according to the Hazardous Products Regulations



# **Grazoprevir Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/04/2023 5.1 09/30/2023 402543-00021 Date of first issue: 01/07/2016

#### **SECTION 1. IDENTIFICATION**

Product name : Grazoprevir Formulation

Other means of identification : No data available

## Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

#### GHS classification in accordance with the Hazardous Products Regulations

Specific target organ toxicity

- repeated exposure (Oral)

: Category 2 (Liver, Testis)

#### **GHS** label elements

Hazard pictograms

Signal Word : Warning

Hazard Statements : H373 May cause damage to organs (Liver, Testis) through pro-

longed or repeated exposure if swallowed.

Precautionary Statements : Prevention:

P260 Do not breathe dust.

Response:

P314 Get medical attention if you feel unwell.

Disposal:

P501 Dispose of contents and container to an approved waste

disposal plant.

### Other hazards

Dust contact with the eyes can lead to mechanical irritation.

May form explosive dust-air mixture during processing, handling or other means.

### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

according to the Hazardous Products Regulations



# **Grazoprevir Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/04/2023 5.1 09/30/2023 402543-00021 Date of first issue: 01/07/2016

Substance / Mixture : Mixture

#### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Grazoprevir	No data availa- ble	1350462-55-3	>= 10 - < 30 *
Sodium n-dodecyl sulfate	Sulfuric acid monododecyl ester sodium salt	151-21-3	>= 1 - < 5 *
Magnesium stearate	Octadecanoic acid, magnesi- um salt (2:1)	557-04-0	>= 1 - < 5 *

<sup>\*</sup> Actual concentration or concentration range is withheld as a trade secret

#### **SECTION 4. FIRST AID MEASURES**

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

advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

Get medical attention if symptoms occur.

In case of skin contact : In case of contact, immediately flush skin with plenty of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

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

Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention if symptoms occur.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

Protection of first-aiders

Notes to physician

Headache

delayed

Gastrointestinal discomfort

May cause damage to organs through prolonged or repeated

exposure if swallowed.

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.

### **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

according to the Hazardous Products Regulations



# Grazoprevir Formulation

Version Revision Date: SDS Number: Date of last issue: 04/04/2023 09/30/2023 402543-00021 Date of first issue: 01/07/2016 5.1

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

Nitrogen oxides (NOx)

Metal oxides

Chlorine compounds

Sulfur oxides

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

SO

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 Use only with adequate ventilation.

according to the Hazardous Products Regulations



# **Grazoprevir Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/04/2023 5.1 09/30/2023 402543-00021 Date of first issue: 01/07/2016

Advice on safe handling : Do not get on skin or clothing.

Do not breathe dust.

Do not swallow.

Avoid contact with eyes.

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
Grazoprevir	1350462-55- 3	TWA	85 μg/m3 (OEB 3)	Internal
		Wipe limit	850 μg/100 cm <sup>2</sup>	Internal
Magnesium stearate	557-04-0	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWAEV	10 mg/m <sup>3</sup>	CA QC OEL
		TWA (Inhal- able)	10 mg/m³	CA BC OEL
		TWA (Respirable)	3 mg/m³	CA BC OEL
		TWA (Inhalable particulate matter)	10 mg/m³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m³	ACGIH

**Engineering measures** : All engineering controls should be implemented by facility

design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face

containment devices).

Minimize open handling.

according to the Hazardous Products Regulations



# **Grazoprevir Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/04/2023 5.1 09/30/2023 402543-00021 Date of first issue: 01/07/2016

Personal protective equipment

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

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection.

Filter type

Particulates type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Hygiene measures : If exposure to chemical is likely during typical use, provide

eye flushing systems and safety showers close to the

working place.

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

## **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : powder

Color : No data available

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

according to the Hazardous Products Regulations



# **Grazoprevir Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/04/2023 5.1 09/30/2023 402543-00021 Date of first issue: 01/07/2016

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

handling or other means.

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : Not applicable

Relative vapor density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

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

Particle 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,

handling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.
Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

according to the Hazardous Products Regulations



# **Grazoprevir Formulation**

Version 5.1

Revision Date: 09/30/2023

SDS Number: 402543-00021

Date of last issue: 04/04/2023 Date of first issue: 01/07/2016

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

### Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

### **Acute toxicity**

Not classified based on available information.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

**Components:** 

Grazoprevir:

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

Sodium n-dodecyl sulfate:

Acute oral toxicity : LD50 (Rat): 1,200 mg/kg

Method: OECD Test Guideline 401

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 402

Remarks: Based on data from similar materials

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

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

Grazoprevir:

Result : No skin irritation

Sodium n-dodecyl sulfate:

Species : Rabbit
Result : Skin irritation

according to the Hazardous Products Regulations



# **Grazoprevir Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/04/2023 5.1 09/30/2023 402543-00021 Date of first issue: 01/07/2016

Magnesium stearate:

Species : Rabbit

Result : No skin irritation

Remarks : Based on data from similar materials

Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

Grazoprevir:

Species : Bovine cornea Result : No eye irritation

Sodium n-dodecyl sulfate:

Species : Rabbit

Result : Irreversible effects on the eye Method : OECD Test Guideline 405

Magnesium stearate:

Species : Rabbit

Result : No eye irritation

Remarks : Based on data from similar materials

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

**Components:** 

Grazoprevir:

Test Type : Local lymph node assay (LLNA)

Routes of exposure : Dermal

Result : Not a skin sensitizer.

