SECTION 1. IDENTIFICATION

Product name: Doravirine Formulation
Other means of identification: No data available

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTeward@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Not a hazardous substance or mixture.

GHS label elements
No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
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>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>No data available</td>
<td>9004-34-6</td>
<td>&gt;= 10 - &lt; 30 *</td>
</tr>
<tr>
<td>Doravirine</td>
<td>3-Chloro-5-((1-((4-methyl-5-oxo-4,5-dihydro-1H-1,2,4-triazol-3-yl)methyl)-2-oxo-4-(trifluoromethyl)-1,2-dihydropyridin-3-yl)oxy)benz</td>
<td>1338225-97-0</td>
<td>&gt;= 10 - &lt; 30 *</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Octadecanoic acid, magnesium</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
</tbody>
</table>
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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 if symptoms occur.
In case of skin contact : Wash with water and soap. Get medical attention if symptoms occur.
In case of eye contact : If in eyes, rinse well with water. Get medical attention if irritation develops and persists.
If swallowed : If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed : Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.
Protection of first-aiders : No special precautions are necessary for first aid responders.
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
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 fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.
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SECTION 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures:**
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

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

**Methods and materials for containment and cleaning up:**
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

**Technical measures:**
Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

**Local/Total ventilation:**
Use only with adequate ventilation.

**Advice on safe handling:**
- Do not breathe dust.
- 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.

**Conditions for safe storage:**
- Keep in properly labeled containers.
- 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

**Ingredients with workplace control parameters**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</th>
<th>Control parameter</th>
<th>Basis</th>
</tr>
</thead>
</table>

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<table>
<thead>
<tr>
<th>Material</th>
<th>Form of exposure</th>
<th>Permissible concentration</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td>Doravirine</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td>TWAEV</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td>TWA (Inhalable)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td>TWA (Respirable)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Silicon, amorphous</td>
<td>TWA (Respirable)</td>
<td>1.5 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td>TWA (Total)</td>
<td>4 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td>TWAEV (respirable dust)</td>
<td>6 mg/m³</td>
<td>CA QC OEL</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.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder
Color: off-white
Odor: No data available
Odor Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: Not applicable
Evaporation rate: Not applicable
Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapor pressure: Not applicable
Relative vapor density: Not applicable
Relative density: No data available
Density: No data available
Solubility(ies):
Water solubility: No data available
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Partition coefficient: n-octanol/water: Not applicable
Autoignition temperature: No data available
Decomposition temperature: No data available
Viscosity
Viscosity, kinematic: Not applicable
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.

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

Information on likely routes of exposure
Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

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
**SAFETY DATA SHEET**

**Doravirine Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>04/04/2023</td>
<td>58373-00023</td>
<td>10/01/2022</td>
<td>02/16/2015</td>
</tr>
</tbody>
</table>

### Doravirine:

**Acute oral toxicity**

| LD50 (Rat): > 750 mg/kg | Remarks: No mortality observed at this dose.
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(Rat): Method: Phototoxicity</td>
<td>Remarks: No evidence of phototoxicity was observed</td>
</tr>
<tr>
<td>LD50 (Dog): &gt; 1,000 mg/kg</td>
<td>Remarks: No mortality observed at this dose.</td>
</tr>
<tr>
<td>LD50 (Mouse): &gt; 450 mg/kg</td>
<td>Remarks: No mortality observed at this dose.</td>
</tr>
</tbody>
</table>

### Magnesium stearate:

**Acute oral toxicity**

<table>
<thead>
<tr>
<th>LD50 (Rat): &gt; 2,000 mg/kg</th>
<th>Method: OECD Test Guideline 423</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment: The substance or mixture has no acute oral toxicity</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Acute dermal toxicity**

| LD50 (Rabbit): > 2,000 mg/kg | Remarks: Based on data from similar materials |

### Silicon, amorphous:

**Acute oral toxicity**

<table>
<thead>
<tr>
<th>LD50 (Rat): &gt; 5,000 mg/kg</th>
<th>Method: OECD Test Guideline 401</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

**Acute inhalation toxicity**

<table>
<thead>
<tr>
<th>LC50 (Rat): &gt; 2.08 mg/l</th>
<th>Exposure time: 4 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test atmosphere: dust/mist</td>
<td>Assessment: The substance or mixture has no acute inhalation toxicity</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

**Acute dermal toxicity**

| LD50 (Rabbit): > 5,000 mg/kg | Remarks: Based on data from similar materials |

### Skin corrosion/irritation

Not classified based on available information.

**Components:**

**Doravirine:**

| Remarks | No data available |

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Silicon, amorphous:**

---

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**SAFETY DATA SHEET**

**Doravirine Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
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<td>04/04/2023</td>
<td>58373-00023</td>
<td>10/01/2022</td>
<td>02/16/2015</td>
</tr>
</tbody>
</table>

**Species**: Rabbit

**Method**: OECD Test Guideline 404

**Result**: No skin irritation

**Remarks**: Based on data from similar materials

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**Doravirine:**

| Remarks | No data available |

**Magnesium stearate:**

| Species   | Rabbit           |
| Result    | No eye irritation|
| Remarks   | Based on data from similar materials |

**Silicon, amorphous:**

| Species   | Rabbit           |
| Result    | No eye irritation|
| Method    | OECD Test Guideline 405 |
| Remarks   | Based on data from similar materials |

**Respiratory or skin sensitization**

**Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:**

**Doravirine:**

| Remarks | No data available |

**Magnesium stearate:**

| Test Type               | Maximization Test |
| Routes of exposure      | Skin contact      |
| Species                 | Guinea pig        |
| Method                  | OECD Test Guideline 406 |
| Result                  | negative          |
| Remarks                 | Based on data from similar materials |

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**Cellulose:**

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

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

Magnesium stearate:

Genotoxicity in vitro:
Test Type: In vitro mammalian cell gene mutation test
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

Silicon, amorphous:

Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo:
Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials
### Carcinogenicity
Not classified based on available information.

