SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Efavirenz Solid Formulation

Version 3.6
Revision Date: 10.10.2020
SDS Number: 88523-00019
Date of last issue: 23.03.2020
Date of first issue: 02.04.2015

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
             Shotton Lane
             NE23 3JU Cramlington NU - Great Britain
   Telephone : 44 1 670 59 30 00
   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 : 
   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

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Concentration (% w/w)</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Efavirenz</td>
<td>154598-52-4</td>
<td></td>
<td></td>
<td></td>
<td>&gt;= 30 - &lt; 50</td>
<td>Acute Tox. 4; H302 Eye Irrit. 2; H319 Repr. 1B; H360D STOT RE 1; H372 (Central nervous system, Skin) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1</td>
</tr>
<tr>
<td></td>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3 205-788-1</td>
<td></td>
<td></td>
<td></td>
<td>&gt;= 1 - &lt; 2.5</td>
<td>Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Aquatic Chronic 3;</td>
</tr>
</tbody>
</table>
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.
<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>3.6</td>
<td>10.10.2020</td>
<td>88523-00019</td>
<td>23.03.2020</td>
<td>02.04.2015</td>
</tr>
</tbody>
</table>

Carbon dioxide (CO2)  
Dry chemical  

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 (see section 7) and personal protective equipment recommendations (see section 8).  

6.2 Environmental precautions  
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.  

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 dis-
posal 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. 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.

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

### Occupational Exposure Limits

<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>
<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 (inhalable dust)</td>
<td>10 mg/m³</td>
<td>GB EH40</td>
</tr>
</tbody>
</table>

Further information: For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols. The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m⁻³ 8-hour TWA of inhalable dust or 4 mg.m⁻³ 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits. Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed 'inhalable' and 'respirable'. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4. Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with.

| TWA (Respirable dust) | 4 mg/m³ | GB EH40 |

Further information: For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols. The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m⁻³ 8-hour TWA of inhalable dust or 4 mg.m⁻³ 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits. Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed 'inhalable' and 'respirable'. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the.
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>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>4060 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>85 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>2440 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>24 mg/kg bw/day</td>
</tr>
</tbody>
</table>

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</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>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1.35 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>6.97 mg/kg dry weight</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.697 mg/kg dry weight</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>1.29 mg/kg dry weight</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
- Equipment should conform to BS EN 166

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.

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.

- Equipment should conform to BS EN 143

Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>white to off-white</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Efavirenz Solid Formulation

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 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

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

Genotoxicity in vivo:  
Test Type: In vitro mammalian cell gene mutation test  
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

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

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.
Efavirenz Solid Formulation

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

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
Symptoms: Rash
Target Organs: Central nervous system
Symptoms: Dizziness, insomnia
Target Organs: Heart
Symptoms: irregular heart beat
SECTION 12: Ecological information

12.1 Toxicity

Components:

Efavirenz:
- Toxicity to fish: \( LC_{50} \) (\( Lepomis macrochirus \) (Bluegill sunfish)): 0.85 mg/l
  Exposure time: 96 h
  Method: FDA 4.11

- Toxicity to daphnia and other aquatic invertebrates: \( EC_{50} \) (\( Daphnia magna \) (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: \( LC_{50} \) (\( Pimephales promelas \) (fathead minnow)): 29 mg/l
  Exposure time: 96 h

- Toxicity to daphnia and other aquatic invertebrates: \( EC_{50} \) (\( Ceriodaphnia dubia \) (water flea)): 5.55 mg/l
  Exposure time: 48 h

- Toxicity to algae/aquatic plants: \( ErC_{50} \) (\( Desmodesmus subspicatus \) (green algae)): > 120 mg/l
  Exposure time: 72 h
  NOEC (\( Desmodesmus subspicatus \) (green algae)): 30 mg/l
  Exposure time: 72 h

- Toxicity to microorganisms: \( EC_{50} \): 135 mg/l
  Exposure time: 3 h
Toxicity to fish (Chronic toxicity): NOEC: \( \geq 1.357 \, \text{mg/l} \)
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-octanol/water: \( \log \text{Pow}: 5.4 \)

**Sodium n-dodecyl sulfate:**
- **Partition coefficient: n-octanol/water:** \( \log \text{Pow}: 0.83 \)

### 12.4 Mobility in soil

**Components:**

**Efavirenz:**
- Distribution among environmental compartments: \( \log \text{Koc}: 3.36 \)
  - 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. (Efavirenz)
- **IMDG** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Efavirenz)
- **IATA** : Environmentally hazardous substance, solid, n.o.s. (Efavirenz)

14.3 Transport hazard class(es)
- **ADN** : 9
- **ADR** : 9
- **RID** : 9
- **IMDG** : 9
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)**
Efavirenz Solid Formulation

Environmetally 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**

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)  :  Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).  :  Not applicable

REACH - List of substances subject to authorisation (Annex XIV)  :  Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer  :  Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast)  :  Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals


<table>
<thead>
<tr>
<th>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>100 t</td>
<td>200 t</td>
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</tbody>
</table>

**Other regulations:**

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

**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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Efavirenz Solid Formulation

Version 3.6 Revision Date: 10.10.2020 SDS Number: 88523-00019 Date of last issue: 23.03.2020

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 exposure.
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
GB EH40 : UK EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL : Short-term exposure limit (15-minute reference period)

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; AIIC - Australian Inventory of Industrial Chemicals; 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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Efavirenz Solid Formulation

Version 3.6  Revision Date: 10.10.2020  SDS Number: 88523-00019  Date of last issue: 23.03.2020

Further information

Classification of the mixture:

| Acute Tox. 4 | Eye Irrit. 2 | Repr. 1B | STOT RE 1 | Aquatic Acute 1 | Aquatic Chronic 1 |
| H302 | H319 | H360D | H372 | H400 | H410 |

Classification procedure:
Calculation method

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.

GB / EN