

**Grazoprevir Formulation**

Version 4.1      Revision Date: 30.09.2023      SDS Number: 402512-00020      Date of last issue: 04.04.2023  
Date of first issue: 07.01.2016

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**SECTION 1: IDENTIFICATION**

Product name : Grazoprevir Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : Building A - Level 1/26 Talavera Rd  
Macquarie Park NSW, Australia 2113

Telephone : 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

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

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 prolonged or repeated exposure if swallowed.

Precautionary statements :

**Prevention:**

P260 Do not breathe dust.

**Response:**

P314 Get medical advice/ attention if you feel unwell.

**Disposal:**

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

## Grazoprevir Formulation

Version 4.1      Revision Date: 30.09.2023      SDS Number: 402512-00020      Date of last issue: 04.04.2023  
Date of first issue: 07.01.2016

### Other hazards which do not result in classification

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

Substance / Mixture : Mixture

### Components

| Chemical name            | CAS-No.      | Concentration (% w/w) |
|--------------------------|--------------|-----------------------|
| Grazoprevir              | 1350462-55-3 | >= 10 -< 30           |
| Sodium n-dodecyl sulfate | 151-21-3     | >= 1 -< 3             |
| Magnesium stearate       | 557-04-0     | < 10                  |

## 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 delayed : Headache  
Gastrointestinal discomfort  
May cause damage to organs through prolonged or repeated exposure if swallowed.  
Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

## SECTION 5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media : None known.

Specific hazards during fire- : Avoid generating dust; fine dust dispersed in air in sufficient

## Grazoprevir Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04.04.2023  |
| 4.1     | 30.09.2023     | 402512-00020 | Date of first issue: 07.01.2016 |

---

|   |   |   |
|---|---|---|
| fighting                                      |   | concentrations, and in the presence of an ignition source is a potential dust explosion hazard.<br>Exposure to combustion products may be a hazard to health.   |
| Hazardous combustion products                 | : | Carbon oxides<br>Nitrogen oxides (NOx)<br>Metal oxides<br>Chlorine compounds<br>Sulphur oxides  |
| Specific extinguishing methods                | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |

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**SECTION 6. ACCIDENTAL RELEASE MEASURES**

|   |   |  |
|---|---|--|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).   |
| Environmental precautions   | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>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.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).<br>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.<br>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.<br>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

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**SECTION 7. HANDLING AND STORAGE**

|                         |   |  |
|-------------------------|---|--|
| Technical measures      | : | Static electricity may accumulate and ignite suspended dust causing an explosion.<br>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. |
| Local/Total ventilation | : | Use only with adequate ventilation.  |

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## Grazoprevir Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04.04.2023  |
| 4.1     | 30.09.2023     | 402512-00020 | Date of first issue: 07.01.2016 |

- 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.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- Conditions for safe storage : Keep in properly labelled containers.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Components with workplace control parameters

| Components         | CAS-No.      | Value type<br>(Form of exposure)    | Control parameters / Permissible concentration | Basis    |
|--------------------|--------------|-------------------------------------|--|----------|
| Grazoprevir        | 1350462-55-3 | TWA                                 | 85 µg/m <sup>3</sup> (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>                           | AU OEL   |
|                    |              | TWA (Inhalable particulate matter)  | 10 mg/m <sup>3</sup>                           | ACGIH    |
|                    |              | TWA (Respirable particulate matter) | 3 mg/m <sup>3</sup>                            | 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

## Grazoprevir Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04.04.2023  |
| 4.1     | 30.09.2023     | 402512-00020 | Date of first issue: 07.01.2016 |

---

are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

**Personal protective equipment**

- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Particulates type
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- Eye protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Skin and body protection : Work uniform or laboratory coat.  
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

- Appearance : powder
- Colour : No data available
- Odour : No data available
- Odour Threshold : No data available
- pH : No data available
- Melting point/freezing point : No data available
- Initial boiling point and boiling range : No data available
- Flash point : Not applicable
- Evaporation rate : Not applicable
- Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

**Grazoprevir Formulation**

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04.04.2023  |
| 4.1     | 30.09.2023     | 402512-00020 | Date of first issue: 07.01.2016 |

