

Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 7.1 30.09.2023 59626-00028 Date of first issue: 16.02.2015

SECTION 1. IDENTIFICATION

Product name : Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer

Formulation

Manufacturer or supplier's details

Company : MSD

Address : 855 Leandro N. Alem St., 8 Floor

Buenos Aires, Argentina C1001AFB

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)

Short-term (acute) aquatic

hazard

Category 3

GHS label elements

Hazard pictograms



Signal Word : Warning



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 7.1 30.09.2023 59626-00028 Date of first issue: 16.02.2015

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.

H402 Harmful to aquatic life.

Precautionary Statements :

Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P260 Do not breathe dust.

P264 Wash skin thoroughly after handling. P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ 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/ doctor if you feel unwell.

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

tion.

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

tention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

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.	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



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 7.1 30.09.2023 59626-00028 Date of first issue: 16.02.2015

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.

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).

Notes to physician : Treat symptomatically and supportively.

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

SO.

Evacuate area.

Special protective equipment : In the event of fire, wear self-contained breathing apparatus.



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 7.1 30.09.2023 59626-00028 Date of first issue: 16.02.2015

for fire-fighters 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

cannot be contained.

Methods and materials for containment and cleaning up Sweep up or vacuum up spillage and collect in suitable

container for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to

determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation Advice on safe handling Use only with adequate ventilation. 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.

Keep in properly labeled containers. Conditions for safe storage

Store locked up.

Store in accordance with the particular national regulations.

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



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 7.1 30.09.2023 59626-00028 Date of first issue: 16.02.2015

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	CMP	10 mg/m ³	AR OEL
		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

Particulates type

Hand protection

Material Chemical-resistant gloves

Eye protection Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection

Work uniform or laboratory coat.

If exposure to chemical is likely during typical use, provide Hygiene measures

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 7.1 30.09.2023 59626-00028 Date of first issue: 16.02.2015

Appearance : powder

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : May form explosive dust-air mixture during processing,

handling or other means.

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : Not applicable

Relative vapor density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Autoignition temperature : No data available

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.



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 7.1 30.09.2023 59626-00028 Date of first issue: 16.02.2015

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-

tions

May form explosive dust-air mixture during processing,

handling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation. Oxidizing agents

Incompatible materials

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 oral toxicity : Acute toxicity estimate: 2.605 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 : LD50 (Rat): > 2.000 mg/kg



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 7.1
 30.09.2023
 59626-00028
 Date of first issue: 16.02.2015

administration) Application Route: Intravenous

Tenofovir:

Acute oral toxicity : LD50 (Rat): > 1.500 mg/kg

LD50 (Dog): 30 mg/kg

Doravirine:

Acute oral toxicity : LD50 (Rat): > 750 mg/kg

Remarks: No mortality observed at this dose.

(Rat): Method: Phototoxicity

Remarks: No evidence of phototoxicity was observed

LD50 (Dog): > 1.000 mg/kg

Remarks: No mortality observed at this dose.

LD50 (Mouse): > 450 mg/kg

Remarks: No mortality observed at this dose.

Skin corrosion/irritation

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 / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 7.1 30.09.2023 59626-00028 Date of first issue: 16.02.2015

Doravirine:

Remarks : No data available

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Lamivudine:

Routes of exposure : Dermal Species : Guinea pig

Result : Not a skin sensitizer.

Tenofovir:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig

Result : Not a skin sensitizer.

Doravirine:

Remarks : No data available

Germ cell mutagenicity

Not classified based on available information.

Components:

Cellulose:

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

Result: negative

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



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 7.1 30.09.2023 59626-00028 Date of first issue: 16.02.2015

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Rat

Application Route: Oral Result: negative

Test Type: Unscheduled DNA synthesis (UDS) test with

mammalian liver cells in vivo

Species: Rat Result: negative

Tenofovir:

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

Result: equivocal

Test Type: In vitro mammalian cell gene mutation test

Result: positive

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

cytogenetic test, chromosomal analysis)

Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

Doravirine:

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

Result: negative

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

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

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



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 7.1 30.09.2023 59626-00028 Date of first issue: 16.02.2015

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

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



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 7.1 30.09.2023 59626-00028 Date of first issue: 16.02.2015

development were detected.

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rabbit Application Route: Oral

Symptoms: Preimplantation loss., Skeletal malformations. Result: Embryotoxic effects and adverse effects on the

offspring were detected.

Test Type: Embryo-fetal development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 45 mg/kg body weight

Symptoms: Effects on fetal development.

Result: positive

Reproductive toxicity - 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.



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 7.1 30.09.2023 59626-00028 Date of first issue: 16.02.2015

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 disor-

ders, Gastrointestinal disturbance

Species: MouseNOAEL: 500 mg/kgApplication Route: OralExposure time: 1 MonthsTarget Organs: Blood



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 7.1 30.09.2023 59626-00028 Date of first issue: 16.02.2015

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

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, Fatique, Respiratory disorders, Diar-

rhea, Cough

Tenofovir:



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 7.1 30.09.2023 59626-00028 Date of first issue: 16.02.2015

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

ache, Rash

Doravirine:

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

abnormal dreams, flushing, Neurological disorders, mental

depression

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

Lamivudine:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 97,7 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

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/

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



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 7.1 30.09.2023 59626-00028 Date of first issue: 16.02.2015

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

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



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version 7.1

Revision Date: 30.09.2023

SDS Number: 59626-00028

Date of last issue: 04.04.2023 Date of first issue: 16.02.2015

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-

log Pow: -1,44

octanol/water
Tenofovir:

Partition coefficient: n-

log Pow: 1,06

octanol/water pH: 7

Doravirine:

Partition coefficient: n-

: log Pow: 2,08

octanol/water

Mobility in soil

Components:

Lamivudine:

Distribution among environ-

mental compartments

: log Koc: 2,03



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 7.1 30.09.2023 59626-00028 Date of first issue: 16.02.2015

Tenofovir:

Distribution among environ-

mental compartments

log Koc: 3,33

Method: OECD Test Guideline 106

Doravirine:

Distribution among environmental compartments

log Koc: 2,86

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

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.

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents

Not applicable

Registry.

Control of precursors and essential chemicals for the

Not applicable

preparation of drugs.

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

AICS : not determined



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 7.1 30.09.2023 59626-00028 Date of first issue: 16.02.2015

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

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

Further information

Sources of key data used to compile the Material Safety

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average AR OEL / CMP : TLV (Threshold Limit Value)

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for 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 Recom-



Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 7.1 30.09.2023 59626-00028 Date of first issue: 16.02.2015

mendations 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.

AR / Z8