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 28.09.2024
 9372450-00008
 Date of first issue: 27.08.2021

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Efavirenz Solid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub- : Pharmaceutical

stance/Mixture

Recommended restrictions : Not applicable

on use

1.3 Details of the supplier of the safety data sheet

Company : MSD

120 Moorgate

EC2M 6UR London, United Kingdom

Telephone : +44 (0) 2081548000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

1-908-423-6000

### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Acute toxicity, Category 4 H302: Harmful if swallowed.

Eye irritation, Category 2

Reproductive toxicity, Category 1B

H319: Causes serious eye irritation.

H360D: May damage the unborn child.

Specific target organ toxicity - repeated H372: Causes damage to organs through pro-

exposure, Category 1 longed or repeated exposure.
Short-term (acute) aquatic hazard, Cate-H400: Very toxic to aquatic life.

gory 1

Long-term (chronic) aquatic hazard, Cat-

egory 1

H410: Very toxic to aquatic life with long lasting

effects.

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#### 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

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 through prolonged or

repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P260 Do not breathe dust.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye

protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

P391 Collect spillage.

Hazardous components which must be listed on the label:

Efavirenz

Sodium n-dodecyl sulfate

#### 2.3 Other hazards

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

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

#### **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

#### Components

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
Efavirenz	154598-52-4	Acute Tox. 4; H302	>= 30 - < 50
		Eye Irrit. 2; H319	

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Sodiu	m n-dodecyl sulfate	151-21-3 205-788-1	Repr. 1B; H360D STOT RE 1; H372 (Central nervous system, Skin) Aquatic Acute 1; H400 Aquatic Chronic 1; H410  M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1 Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Aquatic Chronic 3; H412  specific concentration limit Eye Irrit. 2; H319 10 - < 20 % Eye Dam. 1; H318 >= 20 % Eye Irrit. 2; H319 10 - < 20 % Eye Dam. 1; H318 >= 20 % Eye Dam. 1; H318	>= 1 - < 2.5
Subst	ances with a workplac	e exposure limit : 9004-34-6		>= 10 - < 20
Condi	300	232-674-9		>= 10 \ \ Z0

For explanation of abbreviations see section 16.

#### **SECTION 4: First aid measures**

### 4.1 Description of first aid measures

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

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

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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, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Harmful if swallowed.

Causes serious eye irritation. May damage the unborn child.

Causes damage to organs through prolonged or repeated

exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

# **SECTION 5: Firefighting measures**

# 5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

#### 5.2 Special hazards arising from the substance or mixture

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

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5.3 Advice for firefighters

Special protective equipment :

for firefighters

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

Use personal protective equipment.

Specific extinguishing 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.

#### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

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

tective equipment recommendations (see section 8).

#### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

#### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable con-

tainer 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.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

# **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

Technical measures : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

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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.

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 contami-

nated clothing before re-use.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national

regulations.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

7.3 Specific end use(s)

Specific use(s) : No data available

#### **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

#### **Occupational Exposure Limits**

dust of any kind 10 mg/m3

Value type (Form of exposure): TWA (Inhalable)

Basis: GB EH40

4 mg/m3

Value type (Form of exposure): TWA (Respirable fraction)

Basis: GB EH40

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Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Efavirenz	154598-52- 4	TWA	100 μg/m3	Internal
Cellulose	9004-34-6	TWA (inhalable dust)	10 mg/m3	GB EH40
		TWA (Respirable dust)	4 mg/m3	GB EH40
		STEL (inhalable dust)	20 mg/m3	GB EH40

#### **Derived No Effect Level (DNEL)**

Substance name	End Use	Exposure routes	Potential health effects	Value
Sodium n-dodecyl sulfate	Workers	Inhalation	Long-term systemic effects	285 mg/m3
	Workers	Skin contact	Long-term systemic effects	4060 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	85 mg/m3
	Consumers	Skin contact	Long-term systemic effects	2440 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	24 mg/kg bw/day

### **Predicted No Effect Concentration (PNEC)**

Substance name	Environmental Compartment	Value
Sodium n-dodecyl sulfate	Fresh water	0.176 mg/l
	Marine water	0.018 mg/l
	Sewage treatment plant	1.35 mg/l
	Fresh water sediment	6.97 mg/kg dry weight (d.w.)
	Marine sediment	0.697 mg/kg dry weight (d.w.)
	Soil	1.29 mg/kg dry weight (d.w.)

