

Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 06.07.2024 76508-00028 Date of first issue: 17.03.2015

SECTION 1. IDENTIFICATION

Product name : Grazoprevir / Elbasvir Formulation

Manufacturer or supplier's details

Company : MSD

Address : 855 Leandro N. Alem St., 8 Floor

Buenos Aires, Argentina C1001AFB

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Short-term (acute) aquatic

hazard

Category 3

Long-term (chronic) aquatic

hazard

Category 1

GHS label elements

Hazard pictograms

¥2>

Signal Word : Warning

Hazard Statements : H402 Harmful to aquatic life.

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



Grazoprevir / Elbasvir Formulation

Version **Revision Date:** SDS Number: Date of last issue: 06.04.2024 06.07.2024 76508-00028 Date of first issue: 17.03.2015 6.0

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)	
Sodium chloride	7647-14-5	>= 5 -< 10	
Cellulose	9004-34-6	>= 5 -< 10	
Grazoprevir	1350462-55-3	>= 5 -< 10	
Elbasvir	1370468-36-2	>= 2,5 -< 5	
Magnesium stearate	557-04-0	>= 1 -< 5	
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.

Most important symptoms

Protection of first-aiders

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.

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).

Treat symptomatically and supportively. Notes to physician

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

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



Grazoprevir / Elbasvir Formulation

Version **Revision Date:** SDS Number: Date of last issue: 06.04.2024 06.07.2024 76508-00028 Date of first issue: 17.03.2015 6.0

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)

Specific extinguishing meth-

ods

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

Evacuate area.

Special protective equipment:

for fire-fighters

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

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions Avoid release to the environment.

> Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for

containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable

container for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to

determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation Advice on safe handling

Use only with adequate ventilation. Do not breathe dust.

Do not swallow.

Avoid contact with eyes.



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 06.07.2024 76508-00028 Date of first issue: 17.03.2015

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 labeled containers.

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis		
Cellulose	9004-34-6	CMP	10 mg/m³	AR OEL		
		TWA	10 mg/m ³	ACGIH		
Grazoprevir	1350462-55- 3	TWA	85 μg/m3 (OEB 3)	Internal		
		Wipe limit	850 µg/100 cm ²	Internal		
Elbasvir	1370468-36- 2	TWA	150 μg/m3 (OEB 2)	Internal		
Magnesium stearate	557-04-0	CMP	10 mg/m ³	AR OEL		
	Further inform	Further information: A4 - Not classifiable as a human carcinogen				
		TWA (Inhalable particulate matter)	10 mg/m³	ACGIH		
		TWA (Respirable particulate matter)	3 mg/m³	ACGIH		
Titanium dioxide	13463-67-7	CMP	10 mg/m³	AR OEL		
	Further inform	Further information: A4 - Not classifiable as a human carcinoge				

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

ene compound to uncontrolled areas (e.g

containment devices). Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 06.07.2024 76508-00028 Date of first issue: 17.03.2015

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Color : white

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : May form explosive dust-air mixture during processing,

handling or other means.



Grazoprevir / Elbasvir Formulation

Version **Revision Date:** SDS Number: Date of last issue: 06.04.2024 06.07.2024 76508-00028 Date of first issue: 17.03.2015 6.0

Flammability (liquids) No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure Not applicable

Relative vapor density Not applicable

Relative density No data available

Density No data available

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

Not applicable

No data available Autoignition temperature

Decomposition temperature No data available

Viscosity

Viscosity, kinematic Not applicable

Explosive properties Not explosive

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

Particle characteristics

Particle size No data available

SECTION 10. STABILITY AND REACTIVITY

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

Possibility of hazardous reac-

tions

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

No hazardous decomposition products are known.

products

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of: Inhalation



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 06.07.2024 76508-00028 Date of first issue: 17.03.2015

exposure Skin contact

Ingestion

Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg

Method: Calculation method

Components:

Sodium chloride:

Acute oral toxicity : LD50 (Rat): 3.550 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 42 mg/l

Exposure time: 1 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 5.000 mg/kg

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

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



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 06.07.2024 76508-00028 Date of first issue: 17.03.2015

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:

Sodium chloride:

Species : Rabbit

Result : No skin irritation

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:

Sodium chloride:

Species : Rabbit

Result : No eye irritation

Grazoprevir:

Species : Bovine cornea Result : No eye irritation

Elbasvir:

Species : Bovine cornea
Result : No eye irritation



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 06.07.2024 76508-00028 Date of first issue: 17.03.2015

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 sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Sodium chloride:

Test Type : Local lymph node assay (LLNA)

Routes of exposure : Skin contact Species : Mouse Result : negative

Grazoprevir:

Test Type : Local lymph node assay (LLNA)

Routes of exposure : Dermal

Result : Not a skin sensitizer.

