

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06/16/2025 |
| 6.1 | 11/20/2025 | 58619-00030 | Date of first issue: 02/16/2015 |

SECTION 1. IDENTIFICATION

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

Other means of identification : No data available

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc

Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

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:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves, protective clothing, eye protection

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Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

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Date of first issue: 02/16/2015

and face protection.

Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P308 + P313 IF exposed or concerned: Get medical attention.

P337 + P313 If eye irritation persists: Get medical attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | Common Name/Synonym | CAS-No. | Concentration (% w/w) |
|---------------|--|--------------|-----------------------|
| Cellulose | No data available | 9004-34-6 | $\geq 10 - < 30$ * |
| Lamivudine | No data available | 134678-17-4 | $\geq 10 - < 30$ * |
| Tenofovir | No data available | 202138-50-9 | $\geq 10 - < 30$ * |
| Doravirine | 3-Chloro-5-((1-((4-methyl-5-oxo-4,5-dihydro-1H-1,2,4-triazol-3-yl)methyl)-2-oxo-4-(trifluoromethyl)-1,2-dihydropyridin-3-yl)oxy)benz | 1338225-97-0 | $\geq 5 - < 10$ * |

* Actual concentration or concentration range is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.

SAFETY DATA SHEET

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| | | | |
|----------------|------------------------------|----------------------------|---|
| Version 6.1 | Revision Date: 11/20/2025 | SDS Number: 58619-00030 | Date of last issue: 06/16/2025 Date of first issue: 02/16/2015 |
|----------------|------------------------------|----------------------------|---|

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| In case of skin contact | : Get medical attention. In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. |
| In case of eye contact | : Thoroughly clean shoes before reuse. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention. |
| If swallowed | : If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. |
| Most important symptoms and effects, both acute and delayed | : Causes serious eye irritation. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure if swallowed. |
| Protection of first-aiders | : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8). |
| Notes to physician | : Treat symptomatically and supportively. |

SECTION 5. FIRE-FIGHTING MEASURES

| | |
|--|---|
| Suitable extinguishing media | : Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical |
| Unsuitable extinguishing media | : None known. |
| Specific hazards during fire fighting | : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : Carbon oxides Nitrogen oxides (NO _x) Halogenated compounds Metal oxides |
| Specific extinguishing methods | : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area. |
| Special protective equipment for fire-fighters | : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. |

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06/16/2025 |
| 6.1 | 11/20/2025 | 58619-00030 | Date of first issue: 02/16/2015 |

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- 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.
- Methods and materials for containment and 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.

SECTION 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.
Store locked up.
Store in accordance with the particular national regulations.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version 6.1 Revision Date: 11/20/2025 SDS Number: 58619-00030 Date of last issue: 06/16/2025
Date of first issue: 02/16/2015

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|------------|--------------|----------------------------------|--|-----------|
| Cellulose | 9004-34-6 | TWA | 10 mg/m ³ | CA AB OEL |
| | | TWA (Total dust) | 10 mg/m ³ | CA BC OEL |
| | | TWA (respirable dust fraction) | 3 mg/m ³ | CA BC OEL |
| | | TWAEV (total dust) | 10 mg/m ³ | CA QC OEL |
| | | TWA | 10 mg/m ³ | ACGIH |
| Lamivudine | 134678-17-4 | TWA | 100 µg/m ³ (OEB 2) | Internal |
| Tenofovir | 202138-50-9 | TWA | 150 µg/m ³ (OEB 2) | Internal |
| Doravirine | 1338225-97-0 | TWA | 500 µg/m ³ (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

Material : Chemical-resistant gloves

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.

Skin and body protection : Work uniform or laboratory coat.

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.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

| | | | |
|----------------|------------------------------|----------------------------|---|
| Version 6.1 | Revision Date: 11/20/2025 | SDS Number: 58619-00030 | Date of last issue: 06/16/2025 Date of first issue: 02/16/2015 |
|----------------|------------------------------|----------------------------|---|

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|--|---|
| Appearance | : powder |
| Color | : No data available |
| Odor | : No data available |
| Odor Threshold | : No data available |
| pH | : No data available |
| Melting point/freezing point | : No data available |
| Initial boiling point and boiling range | : No data available |
| Flash point | : Not applicable |
| Evaporation rate | : Not applicable |
| Flammability (solid, gas) | : May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids) | : No data available |
| Upper explosion limit / Upper flammability limit | : No data available |
| Lower explosion limit / Lower flammability limit | : No data available |
| Vapor pressure | : Not applicable |
| Relative vapor density | : Not applicable |
| Relative density | : No data available |
| Density | : No data available |
| Solubility(ies) Water solubility | : No data available |
| Partition coefficient: n-octanol/water | : Not applicable |
| Autoignition temperature | : No data available |

