Annora

SAFETY DATA SHEET

Section 1: Identification	
Material	Efavirenz, Emtricitabine and Tenofovir DF Tablets 600 mg/200 mg/300 mg
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
Distributor	**Camber Pharmaceuticals, Inc.**, Piscataway, NJ 08854

Section 2: Hazard(s) Identification	
Hazard(s) identification	Efavirenz, Emtricitabine and tenofovir disoproxil fumarate tablets used alone or with other HIV medications to help control HIV infection.
Fire and Explosion	Expected to be non-combustible.
Environment	No information is available about the potential of this product to produce adverse environmental effects.

Section 3: Composition/Information on Ingredients			
Ingredients	Efavirenz	Emtricitabine	Tenofovir Disoproxil Fumarate
CAS	154598-52-4	143491-57-0	202138-50-9

Section 4: First-Aid Measures	
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.
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 PROFESSIONAL	
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

Extinguishing Media	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
Fire and Explosion Hazards	Assume that this product is capable of sustaining combustion.
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

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

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 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

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

Physical Form	Tablet
Colour	Pink
Description	Efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets 600 mg/200 mg/300 mg are white to off-white colored, capsule shaped, film-coated tablets debossed with 'H' on one side and '128' on the other side. Each bottle contains 30 tablets (NDC 31722-736-30) and silica gel desiccant, and is closed with a child-resistant closure.

Section 10: Stability and Reactivity	
Stability and reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.

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 SDS : 235/00 Page 4 of 5 Effective Date : 11/01/2021 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
No relevant studies identified.

Section 13: Disposal Considerations
Incinerate in an approved facility. Follow all federal state and local environmental regulations.

Section 14: Transport Information

TA/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

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

Section 16: Other Information

Issue Date : 12-01-2022

Version : 00

Further information

Revision date: New issue

Revision note: New issue

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. 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.

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