

**Grazoprevir / Elbasvir Formulation**

Version 5.1      Revision Date: 2023/09/30      SDS Number: 76210-00026      Date of last issue: 2023/04/04  
Date of first issue: 2015/03/17

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**1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Grazoprevir / Elbasvir Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : JL Raya Pandaan KM. 48  
Pandaan, Jawa Timur - Indonesia

Telephone : 908-740-4000

Emergency telephone number : 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

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**2. HAZARDS IDENTIFICATION****GHS Classification**

Long-term (chronic) aquatic hazard : Category 1

**GHS label elements**

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.

**Disposal:**

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

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### 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.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	< 10
Grazoprevir	1350462-55-3	< 10
Elbasvir	1370468-36-2	>= 2.5 -< 10
Magnesium stearate	557-04-0	< 10
Titanium dioxide	13463-67-7	< 1

### 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.

### 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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

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- potential dust explosion hazard.  
Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Metal oxides  
Chlorine compounds  
Nitrogen oxides (NO<sub>x</sub>)
- 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 firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

### 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.

### 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.

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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 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 labelled containers.  
 Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:  
 Strong oxidizing agents

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	NAB	10 mg/m <sup>3</sup>	ID OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Grazoprevir	1350462-55-3	TWA	85 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	850 µg/100 cm <sup>2</sup>	Internal
Elbasvir	1370468-36-2	TWA	150 µg/m <sup>3</sup> (OEB 2)	Internal
Magnesium stearate	557-04-0	NAB	10 mg/m <sup>3</sup>	ID OEL
	Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals			
		TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
Titanium dioxide	13463-67-7	NAB	10 mg/m <sup>3</sup>	ID OEL
	Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals			
		TWA (Respirable particulate matter)	2.5 mg/m <sup>3</sup> (Titanium dioxide)	ACGIH

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**Engineering measures** : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).  
Minimize open handling.

**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 : Consider double gloving.  
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. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

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.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : powder  
Colour : white  
Odour : No data available  
Odour 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
Vapour pressure	:	Not applicable
Relative vapour 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
Auto-ignition 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 size	:	No data available

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**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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**11. TOXICOLOGICAL INFORMATION**

Information on likely routes of exposure :

- Inhalation
- Skin contact
- Ingestion
- Eye contact

**Acute toxicity**

Not classified based on available information.

**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

**Grazoprevir:**

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg
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**Elbasvir:**

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg
		LD50 (Mouse): > 1,000 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

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**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:****Grazoprevir:**

Result : No skin irritation

**Elbasvir:**

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

**Magnesium stearate:**

Species : Rabbit  
Result : No skin irritation  
Remarks : Based on data from similar materials

**Titanium dioxide:**

Species : Rabbit  
Result : No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Grazoprevir:**

Species : Bovine cornea  
Result : No eye irritation

**Elbasvir:**

Species : Bovine cornea  
Result : No eye irritation

**Magnesium stearate:**

Species : Rabbit  
Result : No eye irritation  
Remarks : Based on data from similar materials



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**Titanium dioxide:**

Species : Rabbit  
Result : No eye irritation

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****Grazoprevir:**

Test Type : Local lymph node assay (LLNA)  
Exposure routes : Dermal  
Result : Not a skin sensitizer.

**Elbasvir:**

Test Type : Local lymph node assay (LLNA)  
Exposure routes : Dermal  
Species : Mouse  
Result : negative

**Magnesium stearate:**

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative  
Remarks : Based on data from similar materials

**Titanium dioxide:**

Test Type : Local lymph node assay (LLNA)  
Exposure routes : 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

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Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Result: negative

**Grazoprevir:**

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

Test Type: Chromosome aberration test in vitro  
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test  
Application Route: Oral  
Result: negative

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

**Elbasvir:**

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

Test Type: Chromosome aberration test in vitro  
Result: negative

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.

**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

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**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:****Cellulose:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 72 weeks  
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 foetal development : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative

**Grazoprevir:**

Effects on fertility : Test Type: Fertility  
Species: Rat

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Application Route: Oral  
 Fertility: NOAEL: 400 mg/kg body weight  
 Result: negative

Test Type: Multi-generation study  
 Species: Rat  
 Application Route: Oral  
 Fertility: NOAEL: 400 mg/kg body weight  
 Result: No effects on fertility, No effects on foetal development

Effects on foetal development : Test Type: Embryo-foetal development  
 Species: Rat  
 Application Route: Oral  
 Embryo-foetal toxicity: NOAEL: 200 mg/kg body weight  
 Result: No effects on foetal development

