SAFETY DATA SHEET

Efavirenz Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	06.07.2024	88513-00026	Date of first issue: 02.04.2015

SECTION 1. IDENTIFICATION

Product name : Efavirenz Solid Formulation

Manufacturer or supplier's details

Company : MSD

Address : 855 Leandro N. Alem St., 8 Floor
Buenos Aires, Argentina C1001AFB

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Acute toxicity (Oral) : Category 4

Skin corrosion/irritation : Category 3

Serious eye damage/eye irritation : Category 2A

Reproductive toxicity : Category 1B

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

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

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 (Central nervous system, Skin) 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 protection/ face protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards which do not result in classification

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Efavirenz	154598-52-4	>= 30 -< 50
Cellulose	9004-34-6	>= 10 -< 20
Magnesium stearate	557-04-0	>= 1 -< 5
Sodium n-dodecyl sulfate	151-21-3	>= 1 -< 2,5

Titanium dioxide	13463-67-7	>= 0,1 -< 1

SECTION 4. FIRST AID MEASURES

General advice	:	In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	:	If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	:	In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention. 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).
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING 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 products	:	Carbon oxides Metal oxides Sulfur oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers.

		Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. 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 determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures	:	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation	:	If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	:	Do not get on skin or clothing. Do not breathe dust. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges.

Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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	CMP	10 mg/m³	AR OEL
		TWA	10 mg/m³	ACGIH
Magnesium stearate	557-04-0	CMP	10 mg/m³	AR OEL
	Further information: A4 - Not classifiable as a human carcinogen			
		TWA (Inhalable particulate matter)	10 mg/m³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m³	ACGIH
Titanium dioxide	13463-67-7	CMP	10 mg/m³	AR OEL
	Further information: A4 - Not classifiable as a human carcinogen			

Engineering measures : Minimize workplace exposure concentrations.
Apply measures to prevent dust explosions.
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).
If sufficient ventilation is unavailable, use with local exhaust ventilation.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection

Material : Chemical-resistant gloves

Remarks	:	Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.
Eye protection	:	Wear the following personal protective equipment: Safety goggles
Skin and body protection	:	Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	white to off-white
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available

Relative vapor density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics		
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 849,05 mg/kg

Method: Calculation method

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 toxicity Remarks: Based on data from similar materials
Acute dermal toxicity	:	LD50 (Rabbit): > 2.000 mg/kg Remarks: Based on data from similar materials

Sodium n-dodecyl sulfate:

Acute oral toxicity	:	LD50 (Rat): 1.200 mg/kg Method: OECD Test Guideline 401
Acute dermal toxicity	:	LD50 (Rat): > 2.000 mg/kg Method: OECD Test Guideline 402 Remarks: Based on data from similar materials

Titanium dioxide:

Acute oral toxicity	:	LD50 (Rat): > 5.000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 6,82 mg/l Exposure time: 4 h Test atmosphere: dust/mist Assessment: The substance or mixture has no acute inhalation toxicity

Skin corrosion/irritation

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

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 sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Efavirenz:

Test Type	:	Maximization Test

Routes of exposure	:	Dermal
Species	:	Guinea pig
Assessment	:	Does not cause skin sensitization.
Result	:	negative

Magnesium stearate:

Test Type	:	Maximization Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative
Remarks	:	Based on data from similar materials

Sodium n-dodecyl sulfate:

Test Type	:	Maximization Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Result	:	negative
Remarks	:	Based on data from similar materials

Titanium dioxide:

Test Type	:	Local lymph node assay (LLNA)
Routes of exposure	:	Skin contact
Species	:	Mouse
Result	:	negative

Germ cell mutagenicity

Not classified based on available information.

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

Sodium n-dodecyl sulfate:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative Test Type: In vitro mammalian cell gene mutation test Result: negative
Genotoxicity in vivo	:	Test Type: Rodent dominant lethal test (germ cell) (in vivo) Species: Mouse Application Route: Ingestion Result: negative

Titanium dioxide:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	:	Test Type: In vivo micronucleus test Species: Mouse Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Efavirenz:

Species	:	Mouse
Application Route	:	Oral
Exposure time	:	2 Years
Target Organs	:	Lungs, Liver
Remarks	:	The mechanism or mode of action may not be relevant in humans.

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

Cellulose:

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

Sodium n-dodecyl sulfate:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	2 Years
Method	:	OECD Test Guideline 453
Result	:	negative
Remarks	:	Based on data from similar materials

Titanium dioxide:

Species	:	Rat
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	2 Years
Method	:	OECD Test Guideline 453
Result	:	positive
Remarks	:	The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment	:	Limited evidence of carcinogenicity in inhalation studies with animals.

Reproductive toxicity

May damage the unborn child.

