

**Efavirenz Solid Formulation**

Version 5.0      Revision Date: 04.04.2023      SDS Number: 86787-00024      Date of last issue: 01.10.2022  
Date of first issue: 02.04.2015

---

**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Efavirenz Solid Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : Rua Coronel Bento Soares, 530  
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical

Restrictions on use :  
Not applicable

---

**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification in accordance with ABNT NBR 14725 Standard**

Acute toxicity (Oral) : Category 4

Skin irritation : Category 3

Eye irritation : Category 2A

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure : Category 1 (Central nervous system, Skin)

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

**GHS label elements in accordance with ABNT NBR 14725 Standard**

Hazard pictograms :



Signal Word : Danger

---

## Efavirenz Solid Formulation

Version 5.0      Revision Date: 04.04.2023      SDS Number: 86787-00024      Date of last issue: 01.10.2022  
 Date of first issue: 02.04.2015

Hazard Statements : H302 Harmful if swallowed.  
 H316 Causes mild skin irritation.  
 H319 Causes serious eye irritation.  
 H360D May damage the unborn child.  
 H372 Causes damage to organs (Central nervous system, Skin) through prolonged or repeated exposure.  
 H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements : **Prevention:**  
 P201 Obtain special instructions before use.  
 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.

**Other hazards which do not result in classification**

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

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Efavirenz	154598-52-4	Acute toxicity (Oral), Category 4 Eye irritation, Category 2B Reproductive toxicity, Category 1B Specific target organ toxicity - repeated exposure (Central nervous system, Skin), Category 1 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1	>= 30 -< 50
Cellulose	9004-34-6		>= 10 -< 20
Magnesium stearate	557-04-0		>= 1 -< 5
Sodium n-dodecyl sulfate	151-21-3	Acute toxicity (Oral), Category 4 Skin irritation, Category 2	>= 1 -< 2,5

## Efavirenz Solid Formulation

Version 5.0      Revision Date: 04.04.2023      SDS Number: 86787-00024      Date of last issue: 01.10.2022  
 Date of first issue: 02.04.2015

		Serious eye damage, Category 1 Short-term (acute) aquatic hazard, Category 2 Long-term (chronic) aquatic hazard, Category 3	
Titanium dioxide	13463-67-7	Carcinogenicity (Inhalation), Category 2	$\geq 0,1$ - $< 1$

## SECTION 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.  
If easy to do, remove contact lens, if worn.  
Get medical attention.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.  
Never give anything by mouth to an unconscious person.
- Most important symptoms and effects, both acute and delayed : Harmful if swallowed.  
Causes mild skin irritation.  
Causes serious eye irritation.  
May damage the unborn child.  
Causes damage to organs through prolonged or repeated exposure.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

## SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.

## Efavirenz Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
5.0	04.04.2023	86787-00024	Date of first issue: 02.04.2015

---

- Specific hazards during fire fighting : 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  
Sulfur oxides
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
- Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
- 

### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- 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.
- Methods and materials for containment and 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.
- 

### SECTION 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing. Do not breathe dust.
-

## Efavirenz Solid Formulation

Version 5.0      Revision Date: 04.04.2023      SDS Number: 86787-00024      Date of last issue: 01.10.2022  
 Date of first issue: 02.04.2015

- 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.
- Conditions for safe storage : Wash contaminated clothing before re-use.  
 Keep in properly labeled containers.  
 Store locked up.  
 Keep tightly closed.  
 Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
 Strong oxidizing agents  
 Self-reactive substances and mixtures  
 Organic peroxides  
 Explosives  
 Gases

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Efavirenz	154598-52-4	TWA	100 µg/m <sup>3</sup>	Internal
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
Magnesium stearate	557-04-0	TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
Titanium dioxide	13463-67-7	TWA (Respirable particulate matter)	2,5 mg/m <sup>3</sup> (Titanium dioxide)	ACGIH

- Engineering measures : Minimize workplace exposure concentrations.  
 Apply measures to prevent dust explosions.

## Efavirenz Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
5.0	04.04.2023	86787-00024	Date of first issue: 02.04.2015

---

Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). If sufficient ventilation is unavailable, use with local exhaust ventilation.

### Personal protective equipment

- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Particulates type
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.
- Eye protection : Wear the following personal protective equipment:  
Safety goggles
- Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.  
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

---

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : powder
- Color : white to off-white
- Odor : No data available
- Odor 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.

