SAFETY DATA SHEET

Efavirenz Solid Formulation

Version 7.0  Revision Date: 04/04/2023  SDS Number: 86803-00024  Date of last issue: 10/01/2022  Date of first issue: 04/02/2015

SECTION 1. IDENTIFICATION

Product name : Efavirenz Solid 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
Acute toxicity (Oral) : Category 4
Eye irritation : Category 2A
Carcinogenicity (Inhalation) : Category 2
Reproductive toxicity : Category 1B
Specific target organ toxicity - repeated exposure : Category 1 (Central nervous system, Skin)

GHS label elements
Hazard pictograms

Signal Word : Danger
Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
H302 Harmful if swallowed.
H319 Causes serious eye irritation.
H351 Suspected of causing cancer if inhaled.
H360D May damage the unborn child.
H372 Causes damage to organs (Central nervous system, Skin) through prolonged or repeated exposure.
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.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

**Response:**
P301 + P312 + P330 IF SWALLOWED: Call a doctor if you feel unwell. Rinse mouth.
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 attention.
P337 + P313 IF eye irritation persists: Get medical attention.

**Storage:**
P405 Store locked up.

**Disposal:**
P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards:
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Components</strong></td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>Efavirenz</td>
<td>154598-52-4</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</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.

**In case of skin contact:**
In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes.
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Efavirenz Solid 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>7.0</td>
<td>04/04/2023</td>
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</tr>
</tbody>
</table>

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Get medical attention.</td>
<td>Wash clothing before reuse.</td>
<td>Thoroughly clean shoes before reuse.</td>
<td></td>
</tr>
</tbody>
</table>

**In case of eye contact:**
- In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
- If easy to do, remove contact lens, if worn.
- Get medical attention.

**If swallowed:**
- If swallowed, DO NOT induce vomiting.
- Get medical attention.
- Rinse mouth thoroughly with water.
- Never give anything by mouth to an unconscious person.

**Most important symptoms and effects, both acute and delayed:**
- Harmful if swallowed.
- Causes serious eye irritation.
- Suspected of causing cancer if inhaled.
- May damage the unborn child.
- Causes damage to organs through prolonged or repeated exposure.

**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
- Metal oxides
- Sulfur 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:**
- 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 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:
- If sufficient ventilation is unavailable, use with local exhaust 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
- Keep container tightly closed.
- 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.
- Do not eat, drink or smoke when using this product.
- Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
- Keep in properly labeled containers.
- Store locked up.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents
  - Self-reactive substances and mixtures
  - Organic peroxides
  - Explosives
  - Gases
## 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): TWA (total dust)</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Basis: OSHA Z-3</td>
<td></td>
</tr>
<tr>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Value type (Form of exposure): TWA (respirable fraction)</td>
<td></td>
</tr>
<tr>
<td>Basis: OSHA Z-3</td>
<td></td>
</tr>
<tr>
<td>15 Million particles per cubic foot</td>
<td></td>
</tr>
<tr>
<td>Value type (Form of exposure): TWA (respirable fraction)</td>
<td></td>
</tr>
<tr>
<td>Basis: OSHA Z-3</td>
<td></td>
</tr>
</tbody>
</table>

### Dust, nuisance dust and particulates

<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>Efavirenz</td>
<td>154598-52-4</td>
<td>TWA</td>
<td>100 µg/m³</td>
<td>Internal</td>
</tr>
<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>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>Titanium dioxide</td>
<td>13463-67-7</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 particulate matter)</td>
<td>2.5 mg/m³ (Titanium dioxide)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
Engineering measures:
Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). If sufficient ventilation is unavailable, use with local exhaust ventilation.

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
Remarks: Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection:
Wear the following personal protective equipment:
Safety goggles

Skin and body protection:
Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder
Color: white to 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 : No data available
Evaporation rate : No data available
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 : No data available
Relative vapor density : No data available
Density : No data available
Solubility(ies)
  Water solubility : No data available
Partition coefficient: n-octanol/water
  Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity
  Viscosity, dynamic : No data available
  Viscosity, kinematic : No data available
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
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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
Harmful if swallowed.

