1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Manufacturer or supplier's details
Company : MSD
Address : Brihnager - Off Pune Nagar Road
          Wagholi - Pune - India 412 207
Telephone : +1-908-740-4000
Emergency telephone number : +1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989
Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Acute toxicity (Oral) : Category 5
Skin corrosion/irritation : Category 3
Serious eye damage/eye irri-
tation : Category 2A
Reproductive toxicity : Category 2
Specific target organ toxicity -
repeated exposure (Oral) : Category 2 (Blood, Bone, Kidney)
Short-term (acute) aquatic hazard : Category 3

GHS label elements
Hazard pictograms :
Signal word : Warning

Hazard statements : H303 May be harmful if swallowed.
H316 Causes mild skin irritation.
H319 Causes serious eye irritation.
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs (Blood, Bone, Kidney) through prolonged or repeated exposure if swallowed.
H402 Harmful to aquatic life.

Precautionary statements : Prevention:
P203 Obtain, read and follow all safety instructions before use.
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P301 + P332 + P317 IF SWALLOWED or if skin irritation occurs: Get medical help.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P318 IF exposed or concerned, get medical advice.
P337 + P317 IF eye irritation persists: Get medical help.

Storage:
P405 Store locked up.

Disposal: P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification
May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Lamivudine</td>
<td>134678-17-4</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Tenofovir</td>
<td>202138-50-9</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Doravirine</td>
<td>1338225-97-0</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

<table>
<thead>
<tr>
<th>Situation</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>If inhaled</td>
<td>If inhaled, remove to fresh air. Get medical attention.</td>
</tr>
<tr>
<td>In case of skin contact</td>
<td>In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.</td>
</tr>
<tr>
<td>In case of eye contact</td>
<td>In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.</td>
</tr>
<tr>
<td>If swallowed</td>
<td>If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.</td>
</tr>
</tbody>
</table>

Most important symptoms and effects, both acute and delayed:

- May be harmful if swallowed.
- Causes mild skin irritation.
- Causes serious eye irritation.
- Suspected of damaging the unborn child.
- May cause damage to organs through prolonged or repeated exposure if swallowed.

Protection of first-aiders:

- First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician:

- Treat symptomatically and supportively.

### 5. FIREFIGHTING MEASURES

- **Suitable extinguishing media**
  - Water spray
  - Alcohol-resistant foam
  - Carbon dioxide (CO2)
  - Dry chemical

- **Unsuitable extinguishing media**
  - None known.

- **Specific hazards during firefighting**
  - Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

- **Hazardous combustion products**
  - Carbon oxides
  - Nitrogen oxides (NOx)
  - Halogenated compounds

- **Specific extinguishing methods**
  - Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
  - Use water spray to cool unopened containers.
  - Remove undamaged containers from fire area if it is safe to do so.
  - Evacuate area.

- **Special protective equipment for firefighters**
  - In the event of fire, wear self-contained breathing apparatus.
  - Use personal protective equipment.
6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up:
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
- Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Technical measures:
- Static electricity may accumulate and ignite suspended dust causing an explosion.
- Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation:
- Use only with adequate ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe dust.
- Do not swallow.
- Do not get in eyes.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
- Keep in properly labelled containers.
- Store locked up.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Lamivudine</td>
<td>134678-17-4</td>
<td>TWA</td>
<td>150 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Tenofovir</td>
<td>202138-50-9</td>
<td>TWA</td>
<td>150 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Doravirine</td>
<td>1338225-97-0</td>
<td>TWA</td>
<td>500 µg/m³ (OEB2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures: Use feasible engineering controls to minimize exposure to compound.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Personal protective equipment

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type Particulates type
Hand protection Material Chemical-resistant gloves
Eye protection: Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection: Work uniform or laboratory coat.
Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder
Colour: No data available
SAFETY DATA SHEET

Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version 5.9  Revision Date: 10.10.2020  SDS Number: 59642-00021  Date of last issue: 11.05.2020  Date of first issue: 16.02.2015

Odour: No data available
Odour Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: Not applicable
Evaporation rate: Not applicable
Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapour pressure: Not applicable
Relative vapour density: Not applicable
Relative density: No data available
Density: No data available
Solubility(ies)
Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Auto-ignition temperature: No data available
Decomposition temperature: No data available
Viscosity
Viscosity, kinematic: Not applicable
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Molecular weight: No data available
Particle size: No data available
10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

Conditions to avoid: Heat, flames and sparks.
Avoid dust formation.

Incompatible materials: Oxidizing agents

Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure: Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity: May be harmful if swallowed.

Product:
Acute oral toxicity: Acute toxicity estimate: 2,605 mg/kg
Method: Calculation method

Components:

Cellulose:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

Lamivudine:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg

LD50 (Mouse): 4,000 mg/kg
Remarks: No mortality observed at this dose.

