1. Identification

Product identifier: Tenofovir Disoproxil Fumarate

Other means of identification:
- Catalog number: 1643656
- CAS number: 202138-50-9

Recommended use: Specified quality tests and assay use only.

Recommended restrictions: Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer:
- Company name: U. S. Pharmacopeia
- Address: 12601 Twinbrook Parkway, Rockville, MD 20852-1790, United States
- Telephone: RS Technical Services 301-816-8129
- Website: www.usp.org
- E-mail: RSTECH@usp.org
- CHEMTREC within US & Canada: 1-800-424-9300
- CHEMTREC outside US & Canada: +1 703-527-3887

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards:
- Serious eye damage/eye irritation: Category 1

Environmental hazards: Not classified.

OSHA defined hazards: Not classified.

Label elements

Signal word: Danger

Hazard statement: Causes serious eye damage.

Precautionary statement
- Prevention: Wear eye protection/face protection.
- Response: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor.
- Storage: Not available.
- Disposal: Not available.

Hazard(s) not otherwise classified (HNOC): None known.

Supplemental information: Pharmacologically active material.

3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tenofovir Disoproxil Fumarate</td>
<td></td>
<td>202138-50-9</td>
<td>100</td>
</tr>
</tbody>
</table>
4. First-aid measures

**Inhalation**
If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

**Skin contact**
Rinse skin with water/shower. Get medical attention if irritation develops and persists.

**Eye contact**
Flush eyes immediately with large amounts of water. Call a physician or poison control center immediately.

**Ingestion**
Rinse mouth. If ingestion of a large amount does occur, call a physician or poison control center immediately.

**Most important symptoms/effects, acute and delayed**
Irritant effects. Pharmacologically active material. Occupational exposure may cause physiological effects.

**Indication of immediate medical attention and special treatment needed**
Provide general supportive measures and treat symptomatically.

**General information**
Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

**Suitable extinguishing media**
Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.

**Unsuitable extinguishing media**
None known.

**Specific hazards arising from the chemical**
No unusual fire or explosion hazards noted.

**Special protective equipment and precautions for firefighters**
Wear suitable protective equipment.

**Fire fighting equipment/instructions**
Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

**Specific methods**
Use standard firefighting procedures and consider the hazards of other involved materials.

**General fire hazards**
No unusual fire or explosion hazards noted.

6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**
Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

**Methods and materials for containment and cleaning up**
For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

**Environmental precautions**
Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

**Precautions for safe handling**
As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

**Conditions for safe storage, including any incompatibilities**
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

**Occupational exposure limits**
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

**Exposure limit values**

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tenofovir Disoproxil Fumarate (CAS 202138-50-9)</td>
<td>TWA</td>
<td>200 micrograms/m3</td>
</tr>
</tbody>
</table>

**Biological limit values**
No biological exposure limits noted for the ingredient(s).
For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

**Eye/face protection**
Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

**Skin protection**
- **Hand protection**
  Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
- **Other**
  Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

**Respiratory protection**
Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Chose respiratory protection appropriate to the task and the level of existing engineering controls.

**General hygiene considerations**
Handle in accordance with good industrial hygiene and safety practice. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

**Appearance**
Appearance descriptions are general information and not specific to any USP lot.

- **Physical state**
  Solid.
- **Form**
  Powder.
- **Color**
  White. Off-white.
- **Odor**
  Odorless.
- **Odor threshold**
  Not available.
- **pH**
  Not available.
- **Melting point/freezing point**
  233.6 - 246.2 °F (112 - 119 °C)
- **Initial boiling point and boiling range**
  Not available.
- **Flash point**
  Not available.
- **Evaporation rate**
  Not available.
- **Flammability (solid, gas)**
  Not available.

**Upper/lower flammability or explosive limits**
- **Flammability limit - lower (%)**
  Not available.
- **Flammability limit - upper (%)**
  Not available.
- **Explosive limit - lower (%)**
  Not available.
- **Explosive limit - upper (%)**
  Not available.

- **Vapor pressure**
  Not available.
- **Vapor density**
  Not available.
- **Relative density**
  Not available.

**Solubility(ies)**
- **Solubility (water)**
  Sparingly soluble.
- **Solubility (other)**
  Hydrochloric acid: Soluble.
  Ethanol: Soluble.
  Acetone: Sparingly soluble.
  Isopropanol: Sparingly soluble.
  Acetonitrile: Slightly soluble.
  Dichloromethane: Insoluble.
  Hexane: Insoluble.
  Ethyl acetate: Slightly soluble.
  Methanol: Soluble.
- **Partition coefficient (n-octanol/water)**
  1.18 (at pH 7)
- **Auto-ignition temperature**
  > 392 °F (> 200 °C)
Decomposition temperature  Not available.
Viscosity  Not available.
Other information
  Chemical family  Nucleotide analog.
  Molecular formula  C19H30N5O10P . C4H4O4
  Molecular weight  635.51

10. Stability and reactivity
Reactivity  The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability  Material is stable under normal conditions.
Possibility of hazardous reactions  No dangerous reaction known under conditions of normal use.
Conditions to avoid  Contact with incompatible materials.
Incompatible materials  Strong oxidizing agents.
Hazardous decomposition products  NOx, POx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information
Information on likely routes of exposure
  Inhalation  Knowledge about health hazard is incomplete.
  Skin contact  Knowledge about health hazard is incomplete.
  Eye contact  Causes serious eye damage.
  Ingestion  Knowledge about health hazard is incomplete.