Product:
Acute oral toxicity: Acute toxicity estimate: 849.05 mg/kg
Method: Calculation method

Components:
Efavirenz:
Acute oral toxicity: LD50 (Rat, female): 419 mg/kg
LDL0 (Rat, male): 1,000 mg/kg

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

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
Sodium n-dodecyl sulfate:
- **Acute oral toxicity**: LD50 (Rat): 1,200 mg/kg
  Method: OECD Test Guideline 401
- **Acute dermal toxicity**: LD50 (Rat): > 2,000 mg/kg
  Method: OECD Test Guideline 402
  Remarks: Based on data from similar materials

Titanium dioxide:
- **Acute oral toxicity**: LD50 (Rat): > 5,000 mg/kg
- **Acute inhalation toxicity**: LC50 (Rat): > 6.82 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Assessment: The substance or mixture has no acute inhalation toxicity

Skin corrosion/irritation
Not classified based on available information.

Components:

**Efavirenz:**
- **Result**: Mild skin irritation
- **Remarks**: slight irritation

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

**Sodium n-dodecyl sulfate:**
- **Species**: Rabbit
- **Result**: Skin irritation

**Titanium dioxide:**
- **Species**: Rabbit
- **Result**: No skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

**Efavirenz:**
- **Remarks**: Moderate eye irritation

**Magnesium stearate:**
- **Species**: Rabbit
- **Result**: No eye irritation
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<table>
<thead>
<tr>
<th>Remarks</th>
<th>Based on data from similar materials</th>
</tr>
</thead>
</table>

**Sodium n-dodecyl sulfate:**
- **Species**: Rabbit
- **Result**: Irreversible effects on the eye
- **Method**: OECD Test Guideline 405

**Titanium dioxide:**
- **Species**: Rabbit
- **Result**: No eye irritation

**Respiratory or skin sensitization**

**Skin sensitization**
Not classified based on available information.

**Respiratory sensitization**
Not classified based on available information.

**Components**:

**Efavirenz**:
- **Test Type**: Maximization Test
- **Routes of exposure**: Dermal
- **Species**: Guinea pig
- **Assessment**: Does not cause skin sensitization
- **Result**: negative

**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

**Sodium n-dodecyl sulfate**:
- **Test Type**: Maximization Test
- **Routes of exposure**: Skin contact
- **Species**: Guinea pig
- **Result**: negative
- **Remarks**: Based on data from similar materials

**Titanium dioxide**:
- **Test Type**: Local lymph node assay (LLNA)
- **Routes of exposure**: Skin contact
- **Species**: Mouse
- **Result**: negative

**Germ cell mutagenicity**
Not classified based on available information.
## Components:

### Efavirenz:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES) Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: In vitro mammalian cell gene mutation test Result: negative</td>
</tr>
<tr>
<td></td>
<td>Test Type: Chromosome aberration test in vitro Result: negative</td>
</tr>
</tbody>
</table>

**Genotoxicity in vivo**

| Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Oral Result: negative |

**Germ cell mutagenicity - Assessment**

Weight of evidence does not support classification as a germ cell mutagen.

### Cellulose:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES) Result: negative</th>
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</thead>
<tbody>
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<td></td>
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</tr>
</tbody>
</table>

**Genotoxicity in vivo**

| Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative |

### Magnesium stearate:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: In vitro mammalian cell gene mutation test Result: negative Remarks: Based on data from similar materials</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Sodium n-dodecyl sulfate:

| Genotoxicity in vitro | Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative |
**Test Type:** In vitro mammalian cell gene mutation test  
Result: negative

**Genotoxicity in vivo**

**Titanium dioxide:**

**Test Type:** Rodent dominant lethal test (germ cell) (in vivo)  
Species: Mouse  
Application Route: Ingestion  
Result: negative

**Genotoxicity in vitro**

**Titanium dioxide:**

**Test Type:** Bacterial reverse mutation assay (AMES)  
Result: negative

**Genotoxicity in vivo**

**Carcinogenicity**
Suspected of causing cancer if inhaled.

**Components:**

**Efavirenz:**

<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>: 2 Years</td>
</tr>
<tr>
<td>Target Organs</td>
<td>: Lungs, Liver</td>
</tr>
<tr>
<td>Remarks</td>
<td>The mechanism or mode of action may not be relevant in humans.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>: Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>: 2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**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>

**Sodium n-dodecyl sulfate:**

<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>: 2 Years</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 453</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>

**Titanium dioxide:**

<table>
<thead>
<tr>
<th>Species</th>
<th>: Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>inhalation (dust/mist/fume)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>: 2 Years</td>
</tr>
</tbody>
</table>
Method: OECD Test Guideline 453
Result: positive
Remarks: The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment: Limited evidence of carcinogenicity in inhalation studies with animals.

