

Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 2024/04/06

 13.0
 2024/09/28
 58629-00031
 Date of first issue: 2015/02/16

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer

Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.

Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Serious eye damage/eye irri-

tation

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

Hazard statements : H319 Causes serious eye irritation.

H361d Suspected of damaging the unborn child.



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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.

P308 + P313 IF exposed or concerned: Get medical advice/

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

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

Important symptoms and out: : lines of the emergency as-

sumed

May form explosive dust-air mixture during processing, han-

dling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Cellulose	9004-34-6	>= 20 - < 30	
Lamivudine	134678-17-4	>= 10 - < 20	-
Tenofovir	202138-50-9	>= 10 - < 20	-
Doravirine	1338225-97-0	>= 2.5 - < 10	



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4. FIRST AID MEASURES

General advice In the case of accident or if you feel unwell, seek medical ad-

vice 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 contact, immediately flush eyes with plenty of water In case of eye contact

for at least 15 minutes.

If easy to do, remove contact lens, if worn.

Get medical attention.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms

and effects, both acute and

delayed

Causes serious eye irritation.

Suspected of damaging the unborn child.

May cause damage to organs through prolonged or repeated

exposure if swallowed.

Protection of first-aiders First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician Treat symptomatically and supportively.

5. FIREFIGHTING 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.



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Use water spray to cool unopened containers.

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

SO.

Evacuate area.

Special protective equipment :

for firefighters

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

Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

tive equipment and emergency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 con-

tainer 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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

7. HANDLING AND STORAGE

Handling

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



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practice, based on the results of the workplace exposure as-

sessment

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.

Avoidance of contact

Hygiene measures

: Oxidizing agents

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.

Storage

Conditions for safe storage :

Keep in properly labelled 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

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Concentration standard / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
Lamivudine	134678-17-4	TWA	100 μg/m3 (OEB 2)	Internal
Tenofovir	202138-50-9	TWA	150 ug/m3 (OEB 2)	Internal
Doravirine	1338225-97- 0	TWA	500 ug/m3 (OEB2)	Internal

Engineering measures: Use feasible engineering controls to minimize exposure to

compound.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to



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protect products, workers, and the environment.

Personal protective equipment

Respiratory protection If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state powder

Colour No data available

Odour No data available

Odour Threshold No data available

Melting point/freezing point No data available

Boiling point, initial boiling

point and boiling range

No data available

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

dling or other means.

Flammability (liquids) No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- : No data available

per flammability limit

Lower explosion limit /

Lower flammability limit

No data available

Flash point Not applicable

No data available Decomposition temperature

pΗ No data available



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Evaporation rate Not applicable

Auto-ignition temperature No data available

Viscosity

Viscosity, kinematic Not applicable

Solubility(ies)

No data available Water solubility

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure Not applicable

Density and / or relative density

Relative density No data available

Density No data available

Relative vapour density Not applicable

Explosive properties Not explosive

Oxidizing properties The substance or mixture is not classified as oxidizing.

No data available Molecular weight

Particle characteristics

Particle size No data available

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, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of: Inhalation



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exposure Skin contact

> Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

Components:

Cellulose:

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

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

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.



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II

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 sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Lamivudine:

Exposure routes : Dermal Species : Guinea pig

Result : Not a skin sensitizer.



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Tenofovir:

Test Type : Maximisation Test
Exposure routes : 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)



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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: RatApplication Route: IngestionExposure time: 72 weeksResult: negative

Lamivudine:

Species : Rat
Exposure time : 2 Years
Result : negative

Species : Mouse
Exposure time : 2 Years
Result : negative



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Tenofovir:

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

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

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 foetal develop-

ment

Test Type: Fertility/early embryonic development Species: Rat

Application Route: Ingestion

Result: negative

Lamivudine:

Test Type: Two-generation reproduction toxicity study Effects on fertility

Species: Rat

Application Route: Oral

Fertility: NOAEL: 900 mg/kg body weight

Result: No effects on fertility and early embryonic develop-

ment were detected.

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Oral

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

spring were detected.



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Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 45 mg/kg body weight

Symptoms: Effects on foetal 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 foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral Result: No adverse effects

Test Type: Embryo-foetal 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 foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral

Developmental Toxicity: NOAEL: 450 mg/kg body weight

Result: No adverse effects

Test Type: Embryo-foetal 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:

Exposure routes : 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, Diarrhoea, Changes in the blood count, Liver dis-

orders, Gastrointestinal disturbance

Species : Mouse
NOAEL : 500 mg/kg
Application Route : Oral
Exposure time : 1 Months
Target Organs : Blood

Tenofovir:

Species : Rat



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NOAEL : 30 mg/kg
LOAEL : 300 mg/kg
Application Route : Oral
Exposure time : 13 Weeks
Target Organs : Bone

Species: DogNOAEL: 3 mg/kgLOAEL: >= 10 mg/kgApplication Route: OralExposure time: 42 WeeksTarget 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

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, Diar-

rhoea, Cough

Tenofovir:



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

ache, Rash

Doravirine:

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

abnormal dreams, flushing, Neurological disorders, mental

depression

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



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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

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



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Remarks: No toxicity at the limit of solubility

Toxicity to microorganisms : EC50: > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC: 1,000 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Persistence and degradability

Components:

Cellulose:

Biodegradability : Result: Readily biodegradable.

Lamivudine:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 4 % Exposure time: 28 d

Tenofovir:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 3.66 % Exposure time: 28 d

Method: OECD Test Guideline 314

Doravirine:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 2 % Exposure time: 28 d

Bioaccumulative potential

Components:

Lamivudine:

Partition coefficient: n-

: log Pow: -1.44

octanol/water
Tenofovir:

Partition coefficient: n-

: log Pow: 1.06

octanol/water

pH: 7

Doravirine:



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Partition coefficient: n-

octanol/water

log Pow: 2.08

Mobility in soil

Components:

Lamivudine:

Distribution among environmental compartments

log Koc: 2.03

Tenofovir:

Distribution among environ-

mental compartments

log Koc: 3.33

Method: OECD Test Guideline 106

Doravirine:

Distribution among environ-

mental compartments

log Koc: 2.86

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable



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Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo : Not applicable

aircraft)

Packing instruction (passen: :

ger aircraft)

Not applicable

IMDG-Code

Not applicable UN number Not applicable Proper shipping name Class Not applicable Subsidiary risk Not applicable Not applicable Packing group Labels Not applicable **EmS Code** Not applicable Not applicable Marine pollutant

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

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable



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Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Not applicable

Substances Subject to be Indicated Names

Not applicable

Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2)

Not applicable

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Not regulated as a dangerous good

Aviation Law

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance



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Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS not determined

DSL not determined

IECSC not determined

16. OTHER INFORMATION

Further information

compile the Safety Data Sheet

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA 8-hour, time-weighted average

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



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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

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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