

Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 76218-00027 Date of first issue: 17.03.2015

Section 1: Identification

Product identifier : Grazoprevir / Elbasvir Formulation

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

Manufacturer or supplier's details

Company : MSD

Address : 50 Tuas West Drive

Singapore - Singapore 638408

Telephone : +1-908-740-4000

Emergency telephone number : 65 6697 2111 (24/7/365)

E-mail address : EHSDATASTEWARD@msd.com

Section 2: Hazard identification

Classification of the substance or mixture

Long-term (chronic) aquatic

hazard

: Category 1

GHS Label elements, including precautionary statements

Hazard pictograms :

3

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.



Grazoprevir / Elbasvir Formulation

SDS Number: Date of last issue: 06.04.2024 Version Revision Date: 5.0 06.07.2024 76218-00027 Date of first issue: 17.03.2015

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

Description of necessary first-aid measures

General advice In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled If inhaled, remove to fresh air.

Get medical attention.

Wash with water and soap. In case of skin contact

Get medical attention if symptoms occur.

If in eyes, rinse well with water. In case of eye contact

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

Risks Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation. 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).

Indication of any immediate medical attention and special treatment needed

Treatment Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Protection of first-aiders

Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 76218-00027 Date of first issue: 17.03.2015

Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides Metal oxides

Chlorine compounds Nitrogen oxides (NOx)

Special protective actions for fire-fighters

Special protective equipment :

for firefighters

Specific extinguishing meth-

ods

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

Environmental precautions

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

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable con-

tainer 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 deter-

mine which regulations are applicable.



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 76218-00027 Date of first issue: 17.03.2015

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

Section 7: Handling and storage

Precautions for safe handling

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 Advice on safe handling Use only with adequate ventilation.

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 as-

sessment

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, including any incompatibilities

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

Section 8: Exposure controls/personal protection

Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	



Grazoprevir / Elbasvir Formulation

Version **Revision Date:** SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 76218-00027 Date of first issue: 17.03.2015

		exposure)	concentration	
Cellulose	9004-34-6	PEL (long	10 mg/m3	SG OEL
		term)		
		TWA	10 mg/m3	ACGIH
Grazoprevir	1350462-55-	TWA	85 μg/m3 (OEB 3)	Internal
	3			
		Wipe limit	850 μg/100 cm ²	Internal
Elbasvir	1370468-36-	TWA	150 μg/m3 (OEB	Internal
	2		2)	
Magnesium stearate	557-04-0	PEL (long	10 mg/m3	SG OEL
		term)		
		TWA (Inhal-	10 mg/m3	ACGIH
		able particu-		
		late matter)		
		TWA (Res-	3 mg/m3	ACGIH
		pirable par-		
		ticulate mat-		
		ter)		
Titanium dioxide	13463-67-7	PEL (long	10 mg/m3	SG OEL
		term)		

Appropriate engineering control 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 con-

tainment devices). Minimize open handling.

Individual protection measures, such as personal protective equipment (PPE)

Eye/face 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.

Work uniform or laboratory coat. Skin protection

> Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

If adequate local exhaust ventilation is not available or expo-Respiratory protection

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type Hand protection Particulates type

Material Chemical-resistant gloves



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 76218-00027 Date of first issue: 17.03.2015

Remarks : Consider double gloving.

Section 9: Physical and chemical properties

Appearance : powder

Colour : white

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, han-

dling 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



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 76218-00027 Date of first issue: 17.03.2015

Explosive properties : Not explosive

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

Particle characteristics

Particle size : No data available

Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Hazardous decomposition

products

Oxidizing agents

No hazardous decomposition products are known.

Section 11: Toxicological information

Information on likely routes of:

exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

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



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 76218-00027 Date of first issue: 17.03.2015

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 tox-

icity

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 inhala-

tion 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.



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 76218-00027 Date of first issue: 17.03.2015

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

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



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 76218-00027 Date of first issue: 17.03.2015

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

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



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 76218-00027 Date of first issue: 17.03.2015

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

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 hu-

mans.

