SAFETY DATA SHEET

Efavirenz Solid Formulation

Version 1.19  Revision Date: 2021/04/09  SDS Number: 86794-00020  Date of last issue: 2020/10/10
Date of first issue: 2015/04/02

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Efavirenz Solid Formulation

Manufacturer or supplier’s details
Company: Merck & Co., Inc
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS Classification
Acute toxicity (Oral): Category 4
Serious eye damage/eye irritation: Category 2A
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure: Category 1 (Central nervous system, Skin)
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 1

GHS label elements
Hazard pictograms: 

Signal word: Danger
Hazard statements: H302 Harmful if swallowed.
H319 Causes serious eye irritation.
H360D May damage the unborn child.
H372 Causes damage to organs (Central nervous system, Skin) through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

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.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ 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 advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P391 Collect spillage.

**Storage:**
P405 Store locked up.

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

**Other hazards which do not result in classification**
May form explosive dust-air mixture during processing, handling or other means.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Efavirenz</td>
<td>154598-52-4</td>
<td>&gt;= 30 -&lt; 60</td>
</tr>
<tr>
<td></td>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 10 -&lt; 30</td>
</tr>
<tr>
<td></td>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&lt; 10</td>
</tr>
<tr>
<td></td>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3</td>
<td>&gt;= 1 -&lt; 2.5</td>
</tr>
<tr>
<td></td>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>&lt; 1</td>
</tr>
</tbody>
</table>

### 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.
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If inhaled : If inhaled, remove to fresh air. Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

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

If swallowed : If swallowed, DO NOT induce vomiting.
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.
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.

5. FIREFIGHTING 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
Sulphur 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 firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment : Use personal protective equipment.
SAFEHANDLING ADVICE

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.

Conditions for safe storage: Keep in properly labelled 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.
## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of 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>NAB</td>
<td>10 mg/m³</td>
<td>ID OEL</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>NAB</td>
<td>10 mg/m³</td>
<td>ID OEL</td>
</tr>
</tbody>
</table>

Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals.

<table>
<thead>
<tr>
<th>Components</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>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Cellulose</td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>NAB</td>
<td>10 mg/m³</td>
<td>ID OEL</td>
</tr>
</tbody>
</table>

Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals.

TWA 10 mg/m³ (Titanium dioxide) ACGIH

### 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
- If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

#### Hand protection
- Chemical-resistant gloves

#### Remarks
- Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and 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.

<table>
<thead>
<tr>
<th>9. PHYSICAL AND CHEMICAL PROPERTIES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
</tr>
<tr>
<td><strong>Colour</strong></td>
</tr>
<tr>
<td><strong>Odour</strong></td>
</tr>
<tr>
<td><strong>Odour Threshold</strong></td>
</tr>
<tr>
<td><strong>pH</strong></td>
</tr>
<tr>
<td><strong>Melting point/freezing point</strong></td>
</tr>
<tr>
<td><strong>Initial boiling point and boiling range</strong></td>
</tr>
<tr>
<td><strong>Flash point</strong></td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
</tr>
<tr>
<td><strong>Flammability (solid, gas)</strong></td>
</tr>
<tr>
<td><strong>Flammability (liquids)</strong></td>
</tr>
<tr>
<td><strong>Upper explosion limit / Upper flammability limit</strong></td>
</tr>
<tr>
<td><strong>Lower explosion limit / Lower flammability limit</strong></td>
</tr>
<tr>
<td><strong>Vapour pressure</strong></td>
</tr>
<tr>
<td><strong>Relative vapour density</strong></td>
</tr>
<tr>
<td><strong>Density</strong></td>
</tr>
<tr>
<td><strong>Solubility(ies)</strong></td>
</tr>
<tr>
<td><strong>Water solubility</strong></td>
</tr>
<tr>
<td><strong>Partition coefficient: n-</strong></td>
</tr>
</tbody>
</table>
octanol/water
Auto-ignition 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

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.

