

**Efavirenz Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
7.0	04/04/2023	86803-00024	Date of first issue: 04/02/2015

**SECTION 1. IDENTIFICATION**

Product name : Efavirenz Solid Formulation

**Manufacturer or supplier's details**

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.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 the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Combustible dust

Acute toxicity (Oral) : Category 4  
Eye irritation : Category 2A  
Carcinogenicity (Inhalation) : Category 2  
Reproductive toxicity : Category 1B  
Specific target organ toxicity : Category 1 (Central nervous system, Skin)  
- repeated exposure

**GHS label elements**

Hazard pictograms :



Signal Word : Danger

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.  
H302 Harmful if swallowed.  
H319 Causes serious eye irritation.  
H351 Suspected of causing cancer if inhaled.  
H360D May damage the unborn child.  
H372 Causes damage to organs (Central nervous system, Skin) through prolonged or repeated exposure.

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Precautionary Statements : **Prevention:**  
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 and face protection.

**Response:**  
P301 + P312 + P330 IF SWALLOWED: Call a 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 attention.  
P337 + P313 If eye irritation persists: Get medical attention.

**Storage:**  
P405 Store locked up.

**Disposal:**  
P501 Dispose of contents and container to an approved waste disposal plant.

**Other hazards**

None known.

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

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Efavirenz	154598-52-4	>= 30 - < 50
Cellulose	9004-34-6	>= 10 - < 20
Magnesium stearate	557-04-0	>= 1 - < 5
Sodium n-dodecyl sulfate	151-21-3	>= 1 - < 5
Titanium dioxide	13463-67-7	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

**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.

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	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.
If swallowed	: Get medical attention. 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 serious eye irritation. Suspected of causing cancer if inhaled. 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.
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.

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		<p>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.</p>
	Methods and materials for containment and cleaning up	<p>: 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.</p>

### 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.
Conditions for safe storage	:	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

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### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

inert or nuisance dust	50 Million particles per cubic foot Value type (Form of exposure): TWA (total dust) Basis: OSHA Z-3
	15 mg/m <sup>3</sup> Value type (Form of exposure): TWA (total dust) Basis: OSHA Z-3
	5 mg/m <sup>3</sup> Value type (Form of exposure): TWA (respirable fraction) Basis: OSHA Z-3
	15 Million particles per cubic foot Value type (Form of exposure): TWA (respirable fraction) Basis: OSHA Z-3
Dust, nuisance dust and particulates	10 mg/m <sup>3</sup> Value type (Form of exposure): PEL (Total dust) Basis: CAL PEL
	5 mg/m <sup>3</sup> Value type (Form of exposure): PEL (respirable dust fraction) Basis: CAL PEL

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
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1
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 (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Respirable particulate matter)	2.5 mg/m <sup>3</sup> (Titanium dioxide)	ACGIH

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**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** : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**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).

**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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance** : powder

**Color** : white to off-white

**Odor** : No data available

**Odor Threshold** : No data available

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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
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

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**SECTION 10. STABILITY AND REACTIVITY**

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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 exposure**

Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Harmful if swallowed.

**Product:**

Acute oral toxicity	:	Acute toxicity estimate: 849.05 mg/kg Method: Calculation method
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**Components:****Efavirenz:**

Acute oral toxicity	:	LD50 (Rat, female): 419 mg/kg  LDLo (Rat, male): 1,000 mg/kg
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**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

**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



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**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

**Serious eye damage/eye irritation**

Causes serious eye irritation.

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

Remarks	: Moderate eye irritation
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**Magnesium stearate:**

Species	: Rabbit
Result	: No eye irritation

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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 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.

