

Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.0 06.04.2024 58634-00028 Date of first issue: 16.02.2015

Section 1: Identification

Product identifier : Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer

Formulation

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use Not applicable

Manufacturer or supplier's details

MSD Company

Address 50 Tuas West Drive

Singapore - Singapore 638408

Telephone +1-908-740-4000

Emergency telephone number : 65 6697 2111 (24/7/365)

E-mail address EHSDATASTEWARD@msd.com

Section 2: Hazard identification

Classification of the substance or mixture

Serious eye damage/eye irri-

tation

Category 2

Reproductive toxicity Category 2

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

GHS Label elements, including precautionary statements

Hazard pictograms

Signal word Warning

H319 Causes serious eye irritation. Hazard statements

H361d Suspected of damaging the unborn child.

H373 May cause damage to organs (Blood, Bone, Kidney) through prolonged or repeated exposure if swallowed.



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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.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection/ hearing 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/

attention.

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	>= 1 -< 10	

Section 4: First-aid measures

Description of necessary first-aid measures

General advice : In the case of accident or if you feel unwell, seek medical 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.



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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

Risks : 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).

Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Special hazards arising from the substance or mixture

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

Special protective actions for fire-fighters

Special protective equipment :

for firefighters

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

Use personal protective equipment.

Specific extinguishing meth- : Use extinguishing measures that are appropriate to local cir-



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ods 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.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

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

tective equipment recommendations (see section 8).

Environmental precautions

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

Methods for 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.

Section 7: Handling and storage

Precautions for safe 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. Use only with adequate ventilation.

Local/Total ventilation : Use only with adequate ventilati 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 as-



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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.

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, including any incompatibilities

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

Section 8: Exposure controls/personal protection

Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	PEL (long term)	10 mg/m3	SG OEL
		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

Appropriate engineering control 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.



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Individual protection measures, such as personal protective equipment (PPE)

Eye/face 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 protection : Work uniform or laboratory coat.

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

Section 9: Physical and chemical properties

Appearance : powder

Colour : No data available

Odour : No data available

Odour 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, han-

dling 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

Vapour pressure : Not applicable

Relative vapour density : Not applicable



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Relative density : No data available

Density No data available

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

Not applicable

No data available Auto-ignition temperature

Decomposition temperature No data available

Viscosity

Viscosity, kinematic Not applicable

Explosive properties Not explosive

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

Molecular weight No data available

Particle characteristics

No data available Particle size

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, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Hazardous decomposition

products

Oxidizing agents No hazardous decomposition products are known.

Section 11: Toxicological information

Information on likely routes of:

exposure

Inhalation Skin contact

Ingestion Eye contact

Acute toxicity

Not classified based on available information.



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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:

administration)

LD50 (Rat): > 2,000 mg/kg

Application Route: Intravenous

Tenofovir:

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

LD50 (Dog): 30 mg/kg

Doravirine:

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

Remarks: No mortality observed at this dose.

(Rat): Method: Phototoxicity

Remarks: No evidence of phototoxicity was observed

LD50 (Dog): > 1,000 mg/kg

Remarks: No mortality observed at this dose.

LD50 (Mouse): > 450 mg/kg

Remarks: No mortality observed at this dose.

Skin corrosion/irritation

Not classified based on available information.

Components:

Lamivudine:



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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.

Tenofovir:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig

Result : Not a skin sensitizer.



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Doravirine:

Remarks : No data available

Germ cell mutagenicity

Not classified based on available information.

Components:

Cellulose:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Result: negative

Lamivudine:

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

Result: negative

Test Type: Mouse Lymphoma

Result: equivocal

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Rat

Application Route: Oral Result: negative

Test Type: Unscheduled DNA synthesis (UDS) test with

mammalian liver cells in vivo

Species: Rat Result: negative

Tenofovir:

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

Result: equivocal

Test Type: In vitro mammalian cell gene mutation test

Result: positive

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

cytogenetic test, chromosomal analysis)

Species: Mouse



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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

Tenofovir:

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

Species : Rat Application Route : Oral



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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 foetal develop-

ment

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 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.

