

Elbasvir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
9.0	28.09.2024	529954-00025	Date of first issue: 23.02.2016

SECTION 1. IDENTIFICATION

Product identifier : Elbasvir Formulation

Manufacturer or supplier's details

Company : MSD

Address : Avenida Tanner de Melo, Quadra 10 Lote 4A, Galpão A
Parque Industrial Vice Presidente José Alencar Aparecida de
Goiás – GO, Brazil

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 in accordance with ABNT NBR 14725 Standard

Long-term (chronic) aquatic hazard : Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements : **Prevention:**
P273 Avoid release to the environment.
Response:
P391 Collect spillage.**Other hazards which do not result in classification**Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

Elbasvir Formulation

Version 9.0 Revision Date: 28.09.2024 SDS Number: 529954-00025 Date of last issue: 06.07.2024
Date of first issue: 23.02.2016

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Cellulose	9004-34-6		≥ 10 -< 20
Elbasvir	1370468-36-2	Acute Tox. (Oral), 5 Aquatic Chronic, 1	≥ 5 -< 10
Sodium chloride	7647-14-5	Acute Tox. (Oral), 5	≥ 5 -< 10
Titanium dioxide	13463-67-7	Carc. (Inhalation), 2	$\geq 0,1$ -< 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 : Wash with water and soap.
Get medical attention if symptoms occur.

In case of eye contact : If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

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 prod- : Carbon oxides

Elbasvir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
9.0	28.09.2024	529954-00025	Date of first issue: 23.02.2016

- | | | |
|--|---|---|
| ucts | | Metal oxides
Chlorine compounds |
| 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 | : | Use only with adequate ventilation. |
| Advice on safe handling | : | Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure |

Elbasvir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
9.0	28.09.2024	529954-00025	Date of first issue: 23.02.2016

- assessment
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.
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 contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- Conditions for safe storage : Keep in properly labeled containers.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
Elbasvir	1370468-36-2	TWA	150 µg/m ³ (OEB 2)	Internal

- Engineering measures** : Use feasible engineering controls to minimize exposure to compound.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

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 : Chemical-resistant gloves
- Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Skin and body protection : Work uniform or laboratory coat.

Elbasvir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
9.0	28.09.2024	529954-00025	Date of first issue: 23.02.2016

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	:	powder
Color	:	brown
Odor	:	odorless
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	:	Not applicable
Evaporation rate	:	Not applicable
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	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive

Elbasvir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
9.0	28.09.2024	529954-00025	Date of first issue: 23.02.2016

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

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

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg
Method: Calculation method

Components:**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

Elbasvir:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg
LD50 (Mouse): > 1.000 mg/kg

Sodium chloride:

Acute oral toxicity : LD50 (Rat): 3.550 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 42 mg/l

Elbasvir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
9.0	28.09.2024	529954-00025	Date of first issue: 23.02.2016

Acute dermal toxicity	Exposure time: 1 h
	Test atmosphere: dust/mist
	: LD50 (Rabbit): > 5.000 mg/kg

Titanium dioxide:

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

Skin corrosion/irritation

Not classified based on available information.

Components:**Elbasvir:**

Species	: reconstructed human epidermis (RhE)
Result	: No skin irritation

Sodium chloride:

Species	: Rabbit
Result	: No skin irritation

Titanium dioxide:

Species	: Rabbit
Result	: No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Elbasvir:**

Species	: Bovine cornea
Result	: No eye irritation

Sodium chloride:

Species	: Rabbit
Result	: No eye irritation

Titanium dioxide:

Species	: Rabbit
Result	: No eye irritation

Elbasvir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
9.0	28.09.2024	529954-00025	Date of first issue: 23.02.2016

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**Elbasvir:**

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

Sodium chloride:

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

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:**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

Elbasvir:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: Chromosome aberration test in vitro Result: negative

Elbasvir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
9.0	28.09.2024	529954-00025	Date of first issue: 23.02.2016

Genotoxicity in vivo	: Test Type: In vivo micronucleus test Species: Rat Application Route: Oral Result: negative
Germ cell mutagenicity - Assessment	: Weight of evidence does not support classification as a germ cell mutagen.

Sodium chloride:

Genotoxicity in vitro	: Test Type: In vitro mammalian cell gene mutation test Result: positive Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: Saccharomyces cerevisiae, gene mutation assay (in vitro) Result: positive Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Result: positive Test Type: Chromosome aberration test in vitro Result: positive Test Type: Chromosome aberration test in vitro Result: negative
Genotoxicity in vivo	: Test Type: In vivo micronucleus test Species: Mouse Application Route: Intraperitoneal injection Result: negative Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Rat Application Route: Intraperitoneal injection Result: positive
Germ cell mutagenicity - Assessment	: Weight of evidence does not support classification as a germ cell mutagen.

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.

