SAFETY DATA SHEET

Efavirenz Solid Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Efavirenz Solid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company : MSD
               117 16th Road
               07033 Halfway house, Midrand, South Africa
   Telephone : +27 11 655 3000
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Acute toxicity, Category 4 : H302: Harmful if swallowed.
   Eye irritation, Category 2 : H319: Causes serious eye irritation.
   Reproductive toxicity, Category 1B : H360D: May damage the unborn child.
   Specific target organ toxicity - repeated exposure, Category 1 : H372: Causes damage to organs through prolonged or repeated exposure.
   Short-term (acute) aquatic hazard, Category 1 : H400: Very toxic to aquatic life.
   Long-term (chronic) aquatic hazard, Category 1 : H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms : ![Pictogram]
   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 through prolonged or repeated exposure.
H410   Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
P201   Obtain special instructions before use.
P260   Do not breathe dust.
P273   Avoid release to the environment.
P280   Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313  IF exposed or concerned: Get medical advice/attention.
P391   Collect spillage.

Hazardous components which must be listed on the label:
Efavirenz
Sodium n-dodecyl sulfate

2.3 Other hazards
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efavirenz</td>
<td>154598-52-4</td>
<td></td>
<td></td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox.4; H302</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Eye Irrit.2; H319</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Repr.1B; H360D</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>STOT RE1; H372</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aquatic Acute1;</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>H400</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aquatic Chronic1;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>M-Factor</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(Acute aquatic toxicity): 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity): 1</td>
</tr>
</tbody>
</table>

| Sodium n-dodecyl sulfate       | 151-21-3        | 205-788-1    |           | >= 1 - < 2,5          |
|                                |                 |              |           | Acute Tox.4; H302     |
|                                |                 |              |           | Eye Irrit.2; H315     |
|                                |                 |              |           | Eye Dam.1; H318       |
|                                |                 |              |           | Aquatic Chronic3;     |
|                                |                 |              |           | H412                  |

For explanation of abbreviations see section 16.
SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks:
- Harmful if swallowed.
- Causes serious eye irritation.
- May damage the unborn child.
- Causes damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment:
- Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

Unsuitable extinguishing media:
- None known.
5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

Environmental precautions: Discharge into the environment must be avoided. 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.

6.3 Methods and material for containment and cleaning up

Methods for 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.
6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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.
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.
Take care to prevent spills, waste and minimize release to the environment.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:
Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage:
Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

Specific use(s):
No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
</table>

5 / 19
## Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>285 mg/m³</td>
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<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>4060 mg/kg bw/day</td>
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<tr>
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<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>85 mg/m³</td>
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<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>2440 mg/kg bw/day</td>
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<tr>
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<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>24 mg/kg bw/day</td>
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## Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
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<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>Fresh water</td>
<td>0,176 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0,018 mg/l</td>
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<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1,35 mg/l</td>
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<tr>
<td></td>
<td>Fresh water sediment</td>
<td>6,97 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0,697 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>1,29 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>

### 8.2 Exposure controls

#### 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

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

**Hand protection**
Material: 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.

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).

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

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: powder
Colour: white to off-white
Odour: No data available
Odour 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.
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapour pressure: No data available
Relative vapour density: No data available
Density: No data available
Solubility(ies)

Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
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.

9.2 Other information

Flammability (liquids) : No data available
Molecular weight : No data available
Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Information on likely routes of : Inhalation
# SAFETY DATA SHEET

## 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>
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<td>3.2</td>
<td>09/13/2019</td>
<td>86804-00015</td>
<td>24.04.2019</td>
<td>02.04.2015</td>
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</table>

### Exposure

<table>
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<th>Channel</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Skin contact</td>
<td></td>
</tr>
<tr>
<td>Ingestion</td>
<td></td>
</tr>
<tr>
<td>Eye contact</td>
<td></td>
</tr>
</tbody>
</table>

### 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

- **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

### Skin corrosion/irritation

Not classified based on available information.

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

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

### Serious eye damage/eye irritation

Causes serious eye irritation.

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

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

Sodium n-dodecyl sulfate:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

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.