## Efavirenz Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
5.0	04.04.2023	86787-00024	Date of first issue: 02.04.2015

---

Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available

---

### SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

---

### SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of	:	Inhalation
---------------------------------	---	------------





## Efavirenz Solid Formulation

Version 5.0      Revision Date: 04.04.2023      SDS Number: 86787-00024      Date of last issue: 01.10.2022  
 Date of first issue: 02.04.2015

|||      tion toxicity

**Skin corrosion/irritation**

Causes mild skin irritation.

**Components:****Efavirenz:**

||| Result : Mild skin irritation  
 ||| Remarks : slight irritation

**Magnesium stearate:**

||| Species : Rabbit  
 ||| Result : No skin irritation  
 ||| Remarks : Based on data from similar materials

**Sodium n-dodecyl sulfate:**

||| Species : Rabbit  
 ||| Result : Skin irritation

**Titanium dioxide:**

||| Species : Rabbit  
 ||| Result : No skin irritation

**Serious eye damage/eye irritation**

Causes serious eye irritation.

**Components:****Efavirenz:**

||| Remarks : Moderate eye irritation

**Magnesium stearate:**

||| Species : Rabbit  
 ||| Result : No eye irritation  
 ||| Remarks : Based on data from similar materials

**Sodium n-dodecyl sulfate:**

||| Species : Rabbit  
 ||| Result : Irreversible effects on the eye  
 ||| Method : OECD Test Guideline 405

**Titanium dioxide:**

||| Species : Rabbit  
 ||| Result : No eye irritation

## Efavirenz Solid Formulation

Version 5.0      Revision Date: 04.04.2023      SDS Number: 86787-00024      Date of last issue: 01.10.2022  
 Date of first issue: 02.04.2015

---

### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

#### Components:

##### Efavirenz:

Test Type	: Maximization Test
Routes of exposure	: Dermal
Species	: Guinea pig
Assessment	: Does not cause skin sensitization.
Result	: negative

##### Magnesium stearate:

Test Type	: Maximization Test
Routes of exposure	: Skin contact
Species	: Guinea pig
Method	: OECD Test Guideline 406
Result	: negative
Remarks	: Based on data from similar materials

##### Sodium n-dodecyl sulfate:

Test Type	: Maximization Test
Routes of exposure	: Skin contact
Species	: Guinea pig
Result	: negative
Remarks	: Based on data from similar materials

##### Titanium dioxide:

Test Type	: Local lymph node assay (LLNA)
Routes of exposure	: Skin contact
Species	: Mouse
Result	: negative

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### Efavirenz:

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

## Efavirenz Solid Formulation

Version 5.0      Revision Date: 04.04.2023      SDS Number: 86787-00024      Date of last issue: 01.10.2022  
 Date of first issue: 02.04.2015

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
 Species: Mouse  
 Application Route: Oral  
 Result: negative

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

**Cellulose:**

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

Test Type: In vitro mammalian cell gene mutation test  
 Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
 Species: Mouse  
 Application Route: Ingestion  
 Result: negative

**Magnesium stearate:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
 Result: negative  
 Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro  
 Method: OECD Test Guideline 473  
 Result: negative  
 Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)  
 Result: negative  
 Remarks: Based on data from similar materials

**Sodium n-dodecyl sulfate:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
 Method: OECD Test Guideline 471  
 Result: negative

Test Type: In vitro mammalian cell gene mutation test  
 Result: negative

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

**Titanium dioxide:**

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

## Efavirenz Solid Formulation

Version 5.0      Revision Date: 04.04.2023      SDS Number: 86787-00024      Date of last issue: 01.10.2022  
 Date of first issue: 02.04.2015

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

**Carcinogenicity**

Not classified based on available information.

**Components:****Efavirenz:**

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

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

**Cellulose:**

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

**Sodium n-dodecyl sulfate:**

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

**Titanium dioxide:**

Species : Rat  
 Application Route : inhalation (dust/mist/fume)  
 Exposure time : 2 Years  
 Method : OECD Test Guideline 453  
 Result : positive  
 Remarks : The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in inhalation studies with animals.

**Reproductive toxicity**

May damage the unborn child.

