

**Efavirenz Solid Formulation**

Version 7.0      Revision Date: 04.04.2023      SDS Number: 86785-00024      Date of last issue: 01.10.2022  
Date of first issue: 02.04.2015

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**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Efavirenz Solid Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : Building A - Level 1/26 Talavera Rd  
Macquarie Park NSW, Australia 2113

Telephone : 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Pharmaceutical

Restrictions on use :  
Not applicable

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**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Acute toxicity (Oral) : Category 4

Serious eye damage/eye irritation : Category 2A

Reproductive toxicity : Category 1B

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

**GHS label elements**

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 (Central nervous system, Skin) through prolonged or repeated exposure.

Precautionary statements : **Prevention:**

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P201 Obtain special instructions before use.  
 P202 Do not handle until all safety precautions have been read and understood.  
 P260 Do not breathe dust.  
 P264 Wash skin thoroughly after handling.  
 P270 Do not eat, drink or smoke when using this product.  
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.  
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
 P337 + P313 If eye irritation persists: Get medical advice/ attention.

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**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.     | Concentration (% w/w) |
|--------------------------|-------------|-----------------------|
| Efavirenz                | 154598-52-4 | >= 30 -< 60           |
| Cellulose                | 9004-34-6   | >= 10 -< 30           |
| Magnesium stearate       | 557-04-0    | < 10                  |
| Sodium n-dodecyl sulfate | 151-21-3    | >= 1 -< 3             |
| Titanium dioxide         | 13463-67-7  | < 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.

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|                                                             |   |                                                                                                                                                                                                                                           |
|-------------------------------------------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| In case of eye contact                                      | : | Wash clothing before reuse.<br>Thoroughly clean shoes before reuse.<br>In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention. |
| If swallowed                                                | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.<br>Never give anything by mouth to an unconscious person.                                                                           |
| Most important symptoms and effects, both acute and delayed | : | Harmful if swallowed.<br>Causes serious eye irritation.<br>May damage the unborn child.<br>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.                                                                                                                                                                                                   |

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**SECTION 5. FIREFIGHTING MEASURES**

|                                               |   |                                                                                                                                                                                                                                                 |
|-----------------------------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Suitable extinguishing media                  | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical                                                                                                                                                      |
| Unsuitable extinguishing media                | : | None known.                                                                                                                                                                                                                                     |
| 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.<br>Exposure to combustion products may be a hazard to health.                   |
| Hazardous combustion products                 | : | Carbon oxides<br>Metal oxides<br>Sulphur oxides                                                                                                                                                                                                 |
| Specific extinguishing methods                | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.                                                                                                                                            |
| Hazchem Code                                  | : | 2Z                                                                                                                                                                                                                                              |

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**SECTION 6. ACCIDENTAL RELEASE MEASURES**

|                                                                     |   |                                                                                                                                                      |
|---------------------------------------------------------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions                                           | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.                                                           |

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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.  
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.

Conditions for safe storage : Keep in properly labelled 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

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## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Components with workplace control parameters

| Components         | CAS-No.     | Value type<br>(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>                           | AU OEL   |
|                    |             | TWA                                 | 10 mg/m <sup>3</sup>                           | ACGIH    |
| Magnesium stearate | 557-04-0    | TWA                                 | 10 mg/m <sup>3</sup>                           | AU OEL   |
|                    |             | 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                                 | 10 mg/m <sup>3</sup>                           | AU OEL   |
|                    |             | TWA (Respirable particulate matter) | 2.5 mg/m <sup>3</sup><br>(Titanium dioxide)    | ACGIH    |

**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**

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 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.

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

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potential.  
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

|                                                  |   |                                                                                 |
|--------------------------------------------------|---|---------------------------------------------------------------------------------|
| Appearance                                       | : | powder                                                                          |
| Colour                                           | : | white to off-white                                                              |
| Odour                                            | : | No data available                                                               |
| Odour Threshold                                  | : | No data available                                                               |
| pH                                               | : | No data available                                                               |
| Melting point/freezing point                     | : | No data available                                                               |
| Initial boiling point and boiling range          | : | No data available                                                               |
| Flash point                                      | : | No data available                                                               |
| Evaporation rate                                 | : | No data available                                                               |
| Flammability (solid, gas)                        | : | May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids)                           | : | No data available                                                               |
| 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                                                               |

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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

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**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.

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**SECTION 11. TOXICOLOGICAL INFORMATION**

Exposure routes : 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

**Cellulose:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

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**Magnesium stearate:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
 Method: OECD Test Guideline 423  
 Assessment: The substance or mixture has no acute oral toxicity  
 Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
 Remarks: Based on data from similar materials

**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

**Titanium dioxide:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l  
 Exposure time: 4 h  
 Test atmosphere: dust/mist  
 Assessment: The substance or mixture has no acute inhalation toxicity

**Skin corrosion/irritation**

Not classified based on available information.

