

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

Version 6.0	Revision Date: 20.11.2025	SDS Number: 58637-00030	Date of last issue: 14.04.2025 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 Bi-layer Formulation

**1.2 Relevant identified uses of the substance or mixture and uses advised against**

Use of the Sub-stance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

**1.3 Details of the supplier of the safety data sheet**

Company : MSD  
117 16th Road  
1685 Halfway house, Midrand, South Africa

Telephone : +27 11 655 3000

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.

# Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version 6.0      Revision Date: 20.11.2025      SDS Number: 58637-00030      Date of last issue: 14.04.2025  
Date of first issue: 16.02.2015

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.

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

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

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

For explanation of abbreviations see section 16.

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

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.0	20.11.2025	58637-00030	Date of first issue: 16.02.2015

---

**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.<br>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.<br>Get medical attention.  |
| In case of skin contact    | : | In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>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.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention.  |
| If swallowed               | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.   |

**4.2 Most important symptoms and effects, both acute and delayed**

- |       |   |   |
|-------|---|---|
| Risks | : | Causes serious eye irritation.<br>Suspected of damaging the unborn child.<br>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<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical |
| Unsuitable extinguishing media | : | None known.  |

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

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.0	20.11.2025	58637-00030	Date of first issue: 16.02.2015

---

**5.2 Special hazards arising from the substance or mixture**

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 (NO<sub>x</sub>)  
Halogenated compounds  
Metal oxides

**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

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

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.0	20.11.2025	58637-00030	Date of first issue: 16.02.2015

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.<br>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.<br>Do not breathe dust.<br>Do not swallow.<br>Do not get in eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>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.<br>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:<br>Strong oxidizing agents  |

**7.3 Specific end use(s)**

- |                 |   |                   |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
|-----------------|---|-------------------|

# Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version 6.0      Revision Date: 20.11.2025      SDS Number: 58637-00030      Date of last issue: 14.04.2025  
Date of first issue: 16.02.2015

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Cellulose	9004-34-6	OEL-RL	10 mg/m <sup>3</sup>	ZA OEL
Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents				
Lamivudine	134678-17-4	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal
Tenofovir	202138-50-9	TWA	150 µg/m <sup>3</sup> (OEB 2)	Internal
Doravirine	1338225-97-0	TWA	500 µg/m <sup>3</sup> (OEB2)	Internal

#### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Doravirine	Fresh water	0,04 mg/l
	Marine water	0,04 mg/l

### 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/face 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.
Filter type	:	Particulates type (P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state	:	solid
Form	:	powder

# Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version 6.0	Revision Date: 20.11.2025	SDS Number: 58637-00030	Date of last issue: 14.04.2025 Date of first issue: 16.02.2015
----------------	------------------------------	----------------------------	---

---

Colour	:	No data available
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.

## 9.2 Other information

Molecular weight	:	No data available
Particle size	:	No data available

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

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.0	20.11.2025	58637-00030	Date of first issue: 16.02.2015

---

**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 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.

Acute toxicity (other routes of administration) : LD50 (Rat): > 2.000 mg/kg  
Application Route: Intravenous



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

Version 6.0	Revision Date: 20.11.2025	SDS Number: 58637-00030	Date of last issue: 14.04.2025 Date of first issue: 16.02.2015
----------------	------------------------------	----------------------------	---

**II****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:**

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

Version 6.0	Revision Date: 20.11.2025	SDS Number: 58637-00030	Date of last issue: 14.04.2025 Date of first issue: 16.02.2015
----------------	------------------------------	----------------------------	---

||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:****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)
-----------------------	--

# Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.0	20.11.2025	58637-00030	Date of first issue: 16.02.2015

	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 / Lamivudine / Tenofovir Disoproxil  
Fumarate Bilayer Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.0	20.11.2025	58637-00030	Date of first issue: 16.02.2015

**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  Test Type: Embryo-foetal development Species: Rabbit Result: No adverse effects

# Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.0	20.11.2025	58637-00030	Date of first issue: 16.02.2015

II

**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
Symptoms	: Gastrointestinal discomfort, Breathing difficulties, Fatality
Remarks	: Significant toxicity observed in testing

Species	: Dog
---------	-------

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

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.0	20.11.2025	58637-00030	Date of first issue: 16.02.2015

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

# Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version 6.0	Revision Date: 20.11.2025	SDS Number: 58637-00030	Date of last issue: 14.04.2025 Date of first issue: 16.02.2015
----------------	------------------------------	----------------------------	---

**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
----------------------------------	---

# Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.0	20.11.2025	58637-00030	Date of first issue: 16.02.2015

		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 (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



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

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.0	20.11.2025	58637-00030	Date of first issue: 16.02.2015

	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: 0,38 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 environ-	: log Koc: 2,03
-----------------------------	-----------------

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

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.0	20.11.2025	58637-00030	Date of first issue: 16.02.2015

**Environmental compartments****Tenofovir:**

Distribution among environmental compartments : log K<sub>oc</sub>: 3,33  
Method: OECD Test Guideline 106

**Doravirine:**

Distribution among environmental compartments : log K<sub>oc</sub>: 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 Other adverse effects****Product:**

Endocrine disrupting potential : 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.

**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. Do not dispose of waste into sewer.
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**

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good
RID	: Not regulated as a dangerous good
IMDG	: Not regulated as a dangerous good
IATA	: Not regulated as a dangerous good

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

Version 6.0	Revision Date: 20.11.2025	SDS Number: 58637-00030	Date of last issue: 14.04.2025 Date of first issue: 16.02.2015
----------------	------------------------------	----------------------------	---

**14.2 UN proper shipping name**

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good
RID	: Not regulated as a dangerous good
IMDG	: Not regulated as a dangerous good
IATA	: Not regulated as a dangerous good

**14.3 Transport hazard class(es)**

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good
RID	: Not regulated as a dangerous good
IMDG	: Not regulated as a dangerous good
IATA	: Not regulated as a dangerous good

**14.4 Packing group**

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good
RID	: Not regulated as a dangerous good
IMDG	: Not regulated as a dangerous good
IATA (Cargo)	: Not regulated as a dangerous good
IATA (Passenger)	: 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.

---

**SECTION 15: Regulatory information****15.1 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
CA. DSL	: not determined
IECSC	: not determined

## Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.0	20.11.2025	58637-00030	Date of first issue: 16.02.2015

### 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  
ZA OEL : South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits  
ZA OEL / OEL-RL : Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - 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 Harmonised 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 Organisation; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; 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 - Organisation 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 Re-

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

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.0	20.11.2025	58637-00030	Date of first issue: 16.02.2015

striction 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; TECL - Thailand Existing Chemicals Inventory; 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

**Further information**

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

**Classification of the mixture:**

Eye Irrit. 2	H319
Repr. 2	H361d
STOT RE 2	H373

**Classification procedure:**

Calculation method
Calculation method
Calculation method

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

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.

ZA / EN