SECTION 1. IDENTIFICATION

Product name : Doravirine Formulation

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 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

GHS label elements

Signal Word : Warning

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.

Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.

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;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Doravirine</td>
<td>1338225-97-0</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Silicon, amorphous</td>
<td>112945-52-5</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

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 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 fire-fighters: Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

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:
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>Inert or nuisance dust</th>
<th>50 Million particles per cubic foot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value type (Form of exposure):</td>
<td>TWA (total dust)</td>
</tr>
<tr>
<td>Basis:</td>
<td>OSHA Z-3</td>
</tr>
</tbody>
</table>

| 15 mg/m³ |
| Value type (Form of exposure): | TWA (total dust) |
| Basis: | OSHA Z-3 |

| 5 mg/m³ |
| Value type (Form of exposure): | TWA (respirable fraction) |
| Basis: | OSHA Z-3 |
15 Million particles per cubic foot  
Value type (Form of exposure): TWA (respirable fraction)  
Basis: OSHA Z-3

Dust, nuisance dust and particulates  
10 mg/m³  
Value type (Form of exposure): PEL (Total dust)  
Basis: CAL PEL

5 mg/m³  
Value type (Form of exposure): PEL (respirable dust fraction)  
Basis: CAL PEL

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td>Doravirine</td>
<td>1338225-97-0</td>
<td>TWA</td>
<td>500 ug/m³ (OEB2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Silicon, amorphous</td>
<td>112945-52-5</td>
<td>TWA (Dust)</td>
<td>20 Million particles per cubic foot (Silica)</td>
<td>OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Dust)</td>
<td>80 mg/m³ / %SiO2 (Silica)</td>
<td>OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>6 mg/m³ (Silica)</td>
<td>NIOSH REL</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**: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and
use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

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
Hygiene measures : Work uniform or laboratory coat. 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** : 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

**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.

**Magnesium stearate:**
- **Acute oral toxicity**: LD50 (Rat): > 2,000 mg/kg
  - Method: OECD Test Guideline 423
  - Assessment: The substance or mixture has no acute oral toxicity
  - Remarks: Based on data from similar materials
- **Acute dermal toxicity**: LD50 (Rabbit): > 2,000 mg/kg
  - Remarks: Based on data from similar materials

**Silicon, amorphous:**
- **Acute oral toxicity**: LD50 (Rat): > 5,000 mg/kg
  - Method: OECD Test Guideline 401
  - Remarks: Based on data from similar materials
- **Acute inhalation toxicity**: LC50 (Rat): > 2.08 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Assessment: The substance or mixture has no acute inhalation toxicity
  - Remarks: Based on data from similar materials
- **Acute dermal toxicity**: LD50 (Rabbit): > 5,000 mg/kg
Skin corrosion/irritation
Not classified based on available information.

Components:

Doravirine:
Remarks: No data available

Magnesium stearate:
Species: Rabbit
Result: No skin irritation
Remarks: Based on data from similar materials

Silicon, amorphous:
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)
  - 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
SAFETY DATA SHEET
Doravirine Formulation

<table>
<thead>
<tr>
<th>Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
</tr>
<tr>
<td>Result: negative</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Silicon, amorphous:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method: OECD Test Guideline 471</td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

**Carcinogenicity**
Not classified based on available information.

**Components:**

**Cellulose:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>72 weeks</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Doravirine:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>6 Months</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

**Silicon, amorphous:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>103 weeks</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**IARC**
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

**NTP**
No ingredient of this product present at levels greater than or equal to 0.1% is
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.
- **Effects on fetal development**: 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:
   Species: Rat
   NOAEL: >= 9,000 mg/kg
   Application Route: Ingestion
   Exposure time: 90 Days

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

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
SAFETY DATA SHEET

Doravirine Formulation

<table>
<thead>
<tr>
<th>Remarks</th>
<th>Based on data from similar materials</th>
</tr>
</thead>
</table>

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.

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
**SAFETY DATA SHEET**

**Doravirine Formulation**

<table>
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<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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<tbody>
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<td>11.0</td>
<td>04/04/2023</td>
<td>58388-00024</td>
<td>10/01/2022</td>
<td>02/16/2015</td>
</tr>
</tbody>
</table>

**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
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
Remarks: Based on data from similar materials

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

49 CFR
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Combustible dust

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
Cellulose, 2-hydroxypropyl methyl ether, acetate hydrogen butanedioate 71138-97-1
### California Permissible Exposure Limits for Chemical Contaminants

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>D-Glucose, 4-O-β-D-galactopyranosyl-, monohydrate</td>
<td>64044-51-5</td>
</tr>
<tr>
<td>Doravirine</td>
<td>1338225-97-0</td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
</tr>
<tr>
<td>Silicon, amorphous</td>
<td>112945-52-5</td>
</tr>
</tbody>
</table>

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

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

### SECTION 16. OTHER INFORMATION

**Further information**

**NFPA 704:**

<table>
<thead>
<tr>
<th>Flammability</th>
<th>Health</th>
<th>Instability</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**HMIS® IV:**

- **HEALTH**: 0
- **FLAMMABILITY**: 3
- **PHYSICAL HAZARD**: 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

**Full text of other abbreviations**

- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **CAL PEL**: California permissible exposure limits for chemical contaminants (Title 8, Article 107)
- **NIOSH REL**: USA. NIOSH Recommended Exposure Limits
- **OSHA Z-1**: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- **OSHA Z-3**: USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusters
- **ACGIH / TWA**: 8-hour, time-weighted average
- **CAL PEL / PEL**: Permissible exposure limit
SAFETY DATA SHEET

Doravirine Formulation

Version: 11.0
Revision Date: 04/04/2023
SDS Number: 58388-00024
Date of last issue: 10/01/2022
Date of first issue: 02/16/2015

NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour
workday during a 40-hour workweek
OSHA Z-1 / TWA: 8-hour time weighted average
OSHA Z-3 / TWA: 8-hour time weighted average

Alt - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of
Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation,
and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the
German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Sub-
stances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Haz-
ardous Substance; 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 Sys-
tem; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC -
International Agency for Research on Cancer; IATA - International Air Transport Association; IC
- International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in
Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organiza-
tion; 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 Chemi-
cal 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 Pre-
vention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Oth-
erwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse)
Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable
Effect Loading Rate; 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 Sub-
stance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quanti-
tative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act;
REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concern-
ing the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable
Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amend-
ments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Existing Chemicals
Inventory; 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

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

Revision Date: 04/04/2023

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.

US / Z8