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

- |                                     |   |   |
|-------------------------------------|---|---|
| Genotoxicity in vitro               | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Result: negative<br><br>Test Type: Chromosome aberration test in vitro<br>Result: negative |
| Genotoxicity in vivo                | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Oral<br>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)<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Result: negative |
| Genotoxicity in vivo  | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative    |

**Magnesium stearate:**

- |                       |   |   |
|-----------------------|---|---|
| Genotoxicity in vitro | : | Test Type: In vitro mammalian cell gene mutation test<br>Result: negative<br>Remarks: Based on data from similar materials<br><br>Test Type: Chromosome aberration test in vitro<br>Method: OECD Test Guideline 473<br>Result: negative<br>Remarks: Based on data from similar materials<br><br>Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br>Remarks: Based on data from similar materials |
|-----------------------|---|---|

**Sodium n-dodecyl sulfate:**

- |                       |   |   |
|-----------------------|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Method: OECD Test Guideline 471<br>Result: negative |
|-----------------------|---|---|

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Genotoxicity in vivo	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**

Suspected of causing cancer if inhaled.

**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

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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.
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<b>IARC</b>	Group 2B: Possibly carcinogenic to humans	
	Titanium dioxide	13463-67-7

<b>OSHA</b>	No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.
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<b>NTP</b>	No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
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**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 fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 50 mg/kg body weight Result: Embryo-fetal toxicity.  Test Type: Embryo-fetal development Species: Monkey Application Route: Oral Developmental Toxicity: LOAEL: 60 mg/kg body weight Symptoms: Malformations were observed.  Test Type: Embryo-fetal 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.

**Cellulose:**

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

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**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

**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>

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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
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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****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
Toxicity to fish (Chronic toxicity)	: NOEC (Pimephales promelas (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 (Daphnia magna (Water flea)): 0.16 mg/l Exposure time: 21 d Method: OECD Test Guideline 211

**Cellulose:**

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

- |   |   |  |
|---|---|--|
| Toxicity to fish                                    | : | LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l<br>Exposure time: 48 h<br>Method: DIN 38412<br>Remarks: Based on data from similar materials   |
| Toxicity to daphnia and other aquatic invertebrates | : | EL50 (Daphnia magna (Water flea)): > 1 mg/l<br>Exposure time: 47 h<br>Test substance: Water Accommodated Fraction<br>Method: Directive 67/548/EEC, Annex V, C.2.<br>Remarks: Based on data from similar materials<br>No toxicity at the limit of solubility.   |
| Toxicity to algae/aquatic plants                    | : | EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l<br>Exposure time: 72 h<br>Test substance: Water Accommodated Fraction<br>Method: OECD Test Guideline 201<br>Remarks: Based on data from similar materials<br>No toxicity at the limit of solubility.<br><br>NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l<br>Exposure time: 72 h<br>Test substance: Water Accommodated Fraction<br>Method: OECD Test Guideline 201<br>Remarks: Based on data from similar materials |
| Toxicity to microorganisms                          | : | EC10 (Pseudomonas putida): > 100 mg/l<br>Exposure time: 16 h<br>Test substance: Water Accommodated Fraction<br>Remarks: Based on data from similar materials   |

**Sodium n-dodecyl sulfate:**

- |  |   |  |
|--|---|--|
| Toxicity to fish   | : | LC50 (Pimephales promelas (fathead minnow)): 29 mg/l<br>Exposure time: 96 h  |
| Toxicity to daphnia and other aquatic invertebrates                    | : | EC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l<br>Exposure time: 48 h   |
| Toxicity to algae/aquatic plants                                       | : | ErC50 (Desmodesmus subspicatus (green algae)): > 120 mg/l<br>Exposure time: 72 h<br><br>NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l<br>Exposure time: 72 h |
| Toxicity to fish (Chronic toxicity)                                    | : | NOEC (Pimephales promelas (fathead minnow)): >= 1.357 mg/l<br>Exposure time: 42 d  |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Ceriodaphnia dubia (water flea)): 0.88 mg/l<br>Exposure time: 7 d  |
| Toxicity to microorganisms   | : | EC50: 135 mg/l   |

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Exposure time: 3 h

**Titanium dioxide:**

- |   |   |  |
|---|---|--|
| Toxicity to fish                                    | : | LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203 |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 100 mg/l<br>Exposure time: 48 h   |
| Toxicity to algae/aquatic plants                    | : | EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l<br>Exposure time: 72 h                                |
| Toxicity to microorganisms                          | : | EC50: > 1,000 mg/l<br>Exposure time: 3 h<br>Method: OECD Test Guideline 209                                      |

