

Doc. No.: SDS/FM/017

Effective Date: 28/11/2017

Revision No.: 0.0

**Section 1: Chemical Product and Company Identification**

**Product Name:** Efavirenz , Lamivudine and Tenofovir disoproxil fumarate Tablets 600/300/300mg

**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
154598-52-4	Efavirenz	35.29
134678-17-4	Lamivudine	17.64
202138-50-9	Tenofovir disoproxil Fumarate	17.64

**Section 4: First Aid Measures**

**In case of inhalation:**

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

**In case of contact with skin:**

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

**In case of contact with eyes:**

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

**In case of 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:**

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.

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Avoid raising dust. Ventilate area and wash spill site after pick-up complete.

**Section 7: Handling and Storage**

Keep the bottle tightly closed. Store at 20°C–25°C (68° to 77° F), excursion permitted between 15°C to 30°C (59° to 86° F).

**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	:	Capsule shape tablet
Color	:	White
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:** Unknown

**Substances to be avoided:** Unknown

**Hazardous decomposition products:** Unknown

**Section 11: Toxicological Information**

**Toxicology Data**

<b>Components</b>	<b>Species</b>	<b>Test results</b>
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**Efavirenz :**

**Acute**

Oral

LD50

Rat

600 mg/Kg

**Lamivudine: Carcinogenesis, Mutagenesis, Impairment of Fertility**

Long-term carcinogenicity studies with lamivudine in mice and rats showed no evidence of carcinogenic potential at exposures up to 10 times (mice) and 58 times (rats) those observed in humans at the recommended therapeutic dose for HIV-1 infection. Lamivudine was not active in a microbial mutagenicity screen or an in vitro cell transformation assay, but showed weak in vitro mutagenic activity in a cytogenetic assay using cultured human lymphocytes and in the mouse lymphoma assay. However, lamivudine showed no evidence of in vivo genotoxic activity in the rat at oral doses of up to 2,000 mg/kg, producing plasma levels of 35

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to 45 times those in humans at the recommended dose for HIV-1 infection. In a study of reproductive performance, lamivudine administered to rats at doses up to 4,000 mg/kg/day, producing plasma levels 47 to 70 times those in humans, revealed no evidence of impaired fertility and no effect on the survival, growth, and development to weaning of the offspring.

**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.

**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	28/11/2017

Prepared By:   
23/11/17

Reviewed By:   
23/11/17