# LUPIN LIMITED

## SAFETY DATA SHEET

## Section 1: Identification

**Section 1, Identification**

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|---|---|
| **Material** | **Emtricitabine and Tenofovir Disoproxil Fumarate Tablets 200 mg/300 mg** |
| **Manufacturer** | **Lupin Limited**<br>Nagpur-441 108<br>INDIA |
| **Distributor** | Lupin Pharmaceuticals, Inc.<br>111 South Calvert Street,<br>Harborplace Tower, 21st Floor,<br>Baltimore, Maryland 21202<br>United States<br>Tel. 001-410-576-2000<br>Fax. 001-410-576-2221 |

## Section 2: Hazard(s) Identification

**Section 2, Hazard(s) identification**

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| **Fire and Explosion** | Expected to be non-combustible. |
| **Health** | Emtricitabine and tenofovir disoproxil fumarate tablets for HIV-1 PrEP are contraindicated in individuals with unknown or positive HIV-1 status. |
| **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** |
|---|---|
| Emtricitabine | 143491-57-0 |
| Tenofovir Disoproxil Fumarate | 202138-50-9 |

## Section 4: First-Aid Measures

**Section 4, First-aid measures**

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| **Ingestion** | If accidental ingestion occurs, flush mouth out with water and get medical attention. |
| **Inhalation** | The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention. |
| **Skin Contact** | Wash off immediately with plenty of water. Continue to rinse for at least 15 minutes. Get medical attention if irritation develops and persists. |

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| **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**

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| **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** | If overdose occurs, the patient must be monitored for evidence of toxicity, and standard supportive treatment applied as necessary. |

## Section 5: Fire-Fighting Measures

**Section 5, Fire-fighting measures**

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| **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.<br>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**

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| **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

**Section 7, Handling and storage**

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| **Handling** | No special control measures required for the normal handling of this product.<br>Normal room ventilation is expected to be adequate for routine handling of this product. |
| **Storage** | Store at 25º C (77º F); excursions permitted to 15º to 30º C (59º to 86º F) [See USP Controlled Room Temperature].<br>• Keep container tightly closed.<br>• Dispense only in original container. |

## 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**

**Physical Form**

Emtricitabine and tenofovir disoproxil fumarate tablets are available in bottles containing 30 and 100 tablets with child-resistant closure as follows:

200 mg of FTC and 300 mg of TDF (equivalent to 245 mg of tenofovir disoproxil) tablets are white, capsule shaped, biconvex, film-coated, debossed with “LU” on one side and “Q31” on the other side.

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| Bottles of 30 | 68180-287-06 |
| Bottles of 100 | 68180-287-01 |

## 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 long-term oral carcinogenicity studies of FTC, no drug-related increases in tumor incidence were found in mice at doses up to 750 mg/kg/day (26 times the human systemic exposure at the therapeutic dose of 200 mg/day) or in rats at doses up to 600 mg/kg/day (31 times the human systemic exposure at the therapeutic dose).

FTC was not genotoxic in the reverse mutation bacterial test (Ames test), or the mouse lymphoma or mouse micronucleus assays.

FTC did not affect fertility in male rats at approximately 140-fold or in male and female mice at approximately 60-fold higher exposures (AUC) than in humans given the recommended 200 mg daily dose. Fertility was normal in the offspring of mice exposed daily from before birth (in utero) through sexual maturity at daily exposures (AUC) of approximately 60-fold higher than human exposures at the recommended 200 mg daily dose.

Long-term oral carcinogenicity studies of TDF in mice and rats were carried out at exposures up to approximately 16 times (mice) and 5 times (rats) those observed in humans at the therapeutic dose for HIV-1 infection. At the high dose in female mice, liver adenomas were increased at

exposures 16 times that in humans. In rats, the study was negative for carcinogenic findings at exposures up to 5 times that observed in humans at the therapeutic dose.

TDF was mutagenic in the in vitro mouse lymphoma assay and negative in an in vitro bacterial mutagenicity test (Ames test). In an in vivo mouse micronucleus assay, TDF was negative when administered to male mice.

There were no effects on fertility, mating performance, or early embryonic development when TDF was administered to male rats at a dose equivalent to 10 times the human dose based on body surface area comparisons for 28 days prior to mating and to female rats for 15 days prior to mating through day 7 of gestation. There was, however, an alteration of the estrous cycle in female rats.

## Section 12: Ecological Information

**Section 12: Ecological Information**

No relevant studies identified.

## Section 13: Disposal Considerations

**Section 13: Disposal Considerations**

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

## Section 14: Transport Information

**Section 14: Transport Information**

**IATA/ICAO - Not Regulated**

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|---|---|---|
| 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**

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|---|---|---|
| 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**

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|---|---|---|
| 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

**Section 15: Regulatory Information**

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.

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