Acute toxicity (other routes of administration): LD50 (Rat): > 2,000 mg/kg
Application Route: Intravenous

Tenofovir:
Acute oral toxicity: LD50 (Rat): > 1,500 mg/kg
<table>
<thead>
<tr>
<th>LD50 (Dog): 30 mg/kg</th>
</tr>
</thead>
</table>

**Doravirine:**
- **Acute oral toxicity**
  - LD50 (Rat): > 750 mg/kg
  - Remarks: No mortality observed at this dose.
- (Rat): Method: Phototoxicity
  - Remarks: No evidence of phototoxicity was observed
- LD50 (Dog): > 1,000 mg/kg
  - Remarks: No mortality observed at this dose.
- LD50 (Mouse): > 450 mg/kg
  - Remarks: No mortality observed at this dose.

**Skin corrosion/irritation**
Causes mild skin irritation.

**Components:**

**Lamivudine:**
- **Species**: Rabbit
- **Result**: Mild skin irritation

**Tenofovir:**
- **Species**: Rabbit
- **Result**: Mild skin irritation

**Doravirine:**
- **Remarks**: No data available

**Serious eye damage/eye irritation**
Causes serious eye irritation.

**Components:**

**Lamivudine:**
- **Species**: Rabbit
- **Result**: No eye irritation

**Tenofovir:**
- **Species**: Rabbit
- **Result**: Severe irritation

**Doravirine:**
- **Remarks**: No data available
Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Lamivudine:
Exposure routes: Dermal
Species: Guinea pig
Result: Not a skin sensitizer.

Tenofovir:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: Not a skin sensitizer.

Doravirine:
Remarks: No data available

Germ cell mutagenicity
Not classified based on available information.

Components:

Cellulose:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo: Test Type: In vitro mammalian cell gene mutation test
Result: negative

Lamivudine:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Mouse Lymphoma
Result: equivocal

Genotoxicity in vivo: Test Type: Micronucleus test
Species: Rat
Application Route: Oral
Result: negative

Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo
Species: Rat
Result: negative

**Tenofovir:**
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES) Result: equivocal

Test Type: In vitro mammalian cell gene mutation test Result: positive

Genotoxicity in vivo: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Mouse Application Route: Intraperitoneal injection Result: negative

Germ cell mutagenicity - Assessment: Weight of evidence does not support classification as a germ cell mutagen.

**Doravirine:**
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES) Result: negative

Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: negative

Genotoxicity in vivo: Test Type: Micronucleus test Species: Rat Cell type: Bone marrow Application Route: Oral Result: negative

**Carcinogenicity**
Not classified based on available information.

**Components:**

**Cellulose:**
Species: Rat
Application Route: Ingestion
Exposure time: 72 weeks
Result: negative

**Lamivudine:**
Species: Rat
### Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

<table>
<thead>
<tr>
<th>Component</th>
<th>Exposure</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doravirine:</td>
<td>Species: Mouse</td>
<td>Oral</td>
</tr>
<tr>
<td>Tenofovir:</td>
<td>Species: Mouse</td>
<td>Oral</td>
</tr>
<tr>
<td>Lamivudine:</td>
<td>Species: Rat</td>
<td>Oral</td>
</tr>
</tbody>
</table>

**Remarks:**
No significant adverse effects were reported.

### Reproductive toxicity
Suspected of damaging the unborn child.

### Components:

#### Cellulose:
- **Effects on fertility**: Test Type: One-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

#### Lamivudine:
- **Effects on fertility**: Test Type: Two-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Oral
  - Fertility: NOAEL: 900 mg/kg body weight
  - Result: No effects on fertility and early embryonic development were detected.

- **Effects on foetal development**: Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Symptoms: Preimplantation loss, Skeletal malformations
Result: Embryotoxic effects and adverse effects on the offspring were detected.

Test Type: Embry-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 45 mg/kg body weight
Symptoms: Effects on foetal development
Result: positive

Reproductive toxicity - Assessment:
Some evidence of adverse effects on development, based on animal experiments.

**Tenofovir:**

Effects on fertility:
Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Oral
Result: No effects on fertility

Effects on foetal development:
Test Type: Embry-foetal development
Species: Rat
Application Route: Oral
Result: No adverse effects

**Doravirine:**

Effects on fertility:
Test Type: Fertility
Species: Rat, male and female
Fertility: NOAEL: 450 mg/kg body weight
Result: No effects on fertility

Effects on foetal development:
Test Type: Embry-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 450 mg/kg body weight
Result: No adverse effects

Test Type: Embry-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 300 mg/kg body weight
Result: No adverse effects

**STOT - single exposure**
Not classified based on available information.
STOT - repeated exposure
May cause damage to organs (Blood, Bone, Kidney) through prolonged or repeated exposure if swallowed.

Components:

Lamivudine:
- Exposure routes: Ingestion
- Target Organs: Blood
- Assessment: May cause damage to organs through prolonged or repeated exposure.