**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



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### 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

### 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

##### Magnesium stearate:

Test Type : Maximisation Test  
 Exposure routes : 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 : Maximisation Test  
 Exposure routes : Skin contact  
 Species : Guinea pig  
 Result : negative

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Remarks : Based on data from similar materials

**Titanium dioxide:**

Test Type : Local lymph node assay (LLNA)  
 Exposure routes : Skin contact  
 Species : Mouse  
 Result : negative

**Chronic toxicity****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.

**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

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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

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

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**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.

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

Effects on fertility : Species: Rat, male and female  
 Application Route: Oral  
 Fertility: NOAEL: 200 - 400 mg/kg body weight  
 Result: No effects on fertility and early embryonic development were detected.

Effects on foetal development : Test Type: Embryo-foetal development  
 Species: Rat  
 Application Route: Oral  
 Developmental Toxicity: LOAEL: 50 mg/kg body weight  
 Result: Embryo-foetal toxicity

Test Type: Embryo-foetal development  
 Species: Monkey  
 Application Route: Oral  
 Developmental Toxicity: LOAEL: 60 mg/kg body weight  
 Symptoms: Malformations were observed.

Test Type: Embryo-foetal development  
 Species: Rabbit  
 Application Route: Oral  
 Developmental Toxicity: NOAEL: 75 mg/kg body weight  
 Result: No embryotoxic effects

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

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**Cellulose:**

Effects on fertility : Test Type: One-generation reproduction toxicity study  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative

Effects on foetal development : Test Type: Fertility/early embryonic development  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative

**Magnesium stearate:**

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
 Species: Rat  
 Application Route: Ingestion  
 Method: OECD Test Guideline 422  
 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

**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 (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

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|| 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

**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

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

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Efavirenz:**

|           |                                                                                                                                                                             |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Ingestion | : Target Organs: Skin<br>Symptoms: Rash<br>Target Organs: Central nervous system<br>Symptoms: Dizziness, insomnia<br>Target Organs: Heart<br>Symptoms: irregular heart beat |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Efavirenz:**

|                                                                        |                                                                                                                                                                                                                       |
|------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish                                                       | : LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.85 mg/l<br>Exposure time: 96 h<br>Method: FDA 4.11                                                                                                                 |
| Toxicity to daphnia and other aquatic invertebrates                    | : EC50 (Daphnia magna (Water flea)): 1.1 mg/l<br>Exposure time: 48 h<br>Method: FDA 4.08                                                                                                                              |
| Toxicity to algae/aquatic plants                                       | : NOEC (Selenastrum capricornutum (green algae)): 0.026 mg/l<br>Exposure time: 12 d<br>Method: FDA 4.01<br><br>NOEC (Microcystis aeruginosa (blue-green algae)): 0.76 mg/l<br>Exposure time: 12 d<br>Method: FDA 4.01 |
| Toxicity to fish (Chronic toxicity)                                    | : NOEC (Pimephales promelas (fathead minnow)): 0.066 mg/l<br>Exposure time: 33 d<br>Method: OECD Test Guideline 210                                                                                                   |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC (Daphnia magna (Water flea)): 0.16 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211                                                                                                              |

**Cellulose:**

|                  |                                                                               |
|------------------|-------------------------------------------------------------------------------|
| Toxicity to fish | : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l<br>Exposure time: 48 h |
|------------------|-------------------------------------------------------------------------------|

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Remarks: Based on data from similar materials

**Magnesium stearate:**

- Toxicity to fish : LC50 (Leuciscus idus (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 (Daphnia magna (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
- 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)):  $\geq$  1.357 mg/l  
 Exposure time: 42 d
- Toxicity to daphnia and other aquatic invertebrates (Chronic) : NOEC (Ceriodaphnia dubia (water flea)): 0.88 mg/l  
 Exposure time: 7 d



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Acute toxicity)  
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

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

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|| 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 environmental compartments : log Koc: 3.36  
Method: FDA 3.08

**Other adverse effects**

No data available

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**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.

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**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

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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.

**National Regulations****ADG**

UN number : UN 3077  
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,  
 N.O.S.  
 (Efavirenz)  
 Class : 9  
 Packing group : III  
 Labels : 9  
 Hazchem Code : 2Z

**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.

**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

**The components of this product are reported in the following inventories:**

AICS : not determined  
 DSL : not determined  
 IECSC : not determined

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**SECTION 16. OTHER INFORMATION****Further information**

Revision Date : 04.04.2023  
Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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

Date format : dd.mm.yyyy

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.

ACGIH / TWA : 8-hour, time-weighted average  
AU OEL / TWA : Exposure standard - 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; 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; 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

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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.

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