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06/16/2025 |
| 6.1 | 11/20/2025 | 58619-00030 | Date of first issue: 02/16/2015 |

| | | |
|---------------------------|---|--|
| Decomposition temperature | : | No data available |
| Viscosity | : | |
| Viscosity, kinematic | : | Not applicable |
| Explosive properties | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight | : | No data available |
| Particle characteristics | : | |
| Particle size | : | No data available |

SECTION 10. STABILITY AND REACTIVITY

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

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

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 |
|---------------------|---|---------------------------|

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| | | | |
|----------------|------------------------------|----------------------------|---|
| Version 6.1 | Revision Date: 11/20/2025 | SDS Number: 58619-00030 | Date of last issue: 06/16/2025 Date of first issue: 02/16/2015 |
|----------------|------------------------------|----------------------------|---|

Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

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

Lamivudine:

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

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

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

Tenofovir:

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

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Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06/16/2025 |
| 6.1 | 11/20/2025 | 58619-00030 | Date of first issue: 02/16/2015 |

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Lamivudine:

| | | |
|---------|---|-------------------|
| Species | : | Rabbit |
| Result | : | No eye irritation |

Tenofovir:

| | | |
|---------|---|-------------------|
| Species | : | Rabbit |
| Result | : | Severe irritation |

Doravirine:

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

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Lamivudine:

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

Tenofovir:

| | | |
|--------------------|---|------------------------|
| Test Type | : | Maximization Test |
| Routes of exposure | : | Skin contact |
| Species | : | Guinea pig |
| Result | : | Not a skin sensitizer. |

Doravirine:

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

Germ cell mutagenicity

Not classified based on available information.

Components:

Cellulose:

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

SAFETY DATA SHEET

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Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

| | | | |
|----------------|------------------------------|----------------------------|---|
| Version 6.1 | Revision Date: 11/20/2025 | SDS Number: 58619-00030 | Date of last issue: 06/16/2025 Date of first issue: 02/16/2015 |
|----------------|------------------------------|----------------------------|---|

| | | |
|-------------------------------------|---|--|
| | | Test Type: In vitro mammalian cell gene mutation test Result: negative |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative |
| Lamivudine: | | |
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES) Result: negative |
| | | 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 |

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06/16/2025 |
| 6.1 | 11/20/2025 | 58619-00030 | Date of first issue: 02/16/2015 |

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Rat
Cell type: Bone marrow
Application Route: Oral
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Cellulose:

Species : Rat
Application Route : Ingestion
Exposure time : 72 weeks
Result : negative

Lamivudine:

Species : Rat
Exposure time : 2 Years
Result : negative

Species : Mouse
Exposure time : 2 Years
Result : negative

Tenofovir:

Species : Mouse
Application Route : Oral
Exposure time : 104 weeks
Result : negative

Species : Rat
Application Route : Oral
Exposure time : 104 weeks
Result : negative

Doravirine:

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

Reproductive toxicity

Suspected of damaging the unborn child.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06/16/2025 |
| 6.1 | 11/20/2025 | 58619-00030 | Date of first issue: 02/16/2015 |

Components:

Cellulose:

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

Effects on fetal development : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative

Lamivudine:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Oral
Fertility: NOAEL: 900 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
Symptoms: Preimplantation loss., Skeletal malformations.
Result: Embryotoxic effects and adverse effects on the offspring were detected.

Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 45 mg/kg body weight
Symptoms: Effects on fetal development.
Result: positive

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

Tenofovir:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Oral
Result: No effects on fertility.

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Result: No adverse effects.

Test Type: Embryo-fetal development
Species: Rabbit

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06/16/2025 |
| 6.1 | 11/20/2025 | 58619-00030 | Date of first issue: 02/16/2015 |

Result: No adverse effects.

Doravirine:

Effects on fertility : Test Type: Fertility
Species: Rat, male and female
Fertility: NOAEL: 450 mg/kg body weight
Result: No effects on fertility.

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

Test Type: Embryo-fetal 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 (Blood, Bone, Kidney) through prolonged or repeated exposure if swallowed.