Elbasvir:

Test Type : Local lymph node assay (LLNA)

Routes of exposure : Dermal Species : Mouse Result : negative

Magnesium stearate:

Test Type : Maximization Test
Routes of exposure : 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)

Routes of exposure : Skin contact
Species : Mouse
Result : negative



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 06.07.2024 76508-00028 Date of first issue: 17.03.2015

Germ cell mutagenicity

Not classified based on available information.

Components:

Sodium chloride:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Result: positive

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Saccharomyces cerevisiae, gene mutation assay

(in vitro) Result: positive

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)

Result: positive

Test Type: Chromosome aberration test in vitro

Result: positive

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test

Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Rat

Application Route: Intraperitoneal injection

Result: positive

Germ cell mutagenicity -

Assessment

: Weight of evidence does not support classification as a germ

cell mutagen.

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:



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 06.07.2024 76508-00028 Date of first issue: 17.03.2015

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

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.



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 06.07.2024 76508-00028 Date of first issue: 17.03.2015

Components:

Sodium chloride:

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

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.

Reproductive toxicity

Not classified based on available information.

Components:

Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Effects on fetal development : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

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



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 06.07.2024 76508-00028 Date of first issue: 17.03.2015

Fertility: NOAEL: 400 mg/kg body weight

Result: No effects on fertility., No effects on fetal development.

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Oral

Embryo-fetal toxicity.: NOAEL: 200 mg/kg body weight

Result: No effects on fetal development.

Test Type: Embryo-fetal development

Species: Rabbit

Application Route: Oral

Embryo-fetal toxicity.: NOAEL: 200 mg/kg body weight

Result: No effects on fetal development.

Test Type: Embryo-fetal development

Species: Rabbit

Application Route: Intravenous

Embryo-fetal toxicity.: NOAEL: 100 mg/kg body weight

Result: No effects on fetal 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 fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Oral

Developmental Toxicity: NOAEL: 1.000 mg/kg body weight

Result: No effects on early embryonic development.

Test Type: Embryo-fetal development

Species: Rabbit

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 fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 06.07.2024 76508-00028 Date of first issue: 17.03.2015

П

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:

Sodium chloride:

Species : Rat

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

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: DogNOAEL: 15 mg/kgLOAEL: 100 mg/kgApplication Route: OralExposure time: 270 Days

Target Organs : Liver, Blood, Bone marrow, gallbladder, spleen, Testis

Species : Mouse NOAEL : 200 mg/kg LOAEL : 500 mg/kg



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 06.07.2024 76508-00028 Date of first issue: 17.03.2015

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 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 y

Aspiration toxicity

Not classified based on available information.



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 06.07.2024 76508-00028 Date of first issue: 17.03.2015

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

Ecotoxicity

Components:

Sodium chloride:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 5.840 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 4.136 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50: > 2.000 mg/l Exposure time: 96 h

Toxicity to fish (Chronic tox-

city)

NOEC (Pimephales promelas (fathead minnow)): 252 mg/l

Exposure time: 33 d

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia pulex (Water flea)): 314 mg/l

Exposure time: 21 d

Toxicity to microorganisms : EC10: > 1.000 mg/l

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



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 06.07.2024 76508-00028 Date of first issue: 17.03.2015

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.

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



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 06.07.2024 76508-00028 Date of first issue: 17.03.2015

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)

Toxicity to microorganisms

EC50: > 1.000 mg/l

10

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

ma/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

na/l

Exposure time: 72 h



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 06.07.2024 76508-00028 Date of first issue: 17.03.2015 6.0

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

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

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

aquatic invertebrates

Toxicity to daphnia and other : 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)



Grazoprevir / Elbasvir Formulation

Version **Revision Date:** SDS Number: Date of last issue: 06.04.2024 06.07.2024 76508-00028 Date of first issue: 17.03.2015 6.0

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 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.

Contaminated packaging Empty containers should be taken to an approved waste

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number UN 3077

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, Proper shipping name

N.O.S.

(Elbasvir)

Class 9 Ш Packing group

Labels 9 Environmentally hazardous yes

IATA-DGR



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 06.07.2024 76508-00028 Date of first issue: 17.03.2015

UN/ID No. : UN 3077

Proper shipping name : Environmentally hazardous substance, solid, n.o.s.

(Elbasvir)

956

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo

aircraft)

Packing instruction (passen- : 956

ger aircraft)

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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Argentina. Carcinogenic Substances and Agents : Not applicable

Registry.

Control of precursors and essential chemicals for the : Not applicable

preparation of drugs.

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 06.07.2024 Date format : dd.mm.yyyy



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 06.07.2024 76508-00028 Date of first issue: 17.03.2015

Further information

Sources of key data used to compile the Material Safety

eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Internal technical data, data from raw material SDSs, OECD

Data Sheet cy, http://echa

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

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average AR OEL / CMP : TLV (Threshold Limit Value)

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



Grazoprevir / Elbasvir Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.0 06.07.2024 76508-00028 Date of first issue: 17.03.2015

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.

AR / Z8