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- : Some evidence of adverse effects on development, based on



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sessment 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: Test Type: Embryo-foetal development

ment 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.

Components:

Lamivudine:

Exposure routes : Ingestion
Target Organs : Blood

Assessment : May cause damage to organs through prolonged or repeated

exposure.



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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: RatNOAEL: 30 mg/kgLOAEL: 300 mg/kgApplication Route: OralExposure time: 13 WeeksTarget Organs: Bone

Species : Dog



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NOAEL : 3 mg/kg
LOAEL : >= 10 mg/kg
Application Route : Oral
Exposure time : 42 Weeks
Target Organs : Kidney

Species: MonkeyLOAEL: 10 mg/kgApplication Route: SubcutaneousExposure time: 10 MonthsTarget Organs: Bone

Doravirine:

Species : Rat

NOAEL : 450 mg/kg

Application Route : Oral

Exposure time : 6 Months

Remarks : No significant adverse effects were reported

Species: MouseNOAEL: > 450 mg/kgApplication Route: OralExposure time: 3 Months

Remarks : No significant adverse effects were reported

Species : Dog

NOAEL : > 1,000 mg/kg

Application Route : Oral Exposure time : 9 Months

Remarks : No significant adverse effects were reported

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Lamivudine:

Ingestion : Symptoms: Headache, Fatigue, Respiratory disorders, Diar-

rhoea, Cough

Tenofovir:

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

ache, Rash

Doravirine:

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

abnormal dreams, flushing, Neurological disorders, mental

depression



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Section 12: Ecological information

Toxicity

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

ng/i

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



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Method: OECD Test Guideline 209

Persistence and degradability

Components:

Cellulose:

Biodegradability : Result: Readily biodegradable.

Lamivudine:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 4 % Exposure time: 28 d

Tenofovir:

Biodegradability Result: Not readily biodegradable.

Biodegradation: 3.66 %

Exposure time: 28 d

Method: OECD Test Guideline 314

Doravirine:

Biodegradability Result: Not readily biodegradable.

> Biodegradation: 2 % Exposure time: 28 d

Bioaccumulative potential

Components:

Lamivudine:

Partition coefficient: n-

octanol/water

: log Pow: -1.44

Tenofovir:

Partition coefficient: n-

octanol/water

: log Pow: 1.06

pH: 7

Doravirine:

Partition coefficient: n-

log Pow: 2.08

octanol/water

Mobility in soil **Components:**

Lamivudine:

Distribution among environ- : log Koc: 2.03

mental compartments



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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

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.

Empty containers should be taken to an approved waste han-Contaminated packaging

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

Section 14: Transport information

International Regulations

UNRTDG

UN number Not applicable UN proper shipping name Not applicable Transport hazard class(es) Not applicable Subsidiary risk Not applicable Packing group Not applicable Not applicable Labels

Environmentally hazardous no

IATA-DGR

UN/ID No. Not applicable UN proper shipping name Not applicable Not applicable Class Subsidiary risk Not applicable Packing group Not applicable Not applicable Labels Not applicable Packing instruction (cargo

aircraft)

Packing instruction (passen-

ger aircraft)

Not applicable

IMDG-Code

UN number Not applicable UN proper shipping name Not applicable Class Not applicable Not applicable Subsidiary risk



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Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

Section 15: Regulatory information

Safety, health and environmental regulations specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and

Environmental Protection and Management (Hazard-

ous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials)

Regulations

Not applicable

Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

Section 16: Other information

Revision Date : 06.04.2024

Further information

Sources of key data used to compile the Safety Data

eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Sheet 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 : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

SG OEL : Singapore. Workplace Safety and Health (General Provisions)

Regulations - First Schedule Permissible Exposure Limits of

Internal technical data, data from raw material SDSs, OECD



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Toxic Substances.

ACGIH / TWA : 8-hour, time-weighted average

SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

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

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.

SG / EN