according to GB/T 16483 and GB/T 17519



### **Efavirenz Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 2022/10/01 5.0 2023/04/04 86791-00024 Date of first issue: 2015/04/02

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Efavirenz Solid Formulation

Manufacturer or supplier's details

Company : MSD

Address : 199 Wenhai North Road

HEDA, Hangzhou - Zhejiang Province - CHINA 310018

Telephone : 908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use

Not applicable

### 2. HAZARDS IDENTIFICATION

# Emergency Overview

**Appearance** : powder

Colour: white to off-whiteOdour: No data available

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. Very toxic to aquatic life with long lasting effects.

**GHS Classification** 

Acute toxicity (Oral) : Category 4

Skin corrosion/irritation : Category 3

Serious eye damage/eye irri-

tation

Category 2A

Reproductive toxicity : Category 1B

Specific target organ toxicity - :

repeated exposure

Category 1

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

Category 1

1/22

according to GB/T 16483 and GB/T 17519



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hazard

**GHS** label elements

Hazard pictograms







Signal word : Danger

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 through prolonged or repeated

exposure.

H410 Very toxic to aquatic life with long lasting effects.

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.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ 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.

P332 + P313 If skin irritation occurs: Get medical advice/ atten-

tion.

P337 + P313 If eye irritation persists: Get medical advice/ at-

tention.

P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Physical and chemical hazards

Not classified based on available information.

according to GB/T 16483 and GB/T 17519



## **Efavirenz Solid Formulation**

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#### Health hazards

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.

#### **Environmental hazards**

Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.

### Other hazards which do not result in classification

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

### 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 -< 10	
Sodium n-dodecyl sulfate	151-21-3	>= 1 -< 2.5	
Titanium dioxide	13463-67-7	>= 0.1 -< 1	

### 4. FIRST AID MEASURES

General advice In the case of accident or if you feel unwell, seek medical ad-

vice 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).

according to GB/T 16483 and GB/T 17519



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Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

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 prod-

ucts

Carbon oxides

Metal oxides Sulphur oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

according to GB/T 16483 and GB/T 17519



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#### 7. HANDLING AND STORAGE

Handling

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 as-

sessment

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.

Avoidance of contact : Oxidizing agents

Storage

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

Packaging material : Unsuitable material: None known.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

# Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Efavirenz	154598-52-4	TWA	100 μg/m3	Internal
Cellulose	9004-34-6	PC-TWA	10 mg/m3	CN OEL
		TWA	10 mg/m3	ACGIH
Magnesium stearate	557-04-0	TWA (Inhal- able particu- late matter)	10 mg/m3	ACGIH
		TWA (Res- pirable par- ticulate mat-	3 mg/m3	ACGIH

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		ter)			
Titanium dioxide	13463-67-7	PC-TWA	8 mg/m3	CN OEL	
		(Total dust)	_		
	Further information: G2B - Possibly carcinogenic to humans				
		TWA (Res-	2.5 mg/m3	ACGIH	
		pirable par-	(Titanium dioxide)		
		ticulate mat-			
		ter)			

**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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type : Particulates type

Eye/face 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).

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.

Hygiene measures : If exposure to chemical is likely during typical use, provide

eye flushing systems and safety showers close to the work-

ing place.

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Colour : white to off-white

according to GB/T 16483 and GB/T 17519



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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, han-

dling 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

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

according to GB/T 16483 and GB/T 17519



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### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Oxidizing agents

Incompatible materials

Hazardous decomposition

products

: No hazardous decomposition products are known.

#### 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

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 tox-

icity

Remarks: Based on data from similar materials

according to GB/T 16483 and GB/T 17519



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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 inhala-

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

according to GB/T 16483 and GB/T 17519



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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

Remarks : Based on data from similar materials

Titanium dioxide:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact Species : Mouse

according to GB/T 16483 and GB/T 17519



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Result : negative

### Germ cell mutagenicity

Not classified based on available information.

