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

Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version 4.10  Revision Date: 10.10.2020  SDS Number: 59645-00022  Date of last issue: 11.05.2020
Date of first issue: 16.02.2015

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
   Shotton Lane
   NE23 3JU Cramlington NU - Great Britain
   Telephone: 44 1 670 59 30 00
   Telefax: 908-735-1496
   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
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>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lamivudine</td>
<td>134678-17-4</td>
<td></td>
<td></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></td>
<td></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></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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

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 determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.
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.

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

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></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

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 NS EN 143

- Filter type: Particulates type (P)

**SECTION 9: Physical and chemical properties**

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Powder</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling</td>
<td>No data available</td>
</tr>
<tr>
<td>range</td>
<td></td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
</tbody>
</table>
Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Section 7.2 Other information

9.2 Other information

Flammability (liquids) : No data available
Molecular weight : No data available
Particle size : 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

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.
## 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 toxicological effects

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.

**Tenofovir:**
- **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
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:
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
Doravirine / Lamivudine / Tenofovir Disoproxil
Fumarate Bilayer Formulation

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: Weight of evidence does not support classification as a germ cell mutagen.
Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

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.

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

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: Embryofetal development
Specie: 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
- 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
Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

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

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

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

NOEC: > 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition

Method: OECD Test Guideline 209

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

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.
Biodegradation: 2 %
Exposure time: 28 d

12.3 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

12.4 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

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product: Dispose of in accordance with local regulations. 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.

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

14.1 UN 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 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
REACH - List of substances subject to authorisation (Annex XIV): Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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

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 - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TCSA - 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

Further information


Classification of the mixture:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification procedure:</td>
<td>Classification of the mixture:</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Calculation method</td>
<td>Eye Irrit. 2</td>
</tr>
<tr>
<td>Calculation method</td>
<td>H319</td>
</tr>
<tr>
<td>Calculation method</td>
<td>Repr. 2</td>
</tr>
<tr>
<td>Calculation method</td>
<td>H361d</td>
</tr>
<tr>
<td>Calculation method</td>
<td>STOT RE 2</td>
</tr>
<tr>
<td>Calculation method</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.