# SAFETY DATA SHEET

## Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024 |
|---|---|---|---|
| 11.0 | 20.11.2025 | 58618-00029 | Date of first issue: 16.02.2015 |

### SECTION 1. IDENTIFICATION

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

**Manufacturer or supplier's details**

Company : MSD

Address : Avenida Tanner de Melo, Quadra 10 Lote 4A, Galpão A Parque Industrial Vice Presidente José Alencar Aparecida de Goias – GO, Brazil

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

**GHS Classification of the substance or mixture in accordance with ABNT NBR 14725 Standard**

Acute toxicity (Oral) : Category 5

Skin irritation : Category 3

Eye irritation : Category 2A

Reproductive toxicity : Category 2

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

**GHS label elements in accordance with ABNT NBR 14725 Standard**

Hazard pictograms :

Signal Word : Warning

Hazard Statements : H303 May be harmful if swallowed.
H316 Causes mild skin irritation.

H319 Causes serious eye irritation.
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs (Blood, Bone, Kidney) through prolonged or repeated exposure if swallowed.

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:**

P301 + P312 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell.
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 advice/ attention.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

**Storage:**

P405 Store locked up.

**Other hazards which do not result in classification**

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

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name | CAS-No. | Classification | Concentration (% w/w) |
|---|---|---|---|
| Cellulose | 9004-34-6 | | >= 20 -< 30 |
| Lamivudine | 134678-17-4 | Repr., 2<br>STOT RE, (Oral)(Blood) , 2 | >= 10 -< 20 |
| Tenofovir | 202138-50-9 | Acute Tox. (Oral), 4<br>Skin Irrit., 3<br>Eye Irrit., 2A<br>STOT RE, (Oral)(Bone, Kidney) , 2<br>Aquatic Acute, 3 | >= 10 -< 20 |
| Doravirine | 1338225-97-0 | | >= 5 -< 10 |

## SECTION 4. FIRST AID MEASURES

**Description of necessary 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. |
| 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.<br>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 | : | May be harmful if swallowed.<br>Causes mild skin irritation.<br>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). |

**Indication of any immediate medical attention and special treatment needed**

| | | |
|---|---|---|
| Notes to physician | : | Treat symptomatically and supportively. |

## SECTION 5. FIRE-FIGHTING MEASURES

| | | |
|---|---|---|
| Suitable extinguishing media | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<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 (NOx)<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 fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |

## SECTION 6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|---|
| 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. |

## SECTION 7. HANDLING AND STORAGE

| | | |
|---|---|---|
| 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
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.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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

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

## SECTION 8. EXPOSURE CONTROLS/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/m³ | ACGIH |
| Lamivudine | 134678-17-4 | TWA | 100 µg/m3 (OEB 2) | Internal |
| Tenofovir | 202138-50-9 | TWA | 150 ug/m3 (OEB 2) | Internal |
| Doravirine | 1338225-97-0 | TWA | 500 ug/m3 (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.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>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. |

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|---|---|---|
| Physical state | : | 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 |

| | | |
|---|---|---|
| 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.<br>Can react with strong oxidizing agents. |
| Conditions to avoid | : | Heat, flames and sparks.<br>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<br>Skin contact<br>Ingestion<br>Eye contact |

**Acute toxicity**

May be harmful if swallowed.

**Product:**

| | | |
|---|---|---|
| Acute oral toxicity | : | Acute toxicity estimate: 2.605 mg/kg<br>Method: Calculation method |

**Components:**

**Cellulose:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 5.000 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): > 5,8 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist |

| | | |
|---|---|---|
| Acute dermal toxicity | : | LD50 (Rabbit): > 2.000 mg/kg |

**Lamivudine:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 2.000 mg/kg<br><br>LD50 (Mouse): 4.000 mg/kg<br>Remarks: No mortality observed at this dose. |
| Acute toxicity (other routes of administration) | : | LD50 (Rat): > 2.000 mg/kg<br>Application Route: Intravenous |

**Tenofovir:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 1.500 mg/kg<br><br>LD50 (Dog): 30 mg/kg |

**Doravirine:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 750 mg/kg<br>Remarks: No mortality observed at this dose.<br><br>(Rat): Method: Phototoxicity<br>Remarks: No evidence of phototoxicity was observed<br><br>LD50 (Dog): > 1.000 mg/kg<br>Remarks: No mortality observed at this dose.<br><br>LD50 (Mouse): > 450 mg/kg<br>Remarks: No mortality observed at this dose. |

**Skin corrosion/irritation**

Causes mild skin irritation.

**Components:**

**Lamivudine:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | Mild skin irritation |

**Tenofovir:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | Mild skin irritation |

**Doravirine:**

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

**Serious eye damage/eye irritation**

Causes serious eye irritation.

