

Doc. No.: SDS/FM/020

Effective Date: 27/12/2017

Revision No.: 0.0

Section 1: Chemical Product and Company Identification

Product Name:

Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate Tablets 600/200/300 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 housekeeping.

Section 3: Composition/ Information on Ingredients

| CAS # | Chemical name | Percent |
|-------------|-------------------------------|---------|
| 154598-52-4 | Efavirenz | 38.71 |
| 143491-57-0 | Emtricitabine | 19.36 |
| 202138-50-9 | Tenofovir disoproxil Fumarate | 12.90 |

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, excursion permitted between 15°C to 30°C.

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 | : | Pink |
| Melting Point/ Range | : | N/A |
| Flash Point | : | Not Available |
| Flammability | : | N/A |
| Autoignition Temp | : | N/A |
| Oxidizing Properties | : | N/A |
| Explosive Properties | : | N/A |
| Explosion Limits | : | N/A |

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

Efavirenz: Long-term carcinogenicity studies in mice and rats were carried out with efavirenz. Mice were dosed with 0, 25, 75, 150, or 300 mg/kg/day for 2 years. Incidences of hepatocellular adenomas and carcinomas and pulmonary alveolar/bronchiolar adenomas were increased above background in females

Acute Oral toxicity

LD50 Rat: 750-1000 mg/kg

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

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

| | | |
|---|--------------------------------|--------------------|
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| <p>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.</p> <p>Acute Oral toxicity LD50 Rat: >950 mg/kg</p> | | |

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:
Not dangerous goods
IMDG:
Not dangerous goods
IATA:
Not dangerous goods

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 | 27/12/2017 |

Prepared By: 
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Reviewed By: 
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