

Thalidomide

MATERIAL SAFETY DATA SHEET

SECTION 1. COMPANY AND PRODUCT IDENTIFICATION

Manufacturer: **Celgene Corporation**
7 Powder Horn Drive
Warren, New Jersey 07059
(732) 271-1001
(800) 424-9300 (CHEMTREC, for emergencies)

Product Name: Thalidomide

Synonyms: α -(N-Phthalimido)glutarimide; N(2,6-Dioxo-3-piperidyl)-phthalimide; others

SECTION 2. PRODUCT COMPOSITION

<u>Component</u>	<u>CAS Number:</u>	<u>Formula:</u>	<u>Percentage</u>
Thalidomide	50-35-1	C ₁₉ H ₁₆ N ₂ O ₄	100%

SECTION 3. HEALTH HAZARDS

EMERGENCY OVERVIEW

Causes severe, life-threatening, birth defects.
Can cause sedation after single exposure and neurological effects (e.g., peripheral neuropathy) after repeated exposure.

ROUTES OF EXPOSURE: Inhalation, accidental ingestion, skin or eye contact.

EYE: No data available.

SKIN: No data available.

SYSTEMIC: Acute. May cause drowsiness.

Chronic: May cause drowsiness, neurological effects.

REPRODUCTIVE AND DEVELOPMENTAL TOXICITY: Known human teratogen (causes characteristic birth defects that include limb shortening, e.g., amelia, phocomelia, and facial abnormalities).

CARCINOGENICITY: No data available; not listed by NTP, IARC or OSHA as a carcinogen.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: No data available.

OCCUPATIONAL EXPOSURE LIMIT: None established by OSHA or ACGIH. Celgene has established a worker exposure limit of 0.25 microgram/m³ of air as an 8-hour time-weighted average concentration.

SECTION 4. FIRST AID MEASURES

EYE CONTACT: Wash thoroughly with water. If an irritation develops, seek medical attention.

SKIN CONTACT: Wash thoroughly with water. If an irritation develops, seek medical attention.

INHALATION: Move to fresh air. If symptoms develop, seek medical attention.

INGESTION: Rinse mouth with water and seek medical attention.

SECTION 5. FIRE PROTECTION

FLAMMABILITY: No data available.

FIRE FIGHTING INSTRUCTIONS: Use extinguishing media appropriate for surrounding fire (water, foam, vaporizing liquid, or multipurpose dry chemical).

FIRE FIGHTING EQUIPMENT: Wear full fire fighting protective equipment including NIOSH/MSHA-approved (or equivalent) positive pressure self-contained breathing apparatus.

SECTION 6. SPILL AND RELEASE MEASURES

if material is spilled, take proper precautions to minimize exposure. Cordon off spill area. Prevent or minimize material from reaching surface waters, sanitary or storm drains. Wet down with water or appropriate wetting agent to minimize airborne dust generation. Collect spilled material in containers suitable for proper disposal. Alternatively, use vacuum cleaner equipped with high efficiency particulate air (HEPA) filter. Remove contents for proper disposal. Release may need to be reported to regulatory authorities.

SECTION 7. HANDLING AND STORAGE

Avoid contact with skin, eyes, or clothing. Use adequate ventilation. Wash thoroughly after handling. Store in accordance with material specifications.

SECTION 8. EXPOSURE CONTROL/PERSONAL PROTECTION

EYE PROTECTION: Safety glasses suggested.

SKIN PROTECTION: Gloves and overalls to minimize possibility of skin contact.

RESPIRATORY PROTECTION: Wear NIOSH/MSHA-approved respirator as necessary to reduce exposure to below the worker exposure limit.

ENGINEERING CONTROLS: Local exhaust ventilation to control possible airborne release of powders; handle powder in containment devices as much as practicable to reduce airborne levels to below the worker exposure limit.

SECTION 9. PHYSICAL/CHEMICAL PROPERTIES

BOILING POINT:	Solid/Not applicable	SOLUBILITY IN WATER:	<1 mg/mL
MELTING POINT:	269-271 °C	PERCENT VOLATILE:	Negligible
MOLECULAR WEIGHT:	258.2	VAPOR PRESSURE:	Negligible
SPECIFIC GRAVITY:	No data available	VAPOR DENSITY:	Negligible
APPEARANCE, COLOR, ODOR: White to off-white crystalline powder, no odor data			

SECTION 10. STABILITY AND REACTIVITY

CHEMICAL STABILITY: Stable.

INCOMPATIBILITY: Avoid strong oxidizing agents.

HAZARDOUS DECOMPOSITION PRODUCTS: May release nitrogen oxides, carbon monoxide and carbon dioxide.

HAZARDOUS POLYMERIZATION: Will not occur.

SECTION 11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY: Oral LD₅₀ in mouse - >5000 mg/kg; oral LD₅₀ in rat - >3000 mg/kg; oral LD₅₀ in dog - >2000 mg/kg.

ORGAN SYSTEM TOXICITY: In humans, peripheral neuropathy, possibly irreversible, after repeated therapeutic doses of around 50-300 mg/day orally. In mice, increased liver weight at 3000 mg/kg/day after oral administration for 13 weeks; in male and female rats, decreased body weight at 30 and 3000 mg/kg/day, respectively, after oral administration for 13 weeks.

TERATOGENICITY: Causes birth defects characteristic of thalidomide exposure, including limb shortening, e.g., amelia, phocomelia, and facial abnormalities. A single 50 mg dose of thalidomide taken orally has been reported to cause these effects. The most sensitive period of time during pregnancy is around Day 34 to Day 50 after a pregnant woman's last menstrual period.

GENOTOXICITY: Ames test - negative; AS52/XPRT mammalian cell forward mutation test - negative; in vivo mouse micronucleus test - negative.

CARCINOGENICITY: No data available.

SECTION 12. ENVIRONMENTAL INFORMATION

No data available.

SECTION 13. WASTE DISPOSAL METHODS

All wastes containing the product should be specially contained, properly labeled, and stored separately from other facility waste discharges. Dispose of any waste residues according to prescribed federal, state, and local guidelines (e.g., to an appropriately permitted chemical waste incinerator). Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner (e.g.,

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appropriately permitted municipal or on-site wastewater treatment facility or be collected for disposal according to prescribed federal, state and local guidelines).

SECTION 14. TRANSPORTATION INFORMATION

HAZARD CLASS: Not classified per U.S. DOT or IATA.
UN NUMBER: Not assigned per U.S. DOT or IATA.

SECTION 15. LABELING / REGULATORY INFORMATION

HAZARD LABELING: Causes severe, life-threatening, birth defects. Can cause sedation after single exposure and neurological effects (e.g., peripheral neuropathy) after repeated exposure.

EU RISK AND SAFETY PHRASES:

R48 - Danger of serious damage to health by prolonged exposure

R61 - May cause harm to unborn child

S22 - Do not breathe dust

S36 - Wear suitable protective clothing

S53 - Avoid exposure-obtain special instructions before use

S62 - If swallowed, do not induce vomiting; seek medical advice immediately and show this container or label

CALIFORNIA PROPOSITION 65: Listed as a reproductive toxicant.

SECTION 16. OTHER INFORMATION

No additional information.

ABBREVIATIONS

ACGIH: American Conference of Governmental Industrial Hygienists

DOT: Department of Transportation

EU: European Union

IARC: International Agency for Research on Cancer

IATA: International Air Transport Association

MSHA: Mine Safety and Health Administration

NIOSH: National Institute for Occupational Safety and Health

NTP: National Toxicology Program

OSHA: Occupational Safety and Health Act

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