NATCO PHARMA LIMITED

SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification

Material	**Lapatinib Tablets** **250 mg**
Manufacturer	**NATCO Pharma Limited** Kothur- 509 228, Telangana, India
Distributor	Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221

Section 2: Hazard(s) Identification

Section 2, Hazard(s) identification

Fire and Explosion	Expected to be non-combustible.
Health	Lapatinib tablets are contraindicated in patients with known severe hypersensitivity (e.g., anaphylaxis) to this product or any of its components.
Environment	No information is available about the potential of this product to produce adverse environmental effects.

Section 3: Composition/Information on Ingredients

Section 3, Composition/information on ingredients

Ingredients	**CAS**
Lapatinib Ditosylate	388082-77-7

Section 4: First-Aid Measures

Section 4, First-aid measures

Ingestion	Immediately give large quantities of water to drink. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician immediately.
Inhalation	Remove to fresh air. If breathing stops, provide artificial respiration. Get medical attention immediately.

Skin Contact	Wash off immediately with plenty of water. Continue to rinse for at least 15 minutes. Immediately take off all contaminated clothing. Get medical attention if irritation develops and persists.
Eye Contact	In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.
OVERDOSAGE	There is no known antidote for overdoses of lapatinib tablets. The maximum oral doses of lapatinib that have been administered in clinical trials are 1,800 mg once daily. More frequent ingestion of lapatinib tablets could result in serum concentrations exceeding those observed in clinical trials and could result in increased toxicity. Therefore, missed doses should not be replaced and dosing should resume with the next scheduled daily dose. Asymptomatic and symptomatic cases of overdose have been reported. The doses ranged from 2,500 to 9,000 mg daily and where reported, the duration varied between 1 and 17 days. Symptoms observed include lapatinib-associated events [see Adverse Reactions (6.1)] and in some cases sore scalp, sinus tachycardia (with otherwise normal ECG), and/or mucosal inflammation. Because lapatinib is not significantly renally excreted and is highly bound to plasma proteins, hemodialysis would not be expected to be an effective method to enhance the elimination of lapatinib. Treatment of overdose with lapatinib tablets should consist of general supportive measures.

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures

Fire and Explosion Hazards	Assume that this product is capable of sustaining combustion.
Extinguishing Media	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.
Hazardous Combustion Products	Hazardous combustion or decomposition products are expected when the product is exposed to fire.

Section 6: Accidental Release Measures

Section 6, Accidental release measures

Personal Precautions	Wear suitable protective clothing, gloves and eye/face protection.

Environmental Precautions	Avoid release to the environment.
Clean-up Methods	Collect and place it in a suitable, properly labeled container for recovery or disposal.

Section 7: Handling and Storage

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Handling	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
Storage	Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Section 8: Exposure Controls/Personal Protection

Section 8, Exposure controls/personal protection

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

Section 9: Physical and Chemical Properties

Section 9, Physical and chemical properties

Lapatinib tablets, 250 mg are orange colored, oval shaped, film-coated tablets, debossed “NTL” on one side and plain on another side and are available in:

Bottles of 150 tablets: NDC 68180-801-36

Section 10: Stability and Reactivity

Section 10, Stability and reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport.

Section 11: Toxicological Information

Section 11, Toxicological information

Carcinogenesis, Mutagenesis, Impairment of Fertility

In carcinogenicity studies, lapatinib was administered orally for up to 104 weeks at doses of 75 and 150 mg/kg/day in male mice and 75, 150, and 300 mg/kg/day in female mice (approximately 0.7 to 2 times the expected human clinical exposure based on AUC for a clinical dose of 1,250 mg/day plus capecitabine) and 60, 120, 240 and 500 mg/kg/day (approximately 0.6 to 2.3 times the expected human clinical exposure based on AUC) in male rats, and 20, 60, and 180 mg/kg/day (approximately 1.4 to 10 times the expected human clinical exposure based on AUC) in female rats. There was no evidence of carcinogenicity in mice. In male rats, there was an increased incidence of whole body combined hemangiomas and hemangiosarcomas.

Lapatinib was not clastogenic or mutagenic in the Chinese hamster ovary chromosome aberration assay, microbial mutagenesis (Ames) assay, human lymphocyte chromosome aberration assay or the in vivo rat bone marrow chromosome aberration assay at single doses up to 2,000 mg/kg.

There were no effects on male or female rat mating or fertility at doses up to 120 mg/kg/day in females and 180 mg/kg/day in males (approximately 6.4 times and 2.6 times the expected human clinical exposure based on AUC following 1,250-mg dose of lapatinib plus capecitabine, respectively).

The effect of lapatinib on human fertility is unknown. However, when female rats were given oral doses of lapatinib during breeding and through the first 6 days of gestation, a significant decrease in the number of live fetuses was seen at 120 mg/kg/day and in the fetal body weights at greater than or equal to 60 mg/kg/day (approximately 6.4 times and 3.3 times the expected human clinical exposure based on AUC following 1,250-mg dose of lapatinib plus capecitabine, respectively).

Section 12: Ecological Information

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No relevant studies identified.

Section 13: Disposal Considerations

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Incinerate in an approved facility. Follow all federal state and local environmental regulations.

Section 14: Transport Information

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IATA/ICAO - Not Regulated

IATA Proper shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard Class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A

IMDG - Not Regulated

IMDG Proper shipping Name	:	N/A
IMDG UN/ID No	:	N/A
IMDG Hazard Class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

DOT - Not Regulated

DOT Proper shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

Section 15: Regulatory Information

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This Section Contains Information relevant to compliance with other Federal and/or state laws.

Section 16: Other Information

Section 16, Other information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

NATCO shall not be held liable for any damage resulting from handling or from contact with the above product. NATCO reserves the right to revise this SDS.