

# SAFETY DATA SHEET



## Grazoprevir / Elbasvir Formulation

Version 12.0 Revision Date: 07.08.2025 SDS Number: 76217-00031 Date of last issue: 14.04.2025  
Date of first issue: 17.03.2015

---

### Section 1: Identification

Product name : Grazoprevir / Elbasvir Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908  
Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800 CHEMCALL)

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: Hazard identification

#### GHS Classification

Carcinogenicity (Inhalation) : Category 2

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Liver, Testis)

Hazardous to the aquatic environment - chronic hazard : Category 1

#### GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H351 Suspected of causing cancer if inhaled.  
H373 May cause damage to organs (Liver, Testis) through prolonged or repeated exposure if swallowed.  
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**

# SAFETY DATA SHEET



## Grazoprevir / Elbasvir Formulation

Version 12.0 Revision Date: 07.08.2025

SDS Number: 76217-00031

Date of last issue: 14.04.2025  
Date of first issue: 17.03.2015

P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

### Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P391 Collect spillage.

### Storage:

P405 Store locked up.

### Disposal:

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

### Other hazards which do not result in classification

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.

## Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 1 -< 10
Grazoprevir	1350462-55-3	>= 1 -< 10
Elbasvir	1370468-36-2	>= 2.5 -< 10
Magnesium stearate	557-04-0	>= 1 -< 10
Titanium dioxide	13463-67-7	>= 0.1 -< 1

## Section 4: First-aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.  
Get medical attention.

In case of skin contact : 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.

# SAFETY DATA SHEET



## Grazoprevir / Elbasvir Formulation

Version 12.0      Revision Date: 07.08.2025      SDS Number: 76217-00031      Date of last issue: 14.04.2025  
Date of first issue: 17.03.2015

---

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. Suspected of causing cancer if inhaled. May cause damage to organs through prolonged or repeated exposure if swallowed.
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 (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 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.
Hazchem Code	: 2Z

---

### 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.

# SAFETY DATA SHEET



## Grazoprevir / Elbasvir Formulation

Version 12.0	Revision Date: 07.08.2025	SDS Number: 76217-00031	Date of last issue: 14.04.2025 Date of first issue: 17.03.2015
-----------------	------------------------------	----------------------------	---

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

### Materials to avoid

- : Do not store with the following product types:  
Strong oxidizing agents

# SAFETY DATA SHEET



## Grazoprevir / Elbasvir Formulation

Version  
12.0

Revision Date:  
07.08.2025

SDS Number:  
76217-00031

Date of last issue: 14.04.2025  
Date of first issue: 17.03.2015

### Section 8: Exposure controls/personal protection

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Cellulose	9004-34-6	WES-TWA	10 mg/m3	NZ OEL
		TWA	10 mg/m3	ACGIH
Grazoprevir	1350462-55-3	TWA	260 µg/m3 (OEB 2)	Internal
Elbasvir	1370468-36-2	TWA	150 µg/m3 (OEB 2)	Internal
Magnesium stearate	557-04-0	WES-TWA	10 mg/m3	NZ OEL
		TWA (Inhal- able particu- late matter)	10 mg/m3	ACGIH
		TWA (Res- pirable par- ticulate mat- ter)	3 mg/m3	ACGIH
Titanium dioxide	13463-67-7	WES-TWA	10 mg/m3	NZ OEL

**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

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.

### Section 9: Physical and chemical properties

Appearance : powder

Colour : white

# SAFETY DATA SHEET



## Grazoprevir / Elbasvir Formulation

Version 12.0      Revision Date: 07.08.2025      SDS Number: 76217-00031      Date of last issue: 14.04.2025  
Date of first issue: 17.03.2015

---

Odour	:	No data available
Odour 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
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.

# SAFETY DATA SHEET



## Grazoprevir / Elbasvir Formulation

Version 12.0 Revision Date: 07.08.2025 SDS Number: 76217-00031 Date of last issue: 14.04.2025 Date of first issue: 17.03.2015

---

### 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

Exposure routes : 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

#### **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

# SAFETY DATA SHEET



## Grazoprevir / Elbasvir Formulation

Version 12.0      Revision Date: 07.08.2025      SDS Number: 76217-00031      Date of last issue: 14.04.2025  
Date of first issue: 17.03.2015

---

||| 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

### 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

# SAFETY DATA SHEET



## Grazoprevir / Elbasvir Formulation

Version 12.0      Revision Date: 07.08.2025      SDS Number: 76217-00031      Date of last issue: 14.04.2025  
Date of first issue: 17.03.2015

---

Result : No eye irritation

### **Magnesium stearate:**

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

### **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

# SAFETY DATA SHEET



## Grazoprevir / Elbasvir Formulation

Version  
12.0

Revision Date:  
07.08.2025

SDS Number:  
76217-00031

Date of last issue: 14.04.2025  
Date of first issue: 17.03.2015

### Chronic toxicity

#### 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

##### **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

# SAFETY DATA SHEET



## Grazoprevir / Elbasvir Formulation

Version  
12.0

Revision Date:  
07.08.2025

SDS Number:  
76217-00031

Date of last issue: 14.04.2025  
Date of first issue: 17.03.2015

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

### 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

Suspected of causing cancer if inhaled.