Carcinogenicity - Assess-

ment

: Limited evidence of carcinogenicity in inhalation studies with

animals.



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 76218-00027 Date of first issue: 17.03.2015

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 develop-

ment

Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

Grazoprevir:

Effects on fertility : 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 develop-

ment

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



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 76218-00027 Date of first issue: 17.03.2015

Fertility: NOAEL: 1,000 mg/kg body weight

Result: No effects on fertility

Effects on foetal develop-

ment

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

Application Route: Ingestion Method: OECD Test Guideline 422

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

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



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 76218-00027 Date of first issue: 17.03.2015

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
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: DogNOAEL: 20 mg/kgLOAEL: 600 mg/kgApplication Route: OralExposure time: 30 DaysTarget 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



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 76218-00027 Date of first issue: 17.03.2015

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/m3

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 irrita-

tion, rhinitis, Drowsiness, nasal congestion

Section 12: Ecological information

Toxicity

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

ma/l



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 76218-00027 Date of first issue: 17.03.2015

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

Method: OECD Test Guideline 201

Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic tox-

icity)

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 (Chron-

ic 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



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 76218-00027 5.0 06.07.2024 Date of first issue: 17.03.2015

aquatic invertebrates

Toxicity to daphnia and other : 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

Toxicity to fish (Chronic tox-

icity)

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 (Chron-

ic 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:

LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l Toxicity to fish

> 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.



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 76218-00027 Date of first issue: 17.03.2015

Remarks: Based on data from similar materials

No toxicity at the limit of solubility

Toxicity to algae/aquatic

plants

EL50 (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

No toxicity at the limit of solubility

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (Pseudomonas putida): > 100 mg/l

Exposure time: 16 h

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

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



Grazoprevir / Elbasvir Formulation

Version SDS Number: Date of last issue: 06.04.2024 **Revision Date:** 5.0 06.07.2024 76218-00027 Date of first issue: 17.03.2015

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

Elbasvir:

Species: Lepomis macrochirus (Bluegill sunfish) Bioaccumulation

> 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 environ-

mental compartments

log Koc: 4.01

Elbasvir:

Distribution among environ-

mental 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.



Grazoprevir / Elbasvir Formulation

Version SDS Number: Date of last issue: 06.04.2024 Revision Date: 5.0 06.07.2024 76218-00027 Date of first issue: 17.03.2015

Contaminated packaging Empty containers should be taken to an approved waste han-

dling 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

UN proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Elbasvir)

Transport hazard class(es) 9 Packing group Ш Labels 9 Environmental hazards yes

IATA-DGR

UN/ID No. UN 3077

UN proper shipping name Environmentally hazardous substance, solid, n.o.s.

(Elbasvir)

Transport hazard class(es) 9 Packing group Ш

Miscellaneous Labels

Packing instruction (cargo 956

aircraft)

Packing instruction (passen-956

ger aircraft)

Environmentally hazardous yes

IMDG-Code

UN number UN 3077

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, Proper shipping name

N.O.S.

(Elbasvir)

Transport hazard class(es) Ш Packing group Labels 9 F-A, S-F EmS Code Marine pollutant yes

Transport in bulk according to IMO instruments

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.



Grazoprevir / Elbasvir Formulation

Date of last issue: 06.04.2024 Version Revision Date: SDS Number: 5.0 06.07.2024 76218-00027 Date of first issue: 17.03.2015

Section 15: Regulatory information

Safety, health and environmental regulations specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and

Environmental Protection and Management (Hazard-

ous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials)

Regulations

Not applicable

Not applicable

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 06.07.2024

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 Agen-

cy, 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)

SG OEL Singapore. Workplace Safety and Health (General Provisions)

Regulations - First Schedule Permissible Exposure Limits of

Toxic Substances.

ACGIH / TWA 8-hour, time-weighted average

SG OEL / PEL (long term) Permissible Exposure Level (PEL) Long Term

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



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 76218-00027 Date of first issue: 17.03.2015

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.

SG / EN