

Doc. No.: SDS/FM/014

Effective Date: 24/05/18

Revision No.: 1.0

**Section 1: Chemical Product and Company Identification**
**Product Name:** Emtricitabine and Tenofovir Disoproxil Fumarate Tablets 200/300 mg.

**Synonyms:** --

**CAS No.:** --

**Chemical Formula:** --

**Molecular Weight:** --

**NFPA Rating:**

 Health: - ; Flammability: - ; Reactivity: - ;  
 Specific Hazard: - .

**Contact Information:**
**Corporate Address :**

 Laurus Labs Limited,  
 2nd Floor, Serene Chambers, Road No #  
 7, Banjara Hills, Hyderabad – 500034  
 Ph: 040 – 3980 4333

**Section 2: Hazards Identification**

Not considered hazardous when handled under normal conditions with good house keeping.

**Section 3: Composition/ Information on Ingredients**

CAS #	Chemical name	Percent
143491-57-0	Emtricitabine	20.00
202138-50-9	Tenofovir disoproxil fumarate (ASTM #40)	30.00
64044-51-5	Lactose Anhydrous (Super Tab 24 AN)	14.50
9004-34-6	Microcrystalline Cellulose (Avicel PH 112) <sup>@</sup>	26.00
74811-65-7	Croscarmellose Sodium (Ac-di-sol)	8.00
557-04-0	Magnesium stearate (Material No. 5712-88)	1.50
13436-67-7	Opadry II Blue 32K505040	--
--	Purified Water	--

**Section 4: First Aid Measures**
**Inhalation**

Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

**Skin contact**

Immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.

**Eye contact**

Immediately flush eyes with copious amounts of water for at least 15 minutes. Seek medical advice.

**Ingestion**

If swallowed, wash out mouth with water, provided person is conscious. Seek medical advice.

**Section 5: Fire and Explosion Data**
**Extinguishing Media:**

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

**Special fire fighting procedures:**

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Wear self-contained breathing apparatus and protective clothing to prevent contact with the skin and eyes.

**Section 6: Accidental Release Measures**

Ensuring personal safety, mark out contaminated area with signs and prevent unauthorized access. Sweep-up/absorb in suitable material, place in a container and hold for disposal. Avoid raising dust. Ventilate area and wash spill site after pick-up complete.

**Section 7: Handling and Storage**

Do not store above 30°C. Store in the original container.

**Section 8: Exposure Controls/ Personal Protection**

**Respiratory protection:**

Required when dusts are generated.

**Eye protection:**

Required.

**Hand protection:**

Required.

**Industrial hygiene:**

Immediately change contaminated clothing. Wash hands and face after working with substance.

**Section 9: Physical and Chemical Properties**

Physical State	:	Blue colored, Capsule shaped, Film coated Biconvex tablets debossed with 'LA49' on one side and plain on other side
Melting Point/ Range	:	No data available
Flash Point	:	No data available
Flammability	:	No data available
Autoignition Temp	:	No data available
Oxidizing Properties	:	No data available
Explosive Properties	:	No data available
Explosion Limits	:	No data available

**Section 10: Stability and Reactivity Data**

**Conditions to be avoided**

No data available

**Substances to be avoided**

No data available

**Hazardous decomposition products**

No data available

**Section 11: Toxicological Information**

**Emtricitabine:** In long-term carcinogenicity studies of emtricitabine, 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/day (31 times the human systemic exposure at the therapeutic dose).

Acute Oral toxicity

LD50 Rat: >4000 mg/kg

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**Tenofovir Disoproxil Fumarate:** Long-term oral carcinogenicity studies of tenofovir DF 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.

Acute Oral toxicity

LD50 Rat: >950 mg/kg

**Section 12: Ecological Information**

Do not allow product to enter drinking water supplies, waste water or soil!

**Section 13: Disposal Considerations**

Dissolve or mix material with a suitable combustible solvent and incinerate in a chemical incinerator equipped with an afterburner and scrubber.

Material should be disposed of in keeping with all local and national legislation. Packaging should be disposed of in keeping with all local and national legislation. Handle contaminated containers as product.

**Section 14: Transport Information**

**RID/ADR**

Non-hazardous for road transport.

**IMDG**

Non-hazardous for sea transport.

**IATA**

Non-hazardous for air transport.

**Section 15: Other Regulatory Information**

No data available

**Section 16: Other Information**

**Disclaimer:**

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product.

**Revision Log:**

Revision No.	Reason for revision	Effective Date
0.0	First Issue	20/11/17
1.0	Section: 03,07, 11 modified.	24/05/18

Prepared By:

*[Signature]*  
24/05/18

Reviewed By:

*[Signature]*  
24/05/18