SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

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

Manufacturer or supplier's details
Company: MSD
Address: 855 Leandro N. Alem St., 8 Floor
Buenos Aires, Argentina C1001AFB
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Acute toxicity (Oral): Category 5
Skin irritation: Category 3
Eye irritation: 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:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
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:**
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312 Call a POISON CENTER/ doctor if you feel unwell.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

**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.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Cellulose</td>
</tr>
<tr>
<td></td>
<td>Lamivudine</td>
</tr>
<tr>
<td></td>
<td>Tenofovir</td>
</tr>
<tr>
<td></td>
<td>Doravirine</td>
</tr>
</tbody>
</table>

**SECTION 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.
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.

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.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media

None known.

Specific hazards during fire fighting

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 fire-fighters

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment

Use personal protective equipment.
SAFETY DATA SHEET

Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.9</td>
<td>10.10.2020</td>
<td>59626-00021</td>
<td>11.05.2020</td>
<td>16.02.2015</td>
</tr>
</tbody>
</table>

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

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.

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.

SECTION 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 labeled 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.
SECTION 8. EXPOSURE CONTROLS/PERSO
Color : No data available
Odor : No data available
Odor 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
Vapor pressure : Not applicable
Relative vapor 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
Autoignition 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
SECTION 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.

SECTION 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:

Particle size: No data available
Acute oral toxicity: LD50 (Rat): > 1.500 mg/kg
LD50 (Dog): 30 mg/kg

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 sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Lamivudine:
Routes of exposure: Dermal
Species: Guinea pig
Result: Not a skin sensitizer.

Tenofovir:
Test Type: Maximization Test
Routes of exposure: 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 vitro: Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

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

Genotoxicity in vitro: 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
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:**

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

Effects on fetal development: Test Type: Fertility/early embryonic development
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 fetal development: Test Type: Embryo-fetal development
Species: Rabbit

11 / 20
Application Route: Oral
Result: Embryotoxic effects and adverse effects on the offspring were detected.

Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 45 mg/kg body weight
Symptoms: Effects on fetal 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 fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Result: No adverse effects.

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

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:**
- Routes of exposure: 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

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>90 mg/kg</td>
<td>Oral</td>
<td>12 Months</td>
<td>Blood, spleen, Liver</td>
<td>Salivation, Diarrhea, Changes in the blood count, Liver disorders, Gastrointestinal disturbance</td>
</tr>
</tbody>
</table>

**Tenofovir:**
- Species: Mouse
- NOAEL: 500 mg/kg
- Application Route: Oral
- Exposure time: 1 Months
- Target Organs: Blood
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, Diarrhea, Cough

**Tenofovir:**

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

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

Toxicity to daphnia and other aquatic invertebrates: NOEC (Daphnia magna (Water flea)): 12 mg/l
aquatic invertebrates (Chronic toxicity)

- Exposure time: 21 d
- Method: OECD Test Guideline 211

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

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC (Daphnia magna (Water flea)): 6,7 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211
  - 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
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:
Distribution among environmental compartments : log Koc: 2.03

Tenofovir:
Distribution among environmental compartments : log Koc: 3.33
Method: OECD Test Guideline 106
Doravirine:
Distribution among environmental compartments: log Koc: 2.86
Other adverse effects: No data available

SECTION 13. 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.

SECTION 14. 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 Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Argentina. Carcinogenic Substances and Agents Registry: Not applicable
Control of precursors and essential chemicals for the preparation of drugs: Not applicable

International Regulations

The ingredients of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined
SECTION 16. OTHER INFORMATION

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

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
AR OEL: Argentina. Occupational Exposure Limits
ACGIH / TWA: 8-hour, time-weighted average
AR OEL / CMP: TLV (Threshold Limit Value)

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemicals and Chemical Substances; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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...
SAFETY DATA SHEET

Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue: 11.05.2020</th>
<th>Date of first issue: 16.02.2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.9</td>
<td>10.10.2020</td>
<td>59626-00021</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

AR / Z8