

Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.1 30.09.2023 58631-00026 Date of first issue: 16.02.2015

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bi-

layer Formulation

Manufacturer or supplier's details

Company name of supplier : MSD

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@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

Acute toxicity (Oral) : Category 5

Skin corrosion/irritation : Category 3

Serious eye damage/eye

irritation

Category 2A

Reproductive toxicity : Category 2

Specific target organ toxicity

- repeated exposure (Oral)

Category 2 (Blood, Bone, Kidney)

GHS label elements

Hazard pictograms





Signal Word : Warning

Hazard Statements : 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.

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/

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.

P312 Call a POISON CENTER or doctor/ physician if you feel

unwell.

P332 + P313 If skin irritation occurs: Get medical advice/ atten-

tion.

P337 + P313 If eye irritation persists: Get medical advice/ atten-

tion.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ 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	CAS-No.	Concentration (% w/w)	
Cellulose	9004-34-6	>= 20 -< 30	
Lamivudine	134678-17-4	>= 10 -< 20	
Tenofovir	202138-50-9	>= 10 -< 20	
Doravirine	1338225-97-0	>= 5 -< 10	

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



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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

May be harmful if swallowed. Causes mild skin irritation. 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).

Treat symptomatically and supportively. Notes to physician

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

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 prod-

ucts

Carbon oxides

Nitrogen oxides (NOx) Halogenated compounds

Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

Evacuate area.

Special protective equipment :

for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

tive equipment and emer-

gency 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



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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. Use only with adequate ventilation.

Local/Total 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.

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



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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	VLE-PPT	10 mg/m ³	NOM-010- STPS-2014
		TWA	10 mg/m ³	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

Hand protection

Particulates type

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.

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



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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 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 reac- : May form explosive dust-air mixture during processing,



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handling or other means. tions

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

May be harmful if swallowed.

Product:

Acute toxicity estimate: 2,605 mg/kg Acute oral toxicity

Method: Calculation method

Components:

Cellulose:

: LD50 (Rat): > 5,000 mg/kg Acute oral toxicity

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:

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

LD50 (Dog): 30 mg/kg

Doravirine:



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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

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.



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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 Guinea pig **Species**

Result : Not a skin sensitizer.

Doravirine:

No data available Remarks

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

Test Type: Mammalian erythrocyte micronucleus test (in vivo Genotoxicity 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



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mammalian liver cells in vivo

Species: Rat Result: negative

Tenofovir:

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

Result: equivocal

Test Type: In vitro mammalian cell gene mutation test

Result: positive

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

Doravirine:

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

Result: negative

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

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

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



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Exposure time : 2 Years
Result : negative

Tenofovir:

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

Species: RatApplication Route: OralExposure time: 104 weeksResult: 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

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 - As-

sessment

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 : >= 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 disor-

ders, 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



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Exposure time : 13 Weeks Target Organs : Bone

Species : Dog
NOAEL : 3 mg/kg
LOAEL : >= 10 mg/kg
Application Pouts : Oral

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

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, Fatique, Respiratory disorders, Diar-

rhea, Cough

Tenofovir:

Ingestion : Symptoms: Nausea, Diarrhea, Vomiting, flatulence, Head-

ache, Rash

Doravirine:

Ingestion : Symptoms: confusion, Headache, Dizziness, Nausea, Rash,

abnormal dreams, flushing, Neurological disorders, mental



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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 tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 9 mg/l

Exposure time: 32 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

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

Exposure time: 21 d

Method: OECD Test Guideline 211



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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 tox-

icity)

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 (Chron-

ic 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
Method: OECD Test Guideline 209



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Persistence and degradability

Components:

Cellulose:

Biodegradability Result: Readily biodegradable.

Lamivudine:

Biodegradability Result: Not readily biodegradable.

> Biodegradation: 4 % Exposure time: 28 d

Tenofovir:

Result: Not readily biodegradable. Biodegradability

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: nlog Pow: 1.06

octanol/water pH: 7

Doravirine:

Partition coefficient: n-

log Pow: 2.08

octanol/water

Mobility in soil **Components:**

Lamivudine:

Distribution among environmental compartments

log Koc: 2.03

Tenofovir:

Distribution among environ-

log Koc: 3.33

mental compartments Method: OECD Test Guideline 106



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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

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

NOM-002-SCT

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills.

Not applicable

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

AICS : not determined

DSL : not determined



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IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 30.09.2023 Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting

the Work Environment - Identification, Assessment and Con-

trol - Appendix 1 Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average NOM-010-STPS-2014 / VLE- : Time weighted average limit value

PPT

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with 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 Organisation 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; 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, Authorisation 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

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 Agen-

cy, http://echa.europa.eu/



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The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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