SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name : Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
Company : MSD
Piercetown
A86 HD21 Dunboyne, Ireland

Telephone : 908-740-4000
E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Eye irritation, Category 2 : H319: Causes serious eye irritation.
Reproductive toxicity, Category 2 : H361d: Suspected of damaging the unborn child.
Specific target organ toxicity - repeated exposure, Category 2 : H373: May cause damage to organs through prolonged or repeated exposure.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms : 

Signal word : Warning

Hazard statements : H319 : Causes serious eye irritation.
H361d: Suspected of damaging the unborn child.
H373 : May cause damage to organs through prolonged or repeated exposure.
Precautionary statements: Prevention:
P201 Obtain special instructions before use.
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

Hazardous components which must be listed on the label:
Lamivudine
Tenofovir

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lamivudine</td>
<td>134678-17-4</td>
<td>Repr. 2; H361d STOT RE 2; H373 (Blood)</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Tenofovir</td>
<td>202138-50-9</td>
<td>Acute Tox. 4; H302 Eye Irrit. 2; H319 STOT RE 2; H373 (Bone, Kidney)</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Doravirine</td>
<td>1338225-97-0</td>
<td></td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.
SECTION 4: First aid measures

4.1 Description of 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.

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).

If inhaled: If inhaled, remove to fresh air. Get medical attention.

In case of skin contact: 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.

In case of eye contact: 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.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks: Causes serious eye irritation. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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 deter-
Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:
- Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.

Advice on common storage:
- Do not store with the following product types:
  - Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s):
- No data available

mine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
SECTION 8: Exposure controls/personal protection

8.1 Control parameters

### Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>OELV - 8 hrs (TWA)</td>
<td>10 mg/m³</td>
<td>IE OEL</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>

8.2 Exposure controls

**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**

- **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.

- **Hand protection**
  - Material: Chemical-resistant gloves

- **Skin and body protection**
  - Work uniform or laboratory coat.

- **Respiratory protection**
  - If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
  - Equipment should conform to I.S. EN 143

  - Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- **Physical state**: powder
- **Colour**: No data available
- **Odour**: No data available
- **Odour Threshold**: No data available
- **Melting point/freezing point**: No data available
Initial boiling point and boiling range: No data available
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
Flash point: Not applicable
Auto-ignition temperature: No data available
Decomposition temperature: No data available
pH: No data available
Viscosity: Not applicable
Viscosity, kinematic: Not applicable
Solubility(ies)
Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Vapour pressure: Not applicable
Relative density: No data available
Density: No data available
Relative vapour density: Not applicable
Particle characteristics
Particle size: No data available

9.2 Other information
Explosives: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Evaporation rate: Not applicable
Molecular weight: No data available
SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

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

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
Information on likely routes of exposure: Inhalation, Skin contact, Ingestion, Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method

Components:
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
LD50 (Dog): 30 mg/kg

Doravirine:
Acute oral toxicity:
(Rat): LD50 (Rat): > 750 mg/kg
(Rat): Method: Phototoxicity
Remarks: No evidence of phototoxicity was observed
(Rat): 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
Not classified based on available information.

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:
**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:**

**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:**

**Lamivudine:**
- Species: Rat
- Exposure time: 2 Years
- Result: negative
- Species: Mouse
- Exposure time: 2 Years
- Result: negative

**Tenofovir:**
- Species: Mouse
  Application Route: Oral
  Exposure time: 104 weeks
  Result: negative
- Species: Rat
  Application Route: Oral
Exposure time: 104 weeks
Result: negative

Doravirine:
Species: Mouse
Application Route: Oral
Exposure time: 6 Months
Result: negative
Remarks: No significant adverse effects were reported

Reproductive toxicity
Suspected of damaging the unborn child.

Components:

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: Embryo-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: Embryo-foetal development
Species: Rat
Application Route: Oral
Result: No adverse effects
Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

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

Test Type: Embryo-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 through prolonged or repeated exposure.

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:

Lamivudine:
Species: Rat  
NOAEL: 425 mg/kg  
Application Route: Oral  
Exposure time: 6 Months  
Target Organs: Blood
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version 4.12 Revision Date: 27.08.2021 SDS Number: 59641-00024 Date of last issue: 09.04.2021
Date of first issue: 16.02.2015

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.

