SAFETY DATA SHEET

Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation

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: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical

Section 2: Hazard identification

GHS Classification

Serious eye damage/eye irritation: Category 2A
Reproductive toxicity: Category 2
Specific target organ toxicity - repeated exposure (Oral): Category 2 (Blood, Bone, Kidney)

GHS label elements

Hazard pictograms:

Signal word: Warning

Hazard statements: 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.
P260 Do not breathe dust.
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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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Lamivudine</td>
<td>134678-17-4</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Tenofovir</td>
<td>202138-50-9</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Doravirine</td>
<td>1338225-97-0</td>
<td>&lt; 10</td>
</tr>
</tbody>
</table>

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.
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 firefighting:
- 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

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 emergency procedures:
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up:
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
- Dust deposits should not be allowed to accumulate on surfa-
es, 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of Control parameters / Permissible)</th>
<th>Basis</th>
</tr>
</thead>
</table>

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### SAFFETY DATA SHEET

**Doravirine / Lamivudine / Tenofovir Disoproxil Fumarate Bilayer Formulation**

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**SDS Number**: 58633-00021  
**Date of last issue**: 10.10.2020  
**Date of first issue**: 16.02.2015

<table>
<thead>
<tr>
<th>Substance</th>
<th>Exposure</th>
<th>Concentration</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td>Lamivudine</td>
<td>TWA</td>
<td>150 µg/m³</td>
<td>ACGIH, OEB2</td>
</tr>
<tr>
<td>Tenofovir</td>
<td>TWA</td>
<td>150 µg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td>Doravirine</td>
<td>TWA</td>
<td>500 µg/m³</td>
<td>Internal (OEB2)</td>
</tr>
</tbody>
</table>

#### 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
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.

Incompatible materials: Avoid dust formation. 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 - As:**
Some evidence of adverse effects on development, based on
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 development:
- Test Type: Embryo-foetal development
- Species: Rat
- Application Route: Oral
- 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: \( \geq 9,000 \text{ mg/kg} \)
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: \( \geq 10 \text{ mg/kg} \)
Application Route: Oral
Exposure time: 42 Weeks
Target Organs: Kidney
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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 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 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 %
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**: 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
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 2017

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

Further information

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
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