### **Components:**

#### Efavirenz:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse Application Route: Oral Result: negative

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

### 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

according to GB/T 16483 and GB/T 17519



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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 hu-

mans.

Species: RatApplication Route: OralExposure time: 2 YearsResult: 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

according to GB/T 16483 and GB/T 17519



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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 hu-

mans.

Carcinogenicity - Assess-

ment

: 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 develop-

ment were detected.

Effects on foetal develop-

ment

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 - As-

sessment

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

according to GB/T 16483 and GB/T 17519



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Result: negative

Effects on foetal develop-

ment

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 develop-

ment

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 develop-

ment

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 through prolonged or repeated exposure.

**Components:** 

Efavirenz:

Target Organs : Central nervous system

Assessment : Causes damage to organs through prolonged or repeated

exposure.

according to GB/T 16483 and GB/T 17519



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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 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

Species : Rat

according to GB/T 16483 and GB/T 17519



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NOAEL : 10 mg/m3

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

Symptoms: Rash

Target Organs: Central nervous system

Symptoms: Dizziness, insomnia

Target Organs: Heart

Symptoms: irregular heart beat

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

M-Factor (Acute aquatic tox- : 1

icity)

Toxicity to fish (Chronic tox-:

icity)

NOEC (Pimephales promelas (fathead minnow)): 0.066 mg/l

Exposure time: 33 d

Method: OECD Test Guideline 210

NOEC (Daphnia magna (Water flea)): 0.16 mg/l

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

Exposure time: 21 d

: 1

ic toxicity)

Method: OECD Test Guideline 211

M-Factor (Chronic aquatic

toxicity)

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according to GB/T 16483 and GB/T 17519



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Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l

Exposure time: 48 h

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 tox- : NOEC (Pimephales promelas (fathead minnow)): >= 1.357

according to GB/T 16483 and GB/T 17519



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icity) mg/l

Exposure time: 42 d

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

Toxicity to microorganisms

NOEC (Ceriodaphnia dubia (water flea)): 0.88 mg/l

Exposure time: 7 d

: 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

aquatic invertebrates

Toxicity to daphnia and other : 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

according to GB/T 16483 and GB/T 17519



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### 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-

log Pow: > 4

octanol/water

Sodium n-dodecyl sulfate:

Partition coefficient: n-

octanol/water

log Pow: 0.83

Mobility in soil

**Components:** 

Efavirenz:

Distribution among environ-

mental compartments

log Koc: 3.36 Method: FDA 3.08

Other adverse effects

No data available

### 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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

### 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** 

according to GB/T 16483 and GB/T 17519



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UN/ID No. : UN 3077

Proper shipping name : Environmentally hazardous substance, solid, n.o.s.

(Efavirenz)

956

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo :

aircraft)

Packing instruction (passen- : 956

ger aircraft)

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**

GB 6944/12268

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S. (Efavirenz)

Class : 9
Packing group : III
Labels : 9

### 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.

### 15. REGULATORY INFORMATION

## National regulatory information

Law on the Prevention and Control of Occupational Diseases

### Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

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

AICS : not determined

according to GB/T 16483 and GB/T 17519



### Efavirenz Solid Formulation

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DSL not determined

**IECSC** not determined

### **16. OTHER INFORMATION**

**Revision Date** 2023/04/04

**Further information** 

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 Agen-

cy, 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 : yyyy/mm/dd

Full text of other abbreviations

**ACGIH** USA. ACGIH Threshold Limit Values (TLV)

**CN OEL** Occupational exposure limits for hazardous agents in the

workplace - Chemical hazardous agents.

ACGIH / TWA 8-hour, time-weighted average

CN OEL / PC-TWA Permissible concentration - 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 Recom-

according to GB/T 16483 and GB/T 17519



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mendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

### **Disclaimer**

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.

CN / EN