## Efavirenz Solid Formulation

Version 5.0      Revision Date: 04.04.2023      SDS Number: 86787-00024      Date of last issue: 01.10.2022  
 Date of first issue: 02.04.2015

### Components:

#### **Efavirenz:**

- |                                    |   |   |
|------------------------------------|---|---|
| Effects on fertility               | : | Species: Rat, male and female<br>Application Route: Oral<br>Fertility: NOAEL: 200 - 400 mg/kg body weight<br>Result: No effects on fertility and early embryonic development were detected. |
| Effects on fetal development       | : | Test Type: Embryo-fetal development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 50 mg/kg body weight<br>Result: Embryo-fetal toxicity.                     |
|                                    |   | Test Type: Embryo-fetal development<br>Species: Monkey<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 60 mg/kg body weight<br>Symptoms: Malformations were observed.          |
|                                    |   | Test Type: Embryo-fetal development<br>Species: Rabbit<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 75 mg/kg body weight<br>Result: No embryotoxic effects.                 |
| Reproductive toxicity - Assessment | : | Clear evidence of adverse effects on development, based on animal experiments.  |

#### **Cellulose:**

- |                              |   |   |
|------------------------------|---|---|
| Effects on fertility         | : | Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |
| Effects on fetal development | : | Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative      |

#### **Magnesium stearate:**

- |                              |   |  |
|------------------------------|---|--|
| Effects on fertility         | : | Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test<br>Species: Rat<br>Application Route: Ingestion<br>Method: OECD Test Guideline 422<br>Result: negative<br>Remarks: Based on data from similar materials |
| Effects on fetal development | : | Test Type: Embryo-fetal development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative  |

## Efavirenz Solid Formulation

Version 5.0      Revision Date: 04.04.2023      SDS Number: 86787-00024      Date of last issue: 01.10.2022  
 Date of first issue: 02.04.2015

Remarks: Based on data from similar materials

**Sodium n-dodecyl sulfate:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
 Species: Rat  
 Application Route: Ingestion  
 Method: OECD Test Guideline 416  
 Result: negative  
 Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative  
 Remarks: Based on data from similar materials

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

Causes damage to organs (Central nervous system, Skin) through prolonged or repeated exposure.

**Components:****Efavirenz:**

Target Organs : Central nervous system  
 Assessment : Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****Efavirenz:**

Species : Rat  
 LOAEL : 50 mg/kg  
 Application Route : Oral  
 Exposure time : 3 Months  
 Target Organs : Kidney

Species : Monkey  
 LOAEL : 100 mg/kg  
 Application Route : Oral  
 Exposure time : 1 - 2 y  
 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

**Efavirenz Solid Formulation**

Version 5.0      Revision Date: 04.04.2023      SDS Number: 86787-00024      Date of last issue: 01.10.2022  
Date of first issue: 02.04.2015

---

**Cellulose:**

Species : Rat  
NOAEL : >= 9.000 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

**Magnesium stearate:**

Species : Rat  
NOAEL : > 100 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days  
Remarks : Based on data from similar materials

**Sodium n-dodecyl sulfate:**

Species : Rat  
NOAEL : 488 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days  
Remarks : Based on data from similar materials

**Titanium dioxide:**

Species : Rat  
NOAEL : 24.000 mg/kg  
Application Route : Ingestion  
Exposure time : 28 Days

Species : Rat  
NOAEL : 10 mg/m<sup>3</sup>  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 2 y

**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

## Efavirenz Solid Formulation

Version 5.0      Revision Date: 04.04.2023      SDS Number: 86787-00024      Date of last issue: 01.10.2022  
 Date of first issue: 02.04.2015

## SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity****Components:****Efavirenz:**

Toxicity to fish	:	LC50 ( <i>Lepomis macrochirus</i> (Bluegill sunfish)): 0,85 mg/l Exposure time: 96 h Method: FDA 4.11
Toxicity to daphnia and other aquatic invertebrates	:	EC50 ( <i>Daphnia magna</i> (Water flea)): 1,1 mg/l Exposure time: 48 h Method: FDA 4.08
Toxicity to algae/aquatic plants	:	NOEC ( <i>Selenastrum capricornutum</i> (green algae)): 0,026 mg/l Exposure time: 12 d Method: FDA 4.01  NOEC ( <i>Microcystis aeruginosa</i> (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 ( <i>Pimephales promelas</i> (fathead minnow)): 0,066 mg/l Exposure time: 33 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC ( <i>Daphnia magna</i> (Water flea)): 0,16 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	:	1

**Cellulose:**

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

**Magnesium stearate:**

Toxicity to fish	:	LC50 ( <i>Leuciscus idus</i> (Golden orfe)): > 100 mg/l Exposure time: 48 h Method: DIN 38412 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EL50 ( <i>Daphnia magna</i> (Water flea)): > 1 mg/l Exposure time: 47 h Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.2. Remarks: Based on data from similar materials No toxicity at the limit of solubility.