Components:

Lamivudine:

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

Tenofovir:

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

Repeated dose toxicity

Components:

Cellulose:

Species : Rat
NOAEL : $\geq 9,000$ mg/kg
Application Route : Ingestion
Exposure time : 90 Days

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06/16/2025 |
| 6.1 | 11/20/2025 | 58619-00030 | Date of first issue: 02/16/2015 |

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, Diarrhea, 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 |

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06/16/2025 |
| 6.1 | 11/20/2025 | 58619-00030 | Date of first issue: 02/16/2015 |

| | |
|-------------------|--|
| Species | : Mouse |
| NOAEL | : > 450 mg/kg |
| Application Route | : Oral |
| Exposure time | : 3 Months |
| Remarks | : No significant adverse effects were reported |

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

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Lamivudine:

| | |
|-----------|---|
| Ingestion | : Symptoms: Headache, Fatigue, Respiratory disorders, Diarrhea, Cough |
|-----------|---|

Tenofovir:

| | |
|-----------|--|
| Ingestion | : Symptoms: Nausea, Diarrhea, Vomiting, flatulence, Headache, Rash |
|-----------|--|

Doravirine:

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cellulose:

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

Lamivudine:

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

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

according to the Hazardous Products Regulations



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06/16/2025 |
| 6.1 | 11/20/2025 | 58619-00030 | Date of first issue: 02/16/2015 |

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 96.9 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 96.9 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Tenofovir:

Toxicity to algae/aquatic plants : EC50 (Raphidocelis subcapitata (freshwater green alga)): 69 mg/l
End point: Growth
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Raphidocelis subcapitata (freshwater green alga)): 18 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

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

Toxicity to daphnia and other aquatic invertebrates (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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06/16/2025 |
| 6.1 | 11/20/2025 | 58619-00030 | Date of first issue: 02/16/2015 |

| | |
|--|--|
| | mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility. |
| Toxicity to fish (Chronic toxicity) | : NOEC (Pimephales promelas (fathead minnow)): 1 mg/l Exposure time: 32 d Method: OECD Test Guideline 210 Remarks: No toxicity at the limit of solubility. |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC (Daphnia magna (Water flea)): 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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

| | | | |
|----------------|------------------------------|----------------------------|---|
| Version 6.1 | Revision Date: 11/20/2025 | SDS Number: 58619-00030 | Date of last issue: 06/16/2025 Date of first issue: 02/16/2015 |
|----------------|------------------------------|----------------------------|---|

Bioaccumulative potential

Components:

Lamivudine:

Partition coefficient: n-octanol/water : log Pow: -1.44

Tenofovir:

Partition coefficient: n-octanol/water : log Pow: 1.06
pH: 7

Doravirine:

Partition coefficient: n-octanol/water : log Pow: 2.08

Mobility in soil

Components:

Lamivudine:

Distribution among environmental compartments : log Koc: 2.03

Tenofovir:

Distribution among environmental compartments : log Koc: 3.33
Method: OECD Test Guideline 106

Doravirine:

Distribution among environmental compartments : log Koc: 2.86

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

| | |
|------------------------|---|
| Waste from residues | : Do not dispose of waste into sewer. Dispose of in accordance with local regulations. |
| Contaminated packaging | : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product. |

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

| | | | |
|----------------|------------------------------|----------------------------|---|
| Version 6.1 | Revision Date: 11/20/2025 | SDS Number: 58619-00030 | Date of last issue: 06/16/2025 Date of first issue: 02/16/2015 |
|----------------|------------------------------|----------------------------|---|

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

Domestic regulation

TDG

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:

AICS : not determined

CA. DSL : not determined

IECSC : not determined

Canadian lists

No substances are subject to CEPA Section 84 Ministerial Conditions.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

| | |
|-----------------|---|
| ACGIH | : USA. ACGIH Threshold Limit Values (TLV) |
| CA AB OEL | : Canada. Alberta, Occupational Health and Safety Code (table 2: OEL) |
| CA BC OEL | : Canada. British Columbia OEL |
| CA QC OEL | : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants |
| ACGIH / TWA | : 8-hour, time-weighted average |
| CA AB OEL / TWA | : 8-hour Occupational exposure limit |
| CA BC OEL / TWA | : 8-hour time weighted average |
| CA QC OEL / TWA | : Time-weighted average exposure value |

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 Standardization; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized Sys-

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06/16/2025 |
| 6.1 | 11/20/2025 | 58619-00030 | Date of first issue: 02/16/2015 |

tem; 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 Organization 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; 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 - 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, Authorization 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

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

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Date format : mm/dd/yyyy

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