

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Elbasvir Formulation

Version 13.1      Revision Date: 05/09/2026      SDS Number: 529970-00028      Date of last issue: 12/13/2025  
Date of first issue: 02/23/2016

### SECTION 1. IDENTIFICATION

Product name : Elbasvir Formulation

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.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 the OSHA Hazard Communication Standard (29 CFR 1910.1200)

#### Hazards for the product as supplied

Not a hazardous substance or mixture.

#### Other hazards

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.

#### Hazards associated with a change in physical form:

Conditions	Hazards
If small particles are generated during further processing, handling or by other means.	May form combustible dust concentrations in air.

#### GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Cellulose	9004-34-6*	$\geq 7 - \leq 13$	TSC
Elbasvir	1370468-36-2*	$\geq 7 - \leq 13$	TSC
Titanium dioxide	13463-67-7*	$\geq 0.1 - \leq 1$	TSC
Talc	14807-96-6*	$\geq 0.1 - \leq 1$	TSC

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\* Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

### SECTION 4. FIRST AID MEASURES

- |   |   |  |
|---|---|--|
| General advice  | : | In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice. |
| If inhaled  | : | If inhaled, remove to fresh air.<br>Get medical attention if symptoms occur.   |
| In case of skin contact                                     | : | Wash with water and soap.<br>Get medical attention if symptoms occur.  |
| In case of eye contact                                      | : | If in eyes, rinse well with water.<br>Get medical attention if irritation develops and persists.   |
| If swallowed  | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention if symptoms occur.<br>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.<br>Dust contact with the eyes can lead to mechanical irritation.              |
| Protection of first-aiders                                  | : | No special precautions are necessary for first aid responders.   |
| Notes to physician  | : | Treat symptomatically and supportively.  |

### SECTION 5. FIRE-FIGHTING MEASURES

- |  |   |   |
|--|---|---|
| Suitable extinguishing media                   | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>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.<br>Exposure to combustion products may be a hazard to health.                   |
| Hazardous combustion products                  | : | Carbon oxides<br>Metal oxides<br>Chlorine compounds   |
| Specific extinguishing methods                 | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | Wear self-contained breathing apparatus for firefighting if necessary.  |

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Use personal protective equipment.

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : 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.
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### 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.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure 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.
- 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
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### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

inert or nuisance dust      50 Million particles per cubic foot  
Value type (Form of exposure): TWA (total dust)  
Basis: OSHA Z-3

15 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (total dust)  
Basis: OSHA Z-3

5 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (respirable fraction)  
Basis: OSHA Z-3

15 Million particles per cubic foot  
Value type (Form of exposure): TWA (respirable fraction)  
Basis: OSHA Z-3

Dust, nuisance dust and particulates      10 mg/m<sup>3</sup>  
Value type (Form of exposure): PEL (Total dust)  
Basis: CAL PEL

5 mg/m<sup>3</sup>  
Value type (Form of exposure): PEL (respirable dust fraction)  
Basis: CAL PEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1
Elbasvir	1370468-36-2	TWA	150 µg/m <sup>3</sup> (OEB 2)	Internal
Titanium dioxide	13463-67-7	TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Respirable particulate matter)	2.5 mg/m <sup>3</sup> (Titanium dioxide)	ACGIH
Talc	14807-96-6	TWA (Dust)	20 Million particles per cubic foot	OSHA Z-3
		TWA (Respirable)	2 mg/m <sup>3</sup>	NIOSH REL
		TWA (Res-	2 mg/m <sup>3</sup>	ACGIH

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		pirable particulate matter)		
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**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** : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**Hand protection**  
**Material** : 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.  
**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.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance** : powder  
**Color** : brown  
**Odor** : odorless  
**Odor Threshold** : No data available

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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
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Particle characteristics Particle size	:	No data available

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### SECTION 10. STABILITY AND REACTIVITY

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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.

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### 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

##### Titanium dioxide:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 425  
Remarks: The test was conducted according to guideline

Acute inhalation toxicity : LC50 (Rat): > 5.09 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403

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Assessment: The substance or mixture has no acute inhalation toxicity

Remarks: The test was conducted according to guideline

### **Talc:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Remarks: Based on data from similar materials

### **Skin corrosion/irritation**

Not classified based on available information.

### **Components:**

#### **Elbasvir:**

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

#### **Titanium dioxide:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation  
Remarks : The test was conducted equivalent or similar to guideline

### **Talc:**

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

#### **Titanium dioxide:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405  
Remarks : The test was conducted according to guideline

### **Talc:**

Species : Rabbit  
Result : No eye irritation

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### 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

##### Titanium dioxide:

Test Type : Buehler Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative  
Remarks : The test was conducted according to guideline

##### Talc:

Routes of exposure : Skin contact  
Species : Humans  
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

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Genotoxicity in vivo : Result: negative  
: 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.

### **Titanium dioxide:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: The test was conducted according to guideline

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: The test was conducted according to guideline

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: The test was conducted according to guideline

Genotoxicity in vivo : Test Type: Transgenic rodent somatic cell gene mutation assay  
Species: Mouse (male)  
Application Route: Intravenous injection  
Method: OECD Test Guideline 488  
Result: negative  
Remarks: The test was conducted equivalent or similar to guideline

### **Talc:**

Genotoxicity in vitro : Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: negative

Genotoxicity in vivo : Test Type: Chromosome aberration test in vitro  
Species: Rat  
Application Route: Ingestion  
Result: negative

### **Carcinogenicity**

Not classified based on available information.