## Efavirenz Solid Formulation

Version 5.0      Revision Date: 04.04.2023      SDS Number: 86787-00024      Date of last issue: 01.10.2022  
Date of first issue: 02.04.2015

Toxicity to algae/aquatic plants	: EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials No toxicity at the limit of solubility.
	NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
Toxicity to microorganisms	: EC10 (Pseudomonas putida): > 100 mg/l Exposure time: 16 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

**Sodium n-dodecyl sulfate:**

Toxicity to fish	: LC50 (Pimephales promelas (fathead minnow)): 29 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Ceriodaphnia dubia (water flea)): 5,55 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	: ErC50 (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 fish (Chronic toxicity)	: NOEC (Pimephales promelas (fathead minnow)): >= 1,357 mg/l Exposure time: 42 d
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Ceriodaphnia dubia (water flea)): 0,88 mg/l Exposure time: 7 d
Toxicity to microorganisms	: EC50: 135 mg/l Exposure time: 3 h

**Titanium dioxide:**

Toxicity to fish	: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	: EC50 (Skeletonema costatum (marine diatom)): > 10.000 mg/l Exposure time: 72 h

## Efavirenz Solid Formulation

Version 5.0      Revision Date: 04.04.2023      SDS Number: 86787-00024      Date of last issue: 01.10.2022  
Date of first issue: 02.04.2015

---

|| Toxicity to microorganisms : EC50: > 1.000 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209

**Persistence and degradability****Components:****Efavirenz:**

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

**Cellulose:**

|| Biodegradability : Result: Readily biodegradable.

**Magnesium stearate:**

|| Biodegradability : Result: Not biodegradable  
Remarks: Based on data from similar materials

**Sodium n-dodecyl sulfate:**

|| Biodegradability : Result: Readily biodegradable.  
Biodegradation: 95 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

**Bioaccumulative potential****Components:****Efavirenz:**

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

|| Partition coefficient: n-octanol/water : log Pow: 5,4

**Magnesium stearate:**

|| Partition coefficient: n-octanol/water : log Pow: > 4

**Sodium n-dodecyl sulfate:**

|| Partition coefficient: n-octanol/water : log Pow: 0,83

**Mobility in soil****Components:****Efavirenz:**

|| Distribution among environ- : log Koc: 3,36

## Efavirenz Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
5.0	04.04.2023	86787-00024	Date of first issue: 02.04.2015

---

|| mental compartments                      Method: FDA 3.08

### Other adverse effects

No data available

---

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

|| Waste from residues                      : Dispose of in accordance with local regulations.  
Do not dispose of waste into sewer.

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

### International Regulations

#### UNRTDG

UN number                                    : UN 3077  
Proper shipping name                      : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,  
N.O.S.  
(Efavirenz)  
Class    : 9  
Packing group                                : III  
Labels                                         : 9

#### IATA-DGR

UN/ID No.                                    : UN 3077  
Proper shipping name                      : Environmentally hazardous substance, solid, n.o.s.  
(Efavirenz)  
Class    : 9  
Packing group                                : III  
Labels                                         : Miscellaneous  
Packing instruction (cargo aircraft)    : 956  
Packing instruction (passenger aircraft) : 956  
Environmentally hazardous               : yes

#### IMDG-Code

UN number                                    : UN 3077  
Proper shipping name                      : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,  
N.O.S.  
(Efavirenz)  
Class    : 9  
Packing group                                : III  
Labels                                         : 9  
EmS Code                                     : F-A, S-F  
Marine pollutant                             : yes

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Domestic regulation



**Efavirenz Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
5.0	04.04.2023	86787-00024	Date of first issue: 02.04.2015

---

ACGIH / TWA : 8-hour, time-weighted average

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

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.

BR / Z8