Tenofovir:
- Target Organs: Bone, Kidney
- Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Cellulose:
- Species: Rat
- NOAEL: >= 9,000 mg/kg
- Application Route: Ingestion
- Exposure time: 90 Days

Lamivudine:
- Species: Rat
- NOAEL: 425 mg/kg
- Application Route: Oral
- Exposure time: 6 Months
- Target Organs: Blood
- Symptoms: Gastrointestinal discomfort, Breathing difficulties, Fatality
- Remarks: Significant toxicity observed in testing

Species: Dog
- LOAEL: 90 mg/kg
- Application Route: Oral
- Exposure time: 12 Months
- Target Organs: Blood, spleen, Liver
- Symptoms: Salivation, Diarrhoea, Changes in the blood count, Liver disorders, Gastrointestinal disturbance

Species: Mouse
- NOAEL: 500 mg/kg
- Application Route: Oral
- Exposure time: 1 Months
- Target Organs: Blood

Tenofovir:
Species: Rat  
NOAEL: 30 mg/kg  
LOAEL: 300 mg/kg  
Application Route: Oral  
Exposure time: 13 Weeks  
Target Organs: Bone

Species: Dog  
NOAEL: 3 mg/kg  
LOAEL: >= 10 mg/kg  
Application Route: Oral  
Exposure time: 42 Weeks  
Target Organs: Kidney

Species: Monkey  
LOAEL: 10 mg/kg  
Application Route: Subcutaneous  
Exposure time: 10 Months  
Target Organs: Bone

Doravirine:
Species: Rat  
NOAEL: 450 mg/kg  
Application Route: Oral  
Exposure time: 6 Months  
Remarks: No significant adverse effects were reported

Species: Mouse  
NOAEL: > 450 mg/kg  
Application Route: Oral  
Exposure time: 3 Months  
Remarks: No significant adverse effects were reported

Species: Dog  
NOAEL: > 1,000 mg/kg  
Application Route: Oral  
Exposure time: 9 Months  
Remarks: No significant adverse effects were reported

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Lamivudine:
Ingestion: Symptoms: Headache, Fatigue, Respiratory disorders, Diarrhoea, Cough

Tenofovir:
Ingestion: Symptoms: Nausea, Diarrhoea, Vomiting, flatulence, Headache, Rash
Doravirine:
Ingestion: Symptoms: confusion, Headache, Dizziness, Nausea, Rash, abnormal dreams, flushing, Neurological disorders, mental depression

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cellulose:
Toxicity to fish: LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Lamivudine:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): > 97.7 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): > 96.9 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 96.9 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Tenofovir:
Toxicity to algae/aquatic plants: EC50 (Raphidocelis subcapitata (freshwater green alga)): 69 mg/l
End point: Growth
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Raphidocelis subcapitata (freshwater green alga)): 18 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms: EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
<table>
<thead>
<tr>
<th>Test Type</th>
<th>SDS Number</th>
<th>Date of last issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC: &gt; 1,000 mg/l</td>
<td>59642-00021</td>
<td>11.05.2020</td>
</tr>
</tbody>
</table>

Toxicity to fish (Chronic toxicity):
- NOEC: 9 mg/l
- Exposure time: 32 d
- Species: Pimephales promelas (fathead minnow)
- Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC: 12 mg/l
- Exposure time: 21 d
- Species: Daphnia magna (Water flea)
- Method: OECD Test Guideline 211

**Doravirine:**

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): > 39 mg/l
- Exposure time: 48 h
- Method: OECD Test Guideline 202
- Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants:
- EC50 (Pseudokirchneriella subcapitata (green algae)): > 5.8 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201
- Remarks: No toxicity at the limit of solubility

Toxicity to microorganisms:
- EC50: > 1,000 mg/l
- Exposure time: 3 h
- Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity):
- NOEC: 1 mg/l
- Exposure time: 32 d
- Species: Pimephales promelas (fathead minnow)
- Method: OECD Test Guideline 210
- Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other:
- NOEC: 6.7 mg/l
aquatic invertebrates (Chronic toxicity)
  Exposure time: 21 d
  Species: Daphnia magna (Water flea)
  Method: OECD Test Guideline 211
  Remarks: No toxicity at the limit of solubility

Persistence and degradability

**Components:**

**Cellulose:**
Biodegradability: Result: Readily biodegradable.

**Lamivudine:**
Biodegradability: Result: Not readily biodegradable.
  Biodegradation: 4 %
  Exposure time: 28 d

**Tenofovir:**
Biodegradability: Result: Not readily biodegradable.
  Biodegradation: 3.66 %
  Exposure time: 28 d
  Method: OECD Test Guideline 314

**Doravirine:**
Biodegradability: Result: Not readily biodegradable.
  Biodegradation: 2 %
  Exposure time: 28 d

Bioaccumulative potential

**Components:**

**Lamivudine:**
Partition coefficient: n-octanol/water: log Pow: -1.44

**Tenofovir:**
Partition coefficient: n-octanol/water: log Pow: 1.06
  pH: 7

**Doravirine:**
Partition coefficient: n-octanol/water: log Pow: 2.08

Mobility in soil

**Components:**

**Lamivudine:**
18. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

19. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to IMO instruments
Not applicable for product as supplied.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined
SAFETY DATA SHEET

Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version 5.9 Revision Date: 10.10.2020 SDS Number: 59642-00021 Date of last issue: 11.05.2020 Date of first issue: 16.02.2015

16. OTHER INFORMATION

Further information

Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA: 8-hour, time-weighted average

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their
intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

IN / EN