub>H<sub>10</sub>N<sub>2</sub>O<sub>4</sub>

**Synonym:** n/f

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

**CAS Number:** 50-35-1

**RTECS Number:** TI43750000

**Chemical Family:** Glutamic acid derivative

**Therapeutic Category:** Immunomodulator; sedative-hypnotic

### SECTION 2 - INGREDIENT INFORMATION

#### Principle Components

#### Percent

#### Exposure Limits

Thalidomide

Pure Material

ACGIH: TLV 10 mg/m<sup>3</sup> (inhalable particulate); 3 mg/m<sup>3</sup> (respirable particulate)

OSHA: PEL 5 mg/m<sup>3</sup> (respirable fraction); 15 mg/m<sup>3</sup> (total dust)

### SECTION 3 - HEALTH HAZARD INFORMATION

**Usual Adult Dose:** The usual oral adult dose of thalidomide is up to 400 mg a day.

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

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**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.

**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.

## Medical Conditions

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

**Cross Sensitivity:** n/f

**Pregnancy Comments:** Therapeutic use of thalidomide by pregnant women has resulted in severe fetal abnormalities including limb deformities, ear and eye abnormalities, and congenital heart defects. Fetal and newborn death has also occurred. A single small dose early in pregnancy may cause these adverse effects. Males receiving thalidomide therapy are advised to use barrier contraception during sexual contact with women of childbearing potential.

**Pregnancy Category:** X

## SECTION 4 - FIRST AID MEASURES

**General:** 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.

**Overdose Treatment:** Overdose treatment is 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. Because a single dose of thalidomide may cause severe birth defects, any female of childbearing potential exposed to thalidomide should obtain a pregnancy test. [Poisindex 2003]

## SECTION 5 - TOXICOLOGICAL INFORMATION

**Oral Rat:** LD50: 113 mg/kg

**Oral Mouse:** LD50: 2 grams/kg

**Irritancy Data:** n/f

**Target Organ(s):** Central nervous system; immune system.

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

**Other:** No

## SECTION 6 - FIREFIGHTING MEASURES

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<b>Flash Point:</b>	n/f	<b>Upper Flammable Limit:</b>	n/f
<b>Auto-Ignition Temperature:</b>	n/f	<b>Lower Flammable Limit:</b>	n/f
<b>Extinguisher Media:</b>	Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.		
<b>Fire and Explosion Hazards:</b>	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.		
<b>Firefighting Procedures:</b>	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.		

## SECTION 7 - PHYSICAL HAZARDS

<b>Conditions to Avoid:</b>	Avoid exposure to light.		
<b>Incompatibilities:</b>	Strong oxidizing agents.		
<b>Decomposition Products:</b>	When heated to decomposition material emits toxic fumes of NOx. Emits toxic fumes under fire conditions.		
<b>Stable?</b>	Yes	<b>Hazardous Polymerization?</b>	No

## SECTION 8 - HANDLING / SPILL / DISPOSAL MEASURES

<b>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. Wash thoroughly after handling.
<b>Storage:</b>	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.
<b>Spill Response:</b>	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.
<b>Disposal:</b>	Dispose of waste in accordance with all applicable Federal, State and local laws.

## SECTION 9 - EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Respiratory Protection:</b>	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.
<b>Ventilation:</b>	Recommended.
<b>Gloves:</b>	Rubber
<b>Eye Protection:</b>	Safety Goggles
<b>Protective Clothing:</b>	Protect exposed skin.

## SECTION 10 - PHYSICAL AND CHEMICAL PROPERTIES

**NOTE: The data reported below is general information, and is not specific to the USP Reference Standard Lot provided!**

<b>Appearance and Odor:</b>	White to off-white crystalline powder; nearly odorless.		
<b>Melting Point:</b>	269 - 271° C		
<b>Solubility in Water:</b>	Sparingly soluble	<b>Vapor Density:</b>	n/f
<b>Boiling Point:</b>	n/f	<b>Evaporation Rate:</b>	n/f
<b>Specific Gravity:</b>	n/f	<b>Reactivity in Water:</b>	n/f

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**Vapor Pressure:** n/f

**% Volatile by Volume:** n/f