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
              Kilsheean
              Clonmel Tipperary, IE
   Telephone : 353-51-601000
   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:
Hazardous components which must be listed on the label:

Efavirenz

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effavirenz</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</td>
<td>&gt;= 2.5 - &lt; 10</td>
<td></td>
<td></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 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

aquatic toxicity): 1

For explanation of abbreviations see section 16.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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>2.8</td>
<td>27.08.2021</td>
<td>88186-00020</td>
<td>09.04.2021</td>
<td>01.04.2015</td>
</tr>
</tbody>
</table>

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 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. 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.
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

<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-</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 effects</td>
<td>12.61 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>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
                   Equipment should conform to NS 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. 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.
                         Equipment should conform to NS EN 14387
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

- **Physical state**: liquid
- **Colour**: white to off-white
- **Odour**: No data available
- **Odour Threshold**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flammability (solid, gas)**: Not applicable
- **Flammability (liquids)**: No data available
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Flash point**: No data available
- **Auto-ignition temperature**: No data available
- ** Decomposition temperature**: No data available
- **pH**: No data available
- **Viscosity**: No data available
  - **Viscosity, dynamic**: No data available
  - **Viscosity, kinematic**: No data available
- **Solubility(ies)**: No data available
  - **Water solubility**: No data available
- **Partition coefficient: n-octanol/water**: No data available
- **Vapour pressure**: No data available
- **Density**: No data available
- **Relative vapour density**: No data available
- **Particle characteristics**: No data available
  - **Particle size**: No data available

9.2 Other information

- **Explosives**: Not explosive
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 hazard classes as defined in Regulation (EC) No 1272/2008
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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Efavirenz Liquid Formulation

Version 2.8
Revision Date: 27.08.2021
SDS Number: 88186-00020
Date of last issue: 09.04.2021
Date of first issue: 01.04.2015

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

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


EFAVIRENZ LIQUID 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

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

**Product:**
- **Assessment**: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
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

Product:
Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:
Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available
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.

14.1 UN number or ID number

<table>
<thead>
<tr>
<th></th>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>UN 3082</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADR</td>
<td>UN 3082</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RID</td>
<td>UN 3082</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IMDG</td>
<td>UN 3082</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IATA</td>
<td>UN 3082</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th></th>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Efavirenz)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADR</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Efavirenz)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RID</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Efavirenz)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IMDG</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Efavirenz)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IATA</td>
<td>Environmentally hazardous substance, liquid, n.o.s. (Efavirenz)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

14.3 Transport hazard class(es)

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

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

Efavirenz Liquid Formulation

Version 2.8  Revision Date: 27.08.2021  SDS Number: 88186-00020  Date of last issue: 09.04.2021
Date of first issue: 01.04.2015

ADN
Packing group: III
Classification Code: M6
Hazard Identification Number: 90
Labels: 9

ADR
Packing group: III
Classification Code: M6
Hazard Identification Number: 90
Labels: 9
Tunnel restriction code: (-)

RID
Packing group: III
Classification Code: M6
Hazard Identification Number: 90
Labels: 9

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

IATA (Cargo)
Packing instruction (cargo aircraft): 964
Packing instruction (LQ): Y964
Packing group: III
Labels: Miscellaneous

IATA (Passenger)
Packing instruction (passenger aircraft): 964
Packing instruction (LQ): Y964
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 Maritime transport in bulk according to IMO instruments
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) : Conditions of restriction for the following entries should be considered: Number on list 3
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 : Not applicable

<table>
<thead>
<tr>
<th>E2</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>200 t</td>
<td>500 t</td>
</tr>
</tbody>
</table>

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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 Liquid Formulation  

Version  
2.8  
Revision Date:  
27.08.2021  
SDS Number:  
88186-00020  
Date of last issue:  
09.04.2021  
Date of first issue:  
01.04.2015  

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 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 - 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;  
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;  
TECI - Thailand Existing Chemicals 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.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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>2.8</td>
<td>27.08.2021</td>
<td>88186-00020</td>
<td>09.04.2021</td>
<td>01.04.2015</td>
</tr>
</tbody>
</table>

Further information

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

Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Code</th>
<th>Calculation method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repr. 1B</td>
<td>H360D</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT RE 2</td>
<td>H373</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 2</td>
<td>H411</td>
<td>Calculation method</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.

NO / EN