SAFETY DATA SHEET

Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	58633-00027	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 : 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800 CHEMCALL)

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: Hazard identification

GHS Classification

Serious eye damage/eye irritation : Category 2

Reproductive toxicity : Category 2

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

GHS label elements

Hazard pictograms :

Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs (Blood, Bone, Kidney) through prolonged or repeated exposure if swallowed.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
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

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

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with plenty of water.

		Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.
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.

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 products	:	Carbon oxides Nitrogen oxides (NOx) Halogenated compounds Metal oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances 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 for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Section 6: Accidental release measures

Personal precautions, protective equipment and emer-	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro-

gency procedures		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 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	:	Use only with adequate ventilation.
Advice on safe handling	:	Do not get on skin or clothing. Do not breathe dust. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment,

appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage : Keep in properly 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

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	WES-TWA	10 mg/m3	NZ 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

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.

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, 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
Vapour pressure	:	Not applicable
Relative vapour 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
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive

Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available

Section 10: Stability and reactivity

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	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.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes : Inhalation
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 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:

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.

Doravirine:

Remarks	:	No data available

Chronic toxicity

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
Application Route: Intraperitoneal injection
Result: negative

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

Doravirine:

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

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

Result: negative

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

Carcinogenicity

Not classified based on available information.

Components:

Cellulose:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	72 weeks
Result	:	negative

Lamivudine:

Species	:	Rat
Exposure time	:	2 Years
Result	:	negative

Species	:	Mouse
Exposure time	:	2 Years
Result	:	negative

Tenofovir:

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

Species	:	Rat
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 foetal development	:	Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative

Lamivudine:

Effects on fertility	:	Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Oral Fertility: NOAEL: 900 mg/kg body weight Result: No effects on fertility and early embryonic development were detected.
Effects on foetal development	:	Test Type: Embryo-foetal 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-foetal development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 45 mg/kg body weight Symptoms: Effects on foetal development Result: positive
Reproductive toxicity - Assessment	:	Some evidence of adverse effects on development, based on animal experiments.

Tenofovir:

Effects on fertility	:	Test Type: Fertility/early embryonic development Species: Rat Application Route: Oral Result: No effects on fertility
Effects on foetal development	:	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 development : 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.

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 disorders, Gastrointestinal disturbance

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

Tenofovir:

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

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

Species	:	Monkey
LOAEL	:	10 mg/kg
Application Route	:	Subcutaneous
Exposure time	:	10 Months
Target Organs	:	Bone

Doravirine:

Species	:	Rat

NOAEL	:	450 mg/kg
Application Route	:	Oral
Exposure time	:	6 Months
Remarks	:	No significant adverse effects were reported

Species	:	Mouse
NOAEL	:	> 450 mg/kg
Application Route	:	Oral
Exposure time	:	3 Months
Remarks	:	No significant adverse effects were reported

Species	:	Dog
NOAEL	:	> 1,000 mg/kg
Application Route	:	Oral
Exposure time	:	9 Months
Remarks	:	No significant adverse effects were reported

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Lamivudine:

Ingestion	:	Symptoms: Headache, Fatigue, Respiratory disorders, Diarrhoea, Cough

Tenofovir:

Ingestion	:	Symptoms: Nausea, Diarrhoea, Vomiting, flatulence, Headache, 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/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 96.9 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Tenofovir:

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

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

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 9 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic 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 : EC50 (Daphnia magna (Water flea)): > 39 mg/l

aquatic invertebrates		Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility EC50 (Americamysis): 9.1 mg/l Exposure time: 96 h
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 5.8 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility NOEC (Pseudokirchneriella subcapitata (green algae)): 5.8 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility
Toxicity to fish (Chronic toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): 1 mg/l Exposure time: 32 d Method: OECD Test Guideline 210 Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 6.7 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 Remarks: No toxicity at the limit of solubility
Toxicity to microorganisms	:	EC50: > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 NOEC: 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

Persistence and degradability

Components:

Cellulose:

Biodegradability	:	Result: Readily biodegradable.

Lamivudine:

Biodegradability	:	Result: Not readily biodegradable. Biodegradation: 4 % Exposure time: 28 d

Tenofovir:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 3.66 %
Exposure time: 28 d
Method: OECD Test Guideline 314

Doravirine:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 2 %
Exposure time: 28 d

Bioaccumulative potential

Components:

Lamivudine:

Partition coefficient: n-octanol/water : log Pow: -1.44

Tenofovir:

Partition coefficient: n-octanol/water : log Pow: 1.06
pH: 7

Doravirine:

Partition coefficient: n-octanol/water : log Pow: 2.08

Mobility in soil

Components:

Lamivudine:

Distribution among environmental compartments : log Koc: 2.03

Tenofovir:

Distribution among environmental compartments : log Koc: 3.33
Method: OECD Test Guideline 106

Doravirine:

Distribution among environmental compartments : log Koc: 2.86

Other adverse effects

No data available

Section 13: Disposal considerations

Disposal methods

Waste from residues	:	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

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

IATA-DGR

UN/ID No.	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Packing instruction (cargo aircraft)	:	Not applicable
Packing instruction (passenger aircraft)	:	Not applicable

IMDG-Code

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

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

Not applicable for product as supplied.

National Regulations

NZS 5433

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable

Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Hazchem Code	:	Not applicable

Special precautions for user

Not applicable

Section 15: Regulatory information

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

HSNO Approval Number

HSR100425 Pharmaceutical Active Ingredients Group Standard

HSW Controls

Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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	:	30.09.2023

Further information

Sources of key data used to compile the Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/
Date format	:	dd.mm.yyyy

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NZ OEL	:	New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
NZ OEL / WES-TWA	:	Workplace Exposure Standard - 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 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.

NZ / EN