Elbasvir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
9.0	28.09.2024	529954-00025	Date of first issue: 23.02.2016

Components:**Cellulose:**

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

Sodium chloride:

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

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

Not classified based on available information.

Components:**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

Elbasvir:

Effects on fertility	: Test Type: Fertility/early embryonic development Species: Rat, male and female Application Route: Oral Fertility: NOAEL: 1.000 mg/kg body weight Result: No effects on fertility.
Effects on fetal development	: Test Type: Embryo-fetal development Species: Rat Application Route: Oral

Elbasvir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
9.0	28.09.2024	529954-00025	Date of first issue: 23.02.2016

Developmental Toxicity: NOAEL: 1.000 mg/kg body weight
Result: No effects on early embryonic development.

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 1.000 mg/kg body weight
Result: No effects on early embryonic development.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Repeated dose toxicity**Components:****Cellulose:**

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

Elbasvir:

Species	: Rat
NOAEL	: 1.000 mg/kg
Application Route	: Oral
Exposure time	: 180 d
Remarks	: No significant adverse effects were reported

Species	: Dog
NOAEL	: 1.000 mg/kg
Application Route	: Oral
Exposure time	: 270 d
Remarks	: No significant adverse effects were reported

Sodium chloride:

Species	: Rat
LOAEL	: 2.533 mg/kg
Application Route	: Ingestion
Exposure time	: 2 y

Titanium dioxide:

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

Species	: Rat
NOAEL	: 10 mg/m ³
Application Route	: inhalation (dust/mist/fume)

Elbasvir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
9.0	28.09.2024	529954-00025	Date of first issue: 23.02.2016

Exposure time : 2 y

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Elbasvir:**

Ingestion : Symptoms: Headache, Abdominal pain, constipation, Nausea, Fatigue, muscle pain, joint pain, Dizziness, Cough, Skin irritation, rhinitis, Drowsiness, nasal congestion

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Cellulose:**

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

Elbasvir:

Toxicity to fish : LC50 (*Lepomis macrochirus* (Bluegill sunfish)): > 10 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: No toxicity at the limit of solubility.

LC50 (*Menidia beryllina* (Siverside)): > 10 mg/l
Exposure time: 96 h
Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): > 10 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility.

LC50 (*Americamysis*): 7,7 mg/l
Exposure time: 96 h
Method: US-EPA OPPTS 850.1035
Remarks: No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants : EC50 (*Pseudokirchneriella subcapitata* (algae)): > 0,081 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility.

NOEC (*Pseudokirchneriella subcapitata* (green algae)): 0,081 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Elbasvir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
9.0	28.09.2024	529954-00025	Date of first issue: 23.02.2016

Remarks: No toxicity at the limit of solubility.

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0,0023 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0,84 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility.

M-Factor (Chronic aquatic toxicity) : 10

Toxicity to microorganisms : EC50: > 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 271,9 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Sodium chloride:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 5.840 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 4.136 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50: > 2.000 mg/l
Exposure time: 96 h

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 252 mg/l
Exposure time: 33 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia pulex (Water flea)): 314 mg/l
Exposure time: 21 d

Toxicity to microorganisms : EC10: > 1.000 mg/l

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

Elbasvir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
9.0	28.09.2024	529954-00025	Date of first issue: 23.02.2016

Method: OECD Test Guideline 209

Persistence and degradability**Components:****Cellulose:**

Biodegradability : Result: Readily biodegradable.

Elbasvir:Biodegradability : Result: Not readily biodegradable.
Biodegradation: 37 %
Exposure time: 28 d**Bioaccumulative potential****Components:****Elbasvir:**Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 82
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 6,54

Mobility in soil**Components:****Elbasvir:**

Distribution among environmental compartments : log Koc: 5,24

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.

Elbasvir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
9.0	28.09.2024	529954-00025	Date of first issue: 23.02.2016

(Elbasvir)

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. (Elbasvir)
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. (Elbasvir)
Class	: 9
Packing group	: III
Labels	: 9
EmS Code	: F-A, S-F
Marine pollutant	: yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation**ANTT**

UN number	: UN 3077
Proper shipping name	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Elbasvir)
Class	: 9
Packing group	: III
Labels	: 9
Hazard Identification Number	: 90

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**

National List of Carcinogenic Agents for Humans - (LINACH)

Elbasvir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
9.0	28.09.2024	529954-00025	Date of first issue: 23.02.2016

Group 2B: Possibly carcinogenic to humans

Titanium dioxide

13463-67-7

Brazil. List of chemicals controlled by the Federal Police : 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	: 28.09.2024
Date format	: dd.mm.yyyy

Further informationSources 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)

ACGIH / TWA : 8-hour, time-weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Develop-

Elbasvir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
9.0	28.09.2024	529954-00025	Date of first issue: 23.02.2016

ment; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations 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.

BR / Z8