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

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

**Cellulose:**

- |                  |   |                                |
|------------------|---|--------------------------------|
| Biodegradability | : | Result: Readily biodegradable. |
|------------------|---|--------------------------------|

**Magnesium stearate:**

- |                  |   |  |
|------------------|---|--|
| Biodegradability | : | Result: Not biodegradable<br>Remarks: Based on data from similar materials |
|------------------|---|--|

**Sodium n-dodecyl sulfate:**

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

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

- |  |   |  |
|--|---|--|
| Bioaccumulation                        | : | Species: Lepomis macrochirus (Bluegill sunfish)<br>Bioconcentration factor (BCF): 454<br>Method: OECD Test Guideline 305 |
| Partition coefficient: n-octanol/water | : | log Pow: 5.4   |

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**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

**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**

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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****49 CFR**

UN/ID/NA number	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Efavirenz)
Class	:	9
Packing group	:	III
Labels	:	CLASS 9
ERG Code	:	171
Marine pollutant	:	yes(Efavirenz)
Remarks	:	Above applies only to containers over 119 gallons or 450 liters. Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

**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****CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

**SARA 304 Extremely Hazardous Substances Reportable Quantity**

This material does not contain any components with a section 304 EHS RQ.

**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

This material does not contain any components with a section 302 EHS TPQ.

<b>SARA 311/312 Hazards</b>	:	Combustible dust Acute toxicity (any route of exposure) Carcinogenicity Reproductive toxicity Specific target organ toxicity (single or repeated exposure) Serious eye damage or eye irritation
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**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**US State Regulations****Pennsylvania Right To Know**

Efavirenz	154598-52-4
D-Glucose, 4-O-β-D-galactopyranosyl-, monohydrate	64044-51-5
Cellulose	9004-34-6
Hydroxypropyl cellulose	9004-64-2
Croscarmellose sodium	74811-65-7

**California Prop. 65**

WARNING: This product can expose you to chemicals including Titanium dioxide, which is/are known to the State of California to cause cancer. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

**California Permissible Exposure Limits for Chemical Contaminants**

Cellulose	9004-34-6
Magnesium stearate	557-04-0

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

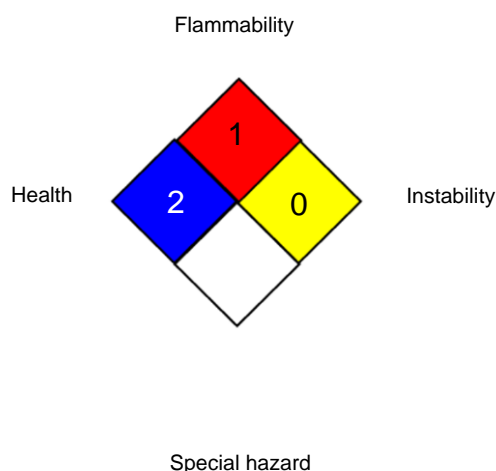
AICS	: not determined
DSL	: not determined
IECSC	: not determined

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

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**NFPA 704:****HMIS® IV:**

<b>HEALTH</b>	*	<b>3</b>
<b>FLAMMABILITY</b>		<b>3</b>
<b>PHYSICAL HAZARD</b>		<b>0</b>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

**Full text of other abbreviations**

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
CAL PEL	: California permissible exposure limits for chemical contaminants (Title 8, Article 107)
NIOSH REL	: USA. NIOSH Recommended Exposure Limits
OSHA Z-1	: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
OSHA Z-3	: USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA	: 8-hour, time-weighted average
CAL PEL / PEL	: Permissible exposure limit
NIOSH REL / TWA	: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA	: 8-hour time weighted average
OSHA Z-3 / TWA	: 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Oth-

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erwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; 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

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

Revision Date : 04/04/2023

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

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.

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