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
### Genotoxicity in vivo

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

**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

### 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.

**Test Type:** Embryo-foetal 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.

**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 through prolonged or repeated exposure.

**Components:**

**Efavirenz:**

Assessment: Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

**Efavirenz:**

**Species**

: Rat

**LOAEL**

: 50 mg/kg

**Exposure time**

: 3 Months

**Target Organs**

: Kidney

**Species**

: Monkey

**LOAEL**

: 100 mg/kg

**Exposure time**

: 1 - 2 yr

**Target Organs**

: Central nervous system, Liver, Kidney, Thyroid, Adrenal gland
Sodium n-dodecyl sulfate:
Species : Rat
NOAEL : 488 mg/kg
Application Route : Ingestion
Exposure time : 90 Days
Remarks : Based on data from similar materials

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Efavirenz:
Ingestion : Target Organs: Skin
Target Organs: Central nervous system
Symptoms: Dizziness, insomnia

SECTION 12: Ecological information

12.1 Toxicity

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: 0,066 mg/l
Exposure time: 33 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0,16 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity) : 1

**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** :
  - ErC50 (Desmodesmus subspicatus (green algae)): > 120 mg/l
  - NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l
  Exposure time: 72 h
- **Toxicity to microorganisms** : EC50: 135 mg/l
  Exposure time: 3 h
- **Toxicity to fish (Chronic toxicity)** :
  NOEC: ≥ 1,357 mg/l
  Exposure time: 42 d
  Species: Pimephales promelas (fathead minnow)
- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)** :
  NOEC: 0.88 mg/l
  Exposure time: 7 d
  Species: Ceriodaphnia dubia (water flea)

### 12.2 Persistence and degradability

**Components:**

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

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

### 12.3 Bioaccumulative potential

**Components:**

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

**Partition coefficient: n-** : log Pow: 5.4
octanol/water

**Sodium n-dodecyl sulfate:**
Partition coefficient: n-octanol/water

: log Pow: 0.83

### 12.4 Mobility in soil

**Components:**

**Efavirenz:**
Distribution among environmental compartments

: log Koc: 3.36

Method: FDA 3.08

### 12.5 Results of PBT and vPvB assessment

Not relevant

### 12.6 Other adverse effects

No data available

### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

**Product:**
Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

**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

#### 14.1 UN number

**ADN:**

: UN 3077

**ADR:**

: UN 3077

**RID:**

: UN 3077

**IMDG:**

: UN 3077

**IATA:**

: UN 3077

#### 14.2 UN proper shipping name

**ADN:**

: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Efavirenz)

**ADR:**

: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Efavirenz)

**RID:**

: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
## 14.3 Transport hazard class(es)

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<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
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<tr>
<td>9</td>
<td>9</td>
<td>9</td>
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</tbody>
</table>

## 14.4 Packing group

**ADN**
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9

**ADR**
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9
- Tunnel restriction code: (-)

**RID**
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9

**IMDG**
- Packing group: III
- Labels: 9
- EmS Code: F-A, S-F

**IATA (Cargo)**
- Packing instruction (cargo aircraft): 956
- Packing instruction (LQ): Y956
- Packing group: III
- Labels: Miscellaneous

**IATA (Passenger)**
- Packing instruction (passenger aircraft): 956
- Packing instruction (LQ): Y956
- Packing group: III
- Labels: Miscellaneous

## 14.5 Environmental hazards
ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

IATA (Passenger)
Environmentally hazardous : yes

IATA (Cargo)
Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements
H302 : Harmful if swallowed.
H315 : Causes skin irritation.
H318 : Causes serious eye damage.
H319 : Causes serious eye irritation.
H360D : May damage the unborn child.
H372 : Causes damage to organs through prolonged or repeated
SAFETY DATA SHEET
Efavirenz Solid Formulation

Version 3.2  Revision Date: 09/13/2019  SDS Number: 86804-00015  Date of last issue: 24.04.2019
Date of first issue: 02.04.2015

H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.
H412: Harmful to aquatic life with long lasting effects.

Full text of other abbreviations
Acute Tox.: Acute toxicity
Aquatic Acute: Short-term (acute) aquatic hazard
Aquatic Chronic: Long-term (chronic) aquatic hazard
Eye Dam.: Serious eye damage
Eye Irrit.: Eye irritation
Repr.: Reproductive toxicity
Skin Irrit.: Skin irritation
STOT RE: Specific target organ toxicity - repeated exposure
ZA OEL: South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
ZA OEL / TWA OEL-RL: Long term occupational exposure limits - recommended limit
ZA OEL / STEL OEL-RL: Short term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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

Efavirenz Solid Formulation

Classified Mixtures

<table>
<thead>
<tr>
<th>Classification of the mixture</th>
<th>Classification procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Tox. 4</td>
<td>H302</td>
</tr>
<tr>
<td>Eye Irrit. 2</td>
<td>H319</td>
</tr>
<tr>
<td>Repr. 1B</td>
<td>H360D</td>
</tr>
<tr>
<td>STOT RE 1</td>
<td>H372</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
</tr>
</tbody>
</table>

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.

ZA / EN