

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

Version 14.0	Revision Date: 2025/11/20	SDS Number: 58629-00033	Date of last issue: 2025/04/14 Date of first issue: 2015/02/16
-----------------	------------------------------	----------------------------	---

**1. PRODUCT AND COMPANY IDENTIFICATION**

Chemical product name : Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

**Supplier's company name, address and phone number**

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.  
Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

**2. HAZARDS IDENTIFICATION****GHS classification of chemical product**

Serious eye damage/eye irritation : Category 2A

Reproductive toxicity : Category 2

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Blood, Bone, Kidney)

**GHS label elements**

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 (Blood, Bone, Kidney) through prolonged or repeated exposure if swallowed.

Precautionary statements : **Prevention:**

Version	Revision Date:	SDS Number:	Date of last issue: 2025/04/14
14.0	2025/11/20	58629-00033	Date of first issue: 2015/02/16

Important symptoms and out- lines of the emergency as- sumed	: May form explosive dust-air mixture during processing, han- dling or other means.
--	--

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Cellulose	9004-34-6	>= 20 - < 30	
Lamivudine	134678-17-4	>= 10 - < 20	-
Tenofovir	202138-50-9	>= 10 - < 20	-
Doravirine	1338225-97-0	>= 1 - < 10	

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.

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

Version 14.0	Revision Date: 2025/11/20	SDS Number: 58629-00033	Date of last issue: 2025/04/14 Date of first issue: 2015/02/16
-----------------	------------------------------	----------------------------	---

- |   |   |   |
|---|---|---|
|   |   | 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.   |
| Most important symptoms and effects, both acute and delayed | : | Causes serious eye irritation.<br>Suspected of damaging the unborn child.<br>May cause damage to organs through prolonged or repeated exposure if swallowed.                |
| Protection of first-aiders                                  | : | First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8). |
| Notes to physician  | : | Treat symptomatically and supportively.   |

**5. FIREFIGHTING MEASURES**

- |   |   |   |
|---|---|---|
| Suitable extinguishing media                  | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>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.<br>Exposure to combustion products may be a hazard to health.                   |
| Hazardous combustion products                 | : | Carbon oxides<br>Nitrogen oxides (NO <sub>x</sub> )<br>Halogenated compounds<br>Metal oxides  |
| Specific extinguishing methods                | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |

**6. ACCIDENTAL RELEASE MEASURES**

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

Version 14.0	Revision Date: 2025/11/20	SDS Number: 58629-00033	Date of last issue: 2025/04/14 Date of first issue: 2015/02/16
-----------------	------------------------------	----------------------------	---

- |   |  |
|---|--|
| Personal precautions, protective equipment and emergency procedures | : Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).   |
| Environmental precautions   | : Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained.  |
| Methods and materials for containment and cleaning up               | : Sweep up or vacuum up spillage and collect in suitable container for disposal.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).<br>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.<br>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.<br>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

**7. HANDLING AND STORAGE****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. |
| Avoidance of contact    | : Oxidizing agents   |
| Hygiene measures        | : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  |

# Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version 14.0      Revision Date: 2025/11/20      SDS Number: 58629-00033      Date of last issue: 2025/04/14  
Date of first issue: 2015/02/16

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.

## Storage

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

Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

Packaging material : Unsuitable material: None known.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Concentration standard / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
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

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

### Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection : Chemical-resistant gloves

Material

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

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

Version 14.0	Revision Date: 2025/11/20	SDS Number: 58629-00033	Date of last issue: 2025/04/14 Date of first issue: 2015/02/16
-----------------	------------------------------	----------------------------	---

potential for direct contact to the face with dusts, mists, or aerosols.  
Skin and body protection : Work uniform or laboratory coat.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

Physical state	: powder
Colour	: No data available
Odour	: No data available
Odour Threshold	: No data available
Melting point/freezing point	: No data available
Boiling point, initial boiling point and boiling range	: No data available
Flammability (solid, gas)	: May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	: No data available
Lower explosion limit and upper explosion limit / flammability limit	
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Flash point	: Not applicable
Decomposition temperature	: No data available
pH	: No data available
Evaporation rate	: Not applicable
Auto-ignition temperature	: No data available
Viscosity	
Viscosity, kinematic	: Not applicable
Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: Not applicable
Vapour pressure	: Not applicable
Density and / or relative density	