#### 8.2 Exposure controls

#### **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

Eye/face protection : Wear the following personal protective equipment:

Safety goggles

Equipment should conform to BS EN 166

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Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending

on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the

end of workday.

Skin and body protection : Select appropriate protective clothing based on chemical re-

sistance data and an assessment of the local exposure poten-

tial.

Skin contact must be avoided by using impervious protective

clothing (gloves, aprons, boots, etc).

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Equipment should conform to BS EN 143

Filter type : Particulates type (P)

#### **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic 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, han-

dling or other means.

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : No data available

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Relative vapour density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available Partition coefficient: n- : No data available

octanol/water

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.

9.2 Other information

Flammability (liquids) : No data available

Molecular weight : No data available

Particle size : No data available

# **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

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#### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

#### **SECTION 11: Toxicological information**

#### 11.1 Information on toxicological effects

Information on likely routes of : Inhalation

exposure 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

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

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

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

Efavirenz:

Result : Mild skin irritation Remarks : slight irritation

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Sodium n-dodecyl sulfate:

Species : Rabbit Result : Skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

**Components:** 

Efavirenz:

Remarks : Moderate eye irritation

Sodium n-dodecyl sulfate:

Species : Rabbit

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

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

Sodium n-dodecyl sulfate:

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

Remarks : Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

Efavirenz:

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

Result: negative

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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- As-

sessment

Weight of evidence does not support classification as a germ

cell mutagen.

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

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

Carcinogenicity

Not classified based on available information.

**Components:** 

Efavirenz:

Species : Mouse Application Route : Oral Exposure time : 2 Years

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Target Organs : Lungs, Liver

Remarks : The mechanism or mode of action may not be relevant in hu-

mans.

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

Cellulose:

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

Reproductive toxicity

May damage the unborn child.

**Components:** 

Efavirenz:

Effects on fertility : Species: Rat, male and female

Application Route: Oral

Fertility: NOAEL: 200 - 400 mg/kg body weight

Result: No effects on fertility and early embryonic 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

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Result: No embryotoxic effects

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on development, based on

animal experiments.

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

Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

#### 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.

#### Repeated dose toxicity

#### **Components:**

Efavirenz:

Species : Rat LOAEL : 50 mg/kg Application Route : Oral

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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

Sodium n-dodecyl sulfate:

Species : Rat
NOAEL : 488 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Remarks : Based on data from similar materials

Cellulose:

Species : Rat

NOAEL : >= 9,000 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

**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

**SECTION 12: Ecological information** 

12.1 Toxicity

**Components:** 

Efavirenz:

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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-

icity)

1

Toxicity to fish (Chronic tox-

icity)

NOEC: 0.066 mg/l

Exposure time: 33 d

Species: Pimephales promelas (fathead minnow)

Method: OECD Test Guideline 210

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0.16 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

Method: OECD Test Guideline 211

M-Factor (Chronic aquatic

toxicity)

1

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 microorganisms : EC50 : 135 mg/l

Exposure time: 3 h

Toxicity to fish (Chronic tox-

icity)

NOEC: >= 1.357 mg/l

Exposure time: 42 d

Species: Pimephales promelas (fathead minnow)

Toxicity to daphnia and other : NOEC: 0.88 mg/l

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aquatic invertebrates (Chron-

Exposure time: 7 d

ic toxicity)

Species: Ceriodaphnia dubia (water flea)

Cellulose:

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

Exposure time: 48 h

Remarks: Based on data from similar materials

#### 12.2 Persistence and degradability

Components:

Efavirenz:

Biodegradability Result: Not readily biodegradable.

> Biodegradation: 11 % Exposure time: 32 d Method: FDA 3.11

Sodium n-dodecyl sulfate:

Biodegradability Result: Readily biodegradable.

Biodegradation: 95 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Cellulose:

Biodegradability Result: Readily biodegradable.