### 11.2 Information on other hazards

#### Endocrine disrupting properties

**Product:**
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

#### 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

### SECTION 12: Ecological information

#### 12.1 Toxicity

**Components:**

**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
<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity to algae/aquatic plants</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)):</th>
<th>Toxicity to algae/aquatic plants</th>
<th>EC50 (Raphidocelis subcapitata (freshwater green alga)):</th>
<th>Toxicity to microorganisms</th>
<th>EC50:</th>
<th>Test Type:</th>
<th>Exposure time:</th>
<th>Test Type:</th>
<th>NOEC:</th>
<th>Test Type:</th>
<th>NOEC:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doravirine</td>
<td></td>
<td>&gt; 96.9 mg/l</td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 96.9 mg/l</td>
<td>NOEC (Raphidocelis subcapitata (freshwater green alga)): 18 mg/l</td>
<td></td>
<td>&gt; 1,000 mg/l</td>
<td>Respiration inhibition</td>
<td>3 h</td>
<td>Respiration inhibition</td>
<td>&gt; 1,000 mg/l</td>
<td>3 h</td>
<td></td>
</tr>
<tr>
<td>Lamivudine</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Tenofovir Disoproxil</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**Remarks:**
- No toxicity at the limit of solubility
- EC50 (Americamysis): 9.1 mg/l
- Exposure time: 96 h
### 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

- **NOEC (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
- **Test Type:** Respiration inhibition
- **Method:** OECD Test Guideline 209

- **NOEC:** $1,000$ mg/l
- **Exposure time:** 3 h
- **Test Type:** Respiration inhibition
- **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 aquatic invertebrates (Chronic toxicity)

- **NOEC:** $6.7$ mg/l
- **Exposure time:** 21 d
- **Species:** Daphnia magna (Water flea)
- **Method:** OECD Test Guideline 211
- **Remarks:** No toxicity at the limit of solubility

### 12.2 Persistence and degradability

#### Components:

**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.
12.3 Bioaccumulative potential

**Components:**

**Lamivudine:**
Partition coefficient: n-octanol/water  \( \log \text{Pow} \): -1.44

**Tenofovir:**
Partition coefficient: n-octanol/water  \( \log \text{Pow} \): 1.06  pH: 7

**Doravirine:**
Partition coefficient: n-octanol/water  \( \log \text{Pow} \): 2.08

12.4 Mobility in soil

**Components:**

**Lamivudine:**
Distribution among environmental compartments  \( \log \text{Koc} \): 2.03

**Tenofovir:**
Distribution among environmental compartments  \( \log \text{Koc} \): 3.33  Method: OECD Test Guideline 106

**Doravirine:**
Distribution among environmental compartments  \( \log \text{Koc} \): 2.86

12.5 Results of PBT and vPvB assessment

**Product:**
Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

**Product:**
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version 4.12  Revision Date: 27.08.2021  SDS Number: 59641-00024  Date of last issue: 09.04.2021

12.7 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

<table>
<thead>
<tr>
<th>Product</th>
<th>Waste treatment methods</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dispose of in accordance with local regulations.</td>
</tr>
<tr>
<td></td>
<td>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.</td>
</tr>
<tr>
<td>Contaminated packaging</td>
<td>Empty containers should be taken to an approved waste handling site for recycling or disposal.</td>
</tr>
<tr>
<td></td>
<td>If not otherwise specified: Dispose of as unused product.</td>
</tr>
</tbody>
</table>

SECTION 14: Transport information

14.1 UN number or ID number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Maritime transport in bulk according to IMO instruments
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

<table>
<thead>
<tr>
<th>Regulation/Act</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Regulation (EC) No 1005/2009 on substances that deplete the ozone layer</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Regulation (EU) 2019/1021 on persistent organic pollutants (recast)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Regulation (EC) No 649/2012 of the European Parlia-</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

19 / 21
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version 4.12
Revision Date: 27.08.2021
SDS Number: 59641-00024
Date of last issue: 09.04.2021
Date of first issue: 16.02.2015

ment and the Council concerning the export and import of
dangerous chemicals
REACH - List of substances subject to authorisation : Not applicable
(Annex XIV)
major-accident hazards involving dangerous substances.
Not applicable

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations,
where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national
regulations, where applicable.

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

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version
are highlighted in the body of this document by two vertical
lines.

Full text of H-Statements
H302 : Harmful if swallowed.
H319 : Causes serious eye irritation.
H361d : Suspected of damaging the unborn child.
H373 : May cause damage to organs through prolonged or repeated
exposure if swallowed.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Eye Irrit. : Eye irritation
Repr. : Reproductive toxicity
STOT RE : Specific target organ toxicity - repeated exposure
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure
Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland
Waterways; ADR - European Agreement concerning the International Carriage of Dangerous
Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for
the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation;
Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN -
Doravirine / Lamivudine / Tenofovir Disoproxil Bilayer Formulation

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<tr>
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</table>

Further information

Sources of key data used to compile the Safety Data Sheet:

Classification of the mixture:

<table>
<thead>
<tr>
<th></th>
<th>Classification procedure:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Irr. 2</td>
<td>H319</td>
</tr>
<tr>
<td>Repr. 2</td>
<td>H361d</td>
</tr>
<tr>
<td>STOT RE 2</td>
<td>H373</td>
</tr>
</tbody>
</table>

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.

IE / EN