according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Efavirenz Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 28.09.2024 88524-00028 Date of first issue: 02.04.2015 5.1

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

Not applicable

Use of the Sub-: Pharmaceutical

stance/Mixture

on use

1.3 Details of the supplier of the safety data sheet

Company **MSD**

Piercetown

A86 HD21 Dunboyne, Ireland

Telephone : 908-740-4000

E-mail address of person

Recommended restrictions

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)

Acute toxicity, Category 4 H302: Harmful if swallowed.

Eye irritation, Category 2 H319: Causes serious eye irritation. Reproductive toxicity, Category 1B 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. H400: Very toxic to aquatic life.

Short-term (acute) aquatic hazard, Cate-

gory 1

Long-term (chronic) aquatic hazard, Cat-H410: Very toxic to aquatic life with long lasting

egory 1 effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Efavirenz Solid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 5.1
 28.09.2024
 88524-00028
 Date of first issue: 02.04.2015

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.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 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

Componente			
Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Efavirenz Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 88524-00028 Date of first issue: 02.04.2015

	Registration number		
Efavirenz	154598-52-4	Acute Tox. 4; H302 Eye Irrit. 2; H319 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	>= 30 - < 50
Sodium n-dodecyl sulfate	151-21-3 205-788-1	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 % Acute toxicity estimate Acute oral toxicity: 1,200 mg/kg	>= 1 - < 2.5

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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Efavirenz Solid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 5.1
 28.09.2024
 88524-00028
 Date of first issue: 02.04.2015

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, 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Efavirenz Solid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 5.1
 28.09.2024
 88524-00028
 Date of first issue: 02.04.2015

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.

Local authorities should be advised if significant spillages

cannot be contained.

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Efavirenz Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 88524-00028 Date of first issue: 02.04.2015

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

dusts non-specific 4 mg/m3

Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable

dust)

Basis: IE OEL

10 mg/m3

Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Efavirenz Solid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 5.1
 28.09.2024
 88524-00028
 Date of first issue: 02.04.2015

dust)

Basis: IE OEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Efavirenz	154598-52- 4	TWA	100 μg/m3	Internal
Cellulose	9004-34-6	OELV - 8 hrs (TWA)	10 mg/m3	IE OEL
Magnesium stea- rate	557-04-0	OELV - 8 hrs (TWA)	10 mg/m3	IE OEL

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

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) according to Regulation (EC) No. 1907/2006

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 I.S. EN 166

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Efavirenz Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 28.09.2024 88524-00028 Date of first issue: 02.04.2015 5.1

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.

Select appropriate protective clothing based on chemical Skin and body protection

resistance data and an assessment of the local exposure

potential.

Skin contact must be avoided by using impervious protective

clothing (gloves, aprons, boots, etc).

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

sure assessment demonstrates exposures outside the rec-

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

Filter type Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state powder

Colour white to off-white

Odour No data available

Odour Threshold No data available

Melting point/freezing point No data available

Initial boiling point and boiling

range

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 : No data available

flammability limit

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Efavirenz Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 88524-00028 Date of first issue: 02.04.2015

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

No data available

Vapour pressure : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics

Particle size : No data available

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

Molecular weight : 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Efavirenz Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 88524-00028 Date of first issue: 02.04.2015

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

Skin corrosion/irritation

Not classified based on available information.

Components:

Efavirenz:

Result : Mild skin irritation Remarks : slight irritation

Sodium n-dodecyl sulfate:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Efavirenz Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 88524-00028 Date of first issue: 02.04.2015

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

Test Type: In vitro mammalian cell gene mutation test

Result: negative

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Efavirenz Solid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 5.1
 28.09.2024
 88524-00028
 Date of first issue: 02.04.2015

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

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 : 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Efavirenz Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 88524-00028 Date of first issue: 02.04.2015

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.

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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Efavirenz Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 88524-00028 Date of first issue: 02.04.2015

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
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

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Efavirenz Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 88524-00028 Date of first issue: 02.04.2015

(EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

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:

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Efavirenz Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 88524-00028 Date of first issue: 02.04.2015

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 :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0.88 mg/l Exposure time: 7 d

Species: Ceriodaphnia dubia (water flea)

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

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Efavirenz Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 88524-00028 Date of first issue: 02.04.2015

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

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 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

12.7 Other adverse effects

No data available

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 or ID number

ADN : UN 3077

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Efavirenz Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 88524-00028 Date of first issue: 02.04.2015

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. (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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Efavirenz Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 88524-00028 Date of first issue: 02.04.2015

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 Packing group : III

Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

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 Maritime transport in bulk according to IMO instruments

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

REACH - Restrictions on the manufacture, placing on : Not applicable

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Efavirenz Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 88524-00028 Date of first issue: 02.04.2015

the market and use of certain dangerous substances,

mixtures and articles (Annex XVII)

REACH - Candidate List of Substances of Very High : Not applicable

Concern for Authorisation (Article 59).

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

layer

Regulation (EU) 2019/1021 on persistent organic pollu- : Not applicable

tants (recast)

Regulation (EU) No 649/2012 of the European Parlia: Not applicable ment and the Council concerning the export and import

of dangerous chemicals

REACH - List of substances subject to authorisation : Not applicable

(Annex XIV)

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of

major-accident hazards involving dangerous substances.

Quantity 1 Quantity 2 E1 ENVIRONMENTAL 100 t 200 t

HAZARDS

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Efavirenz Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 88524-00028 Date of first issue: 02.04.2015

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

IE OEL : Ireland. List of Chemical Agents and Carcinogens with Occu-

pational Exposure Limit Values - Code of Practice, Schedule 1

and 2

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour 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 Testing 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; 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 Agen-

cy, http://echa.europa.eu/

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Efavirenz Solid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 5.1
 28.09.2024
 88524-00028
 Date of first issue: 02.04.2015

Classification of the mixture: Classification procedure:

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. 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.

IE / EN