



HETERO LABS LIMITED

"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018. A.P., INDIA.
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250
e-mail : contact@heterodrugs.com URL : http://www.heterodrugs.com

SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification

Material Name Tenofovir Disoproxil Fumarate Tablets, 300 mg
Relevant Identified Uses of the Substance or Mixture and Uses Advised Against Intended Use: A nucleotide analog HIV-1 reverse transcriptase inhibitor and an HBV reverse transcriptase inhibitor.
Manufacturer Hetero Labs Limited Unit III,
Plot No. 22-110, Part-II, Industrial Development Area
Jeedimetla, Hyderabad, Telangana, India- 500055
Distributor Camber Pharmaceuticals, Inc., Piscatway, NJ 08854

Section 2: Hazard(s) Identification

2.1 Classification of the Substance or Mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP] Not classified

Classification according to Directive 67/548/EEC or 1999/45/EC Not classified

Adverse physicochemical, human health and environmental effects Not classified

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



None

CLP Signal word Warning
Hazard statements (CLP) H302 - Harmful if swallowed
H302+H312 - Harmful if swallowed or in contact with skin
H302+H312+H332 - Harmful if swallowed, in contact with skin or if inhaled
Precautionary statements (CLP) P102 - Keep out of reach of children
P103 - Read label before use
P202 - Do not handle until all safety precautions have been read and understood
P222 - Do not allow contact with air
P233 - Keep container tightly closed
P234 - Keep only in original container
P420 - Store away from other materials
EUH phrases EUH210 - Safety data sheet available on request

2.3. Other hazards

No additional information available



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Section 3: Composition/Information on Ingredients

Hazardous

Name : Tenofovir disoproxil fumarate
CAS No. : 202138-50-9

Section 4: First-Aid Measures

Description of first aid measures

First-aid measures general	Allow the victim to rest in a well ventilated area. Seek immediate Medical attention.
First-aid measures after inhalation	If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.
First-aid measures after skin contact	Immediately wash skin with soap and copious Amounts of water for at least 15 minutes. If Irritation persists seek medical attention.
First-aid measures after eye contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
First-aid measures after ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Most important symptoms and effects, both acute and delayed

No additional information available

Indication of any immediate medical attention and special treatment needed

No additional information available

Section 5: Fire-Fighting Measures

Extinguishing Media

Suitable extinguishing media Use carbon dioxide, dry chemical.

Special hazards arising from the substance or mixture

Explosion hazard Not expected for the product, although the packaging is combustible.

Reactivity Product is not explosive.

Advice for Fire-Fighters

Precautionary measures fire Fight fire from a safe distance. Wear full protective clothing. Use water spray to keep exposed containers and equipment cool. Toxic, corrosive of flammable thermal decomposition products are expected when the product is exposed to fire. Self-contained breathing apparatus and full protective equipment is recommended for firefighters.

Protection during firefighting As with all fires evacuate personnel to safe



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	area fire fighters should use self contained breathing equipment and protective clothing.
Section 6: Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	
General measures	Keep upwind-Mark the danger area-Consider evacuation-Seal off low-lying area-Close doors and windows of adjacent premiss.
For non-emergency personnel	
No additional information available	
For emergency responders	
No additional information available	
Environmental precautions	
For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.	
Methods and materials for containment and cleaning up:	
For containment	Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous solutions.
Methods for cleaning up	Wipe up with a damp cloth and place in container for disposal. Clean spill area thoroughly.
Other information	Wash clothing and equipment after handling.
Reference to other sections	
No additional information available	
Section 7: Handling and Storage	
Precautions for safe handling	
Precautions for safe handling	Gloves
Handling	Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.
Conditions for safe storage, including any incompatibilities	
Storage conditions	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
Section 8: Exposure Controls/Personal Protection	
Control Parameters	
No additional information available	
Exposure controls	



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Hand protection	Gloves.
Eye protection	Safety goggles.
Skin and body protection	Protective clothing
Respiratory protection	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Section 9: Physical and Chemical Properties

Information on basic physical and chemical properties

Physical state	Tablet
Appearance	White colored, almond shaped, film coated tablets
Colour	White
Odor	Not available
Description	White colored, almond shaped, film coated tablets, are debossed with 'H' on one side and '123' on other side. Bottle of 30 tablets (NDC 31722-535-30) Bottle of 60 tablets (NDC 31722-535-60) Bottle of 100 tablets (NDC 31722-535-01) Bottle of 500 tablets (NDC 31722-535-05) Bottle of 1000 tablets (NDC 31722-535-10)

Section 10: Stability and Reactivity

Reactivity

Product is not explosive.

Chemical stability

Stable under defined conditions.

Possibility of hazardous reactions

No additional information available

Conditions to avoid

No additional information available

Incompatible materials

As a precautionary measure. Keep away from strong oxidizers.

Hazardous decomposition products

No additional information available



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Section 11: Toxicological Information

Information on toxicological effects	
Acute toxicity	Not classified
Skin corrosion/irritation	Not classified
Serious eye damage/irritation	Not classified
Respiratory or skin sensitisation	Not classified
Germ cell mutagenicity	Not classified
Carcinogenicity	Not classified
Reproductive toxicity	Not classified
Specific target organ toxicity (single exposure)	Not classified
Specific target organ toxicity (repeated exposure)	Not classified
Aspiration hazard	Not classified

Section 12: Ecological Information

Toxicity	
Ecology - air	Not dangerous for the ozone layer (1999/45/EC).
Persistence and degradability	
Tenofovir disoproxil fumarate (202138-50-9)	
Persistence and degradability	% biodegradation.
Mobility in soil	
Tenofovir disoproxil fumarate (202138-50-9)	
Ecology - soil	The substance has moderate mobility in groundwater. The substance has moderate mobility in soil.
Other adverse effects	
Other information	No other effects known.

Section 13: Disposal Considerations

13.1. Waste Treatment Methods:	
Disposal instructions	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to



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	prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.
Local disposal regulations	No data available
Hazardous waste code	No data available
Waste from residues I unused	No data available
Contaminated packaging	No data available
Section 14: Transport Information	
No dangerous good in sense of transport regulations.	
Section 15: Regulatory Information	
U.S State regulations	
California Proposition 65: This product does not content any proposition 65 chemicals	
Section 16: Other Information	
Issue Date : 15-02-2018	
Version : 00	
<p>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.</p> <p>Hetero Labs Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero Labs Limited reserves the right to revise this SDS.</p>	