IARC
Titanium dioxide 13463-67-7
Group 2B: Possibly carcinogenic to humans

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 identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
May damage the unborn child.

Components:
Efavirenz:
Effects on fertility: Species: Rat, male and female
Application Route: Oral
Fertility: NOAEL: 200 - 400 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.

Effects on fetal development: Test Type: Embryofetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 50 mg/kg body weight
Result: Embryo-fetal toxicity.

Test Type: Embryofetal development
Species: Monkey
Application Route: Oral
Developmental Toxicity: LOAEL: 60 mg/kg body weight
Symptoms: Malformations were observed.

Test Type: Embryofetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 75 mg/kg body weight
Result: No embryotoxic effects.

Reproductive toxicity - Assessment: Clear evidence of adverse effects on development, based on animal experiments.

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

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

Sodium n-dodecyl sulfate:
Effects on fertility: Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 416  
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

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Causes damage to organs (Central nervous system, Skin) through prolonged or repeated exposure.

Components:
Efavirenz:
Target Organs: Central nervous system  
Assessment: Causes damage to organs through prolonged or repeated exposure.
### Repeated dose toxicity

**Components:**

**Efavirenz:**
- **Species:** Rat
- **LOAEL:** 50 mg/kg
- **Application Route:** Oral
- **Exposure time:** 3 Months
- **Target Organs:** Kidney

- **Species:** Monkey
- **LOAEL:** 100 mg/kg
- **Application Route:** Oral
- **Exposure time:** 1 - 2 y
- **Target Organs:** Central nervous system, Liver, Kidney, Thyroid, Adrenal gland

- **Species:** Monkey
- **LOAEL:** 90 mg/kg
- **Application Route:** Oral
- **Exposure time:** 1 Months
- **Target Organs:** Central nervous system
- **Symptoms:** Lethargy, Weakness

**Cellulose:**
- **Species:** Rat
- **NOAEL:** >= 9,000 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 90 Days

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

**Sodium n-dodecyl sulfate:**
- **Species:** Rat
- **NOAEL:** 488 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 90 Days
- **Remarks:** Based on data from similar materials

**Titanium dioxide:**
- **Species:** Rat
- **NOAEL:** 24,000 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 28 Days
- **Species:** Rat
- **NOAEL:** 10 mg/m³
Application Route: inhalation (dust/mist/fume)
Exposure time: 2 y

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Efavirenz:
Ingestion:
Target Organs: Skin
Symptoms: Rash
Target Organs: Central nervous system
Symptoms: Dizziness, insomnia
Target Organs: Heart
Symptoms: irregular heart beat

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Efavirenz:
Toxicity to fish: LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.85 mg/l
Exposure time: 96 h
Method: FDA 4.11

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 1.1 mg/l
Exposure time: 48 h
Method: FDA 4.08

Toxicity to algae/aquatic plants: NOEC (Selenastrum capricornutum (green algae)): 0.026 mg/l
Exposure time: 12 d
Method: FDA 4.01

NOEC (Microcystis aeruginosa (blue-green algae)): 0.76 mg/l
Exposure time: 12 d
Method: FDA 4.01

Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 0.066 mg/l
Exposure time: 33 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 0.16 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Cellulose:
Toxicity to fish: LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials
### Magnesium stearate:

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to fish</strong></td>
<td>LC$_{50}$ (Leuciscus idus (Golden orfe)):  &gt; 100 mg/l</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>48 h</td>
</tr>
<tr>
<td><strong>Method</strong></td>
<td>DIN 38412</td>
</tr>
<tr>
<td><strong>Remarks</strong></td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
<td>EL$_{50}$ (Daphnia magna (Water flea)):  &gt; 1 mg/l</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>47 h</td>
</tr>
<tr>
<td><strong>Remarks</strong></td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>EL$_{50}$ (Pseudokirchneriella subcapitata (green algae)):  &gt; 1 mg/l</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>72 h</td>
</tr>
<tr>
<td><strong>Test substance</strong></td>
<td>Water Accommodated Fraction</td>
</tr>
<tr>
<td><strong>Method</strong></td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td><strong>Remarks</strong></td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

