



Getwell Pharmaceuticals
474, Udyog Vihar, Phase-V,
Gurgaon - 122 016, Haryana, INDIA

Thalidomide Capsules

Section I - IDENTITY

Common/Trade Name: Thalidomide Tablets

Synonyms: 2-(2,6-dioxo-3-piperidinyl)-1H-isoindole-1,3(2H)-dione; Contergan; Kevadon; NSC 66847; NSC 527179;

Manufacturer's Name: GETWELL PHARMACEUTICALS
Address: 474, UDYOG VIHAR, PHASE-V,
GURGAON - 122 016, HARYANA, INDIA

Telephone Number for Info.: +91 124 4014 403 / 04

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Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

CAS # / RTECS #	Hazardous Components (Chemical Name)/ REACH Registration No.	Concentration	EC No./ EC Index No.	Risk Phrases/ GHS Classification
50-35-1 TI4375000	Thalidomide	100.0 %	200-031-1 NA	T; Rp:1, Mu:2, R21-25-46-61-62 Acute Tox.(O) 3: H301 Acute Tox.(D) 4: H312 Toxic Repro. 1A: H360 Mutagen 1A: H340

Section III - HEALTH HAZARD DATA

Classification of the Substance or Mixture:

Classification according to Regulation (EC) No 1272/2008 [CLP]:

Acute Toxicity: Oral, Category 3

Acute Toxicity: Skin, Category 4

Germ Cell Mutagenicity, Category 1A

Toxic To Reproduction, Category 1A

Classification according to Directive 1999/45/EC:

T: Toxic

Reproductive Hazard: 1

Mutagenic Hazard: 2

Risk Phrases: R21, R25, R46, R61, R62

For full text of R- phrases: see SECTION 15.

Label Elements:

Labeling according to Regulation (EC) No 1272/2008 [CLP]:



GHS Signal Word: **Danger**

GHS Hazard Phrases:

H301: Toxic if swallowed.

H312: Harmful in contact with skin.

H340: May cause genetic defects.

H360: May damage fertility or the unborn child.

GHS Precaution Phrases:

P264: Wash {hands} thoroughly after handling.

P280: Wear {protective gloves/protective clothing/eye protection/face protection}.

P362+364: Take off contaminated clothing and wash it before reuse.

P201: Obtain special instructions before use.

P202: Do not handle until all safety precautions have been read and understood.

P281: Use personal protective equipment as required.

GHS Response Phrases:

P301+310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

P330: Rinse mouth.

P302+352: IF ON SKIN: Wash with plenty of soap and water.

P312: Call a {POISON CENTER/doctor/...} if you feel unwell.

P321: Specific treatment {see ... on this label}.

P308+313: IF exposed or concerned: Get medical attention/advice.

GHS Storage and Disposal Phrases:

Please refer to Section 7 for Storage and Section 13 for Disposal information.

Labeling according to Directive 1999/45/EC:



T

Reproductive Hazard: 1; Mutagenic Hazard: 2

Adverse Human Health Effects and Symptoms:

Harmful in contact with skin.

Material may be irritating to the mucous membranes and upper respiratory tract.

May be harmful by inhalation.

May cause eye, skin, or respiratory system irritation.

May cause genetic defects.

May damage fertility or the unborn child.

Toxic if swallowed.

To the best of our knowledge, the toxicological properties have not been thoroughly investigated.

Section IV - FIRST AID MEASURES

Description of First Aid Measures: No data available.

In Case of Inhalation: Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.

In Case of Skin Contact: Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

In Case of Eye Contact: Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

In Case of Ingestion: Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

Section V - FIRE AND EXPLOSION HAZARD DATA

Suitable Extinguishing Media:

Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray.

Use water spray to cool fire-exposed containers.

Unsuitable Extinguishing Media:

A solid water stream may be inefficient.

Flammable Properties and Hazards: No data available.

Flash Pt: No data.

Explosive Limits: LEL: No data. UEL: No data.

Autoignition Pt: No data.

Fire Fighting Instructions: As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

Section VI - ACCIDENTAL RELEASE INFORMATION

Protective Precautions, Protective Equipment and Emergency Procedures:

Avoid raising and breathing dust, and provide adequate ventilation.

As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

Environmental Precautions:

Take steps to avoid release into the environment, if safe to do so.

Methods and Material For Containment and Cleaning Up:

Contain spill and collect, as appropriate.

Transfer to a chemical waste container for disposal in accordance with local regulations.

Section VII - HANDLING AND STORAGE

Precautions To Be Taken in Handling:

Avoid breathing dust/fume/gas/mist/vapours/spray.

Avoid prolonged or repeated exposure.

Precautions To Be Taken in Storing:

Keep container tightly closed.

Store in accordance with information listed on the product insert.