Sodium n-dodecyl sulfate:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

Remarks : Based on data from similar materials

Magnesium stearate:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig

according to the Hazardous Products Regulations



# **Grazoprevir Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/04/2023 5.1 09/30/2023 402543-00021 Date of first issue: 01/07/2016

Method : OECD Test Guideline 406

Result : negative

Remarks : Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:

**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.

Sodium n-dodecyl sulfate:

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

Method: OECD Test Guideline 471

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)

Species: Mouse

**Application Route: Ingestion** 

Result: negative

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

according to the Hazardous Products Regulations



# **Grazoprevir Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/04/2023 5.1 09/30/2023 402543-00021 Date of first issue: 01/07/2016

#### Carcinogenicity

Not classified based on available information.

### Components:

#### Sodium n-dodecyl sulfate:

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

Method : OECD Test Guideline 453

Result : negative

Remarks : Based on data from similar materials

### Reproductive toxicity

Not classified based on available information.

#### Components:

## **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 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.

#### Sodium n-dodecyl sulfate:

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

Species: Rat

Application Route: Ingestion

according to the Hazardous Products Regulations



# **Grazoprevir Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/04/2023 5.1 09/30/2023 402543-00021 Date of first issue: 01/07/2016

Method: OECD Test Guideline 416

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

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

#### 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:**

**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

according to the Hazardous Products Regulations



# **Grazoprevir Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/04/2023 5.1 09/30/2023 402543-00021 Date of first issue: 01/07/2016

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

Sodium n-dodecyl sulfate:

Species : Rat
NOAEL : 488 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Remarks : Based on data from similar materials

Magnesium stearate:

Species : Rat

NOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Remarks : Based on data from similar materials

**Aspiration toxicity** 

Not classified based on available information.

**Experience with human exposure** 

**Components:** 

**Grazoprevir:** 

Ingestion : Symptoms: Headache, Gastrointestinal disturbance

according to the Hazardous Products Regulations



# **Grazoprevir Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/04/2023 5.1 09/30/2023 402543-00021 Date of first issue: 01/07/2016

#### **SECTION 12. ECOLOGICAL INFORMATION**

### **Ecotoxicity**

#### Components:

Grazoprevir:

Toxicity to fish : LC50 (Cyprinodon variegatus (sheepshead minnow)): > 10

mg/l

Exposure time: 96 h

Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 10 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: No toxicity at the limit of solubility.

LC50 (Americamysis): 8.9 mg/l

Exposure time: 96 h

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 10

mg/l

Exposure time: 72 hrs

Method: OECD Test Guideline 201

Remarks: No toxicity at the limit of solubility.

NOEC (Pseudokirchneriella subcapitata (green algae)): 10

mg/l

Exposure time: 72 hrs

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

Sodium n-dodecyl sulfate:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 29 mg/l

according to the Hazardous Products Regulations



# **Grazoprevir Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/04/2023 5.1 09/30/2023 402543-00021 Date of first issue: 01/07/2016

Exposure time: 96 h

Toxicity to daphnia and other : aquatic invertebrates

EC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

ErC50 (Desmodesmus subspicatus (green algae)): > 120 mg/l

Exposure time: 72 h

NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l

Exposure time: 72 h

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): >= 1.357

mg/

Exposure time: 42 d

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Ceriodaphnia dubia (water flea)): 0.88 mg/l

Exposure time: 7 d

Toxicity to microorganisms

EC50: 135 mg/l Exposure time: 3 h

Magnesium stearate:

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

Exposure time: 48 h Method: DIN 38412

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EL50 (Daphnia magna (Water flea)): > 1 mg/l

Exposure time: 47 h

Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.2. Remarks: Based on data from similar materials

No toxicity at the limit of solubility.

Toxicity to algae/aquatic

plants

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

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

No toxicity at the limit of solubility.

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

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

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

Exposure time: 16 h

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

according to the Hazardous Products Regulations



# **Grazoprevir Formulation**

Version 5.1

Revision Date: 09/30/2023

SDS Number: 402543-00021

Date of last issue: 04/04/2023 Date of first issue: 01/07/2016

Persistence and degradability

**Components:** 

Grazoprevir:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 66 % Exposure time: 28 d

Sodium n-dodecyl sulfate:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 95 % Exposure time: 28 d

Method: OECD Test Guideline 301B

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

Sodium n-dodecyl sulfate:

Partition coefficient: n-

octanol/water

log Pow: 0.83

Magnesium stearate:

Partition coefficient: n-

octanol/water

log Pow: > 4

Mobility in soil

**Components:** 

**Grazoprevir:** 

Distribution among environ-

mental compartments

: log Koc: 4.01

Other adverse effects

No data available

according to the Hazardous Products Regulations



# **Grazoprevir Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/04/2023 5.1 09/30/2023 402543-00021 Date of first issue: 01/07/2016

#### **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**

Not regulated as a dangerous good

**IATA-DGR** 

Not regulated as a dangerous good

**IMDG-Code** 

Not regulated as a dangerous good

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### **Domestic regulation**

TDG

Not regulated as a dangerous good

### Special precautions for user

Not applicable

#### **SECTION 15. REGULATORY INFORMATION**

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table

2: OEL)

CA BC OEL : Canada. British Columbia OEL

CA QC OEL : Québec. Regulation respecting occupational health and safe-

ty, Schedule 1, Part 1: Permissible exposure values for air-

according to the Hazardous Products Regulations



# **Grazoprevir Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/04/2023 5.1 09/30/2023 402543-00021 Date of first issue: 01/07/2016

borne contaminants

ACGIH / TWA : 8-hour, time-weighted average
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA BC OEL / TWA : 8-hour time weighted average

CA QC OEL / TWAEV : Time-weighted average exposure 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

Sources of key data used to compile the Material Safety

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Data Sheet

cy, http://echa.europa.eu/

Revision Date : 09/30/2023 Date format : mm/dd/yyyy

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

according to the Hazardous Products Regulations



# **Grazoprevir Formulation**

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context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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