Information on toxicological effects
Acute toxicity

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tenofovir Disoproxil Fumarate (CAS 202138-50-9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>&gt; 950 mg/kg</td>
</tr>
<tr>
<td>NOAEL</td>
<td>Rat</td>
<td>1500 mg/kg</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td></td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td>Serious eye damage/eye irritation</td>
<td></td>
<td>Causes serious eye damage.</td>
</tr>
<tr>
<td><strong>Local effects</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eye irritation, Corneal opacity remained after 21 days. Result: Severe irritant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species: Rabbit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin irritation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result: Slight</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species: Rabbit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory or skin sensitization</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Respiratory sensitization</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Skin sensitization</strong></td>
<td></td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td>Sensitization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result: Negative.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species: Guinea pig</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mutagenicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ames test, with and without activation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result: Negative.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Micronucleus test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result: Negative.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mouse lymphoma assay</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result: Positive.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Mutagenicity
Mutagenicity: In vivo unscheduled DNA synthesis in rat hepatocytes
Result: Positive.

Carcinogenicity
Based on available data, the classification criteria are not met.

100 - 600 mg/kg/day Oral feed study
Result: Duodenal tumors at high dose.
Species: Mouse

30 - 300 mg/kg/day Oral feed study
Result: Negative.
Species: Rat

IARC Monographs. Overall Evaluation of Carcinogenicity
Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens
Not listed.

Reproductive toxicity
Based on available data, the classification criteria are not met.

Reproductivity
0 - 300 mg/kg/day Developmental, administered orally during gestation
Result: NOEL = 300 mg/kg/day
Species: Rabbit

0 - 450 mg/kg/day Developmental, administered orally during gestation
Result: NOEL = 450 mg/kg/day
Species: Rat

0 - 600 mg/kg/day Reproductivity, administered orally
Result: Reproductive NOEL = 300 mg/kg/day; developmental NOEL = 600 mg/kg/day
Species: Rat

30 mg/kg Developmental, administered subcutaneously
Result: Negative.
Species: Rhesus monkey

Specific target organ toxicity - single exposure
Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure
Knowledge about health hazard is incomplete.

Aspiration hazard
Based on available data, the classification criteria are not met.

Further information
Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information

Ecotoxicity

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tenofovir Disoproxil Fumarate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aquatic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Algae</td>
<td>EC50</td>
<td>Freshwater algae</td>
</tr>
<tr>
<td>Crustacea</td>
<td>EC50</td>
<td>Daphnia magna</td>
</tr>
<tr>
<td>Fish</td>
<td>LC50</td>
<td>Rainbow trout, donaldson trout</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Oncorhynchus mykiss)</td>
</tr>
</tbody>
</table>

Persistence and degradability
Not readily biodegradable.

Bioaccumulative potential

Octanol/water partition coefficient log Kow
1.18, (at pH 7)

Mobility in soil
No data available.

Other adverse effects
No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions
Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations
- Dispose in accordance with all applicable regulations.

Hazardous waste code
- The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products
- Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging
- Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT
- Not regulated as dangerous goods.

IATA
- Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
- Not applicable.

General information
- It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations
- This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
- Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)
- Not listed.

SARA 304 Emergency release notification
- Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
- Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Immediate Hazard
- Yes

Delayed Hazard
- No

Fire Hazard
- No

Pressure Hazard
- No

Reactivity Hazard
- No

SARA 302 Extremely hazardous substance
- Not listed.

SARA 311/312 Hazardous chemical
- Yes

SARA 313 (TRI reporting)
- Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
- Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
- Not regulated.

Safe Drinking Water Act (SDWA)
- Not regulated.

US state regulations
- California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
</tbody>
</table>
Country(s) or region | Inventory name                                                                 | On inventory (yes/no)*
--- | --- | ---
Europe | European List of Notified Chemical Substances (ELINCS) | No
Japan | Inventory of Existing and New Chemical Substances (ENCS) | No
Korea | Existing Chemicals List (ECL) | No
New Zealand | New Zealand Inventory | No
Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No
United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No

*A “Yes” indicates that all components of this product comply with the inventory requirements administered by the governing country(s).
A “No” indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date: 12-02-2009
Revision date: 09-01-2017
Version #: 04

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