



Innovating for
affordable healthcare

Shilpa Medicare Limited

Manufacturers and Exporters of Bulk Drugs

12-6-214/A-1, Hyderabad Road,

RAICHUR - 584 135, Karnataka, India.

Phone : +91-8532 - 238704, Fax : +91 - 8532 - 238876

CIN No. L85110KA1987PLC008739

E-Mail : info@vbshilpa.com Web: http://www.vbshilpa.com

MATERIAL SAFETY DATA SHEET OF THALIDOMIDE

1. IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

Substance name	THALIDOMIDE
Grade	USP
Company name	SHILPA MEDICARE LIMITED,
Street address	12-6-214/A-1, Hyderabad Road
City, state, zip, country	RAICHUR, KARNATAKA, 584 135, INDIA
Technical phone	++91-8532-236494
Emergency phone	++91-8532-235006
Fax	++91-8532-238876

2. COMPOSITION/INFORMATION ON INGREDIENT

CAS #	50-35-1
Formula	$C_{13}H_{10}N_2O_4$
Chemical Names	2-(2,6-dioxo-3-piperidyl)isoindole-1,3-dione, 1H-Isoindole-1,3 (2H)-dione, 2-(2,6-dioxo-3-piperidyl)-, (+/-)- 2-(2,6-dioxo-3-piperidyl)-1H-isoindole-1,3(2H)-dione, distaval, softenon, talimol, 2-phthalimidoglutarimide, nibrol,
RTECS Number	TI43750000
Chemical Family	Glutamic acid derivative
Therapeutic Category	Immunomodulator; sedative-hypnotic

3. HAZARDS IDENTIFICATION

Usual Adult Dose: the Usual oral adult dose of thalidomide is up to 400 mg a day

Adverse Effects: Adverse effect may including 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.

Over Dose Effects: Over dose effects include lowered blood pressure, fever and sedation.

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





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Chronic:	Possible hypersensitization, decreased white blood cell count, and nerve damage.
Inhalation:	May cause Irritation. Remove to fresh air. Significant inhalation can cause systematic effect.
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 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, Neutrogena, 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

4. FIRST AID MEASURES

General:	Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reaction 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





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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 nor epinephrine.
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]

In any case seek medical advice and call the nearest poison center.

5. FIRE FIGHTING MEASURES

Extinguishing media:

Water spray. Carbon dioxide, dry chemical powder or appropriate foam.

Fire fighting:

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. Emits toxic fumes under fire conditions. Combustible.

6. ACCIDENTAL RELEASE MEASURES

Procedures of personal precautions:

Wear approved respirator, rubber gloves, chemical safety goggles.

Methods for cleaning up:

Sweep up, place in a bag and hold for waste disposal. Avoid raising dust. Ventilate area and wash spill site after material pick up is complete.

7. HANDLING , STORAGE AND SPILL

Handling:

Avoid all contact and inhalation of dust, mists and/or vapors associated with the material. Wash thoroughly after handling.





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The material should be handled with care only by specially trained people avoiding all exposure and contamination. Pregnant women should avoid handling this substance.

Storage:

Preserve in tight container, protected from light, and store at room temperature.

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.

8. EXPOSURE CONTROLS/PERSONEL PROTECTION

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.

Ventilation: Recommended

Gloves: Rubber

Eye Protection: Safety Goggles

Protection Clothing: Protect exposed skin

Engineering controls:

Mechanical exhaust required.

9. PHYSICAL AND CHEMICALS PROPERTIES

Molecular weight	258.23
Appearance	White to off-white powder
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, in methanol and in water; practically insoluble in benzene, in chloroform, and in ether.
Melting point	269 – 271° C

10. STABILITY AND REACTIVITY

Stability	:	Stable.
Conditions to Avoid	:	Avoid exposure to light
Incompatibilities	:	strong oxidizing agents





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Hazardous decomposition products

NOx . Emits toxic fumes under fire conditions

Hazardous polymerization

Will not occur.

11. TOXICOLOGICAL INFORMATION

Target Organ (s)

: Central nervous system; immune system.

Listed as a Carcinogen

: NTP: No IARC: No OSHA: No Other: No

Acute toxicity

Oral Rat

: LD50: 113 mg/kg

Oral Mouse

: LD50: 2 grams/kg

Irritation and corrosiveness

Irritates skin, eyes and respiratory tract.

Empirical data on effects on humans

Typical adverse effects include: gastrointestinal disturbances like nausea and vomiting. May cause late diarrhea. Animal tests have shown carcinogenic effects.

12. ECOLOGICAL INFORMATION

Not available.

13. DISPOSAL CONSIDERATIONS

The packaging and other material that has been contaminated by Thalidomide should be handled as hazardous waste in accordance with local and state laws and instructions.

14. TRANSPORT INFORMATION

Non-Hazardous for Transport

This substance is considered to be non-hazardous for transport.

Non-Hazardous for Air Transport

Non-hazardous for air transport

15. REGULATORY INFORMATION

Letter code of the warning symbol and indications of danger for the preparation:

Xn

Harmful

R-phrases(s)

R22

Harmful if swallowed.

R46

May cause heritable genetic damage.





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R61	May cause harm to unborn child.
R68	Possible risks of irreversible effects.
<u>S-phrase(s)</u>	
S22	Do not breathe dust.
S36/37/39	Wear suitable protective clothing, gloves and eye/face protection.
S45	In case of accident or if you feel unwell seek medical advice immediately.
S51	Use only in well-ventilated areas.
S53	Avoid exposure-obtain special instructions before use.

Drug License No. KTK/25/256/89

Keep container in a well-ventilated place, protected from light. Keep away from sources of ignition. No smoking. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. In case of accident or if you feel unwell, seek medical advice immediately.

16. OTHER INFORMATION

DISCLAIMER

For manufacturing use only.

WARRANTY

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Shilpa Medicare Limited shall not be held liable for any damage resulting from handling or from contact with the above product.