12.3 Bioaccumulative potential

**Components:** 

Efavirenz:

Bioaccumulation Species: Lepomis macrochirus (Bluegill sunfish)

> Bioconcentration factor (BCF): 454 Method: OECD Test Guideline 305

Partition coefficient: n-

octanol/water

log Pow: 5.4

Sodium n-dodecyl sulfate:

Partition coefficient: n-

octanol/water

log Pow: 0.83

12.4 Mobility in soil

**Components:** 

Efavirenz:

Distribution among environmental compartments

log Koc: 3.36 Method: FDA 3.08

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#### 12.5 Results of PBT and vPvB assessment

**Product:** 

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

#### 12.6 Other adverse effects

**Product:** 

Endocrine disrupting poten-

tial

This substance/mixture does not contain components considered to have endocrine disrupting properties for environment

according to UK REACH Article 57(f).

# **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

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.

### **SECTION 14: Transport information**

#### 14.1 UN number

ADN : UN 3077
ADR : UN 3077
RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

#### 14.2 UN proper shipping name

**ADN** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S. (Efavirenz)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S. (Efavirenz)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

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(Efavirenz)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S. (Efavirenz)

IATA : Environmentally hazardous substance, solid, n.o.s.

(Efavirenz)

14.3 Transport hazard class(es)

Class Subsidiary risks

 ADN
 : 9

 ADR
 : 9

 RID
 : 9

 IMDG
 : 9

 IATA
 : 9

#### 14.4 Packing group

**ADN** 

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

**ADR** 

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

**RID** 

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

**IMDG** 

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

IATA (Cargo)

Packing instruction (cargo : 956

aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen- : 956

ger aircraft)

Packing instruction (LQ) : Y956

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Packing group

Labels Miscellaneous

14.5 Environmental hazards

Environmentally hazardous yes

Environmentally hazardous ves

Environmentally hazardous yes

**IMDG** 

Marine pollutant yes

IATA (Passenger)

Environmentally hazardous yes

IATA (Cargo)

Environmentally hazardous yes

#### 14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

#### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

#### **SECTION 15: Regulatory information**

#### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Not applicable

UK REACH Candidate list of substances of very high Not applicable

concern (SVHC) for Authorisation

The Persistent Organic Pollutants Regulations (retained Not applicable

Regulation (EU) 2019/1021 as amended for Great Brit-

Regulation (EC) on substances that deplete the ozone Not applicable

layer

UK REACH List of substances subject to authorisation Not applicable

(Annex XIV)

GB Export and import of hazardous chemicals - Prior Not applicable

Informed Consent (PIC) Regulation

Control of Major Accident Hazards Regulations 2015 (COMAH)

Quantity 1 Quantity 2

E1 **ENVIRONMENTAL** 100 t 200 t

**HAZARDS** 

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#### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

# **SECTION 16: Other information**

Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

#### **Full text of H-Statements**

H302 : Harmful if swallowed. H315 : Causes skin irritation.

H318 : Causes serious eye damage.
H319 : Causes serious eye irritation.
H360D : May damage the unborn child.

H372 : Causes damage to organs through prolonged or repeated

exposure.

H400 : Very toxic to aquatic life.

H410 : Very toxic to aquatic life with long lasting effects. H412 : Harmful to aquatic life with long lasting effects.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard

Eye Dam. : Serious eye damage

Eye Irrit. : Eye irritation

Repr. : Reproductive toxicity

Skin Irrit. : Skin irritation

STOT RE : Specific target organ toxicity - repeated exposure GB EH40 : UK. EH40 WEL - Workplace Exposure Limits

GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL : Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Test-

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ing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance: PICCS - Philippines Inventory of Chemicals and Chemical Substances: (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

#### **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 Agency, http://echa.europa.eu/

Classification procedure:

#### Classification of the mixture:

#### Acute Tox. 4 H302 Calculation method Eye Irrit. 2 H319 Calculation method Repr. 1B H360D Calculation method STOT RE 1 H372 Calculation method Aquatic Acute 1 H400 Calculation method Aquatic Chronic 1 H410 Calculation method

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.

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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.

GB / EN