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

Version	Revision Date:	SDS Number:	Date of last issue: 2025/04/14
14.0	2025/11/20	58629-00033	Date of first issue: 2015/02/16

Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics	:	
Particle size	:	No data available

**10. STABILITY AND REACTIVITY**

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

**11. TOXICOLOGICAL INFORMATION**

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

**Acute toxicity**

Not classified based on available information.

**Product:**

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 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

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

Version 14.0	Revision Date: 2025/11/20	SDS Number: 58629-00033	Date of last issue: 2025/04/14 Date of first issue: 2015/02/16
-----------------	------------------------------	----------------------------	---

Exposure time: 4 h  
Test atmosphere: dust/mist

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

**Lamivudine:**

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

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

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

**Tenofovir:**

Acute oral toxicity : LD50 (Rat): > 1,500 mg/kg

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



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

Version	Revision Date:	SDS Number:	Date of last issue: 2025/04/14
14.0	2025/11/20	58629-00033	Date of first issue: 2015/02/16

---

**Serious eye damage/eye irritation**

Causes serious eye irritation.

**Components:****Lamivudine:**

Species	: Rabbit
Result	: No eye irritation

**Tenofovir:**

Species	: Rabbit
Result	: Severe irritation

**Doravirine:**

Remarks	: No data available
---------	---------------------

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****Lamivudine:**

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

**Tenofovir:**

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

**Doravirine:**

Remarks	: No data available
---------	---------------------

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Cellulose:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: In vitro mammalian cell gene mutation test

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

Version 14.0	Revision Date: 2025/11/20	SDS Number: 58629-00033	Date of last issue: 2025/04/14 Date of first issue: 2015/02/16
-----------------	------------------------------	----------------------------	---

Genotoxicity in vivo	Result: negative
	: 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
	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

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

Version	Revision Date:	SDS Number:	Date of last issue: 2025/04/14
14.0	2025/11/20	58629-00033	Date of first issue: 2015/02/16

---

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
----------------------	---

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

Version 14.0	Revision Date: 2025/11/20	SDS Number: 58629-00033	Date of last issue: 2025/04/14 Date of first issue: 2015/02/16
-----------------	------------------------------	----------------------------	---

	Species: Rat Application Route: Ingestion Result: negative
Effects on foetal 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 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:**

Effects on fertility	: Test Type: Fertility
----------------------	------------------------

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

Version	Revision Date:	SDS Number:	Date of last issue: 2025/04/14
14.0	2025/11/20	58629-00033	Date of first issue: 2015/02/16

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

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

May cause damage to organs (Blood, Bone, Kidney) through prolonged or repeated exposure if swallowed.

**Components:****Lamivudine:**

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

**Tenofovir:**

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

**Repeated dose toxicity****Components:****Cellulose:**

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

**Lamivudine:**

Species	: Rat
NOAEL	: 425 mg/kg
Application Route	: Oral
Exposure time	: 6 Months

# Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2025/04/14
14.0	2025/11/20	58629-00033	Date of first issue: 2015/02/16

---

Target Organs	: Blood
Symptoms	: Gastrointestinal discomfort, Breathing difficulties, Fatality
Remarks	: Significant toxicity observed in testing

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

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

## Tenofovir:

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

Species	: Dog
NOAEL	: 3 mg/kg
LOAEL	: $\geq 10$ 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

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

Version	Revision Date:	SDS Number:	Date of last issue: 2025/04/14
14.0	2025/11/20	58629-00033	Date of first issue: 2015/02/16

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

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Lamivudine:**

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

**Tenofovir:**

Ingestion	: Symptoms: Nausea, Diarrhoea, Vomiting, flatulence, Headache, Rash
-----------	---