**Components:**

**Lamivudine:**

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

**Tenofovir:**

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

**Doravirine:**

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

**Respiratory or skin sensitization**

**Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:**

**Lamivudine:**

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

**Tenofovir:**

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

**Doravirine:**

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

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**Cellulose:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo |

| | | |
|---|---|---|
| | | cytogenetic assay)<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |

**Lamivudine:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: Mouse Lymphoma<br>Result: equivocal |
| Genotoxicity in vivo | : | Test Type: Micronucleus test<br>Species: Rat<br>Application Route: Oral<br>Result: negative<br><br>Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo<br>Species: Rat<br>Result: negative |

**Tenofovir:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: equivocal<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Result: positive |
| Genotoxicity in vivo | : | Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)<br>Species: Mouse<br>Application Route: Intraperitoneal injection<br>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)<br>Result: negative<br><br>Test Type: Chromosomal aberration<br>Test system: Chinese hamster ovary cells<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Micronucleus test<br>Species: Rat<br>Cell type: Bone marrow<br>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<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |

| | | |
|---|---|---|
| Effects on fetal development | : | Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |

**Lamivudine:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Two-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Oral<br>Fertility: NOAEL: 900 mg/kg body weight<br>Result: No effects on fertility and early embryonic development were detected. |
| Effects on fetal development | : | Test Type: Embryo-fetal development<br>Species: Rabbit<br>Application Route: Oral<br>Symptoms: Preimplantation loss., Skeletal malformations.<br>Result: Embryotoxic effects and adverse effects on the offspring were detected.<br><br>Test Type: Embryo-fetal development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 45 mg/kg body weight<br>Symptoms: Effects on fetal development.<br>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<br>Species: Rat<br>Application Route: Oral<br>Result: No effects on fertility. |
| Effects on fetal development | : | Test Type: Embryo-fetal development<br>Species: Rat<br>Application Route: Oral<br>Result: No adverse effects.<br><br>Test Type: Embryo-fetal development<br>Species: Rabbit<br>Result: No adverse effects. |

**Doravirine:**

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

| | | |
|---|---|---|
| Effects on fetal development | : | Test Type: Embryo-fetal development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 450 mg/kg body weight<br>Result: No adverse effects.<br><br>Test Type: Embryo-fetal development<br>Species: Rabbit<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 300 mg/kg body weight<br>Result: No adverse effects. |

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

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

**Components:**

**Lamivudine:**

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

**Tenofovir:**

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

**Repeated dose toxicity**

**Components:**

**Cellulose:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | >= 9.000 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 90 Days |

**Lamivudine:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 425 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 6 Months |
| Target Organs | : | Blood |
| Symptoms | : | Gastrointestinal discomfort, Breathing difficulties, Fatality |
| Remarks | : | Significant toxicity observed in testing |

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

| | | |
|---|---|---|
| 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<br>Exposure time: 48 h<br>Remarks: Based on data from similar materials |

**Lamivudine:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): > 97,7 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203 |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 100 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 96,9 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 96,9 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |

**Tenofovir:**

| | | |
|---|---|---|
| Toxicity to algae/aquatic plants | : | EC50 (Raphidocelis subcapitata (freshwater green alga)): 69 mg/l<br>End point: Growth<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Raphidocelis subcapitata (freshwater green alga)): 18 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Pimephales promelas (fathead minnow)): 9 mg/l<br>Exposure time: 32 d<br>Method: OECD Test Guideline 210 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 12 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211 |
| Toxicity to microorganisms | : | EC50: > 1.000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209<br><br>NOEC: > 1.000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209 |

**Doravirine:**

| | | |
|---|---|---|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Americamysis): 9,1 mg/l<br>Exposure time: 96 h |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 5,8 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: No toxicity at the limit of solubility.<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 5,8 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: No toxicity at the limit of solubility. |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Pimephales promelas (fathead minnow)): 1 mg/l<br>Exposure time: 32 d<br>Method: OECD Test Guideline 210<br>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<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211 |

Remarks: No toxicity at the limit of solubility.

Toxicity to microorganisms : EC50: > 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

**Persistence and degradability**

**Components:**

**Cellulose:**

Biodegradability : Result: Readily biodegradable.

**Lamivudine:**

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 4 %
Exposure time: 28 d

**Tenofovir:**

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 3,66 %
Exposure time: 28 d
Method: OECD Test Guideline 314

**Doravirine:**

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 2 %
Exposure time: 28 d

**Bioaccumulative potential**

**Components:**

**Lamivudine:**

Partition coefficient: n-octanol/water : log Pow: -1,44

**Tenofovir:**

Partition coefficient: n-octanol/water : log Pow: 1,06
pH: 7

**Doravirine:**

Partition coefficient: n-octanol/water : log Pow: 2,08

**Mobility in soil**

**Components:**

**Lamivudine:**

| | | |
|---|---|---|
| Distribution among environmental compartments | : | log Koc: 2,03 |

**Tenofovir:**

| | | |
|---|---|---|
| Distribution among environmental compartments | : | log Koc: 3,33<br>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.<br>Dispose of in accordance with local regulations. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product. |

## SECTION 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**
Not regulated as a dangerous good

**IATA-DGR**
Not regulated as a dangerous good

**IMDG-Code**
Not regulated as a dangerous good

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
Not applicable for product as supplied.

**Domestic regulation**

**ANTT**
Not regulated as a dangerous good

**Special precautions for user**
Not applicable

## SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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

AICS : not determined

CA. DSL : not determined

IECSC : not determined

## SECTION 16. OTHER INFORMATION

Revision Date : 20.11.2025
Date format : dd.mm.yyyy

**Further information**

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/

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 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 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 System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Or-

ganization 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; TECI - 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.

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