SAFETY DATA SHEET

Efavirenz Liquid Formulation

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

1.1 Product identifier
Trade name : Efavirenz Liquid 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)
Reproductive toxicity, Category 1B H360D: May damage the unborn child.
Specific target organ toxicity - repeated exposure, Category 2 H373: May cause damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 2 H411: 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 : H360D May damage the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure.
H411 Toxic to aquatic life with long lasting effects.
Precautionary statements:

Prevention:
P201 Obtain special instructions before use.
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.

Storage:
P405 Store locked up.

Hazardous components which must be listed on the label:
Efavirenz

2.3 Other hazards
None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efavirenz</td>
<td>154598-52-4</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>
<td>&gt;= 2.5 - &lt; 10</td>
</tr>
</tbody>
</table>

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.
SAFETY DATA SHEET
Efavirenz Liquid Formulation

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 soap and 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: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed
Risks: May damage the unborn child. May cause 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: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides

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

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.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
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:

Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
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:

See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

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 mist or vapours.
Do not swallow.
Avoid contact with 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.
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>
</tbody>
</table>

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>Glycerides, mixed decanoyl and octanoyl</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>177,79 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>25,21 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>43,84 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>12,61 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic</td>
<td>12,61 mg/kg</td>
</tr>
</tbody>
</table>
**SAFETY DATA SHEET**

**Efavirenz Liquid Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5</td>
<td>10.10.2020</td>
<td>86845-00017</td>
<td>01.04.2020</td>
<td>01.04.2015</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>Glycerides, mixed decanoyl and octanoyl</td>
<td>Oral (Secondary Poisoning)</td>
<td>0.03 mg/kg food</td>
</tr>
</tbody>
</table>

### 8.2 Exposure controls

#### Engineering measures

Minimize workplace exposure concentrations.

If sufficient ventilation is unavailable, use with local exhaust ventilation.

#### Personal protective equipment

**Eye protection**

Wear the following personal protective equipment:

- Safety glasses

**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**: Combined particulates and organic vapour type (A-P)

---

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

- **Appearance**: liquid
- **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
SAFETY DATA SHEET

Efavirenz Liquid Formulation

<table>
<thead>
<tr>
<th>Version</th>
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</tr>
</tbody>
</table>

Flammability (solid, gas) : Not applicable

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 : Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : None known.
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
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Components:
Efavirenz:
Acute oral toxicity:
LD50 (Rat, female): 419 mg/kg
LDLo (Rat, male): 1.000 mg/kg

Skin corrosion/irritation
Not classified based on available information.

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

Serious eye damage/eye irritation
Not classified based on available information.

Components:
Efavirenz:
Remarks: Moderate 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

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.

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
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:
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.

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs 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

**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: 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

12.2 Persistence and degradability

Components:

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

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 Pow: 5.4

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 3082 |
| ADR  | : | UN 3082 |
| RID  | : | UN 3082 |
| IMDG | : | UN 3082 |
| IATA | : | UN 3082 |

14.2 UN proper shipping name

| ADN  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Efavirenz) |
| ADR  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Efavirenz) |
| RID  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Efavirenz) |
| IMDG | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Efavirenz) |
| IATA | : | Environmentally hazardous substance, liquid, n.o.s. (Efavirenz) |

14.3 Transport hazard class(es)

| ADN  | : | 9 |
| ADR  | : | 9 |
| RID  | : | 9 |
| IMDG | : | 9 |
| IATA | : | 9 |

14.4 Packing group

| ADN  | : | III |
| ADR  | : | M6 |
| Hazard Identification Number | : | 90 |
| Labels | : | 9 |
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.
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.

Full text of other abbreviations

Acute Tox.: Acute toxicity
Aquatic Acute: Short-term (acute) aquatic hazard
Aquatic Chronic: Long-term (chronic) aquatic hazard
Eye Irrit.: Eye irritation
Repr.: Reproductive toxicity
STOT RE: Specific target organ toxicity - repeated exposure

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.
Further information

Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification procedure:</th>
<th>Classification of the mixture:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repr. 1B</td>
<td>H360D</td>
</tr>
<tr>
<td>STOT RE 2</td>
<td>H373</td>
</tr>
<tr>
<td>Aquatic Chronic 2</td>
<td>H411</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