### Components:

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

**Doravirine:**
- **Species:** Mouse
- **Application Route:** Oral
- **Exposure time:** 6 Months
- **Result:** negative
- **Remarks:** No significant adverse effects were reported

**Silicon, amorphous:**
- **Species:** Rat
- **Application Route:** Ingestion
- **Exposure time:** 103 weeks
- **Result:** negative
- **Remarks:** Based on data from similar materials

### Reproductive toxicity
Not classified based on available information.

### Components:

**Cellulose:**
- **Effects on fertility:**
  - **Test Type:** One-generation reproduction toxicity study
  - **Species:** Rat
  - **Application Route:** Ingestion
  - **Result:** negative

- **Effects on fetal development:**
  - **Test Type:** Fertility/early embryonic development
  - **Species:** Rat
  - **Application Route:** Ingestion
  - **Result:** negative

**Doravirine:**
- **Effects on fertility:**
  - **Test Type:** Fertility
  - **Species:** Rat, male and female
  - **Fertility:** NOAEL: 450 mg/kg body weight
  - **Result:** No effects on fertility.

- **Effects on fetal development:**
  - **Test Type:** Embryo-fetal development
  - **Species:** Rat
  - **Application Route:** Oral
  - **Developmental Toxicity:** NOAEL: 450 mg/kg body weight
  - **Result:** No adverse effects.
Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: NOAEL: 300 mg/kg body weight  
Result: No adverse effects.

**Magnesium stearate:**

**Effects on fertility:**  
Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative  
Remarks: Based on data from similar materials

**Effects on fetal development:**  
Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

**Silicon, amorphous:**

**Effects on fetal development:**  
Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

**STOT-single exposure**  
Not classified based on available information.

**STOT-repeated exposure**  
Not classified based on available information.

**Repeated dose toxicity**

**Components:**

**Cellulose:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>= 9,000 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
</tbody>
</table>

**Doravirine:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>450 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>6 Months</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>&gt; 450 mg/kg</td>
</tr>
</tbody>
</table>
**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

**Magnesium stearate:**  
| **Species** | Rat  
| **NOAEL** | > 100 mg/kg  
| **Application Route** | Ingestion  
| **Exposure time** | 90 Days  
| **Remarks** | Based on data from similar materials

**Silicon, amorphous:**  
| **Species** | Rat  
| **NOAEL** | 1.3 mg/l  
| **Application Route** | inhalation (dust/mist/fume)  
| **Exposure time** | 13 Weeks  
| **Remarks** | Based on data from similar materials

**Aspiration toxicity**  
Not classified based on available information.

**Experience with human exposure**

**Components:**

**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

**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.
Toxicity to algae/aquatic plants:

- **EC50** (Americamysis): 9.1 mg/l
  Exposure time: 96 h

- **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

Magnesium stearate:

Toxicity to fish:

- **LC50** (Leuciscus idus (Golden orfe)): > 100 mg/l
  Exposure time: 48 h
  Method: DIN 38412
  Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:

- **EL50** (Daphnia magna (Water flea)): > 1 mg/l
  Exposure time: 47 h
  Test substance: Water Accommodated Fraction
  Remarks: Based on data from similar materials
  No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants:

- **EL50** (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
  Exposure time: 72 h
  Test substance: Water Accommodated Fraction
  Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
No toxicity at the limit of solubility.

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms:
EC10 (Pseudomonas putida): > 100 mg/l
Exposure time: 16 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Silicon, amorphous:

Toxicity to fish:
LC50 (Danio rerio (zebra fish)): > 10,000 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
Exposure time: 24 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants:
EC50 (Desmodesmus subspicatus (green algae)): > 10,000 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

NOEC (Desmodesmus subspicatus (green algae)): 10,000 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Persistence and degradability

Components:

Cellulose:
Biodegradability: Result: Readily biodegradable.

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

Magnesium stearate:
Biodegradability: Result: Not biodegradable
Bioaccumulative potential

Components:

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

Magnesium stearate:
- Partition coefficient: n-octanol/water: log Pow: > 4

Mobility in soil

Components:

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. Do not dispose of waste into sewer.

Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

TDG
Not regulated as a dangerous good

Special precautions for user
Not applicable
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SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:
- AICS: not determined
- DSL: not determined
- IECSC: not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations:
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- CA BC OEL: Canada. British Columbia OEL
- CA QC OEL: Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
- ACGIH / TWA: 8-hour, time-weighted average
- CA AB OEL / TWA: 8-hour Occupational exposure limit
- CA BC OEL / TWA: 8-hour time weighted average
- CA QC OEL / TWA: Time-weighted average exposure value

Abbreviations:
- AICIC - 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
- 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
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Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 04/04/2023
Date format: mm/dd/yyyy

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

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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