**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

### Sodium n-dodecyl sulfate:

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to fish</strong></td>
<td>LC$_{50}$ (Pimephales promelas (fathead minnow)):  29 mg/l</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>96 h</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
<td>EC$_{50}$ (Ceriodaphnia dubia (water flea)):  5.55 mg/l</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>48 h</td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>ErC$_{50}$ (Desmodesmus subspicatus (green algae)):  &gt; 120 mg/l</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>72 h</td>
</tr>
<tr>
<td><strong>NOEC</strong></td>
<td>Desmodesmus subspicatus (green algae): 30 mg/l</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>72 h</td>
</tr>
<tr>
<td><strong>Toxicity to fish (Chronic toxicity)</strong></td>
<td>NOEC (Pimephales promelas (fathead minnow)):  &gt;= 1.357 mg/l</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>42 d</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</strong></td>
<td>NOEC (Ceriodaphnia dubia (water flea)):  0.88 mg/l</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>7 d</td>
</tr>
<tr>
<td><strong>Toxicity to microorganisms</strong></td>
<td>EC$_{50}$: 135 mg/l</td>
</tr>
</tbody>
</table>
Exposure time: 3 h

Titanium dioxide:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 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

Toxicity to algae/aquatic plants: EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
   Exposure time: 72 h

Toxicity to microorganisms: EC50: > 1,000 mg/l
   Exposure time: 3 h
   Method: OECD Test Guideline 209

Persistence and degradability

Components:

Efavirenz:
Biodegradability: Result: Not readily biodegradable.
   Biodegradation: 11 %
   Exposure time: 32 d
   Method: FDA 3.11

Cellulose:
Biodegradability: Result: Readily biodegradable.

Magnesium stearate:
Biodegradability: Result: Not biodegradable
   Remarks: Based on data from similar materials

Sodium n-dodecyl sulfate:
Biodegradability: Result: Readily biodegradable.
   Biodegradation: 95 %
   Exposure time: 28 d
   Method: OECD Test Guideline 301B

Bioaccumulative potential

Components:

Efavirenz:
Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)
   Bioconcentration factor (BCF): 454
   Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water: log Pow: 5.4
Magnesium stearate:
- Partition coefficient: n-octanol/water: log Pow: > 4

Sodium n-dodecyl sulfate:
- Partition coefficient: n-octanol/water: log Pow: 0.83

Mobility in soil

Components:

Efavirenz:
- Distribution among environmental compartments: log Koc: 3.36
- Method: FDA 3.08

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
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Efavirenz)
  - Class: 9
  - Packing group: III
  - Labels: 9

IATA-DGR
- UN/ID No.: UN 3077
- Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Efavirenz)
  - Class: 9
  - Packing group: III
  - Labels: Miscellaneous
  - Packing instruction (cargo aircraft): 956
  - Packing instruction (passenger aircraft): 956
  - Environmentally hazardous: yes

IMDG-Code
SAFETY DATA SHEET

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UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Efavirenz)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

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
UN/ID/NA number : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (Efavirenz)
Class : 9
Packing group : III
Labels : CLASS 9
ERG Code : 171
Marine pollutant : yes (Efavirenz)
Remarks : Above applies only to containers over 119 gallons or 450 liters. Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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
Acute toxicity (any route of exposure)
Carcinogenicity
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)
Serious eye damage or eye irritation
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
Efavirenz 154598-52-4
D-Glucose, 4-O-β-D-galactopyranosyl-, monohydrate 64044-51-5
Cellulose 9004-34-6
Hydroxypropyl cellulose 9004-64-2
Croscarmellose sodium 74811-65-7

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

California Permissible Exposure Limits for Chemical Contaminants
Cellulose 9004-34-6
Magnesium stearate 557-04-0

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
SAFETY DATA SHEET
Efavirenz Solid Formulation

Version 7.0
Revision Date: 04/04/2023
SDS Number: 86803-00024
Date of last issue: 10/01/2022
Date of first issue: 04/02/2015

NFPA 704:

<table>
<thead>
<tr>
<th>Flammability</th>
<th>Instability</th>
<th>Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>0</td>
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Special hazard

HMIS® IV:

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>*</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

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 Dusts
ACGIH / TWA: 8-hour, time-weighted average
CAL PEL / PEL: Permissible exposure limit
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

AIIC - 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; BC - 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Other...
SAFETY DATA SHEET

Efavirenz Solid Formulation

Version 7.0  Revision Date: 04/04/2023  SDS Number: 86803-00024  Date of last issue: 10/01/2022  Date of first issue: 04/02/2015

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

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