---

|  |   |  |
|--|---|--|
| Flammability (liquids)                           | : | No data available  |
| Upper explosion limit / Upper flammability limit | : | No data available  |
| Lower explosion limit / Lower flammability limit | : | No data available  |
| Vapour pressure                                  | : | Not applicable   |
| Relative vapour density                          | : | Not applicable   |
| Relative density                                 | : | No data available  |
| Density  | : | No data available  |
| Solubility(ies)                                  | : |  |
| Water solubility                                 | : | No data available  |
| Partition coefficient: n-octanol/water           | : | Not applicable   |
| Auto-ignition temperature                        | : | No data available  |
| Decomposition temperature                        | : | No data available  |
| Viscosity  | : |  |
| Viscosity, kinematic                             | : | Not applicable   |
| Explosive properties                             | : | Not explosive  |
| Oxidizing properties                             | : | The substance or mixture is not classified as oxidizing. |
| Particle size                                    | : | No data available  |

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**SECTION 10. STABILITY AND REACTIVITY**

|                                    |   |  |
|------------------------------------|---|--|
| Reactivity                         | : | Not classified as a reactivity hazard.   |
| Chemical stability                 | : | Stable under normal conditions.  |
| Possibility of hazardous reactions | : | May form explosive dust-air mixture during processing, handling or other means.<br>Can react with strong oxidizing agents. |
| Conditions to avoid                | : | Heat, flames and sparks.<br>Avoid dust formation.  |
| Incompatible materials             | : | Oxidizing agents   |
| Hazardous decomposition products   | : | No hazardous decomposition products are known.   |

## Grazoprevir Formulation

Version 4.1      Revision Date: 30.09.2023      SDS Number: 402512-00020      Date of last issue: 04.04.2023  
Date of first issue: 07.01.2016

---

**SECTION 11. TOXICOLOGICAL INFORMATION**

Exposure routes : 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 toxicity  
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

**Grazoprevir Formulation**

Version 4.1      Revision Date: 30.09.2023      SDS Number: 402512-00020      Date of last issue: 04.04.2023  
Date of first issue: 07.01.2016

---

**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 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.

**Sodium n-dodecyl sulfate:**

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

**Magnesium stearate:**

Test Type : Maximisation Test  
Exposure routes : Skin contact



**Grazoprevir Formulation**

Version 4.1      Revision Date: 30.09.2023      SDS Number: 402512-00020      Date of last issue: 04.04.2023  
Date of first issue: 07.01.2016

---

Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative  
Remarks : Based on data from similar materials

**Chronic toxicity****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

## Grazoprevir Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04.04.2023  |
| 4.1     | 30.09.2023     | 402512-00020 | Date of first issue: 07.01.2016 |

---

Remarks: Based on data from similar materials

**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<br>Species: Rat<br>Application Route: Oral<br>Fertility: NOAEL: 400 mg/kg body weight<br>Result: negative  |
|                               |   | Test Type: Multi-generation study<br>Species: Rat<br>Application Route: Oral<br>Fertility: NOAEL: 400 mg/kg body weight<br>Result: No effects on fertility, No effects on foetal development  |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Oral<br>Embryo-foetal toxicity: NOAEL: 200 mg/kg body weight<br>Result: No effects on foetal development           |
|                               |   | Test Type: Embryo-foetal development<br>Species: Rabbit<br>Application Route: Oral<br>Embryo-foetal toxicity: NOAEL: 200 mg/kg body weight<br>Result: No effects on foetal development        |
|                               |   | Test Type: Embryo-foetal development<br>Species: Rabbit<br>Application Route: Intravenous<br>Embryo-foetal toxicity: NOAEL: 100 mg/kg body weight<br>Result: No effects on foetal development |

## Grazoprevir Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04.04.2023  |
| 4.1     | 30.09.2023     | 402512-00020 | Date of first issue: 07.01.2016 |

---

**Sodium n-dodecyl sulfate:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
 Species: Rat  
 Application Route: Ingestion  
 Method: OECD Test Guideline 416  
 Result: negative  
 Remarks: Based on data from similar materials

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

**Magnesium stearate:**

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
 Species: Rat  
 Application Route: Ingestion  
 Method: OECD Test Guideline 422  
 Result: negative  
 Remarks: Based on data from similar materials

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

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

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

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

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

**Repeated dose toxicity****Components:****Grazoprevir:**

Species : Rat  
 NOAEL : 400 mg/kg  
 Application Route : Oral

## Grazoprevir Formulation

Version 4.1      Revision Date: 30.09.2023      SDS Number: 402512-00020      Date of last issue: 04.04.2023  
Date of first issue: 07.01.2016

---

Exposure time : 30 Days  
Remarks : No significant adverse effects were reported

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

Species : Dog  
NOAEL : 15 mg/kg  
LOAEL : 100 mg/kg  
Application Route : Oral  
Exposure time : 270 Days  
Target Organs : Liver, Blood, Bone marrow, gallbladder, spleen, Testis

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

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

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

**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

**Grazoprevir Formulation**

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04.04.2023  |
| 4.1     | 30.09.2023     | 402512-00020 | Date of first issue: 07.01.2016 |

---

**Aspiration toxicity**

Not classified based on available information.