Components:

Efavirenz:

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

Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 50 mg/kg body weight Result: Embryo-fetal toxicity. Test Type: Embryo-fetal development Species: Monkey Application Route: Oral Developmental Toxicity: LOAEL: 60 mg/kg body weight Symptoms: Malformations were observed. Test Type: Embryo-fetal development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 75 mg/kg body weight Result: No embryotoxic effects.
Reproductive toxicity - Assessment	:	Clear evidence of adverse effects on development, based on animal experiments.

Cellulose:

Effects on fertility	:	Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative
Effects on fetal development	:	Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative

Magnesium stearate:

Effects on fertility	:	Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test Species: Rat Application Route: Ingestion Method: OECD Test Guideline 422 Result: negative Remarks: Based on data from similar materials
Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials

Sodium n-dodecyl sulfate:

Effects on fertility	:	Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416

		Result: negative Remarks: Based on data from similar materials
Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Causes damage to organs (Central nervous system, Skin) through prolonged or repeated exposure.

Components:

Efavirenz:

Target Organs	:	Central nervous system
Assessment	:	Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Efavirenz:

Species	:	Rat
LOAEL	:	50 mg/kg
Application Route	:	Oral
Exposure time	:	3 Months
Target Organs	:	Kidney

Species	:	Monkey
LOAEL	:	100 mg/kg
Application Route	:	Oral
Exposure time	:	1 - 2 y
Target Organs	:	Central nervous system, Liver, Kidney, Thyroid, Adrenal gland

Species	:	Monkey
LOAEL	:	90 mg/kg
Application Route	:	Oral
Exposure time	:	1 Months
Target Organs	:	Central nervous system
Symptoms	:	Lethargy, Weakness

Cellulose:

Species	:	Rat
NOAEL	:	>= 9.000 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days

Magnesium stearate:

Species	:	Rat
NOAEL	:	> 100 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days
Remarks	:	Based on data from similar materials

Sodium n-dodecyl sulfate:

Species	:	Rat
NOAEL	:	488 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days
Remarks	:	Based on data from similar materials

Titanium dioxide:

Species	:	Rat
NOAEL	:	24.000 mg/kg
Application Route	:	Ingestion
Exposure time	:	28 Days

Species	:	Rat
NOAEL	:	10 mg/m³
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	2 y

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Efavirenz:

Ingestion	:	Target Organs: Skin Symptoms: Rash Target Organs: Central nervous system Symptoms: Dizziness, insomnia Target Organs: Heart Symptoms: irregular heart beat

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Efavirenz:

Toxicity to fish	:	LC50 (Lepomis macrochirus (Bluegill sunfish)): 0,85 mg/l Exposure time: 96 h Method: FDA 4.11
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 1,1 mg/l Exposure time: 48 h

		Method: FDA 4.08
Toxicity to algae/aquatic plants	:	NOEC (Selenastrum capricornutum (green algae)): 0,026 mg/l Exposure time: 12 d Method: FDA 4.01 NOEC (Microcystis aeruginosa (blue-green algae)): 0,76 mg/l Exposure time: 12 d Method: FDA 4.01
M-Factor (Acute aquatic toxicity)	:	1
Toxicity to fish (Chronic toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): 0,066 mg/l Exposure time: 33 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0,16 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	:	1

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 toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): >= 1,357 mg/l Exposure time: 42 d
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Ceriodaphnia dubia (water flea)): 0,88 mg/l Exposure time: 7 d
Toxicity to microorganisms	:	EC50: 135 mg/l Exposure time: 3 h

Titanium dioxide:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	EC50 (Skeletonema costatum (marine diatom)): > 10.000 mg/l Exposure time: 72 h
Toxicity to microorganisms	:	EC50: > 1.000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209

Persistence and degradability

Components:

Efavirenz:

Biodegradability	:	Result: Not readily biodegradable. Biodegradation: 11 % Exposure time: 32 d Method: FDA 3.11

Cellulose:

Biodegradability : Result: Readily biodegradable.

Magnesium stearate:

Biodegradability : Result: Not biodegradable
Remarks: Based on data from similar materials

Sodium n-dodecyl sulfate:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 95 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Bioaccumulative potential

Components:

Efavirenz:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 454
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 5,4

Magnesium stearate:

Partition coefficient: n-octanol/water : log Pow: > 4

Sodium n-dodecyl sulfate:

Partition coefficient: n-octanol/water : log Pow: 0,83

Mobility in soil

Components:

Efavirenz:

Distribution among environmental compartments : log Koc: 3,36
Method: FDA 3.08

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Efavirenz)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes

IATA-DGR

UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Efavirenz)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	956
Packing instruction (passenger aircraft)	:	956
Environmentally hazardous	:	yes

IMDG-Code

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.

Special precautions for user

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

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry.	:	Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 06.07.2024
Date format : dd.mm.yyyy

Further information

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

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 other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average
AR OEL / CMP : TLV (Threshold Limit Value)

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 Substanc-

es; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for 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.

AR / Z8