### 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
----------------------	---	---

# SAFETY DATA SHEET



## Grazoprevir / Elbasvir Formulation

Version 12.0      Revision Date: 07.08.2025      SDS Number: 76217-00031      Date of last issue: 14.04.2025  
Date of first issue: 17.03.2015

---

		Species: Rat Application Route: Ingestion Result: negative
Effects on foetal development	:	Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative
		Test Type: Fertility Species: Rat 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
<b>Grazoprevir:</b>		
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
<b>Elbasvir:</b>		
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

# SAFETY DATA SHEET



## Grazoprevir / Elbasvir Formulation

Version  
12.0

Revision Date:  
07.08.2025

SDS Number:  
76217-00031

Date of last issue: 14.04.2025  
Date of first issue: 17.03.2015

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  
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**

May cause damage to organs (Liver, Testis) through prolonged or repeated exposure if swallowed.

### **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

:  $\geq 9,000$  mg/kg

Application Route

: Ingestion

Exposure time

: 90 Days

#### **Grazoprevir:**

Species

: Rat

NOAEL

: 400 mg/kg

# SAFETY DATA SHEET



## Grazoprevir / Elbasvir Formulation

Version 12.0      Revision Date: 07.08.2025      SDS Number: 76217-00031      Date of last issue: 14.04.2025  
Date of first issue: 17.03.2015

---

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
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
---------	---	-----

# SAFETY DATA SHEET



## Grazoprevir / Elbasvir Formulation

Version 12.0 Revision Date: 07.08.2025 SDS Number: 76217-00031 Date of last issue: 14.04.2025 Date of first issue: 17.03.2015

---

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>
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
-----------	---

---

## 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
------------------	--

##### **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
---	--

# SAFETY DATA SHEET



## Grazoprevir / Elbasvir Formulation

Version 12.0 Revision Date: 07.08.2025 SDS Number: 76217-00031 Date of last issue: 14.04.2025 Date of first issue: 17.03.2015

---

		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 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
<b>Elbasvir:</b>		
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

# SAFETY DATA SHEET



## Grazoprevir / Elbasvir Formulation

Version 12.0 Revision Date: 07.08.2025 SDS Number: 76217-00031 Date of last issue: 14.04.2025 Date of first issue: 17.03.2015

		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
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
<b>Magnesium stearate:</b>		
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

# SAFETY DATA SHEET



## Grazoprevir / Elbasvir Formulation

Version 12.0 Revision Date: 07.08.2025 SDS Number: 76217-00031 Date of last issue: 14.04.2025 Date of first issue: 17.03.2015

---

Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubility

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (Pseudomonas putida): > 100 mg/l  
Exposure time: 16 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

### 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

# SAFETY DATA SHEET



## Grazoprevir / Elbasvir Formulation

Version 12.0 Revision Date: 07.08.2025 SDS Number: 76217-00031 Date of last issue: 14.04.2025  
Date of first issue: 17.03.2015

---

### **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

##### **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

---

## 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.

# SAFETY DATA SHEET



## Grazoprevir / Elbasvir Formulation

Version 12.0 Revision Date: 07.08.2025 SDS Number: 76217-00031 Date of last issue: 14.04.2025  
Date of first issue: 17.03.2015

---

### 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 Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### National Regulations

##### NZS 5433

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Elbasvir)  
Class : 9  
Packing group : III  
Labels : 9  
Hazchem Code : 2Z  
Marine pollutant : no

# SAFETY DATA SHEET



## Grazoprevir / Elbasvir Formulation

Version 12.0 Revision Date: 07.08.2025 SDS Number: 76217-00031 Date of last issue: 14.04.2025 Date of first issue: 17.03.2015

---

### 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

##### HSNO Approval Number

HSR100425 Pharmaceutical Active Ingredients Group Standard

Tolerable Exposure Limits (TEL)

Not applicable

Environmental Exposure Limits (EEL)

Not applicable

##### HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS : not determined

DSL : not determined

IECSC : not determined

---

### Section 16: Other information

Revision Date : 07.08.2025

#### 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/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : dd.mm.yyyy

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

# SAFETY DATA SHEET



## Grazoprevir / Elbasvir Formulation

Version 12.0	Revision Date: 07.08.2025	SDS Number: 76217-00031	Date of last issue: 14.04.2025 Date of first issue: 17.03.2015
-----------------	------------------------------	----------------------------	---

ACGIH / TWA : 8-hour, time-weighted average  
NZ OEL / WES-TWA : Workplace Exposure Standard - 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 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.

NZ / EN