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

Ingestion : Symptoms: Headache, Gastrointestinal disturbance

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Grazoprevir:**

|  |   |  |
|--|---|--|
| Toxicity to fish   | : | LC50 (Cyprinodon variegatus (sheepshead minnow)): > 10 mg/l<br>Exposure time: 96 h<br>Remarks: No toxicity at the limit of solubility  |
| Toxicity to daphnia and other aquatic invertebrates                    | : | EC50 (Daphnia magna (Water flea)): > 10 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202<br>Remarks: No toxicity at the limit of solubility<br><br>LC50 (Americamysis): 8.9 mg/l<br>Exposure time: 96 h  |
| Toxicity to algae/aquatic plants                                       | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 10 mg/l<br>Exposure time: 72 hrs<br>Method: OECD Test Guideline 201<br>Remarks: No toxicity at the limit of solubility<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 10 mg/l<br>Exposure time: 72 hrs<br>Method: OECD Test Guideline 201<br>Remarks: No toxicity at the limit of solubility |
| Toxicity to fish (Chronic toxicity)                                    | : | NOEC (Pimephales promelas (fathead minnow)): 0.98 mg/l<br>Exposure time: 32 d<br>Method: OECD Test Guideline 210<br>Remarks: No toxicity at the limit of solubility  |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 5 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211  |
| Toxicity to microorganisms   | : | EC50: > 1,000 mg/l<br>Exposure time: 3 h   |

## Grazoprevir Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04.04.2023  |
| 4.1     | 30.09.2023     | 402512-00020 | Date of first issue: 07.01.2016 |

---

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  
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 toxicity) : NOEC (Pimephales promelas (fathead minnow)): >= 1.357 mg/l  
Exposure time: 42 d
- Toxicity to daphnia and other aquatic invertebrates (Chronic 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

**Grazoprevir Formulation**

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04.04.2023  |
| 4.1     | 30.09.2023     | 402512-00020 | Date of first issue: 07.01.2016 |

---

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

**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

## Grazoprevir Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04.04.2023  |
| 4.1     | 30.09.2023     | 402512-00020 | Date of first issue: 07.01.2016 |

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### Mobility in soil

#### Components:

#### Grazoprevir:

Distribution among environmental compartments : log Koc: 4.01

#### Other adverse effects

No data available

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## 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.

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## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable

#### IATA-DGR

UN/ID No. : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction (passenger aircraft) : Not applicable

#### IMDG-Code

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
EmS Code : Not applicable  
Marine pollutant : Not applicable



**Grazoprevir Formulation**

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

Not applicable for product as supplied.

**National Regulations****ADG**

|                      |   |                |
|----------------------|---|----------------|
| UN number            | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class                | : | Not applicable |
| Subsidiary risk      | : | Not applicable |
| Packing group        | : | Not applicable |
| Labels               | : | Not applicable |
| Hazchem Code         | : | Not applicable |

**Special precautions for user**

Not applicable

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

|                                    |   |   |
|------------------------------------|---|---|
| Prohibition/Licensing Requirements | : | There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations. |
|------------------------------------|---|---|

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

|       |   |                |
|-------|---|----------------|
| AICS  | : | not determined |
| DSL   | : | not determined |
| IECSC | : | not determined |

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**SECTION 16: ANY OTHER RELEVANT INFORMATION****Further information**

|   |   |   |
|---|---|---|
| Revision Date   | : | 30.09.2023  |
| Sources of key data used to compile the Safety Data Sheet | : | Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <a href="http://echa.europa.eu/">http://echa.europa.eu/</a> |
| Date format   | : | dd.mm.yyyy  |

**Full text of other abbreviations**

|        |   |  |
|--------|---|--|
| ACGIH  | : | USA. ACGIH Threshold Limit Values (TLV)                            |
| AU OEL | : | Australia. Workplace Exposure Standards for Airborne Contaminants. |

## Grazoprevir Formulation

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ACGIH / TWA : 8-hour, time-weighted average  
AU OEL / TWA : Exposure standard - time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECL - 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.

AU / EN