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Exposure Parameters:

CAS #	Partial Chemical Name	Britain EH40	France VL	Europe
50-35-1	Thalidomide	No data	No data	No data
50-35-1	Thalidomide	No data	No data	No data

Exposure Controls:

Engineering Controls (Ventilation etc.): Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

Personal protection equipment:

Eye Protection: Safety glasses

Protective Gloves: Compatible chemical-resistant gloves

Other Protective Clothing: Lab coat

Respiratory Equipment (Specify Type): NIOSH approved respirator, as conditions warrant.

Work/Hygienic/Maintenance Practices:

Do not take internally.

Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

Wash thoroughly after handling.

No data available.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Information on Basic Physical and Chemical Properties	
Physical State	<input type="checkbox"/> Gas <input type="checkbox"/> Liquid <input checked="" type="checkbox"/> Solid
Appearance and Odor	A white to off-white solid

Melting Point	No data
Boiling Point	No data
Flash Pt	No data
Evaporation Rate	No data
Explosive Limits	LEL: No data. UEL: No data.
Vapor Pressure (vs. Air or mm Hg)	No data
Vapor Density (vs. Air = 1)	No data
Specific Gravity (Water = 1)	No data
Solubility in Water	No data
Solubility Notes	~25 mM in DMSO;
Autoignition Pt	No data
<i>Other information</i>	
Percent Volatile	No data
Molecular Formula & Weight	C ₁₃ H ₁₀ N ₂ O ₄ 258.2

Section X - STABILITY AND REACTIVITY

Reactivity	No data available
Stability	Unstable [] Stable [X]
Stability Note(s): Polymerization:	Stable if stored in accordance with information listed on the product insert. Will occur [] Will not occur [X]
Conditions To Avoid:	No data available
Incompatibility – Materials To Avoid:	No data available
Hazardous Decomposition Or Byproducts:	carbon dioxide carbon monoxide nitrogen oxides

Section XI - TOXICOLOGICAL INFORMATION

Information on Toxicological Effects:	The toxicological effects of this product have not been thoroughly studied. (±)-Thalidomide - Toxicity Data: Oral LD50 (rat): 113 mg/kg; Skin LD50 (rat) 1550 mg/kg; Intraperitoneal LD50 (rat): >6 g/kg; Oral LD50 (mouse): 2 g/kg; Intraperitoneal LDLO (mouse): 800 mg/kg; Subcutaneous LD50 (mouse): >5 g/kg; Subcutaneous TDLO (mouse): 40 mg/kg; Intraperitoneal TDLO (rat): 15 mg/kg; Subcutaneous TDLO (rat): 45 mg/kg; Oral TDLO (rat): 100 mg/kg;
Chronic Toxicological Effects:	(±)-Thalidomide - Investigated as a mutagen, reproductive effector, and tumorigen. Only select Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information. (±)-Thalidomide RTECS Number: TI4375000
Carcinogenicity:	NTP? No IARC Monographs? No OSHA Regulated? No

Section XII - ECOLOGICAL INFORMATION

Toxicity: Avoid release into the environment.

Run off from fire control or dilution water may cause pollution.

Section XIII - DISPOSAL INFORMATION

Waste Disposal Method: Dispose in accordance with local, state, and federal regulations.

Section XIV - TRANSPORTATION INFORMATION

(±)-Thalidomide:

DOT (US): UN-number: 2811, Class: 6.1, Packing group: III; Proper shipping name: Toxic solids, organic, n.o.s. [(±)-Thalidomide]; Marine pollutant: No; Poison Inhalation Hazard: No

IMDG: UN-number: 2811, Class: 6.1, Packing group: III; EMS-No: F-A, S-A; Proper shipping name: TOXIC SOLID, ORGANIC, N.O.S. [(±)-Thalidomide]; Marine pollutant: No

IATA: UN-number: 2811, Class: 6.1, Packing group: III; Proper shipping name: Toxic solid, organic, n.o.s. [(±)-Thalidomide]

Section XV - REGULATORY INFORMATION

EPA SARA (Superfund Amendments and Reauthorization Act of 1986) Lists

CAS #	Hazardous Components (Chemical Name)	S. 302 (EHS)	S. 304 RQ	S. 313 (TRI)
50-35-1	Thalidomide	No	No	No
CAS #	Hazardous Components (Chemical Name)	Other US EPA or State Lists		
50-35-1	Thalidomide	CAA HAP,ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: Yes		

European Community Hazard Symbol codes:



T

Reproductive Hazard: 1; Mutagenic Hazard: 2

European Community Risk and Safety Phrases:

R21 Harmful in contact with skin.

R25 Toxic if swallowed.

R46 May cause heritable genetic damage.

R61 May cause harm to the unborn child.

R62 Risk of impaired fertility.

S22 Do not breathe dust.

S24/25 Avoid contact with skin and eyes.

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 (show the label whenever possible.)

S53 Avoid exposure - obtain special instructions before use.

Regulatory Information Statement: This SDS was prepared in accordance with Regulation (EC) No.1272/2008 and European Directive 67/548/EEC as amended.

Section XVI - OTHER DATA

Additional Information About This Product: No data available.

Company Policy or Disclaimer: DISCLAIMER: This information is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes.