

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04/04/2023  |
| 12.1    | 09/30/2023     | 58636-00029 | Date of first issue: 02/16/2015 |

### SECTION 1. IDENTIFICATION

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

#### 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 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

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

#### GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.  
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

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and understood.  
P260 Do not breathe dust.  
P264 Wash skin thoroughly after handling.  
P280 Wear protective gloves, protective clothing, eye protection 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

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

| Chemical name | CAS-No.      | Concentration (% w/w) |
|---------------|--------------|-----------------------|
| Cellulose     | 9004-34-6    | 21                    |
| Lamivudine    | 134678-17-4  | 19.2                  |
| Tenofovir     | 202138-50-9  | 19.2                  |
| Doravirine    | 1338225-97-0 | 6.4                   |

## 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.  
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.  
If easy to do, remove contact lens, if worn.  
Get medical attention.

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

### SECTION 5. FIRE-FIGHTING 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 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.                                                                                                                                                    |

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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.<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. |
| Conditions for safe storage | : | Keep in properly labeled containers.<br>Store locked up.<br>Store in accordance with the particular national regulations.                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Materials to avoid          | : | Do not store with the following product types:<br>Strong oxidizing agents                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

|                        |                                                                                                           |
|------------------------|-----------------------------------------------------------------------------------------------------------|
| inert or nuisance dust | 50 Million particles per cubic foot<br>Value type (Form of exposure): TWA (total dust)<br>Basis: OSHA Z-3 |
|                        | 15 mg/m <sup>3</sup><br>Value type (Form of exposure): TWA (total dust)<br>Basis: OSHA Z-3                |

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5 mg/m<sup>3</sup>

Value type (Form of exposure): TWA (respirable fraction)

Basis: OSHA Z-3

15 Million particles per cubic foot

Value type (Form of exposure): TWA (respirable fraction)

Basis: OSHA Z-3

Dust, nuisance dust and particulates

10 mg/m<sup>3</sup>

Value type (Form of exposure): PEL (Total dust)

Basis: CAL PEL

5 mg/m<sup>3</sup>

Value type (Form of exposure): PEL (respirable dust fraction)

Basis: CAL PEL

| Components | CAS-No.      | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis     |
|------------|--------------|-------------------------------|------------------------------------------------|-----------|
| Cellulose  | 9004-34-6    | TWA                           | 10 mg/m <sup>3</sup>                           | ACGIH     |
|            |              | TWA (Respirable)              | 5 mg/m <sup>3</sup>                            | NIOSH REL |
|            |              | TWA (total)                   | 10 mg/m <sup>3</sup>                           | NIOSH REL |
|            |              | TWA (total dust)              | 15 mg/m <sup>3</sup>                           | OSHA Z-1  |
|            |              | TWA (respirable fraction)     | 5 mg/m <sup>3</sup>                            | OSHA Z-1  |
| 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 : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide

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

### 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                                                               |

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|                                        |                                                            |
|----------------------------------------|------------------------------------------------------------|
| Vapor pressure                         | : Not applicable                                           |
| Relative vapor density                 | : Not applicable                                           |
| Relative density                       | : No data available                                        |
| Density                                | : No data available                                        |
| Solubility(ies)<br>Water solubility    | : No data available                                        |
| Partition coefficient: n-octanol/water | : Not applicable                                           |
| Autoignition temperature               | : No data available                                        |
| Decomposition temperature              | : No data available                                        |
| Viscosity<br>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 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  
Skin contact

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Ingestion  
Eye contact

### Acute toxicity

Not classified based on available information.

### Product:

Acute oral toxicity : Acute toxicity estimate: 2,604 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  
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.

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### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### Lamivudine:

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

##### Tenofovir:

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

##### Doravirine:

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

### Serious eye damage/eye irritation

Causes serious eye irritation.

#### Components:

##### Lamivudine:

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

##### Tenofovir:

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

##### Doravirine:

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

### Respiratory or skin 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 |
|-----------|---|-------------------|

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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  
  
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

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Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

### Doravirine:

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

Test Type: Chromosomal aberration  
Test system: Chinese hamster ovary cells  
Result: negative

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

### Carcinogenicity

Not classified based on available information.

### Components:

#### 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

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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

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### Reproductive toxicity

Suspected of damaging the unborn child.

### 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.

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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  
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.

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### 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            |

#### **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 |

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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

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:

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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

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

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

##### **Tenofovir:**

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

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

Toxicity to 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 : NOEC (Daphnia magna (Water flea)): 12 mg/l

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aquatic invertebrates (Chronic toxicity) : 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 (Daphnia magna (Water flea)): > 39 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: No toxicity at the limit of solubility.

EC50 (Americamysis): 9.1 mg/l  
Exposure time: 96 h

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 5.8 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility.

NOEC (Pseudokirchneriella subcapitata (green algae)): 5.8 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility.

Toxicity to 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)): 6.7 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

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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:**

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

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 : 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.

## 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

#### 49 CFR

Not regulated as a dangerous good

### Special precautions for user

Not applicable

## SECTION 15. REGULATORY INFORMATION

### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

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**SARA 311/312 Hazards** : Combustible dust  
Reproductive toxicity  
Specific target organ toxicity (single or repeated exposure)  
Serious eye damage or eye irritation

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### US State Regulations

#### Pennsylvania Right To Know

|                                                                        |              |
|------------------------------------------------------------------------|--------------|
| Cellulose, 2-hydroxypropyl methyl ether, acetate hydrogen butanedioate | 71138-97-1   |
| Cellulose                                                              | 9004-34-6    |
| Lamivudine                                                             | 134678-17-4  |
| Tenofovir                                                              | 202138-50-9  |
| Doravirine                                                             | 1338225-97-0 |
| Croscarmellose sodium                                                  | 74811-65-7   |

#### California Permissible Exposure Limits for Chemical Contaminants

|           |           |
|-----------|-----------|
| Cellulose | 9004-34-6 |
|-----------|-----------|

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

|       |                  |
|-------|------------------|
| AICS  | : not determined |
| DSL   | : not determined |
| IECSC | : not determined |

## SECTION 16. OTHER INFORMATION

### Further information

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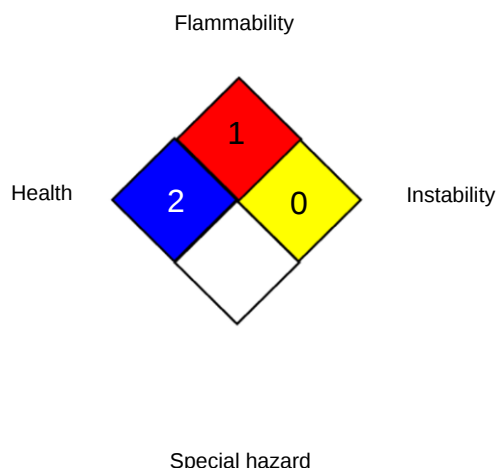
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### NFPA 704:



### HMIS® IV:

|                 |   |   |
|-----------------|---|---|
| HEALTH          | * | 2 |
| FLAMMABILITY    |   | 3 |
| PHYSICAL HAZARD |   | 0 |

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

|                 |   |                                                                                           |
|-----------------|---|-------------------------------------------------------------------------------------------|
| ACGIH           | : | USA. ACGIH Threshold Limit Values (TLV)                                                   |
| CAL PEL         | : | California permissible exposure limits for chemical contaminants (Title 8, Article 107)   |
| NIOSH REL       | : | USA. NIOSH Recommended Exposure Limits                                                    |
| OSHA Z-1        | : | USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants          |
| OSHA Z-3        | : | USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts                        |
| ACGIH / TWA     | : | 8-hour, time-weighted average                                                             |
| CAL PEL / PEL   | : | Permissible exposure limit                                                                |
| NIOSH REL / TWA | : | Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek |
| OSHA Z-1 / TWA  | : | 8-hour time weighted average                                                              |
| OSHA Z-3 / TWA  | : | 8-hour time weighted average                                                              |

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to

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50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECL - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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/>

Revision Date : 09/30/2023

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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