### **Components:**

#### **Cellulose:**

Species : Rat

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

### Talc:

Species : Mouse  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 2 Years  
Result : negative

### IARC

**Group 2A: Probably carcinogenic to humans**

Talc 14807-96-6

**Group 2B: Possibly carcinogenic to humans**

Titanium dioxide 13463-67-7

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### 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  
Developmental Toxicity: NOAEL: 1,000 mg/kg body weight  
Result: No effects on early embryonic development.

Test Type: Embryo-fetal development  
Species: Rabbit

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Application Route: Oral  
Developmental Toxicity: NOAEL: 1,000 mg/kg body weight  
Result: No effects on early embryonic development.

### **Titanium dioxide:**

Effects on fertility : Test Type: Extended one-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 443  
Result: negative  
Remarks: The test was conducted according to guideline

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: negative  
Remarks: The test was conducted according to guideline

### **Talc:**

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

### **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

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Exposure time : 270 d  
Remarks : No significant adverse effects were reported

### **Titanium dioxide:**

Species : Rat  
NOAEL :  $\geq 1,000$  mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days  
Method : OECD Test Guideline 408  
Remarks : The test was conducted according to guideline

### **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

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## 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* (Silverside)):  $> 10$  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

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- 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  
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.
- 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

### Titanium dioxide:

- Toxicity to fish : LL50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
Exposure time: 96 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 203  
Remarks: The test was conducted according to guideline  
Based on transformation/dissolution testing and data from soluble metal compounds
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: The test was conducted according to guideline
- Toxicity to algae/aquatic plants : EL50 (Raphidocelis subcapitata (freshwater green alga)): > 100 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: The test was conducted according to guideline

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NOELR (Raphidocelis subcapitata (freshwater green alga)):  
>= 100 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: The test was conducted according to guideline

Toxicity to microorganisms : NOEC (activated sludge): >= 1,000 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209  
Remarks: The test was conducted according to guideline

### Talc:

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 100,000 mg/l  
Exposure time: 24 h

### 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

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### Endocrine disrupting properties

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

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

Contaminated packaging : Empty containers should be taken to an approved waste 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)

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 IMO instruments

Not applicable for product as supplied.

### Domestic regulation

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### 49 CFR

UN/ID/NA number : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (Elbasvir)  
Class : 9  
Packing group : III  
Labels : CLASS 9  
ERG Code : 171  
Marine pollutant : yes(Elbasvir)  
Remarks : Above applies only to containers over 119 gallons (450 liters) in case of liquids, or 882 lbs. (400 kg) in case of solids. Shipment by ground under DOT is non-regulated for non-bulk packaging; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

### 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.

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## SECTION 15. REGULATORY INFORMATION

### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : No SARA Hazards

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### US State Regulations

#### Pennsylvania Right To Know

Hydroxypropyl methylcellulose	9004-65-3
Croscarmellose sodium	74811-65-7
Cellulose	9004-34-6
D-Glucose, 4-O-β-D-galactopyranosyl-, monohydrate	64044-51-5
Sodium chloride	7647-14-5
Elbasvir	1370468-36-2
Tocopherol polyethyleneglycol succinate	9002-96-4

#### California Prop. 65

WARNING: This product can expose you to chemicals including

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Titanium dioxide, which is/are known to the State of California to cause cancer. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov). **California Permissible Exposure Limits for Chemical Contaminants**

Cellulose 9004-34-6

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

AICS : not determined

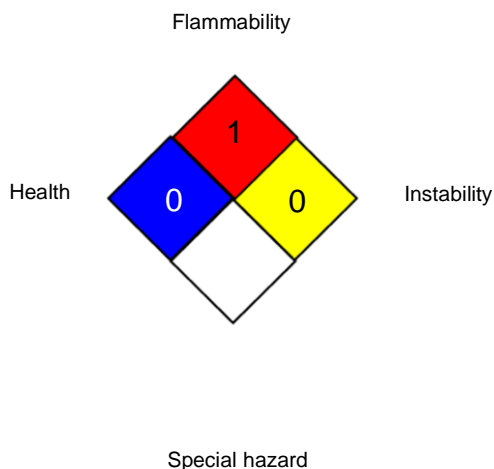
CA. DSL : not determined

CN IECSC : not determined

### SECTION 16. OTHER INFORMATION

#### Further information

##### NFPA 704:



##### HMIS® IV / CED:

HEALTH	/	0
FLAMMABILITY		3
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

- ACGIH : USA. ACGIH Threshold Limit Values (TLV)
- CAL PEL : California permissible exposure limits for chemical contaminants (Title 8, Article 107)
- NIOSH REL : USA. NIOSH Recommended Exposure Limits
- OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
- ACGIH / TWA : 8-hour, time-weighted average
- CAL PEL / PEL : Permissible exposure limit
- NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
- OSHA Z-1 / TWA : 8-hour time weighted average
- OSHA Z-3 / TWA : 8-hour time weighted average

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AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardization; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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 Organization 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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/>

Revision Date : 05/09/2026

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.

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