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
                    LDLo (Rat, male): 1,000 mg/kg
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**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

**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
Remarks : Based on data from similar materials

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 sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Efavirenz:
Test Type : Maximisation Test
Exposure routes : Dermal
Species : Guinea pig
Assessment : Does not cause skin sensitisation.
Result : negative

Magnesium stearate:
Test Type : Maximisation Test
Exposure routes : 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 : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative
Remarks : Based on data from similar materials

**Titanium dioxide:**
Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Result : negative

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Efavirenz:**
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
                      Result: negative
                      Test Type: In vitro mammalian cell gene mutation test
                      Result: negative
                      Test Type: Chromosome aberration test in vitro
                      Result: negative
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:**
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
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

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

Titanium dioxide:  
Genotoxicity in vitro:  
Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Genotoxicity in vivo:  
Test Type: In vivo micronucleus test  
Species: Mouse  
Result: negative

Carcinogenicity  
Not classified based on available information.

Components:  
Efavirenz:  
Species: Mouse  
Application Route: Oral  
Exposure time: 2 Years  
Target Organs: Lungs, Liver  
Remarks: The mechanism or mode of action may not be relevant in humans.

Species: Rat  
Application Route: Oral  
Exposure time: 2 Years
Result: negative

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

**Sodium n-dodecyl sulfate:**
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Method: OECD Test Guideline 453
Result: negative
Remarks: Based on data from similar materials

**Titanium dioxide:**
Species: Rat
Application Route: Inhalation (dust/mist/fume)
Exposure time: 2 Years
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.

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 foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 50 mg/kg body weight
Result: Embryo-foetal toxicity

Test Type: Embryo-foetal development
Species: Monkey
Application Route: Oral
Developmental Toxicity: LOAEL: 60 mg/kg body weight
Symptoms: Malformations were observed.
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 foetal 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 foetal development*: Test Type: Embryo-foetal 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 foetal development*: Test Type: Embryo-foetal 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 yr
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 yr

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

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

M-Factor (Acute aquatic toxicity) : 1

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.066 mg/l
### Cellulose:

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

**M-Factor (Chronic aquatic toxicity)**
- 1

### 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

### Sodium n-dodecyl sulfate:

**Toxicity to fish**
- LC50 (Pimephales promelas (fathead minnow)): 29 mg/l
  - Exposure time: 96 h

**Toxicity to daphnia and other aquatic invertebrates**
- EC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l
  - Exposure time: 48 h
Toxicity to algae/aquatic plants: \( \text{ErC50} \) (\textit{Desmodesmus subspicatus} (green algae)): > 120 mg/l Exposure time: 72 h

NOEC (\textit{Desmodesmus subspicatus} (green algae)): 30 mg/l Exposure time: 72 h

Toxicity to fish (Chronic toxicity): NOEC (\textit{Pimephales promelas} (fathead minnow)): >= 1.357 mg/l Exposure time: 42 d

NOEC (\textit{Desmodesmus subspicatus} (green algae)): 30 mg/l Exposure time: 72 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (\textit{Ceriodaphnia dubia} (water flea)): 0.88 mg/l Exposure time: 7 d

Toxicity to microorganisms: EC50: 135 mg/l Exposure time: 3 h

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

Titanium dioxide:

Toxicity to fish: LC50 (\textit{Oncorhynchus mykiss} (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (\textit{Daphnia magna} (Water flea)): > 100 mg/l Exposure time: 48 h

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

Persistence and degradability

Components:

Efavirenz:


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 %

Method: OECD Test Guideline 209
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

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.

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
SAFETY DATA SHEET

Efavirenz Solid Formulation

Version: 1.19
Revision Date: 2021/04/09
SDS Number: 86794-00020
Date of last issue: 2020/10/10
Date of first issue: 2015/04/02

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
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.

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.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered: Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use: Not applicable
Prohibited substances: Not applicable
Restricted substances: Not applicable
Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision: Not applicable

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

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

16. OTHER INFORMATION

Further information

Date format: yyyy/mm/dd

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ID OEL: Indonesia. Occupational Exposure Limits

ACGIH / TWA: 8-hour, time-weighted average
ID OEL / NAB: Long term exposure limit

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evalua-
SAFETY DATA SHEET

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

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