SAFETY DATA SHEET

Doravirine Formulation

SECTION 1. IDENTIFICATION

Product name: Doravirine Formulation

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
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

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.
Wash with water and soap.
Get medical attention if symptoms occur.
If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.
If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.
No special precautions are necessary for first aid responders.
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:
Sweep up or vacuum up spillage and collect in suitable
containment and cleaning up 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 (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 µg/m³ (OEB2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhal-</td>
<td>10 mg/m³</td>
<td>ACGIH</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**
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
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
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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

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
- Remarks: Based on data from similar materials

### 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
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  
- 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

**IARC**
- Group 1: Carcinogenic to humans
- Silicon, amorphous 112945-52-5

**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**
- Known to be human carcinogen
- Silicon, amorphous 112945-52-5

**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:**

| 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  
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 (Pseudokirchneriella subcapitata (green algae)): 9.1 mg/l
Exposure time: 96 h

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:
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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.
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
- Cellulose 9004-34-6
- D-Glucose, 4-O-.beta.-D-galactopyranosyl-, monohydrate 64044-51-5
- Doravirine 1338225-97-0
- Croscarmellose sodium 74811-65-7
- Silicon, amorphous 112945-52-5

California Prop. 65
WARNING: This product can expose you to chemicals including Silicon, amorphous, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances
- Silicon, amorphous 112945-52-5

California Permissible Exposure Limits for Chemical Contaminants
- Cellulose 9004-34-6
- Magnesium stearate 557-04-0
- Silicon, amorphous 112945-52-5

California Regulated Carcinogens
- Silicon, amorphous 112945-52-5

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:**

- Flammability: 1
- Health: 0
- Instability: 0
- Special hazard: 0

**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)
- 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 Dusts
- ACGIH / TWA : 8-hour, time-weighted average
- 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

AICL - 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 Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous 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 System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; KECl - 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 Pre-
SAFETY DATA SHEET

Doravirine Formulation

Revision Date: 08/27/2021

SDS Number: 58388-00020

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