**Doravirine:**

Ingestion	: Symptoms: confusion, Headache, Dizziness, Nausea, Rash, abnormal dreams, flushing, Neurological disorders, mental depression
-----------	--

**12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Cellulose:**

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

**Lamivudine:**

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

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

Toxicity to algae/aquatic plants	: EC50 ( <i>Pseudokirchneriella subcapitata</i> (green algae)): > 96.9 mg/l
----------------------------------	---

# Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version 14.0      Revision Date: 2025/11/20      SDS Number: 58629-00033      Date of last issue: 2025/04/14  
Date of first issue: 2015/02/16

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 (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 12 mg/l  
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 (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



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

Version 14.0	Revision Date: 2025/11/20	SDS Number: 58629-00033	Date of last issue: 2025/04/14 Date of first issue: 2015/02/16
-----------------	------------------------------	----------------------------	---

	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)): 0.38 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
------------------	--

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

Version 14.0	Revision Date: 2025/11/20	SDS Number: 58629-00033	Date of last issue: 2025/04/14 Date of first issue: 2015/02/16
-----------------	------------------------------	----------------------------	---

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

**Hazardous to the ozone layer**

Not applicable

**Other adverse effects**

No data available

**13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues	: Dispose of in accordance with local regulations. 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.

**14. TRANSPORT INFORMATION****International Regulations**

UNRTDG

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

Version	Revision Date:	SDS Number:	Date of last issue: 2025/04/14
14.0	2025/11/20	58629-00033	Date of first issue: 2015/02/16

---

Not regulated as a dangerous good

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Environmentally hazardous	:	no

**IATA-DGR**

Not regulated as a dangerous good

UN/ID No.	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Packing instruction (cargo aircraft)	:	Not applicable
Packing instruction (passenger aircraft)	:	Not applicable

**IMDG-Code**

Not regulated as a dangerous good

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
EmS Code	:	Not applicable
Marine pollutant	:	Not applicable

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**National Regulations**

Refer to section 15 for specific national regulation.

**Special precautions for user**

Not applicable

---

**15. REGULATORY INFORMATION****Related Regulations****Fire Service Law**

Not applicable to dangerous materials / designated flammables.

**Chemical Substance Control Law**

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

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

Version	Revision Date:	SDS Number:	Date of last issue: 2025/04/14
14.0	2025/11/20	58629-00033	Date of first issue: 2015/02/16

---

**Industrial Safety and Health Law****Harmful Substances Prohibited from Manufacture**

Not applicable

**Harmful Substances Required Permission for Manufacture**

Not applicable

**Substances Prevented From Impairment of Health**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**

Not applicable

**Substances Subject to be Notified Names**

Not applicable

**Substances Subject to be Indicated Names**

Not applicable

**Skin and Eye Damage Substances (ISHL MO Art. 594-2)**

Not applicable

**Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)**

Not applicable

**Ordinance on Prevention of Hazards Due to Specified Chemical Substances**

Not applicable

**Ordinance on Prevention of Lead Poisoning**

Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

**Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

**Poisonous and Deleterious Substances Control Law**

Not applicable

**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

Not applicable

**High Pressure Gas Safety Act**

Not applicable

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

Version	Revision Date:	SDS Number:	Date of last issue: 2025/04/14
14.0	2025/11/20	58629-00033	Date of first issue: 2015/02/16

---

**Explosive Control Law**

Not applicable

**Vessel Safety Law**

Not regulated as a dangerous good

**Aviation Law**

Not regulated as a dangerous good

**Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

**Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

**Waste Disposal and Public Cleansing Law**

Industrial waste

**The components of this product are reported in the following inventories:**

AICS : not determined

CA. DSL : not determined

IECSC : not determined

---

**16. OTHER INFORMATION****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/>

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

Date format : yyyy/mm/dd

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

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

AIIC - 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

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

Version	Revision Date:	SDS Number:	Date of last issue: 2025/04/14
14.0	2025/11/20	58629-00033	Date of first issue: 2015/02/16

---

x% growth rate response; ERG - Emergency Response Guide; 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; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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 Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; 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 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.

JP / EN