Test Type: Embryo-foetal development  
 Species: Rabbit  
 Application Route: Oral  
 Embryo-foetal toxicity: NOAEL: 200 mg/kg body weight  
 Result: No effects on foetal development

Test Type: Embryo-foetal development  
 Species: Rabbit  
 Application Route: Intravenous  
 Embryo-foetal toxicity: NOAEL: 100 mg/kg body weight  
 Result: No effects on foetal development

**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 foetal development : Test Type: Embryo-foetal 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-foetal development  
 Species: Rabbit  
 Application Route: Oral  
 Developmental Toxicity: NOAEL: 1,000 mg/kg body weight  
 Result: No effects on early embryonic development

**Magnesium stearate:**

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
 Species: Rat

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Application Route: Ingestion  
 Method: OECD Test Guideline 422  
 Result: negative  
 Remarks: Based on data from similar materials

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

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Not classified based on available information.

**Components:****Grazoprevir:**

Target Organs : Liver, Testis  
 Assessment : May cause damage to organs through prolonged or repeated exposure.

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

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

**Grazoprevir:**

Species : Rat  
 NOAEL : 400 mg/kg  
 Application Route : Oral  
 Exposure time : 30 Days  
 Remarks : No significant adverse effects were reported

Species : Rat  
 NOAEL : 400 mg/kg  
 Application Route : Oral  
 Exposure time : 180 Days  
 Remarks : No significant adverse effects were reported

Species : Dog  
 NOAEL : 15 mg/kg  
 LOAEL : 100 mg/kg  
 Application Route : Oral

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Exposure time : 270 Days  
Target Organs : Liver, Blood, Bone marrow, gallbladder, spleen, Testis

Species : Mouse  
NOAEL : 200 mg/kg  
LOAEL : 500 mg/kg  
Application Route : Oral  
Exposure time : 90 Days  
Target Organs : Liver, Kidney, Blood

Species : Dog  
NOAEL : 20 mg/kg  
LOAEL : 600 mg/kg  
Application Route : Oral  
Exposure time : 30 Days  
Target Organs : Blood, Testis

Species : Monkey  
NOAEL : 10 mg/kg  
Exposure time : 8 Days  
Remarks : No significant adverse effects were reported

**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

**Magnesium stearate:**

Species : Rat  
NOAEL : > 100 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/m<sup>3</sup>

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Application Route : inhalation (dust/mist/fume)  
Exposure time : 2 yr

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Grazoprevir:**

Ingestion : Symptoms: Headache, Gastrointestinal disturbance

**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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**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

**Grazoprevir:**

Toxicity to fish : LC50 (*Cyprinodon variegatus* (sheepshead minnow)): > 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*): 8.9 mg/l  
Exposure time: 96 h

Toxicity to algae/aquatic plants : EC50 (*Pseudokirchneriella subcapitata* (green algae)): > 10 mg/l  
Exposure time: 72 hrs  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility

NOEC (*Pseudokirchneriella subcapitata* (green algae)): 10 mg/l  
Exposure time: 72 hrs

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- Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility
- Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.98 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210  
Remarks: No toxicity at the limit of solubility
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 5 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211
- Toxicity to microorganisms : EC50: > 1,000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209
- NOEC: 1.3 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209
- 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  
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



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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

**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

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Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

**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:****Cellulose:**

Biodegradability : Result: Readily biodegradable.

**Grazoprevir:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 66 %  
Exposure time: 28 d

**Elbasvir:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 37 %  
Exposure time: 28 d

**Magnesium stearate:**

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

**Bioaccumulative potential****Components:****Grazoprevir:**

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)  
Bioconcentration factor (BCF): 7.62

Partition coefficient: n-octanol/water : log Pow: 3.72

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**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

**Magnesium stearate:**

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

**Mobility in soil****Components:****Grazoprevir:**

Distribution among environmental compartments : log Koc: 4.01

**Elbasvir:**

Distribution among environmental compartments : log Koc: 5.24

**Other adverse effects**

No data available

**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.

**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.

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(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.

**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.

**15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

**Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.**

**Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health**

Hazardous substances that must be registered	:	Not applicable
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**Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances**

Hazardous substances approved for use	:	Not applicable
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Prohibited substances	:	Not applicable
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Restricted substances	:	Not applicable
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**Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials**

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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

AICS	: not determined
DSL	: not determined
IECSC	: not determined

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**16. OTHER INFORMATION**

Revision Date : 2023/09/30

**Further information**

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

Date format : yyyy/mm/dd

**Full text of other abbreviations**

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
ID OEL	: Indonesia. Occupational Exposure Limits

ACGIH / TWA	: 8-hour, time-weighted average
ID OEL / NAB	: Long term exposure limit

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

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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 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.

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