1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Grazoprevir Formulation

Manufacturer or supplier's details
Company : MSD
Address : 199 Wenhai North Road
          HEDA, Hangzhou - Zhejiang Province - CHINA 310018
Telephone : 908-740-4000
Emergency telephone number : 86-571-87268110
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

Emergency Overview

| Appearance | powder |
| Colour     | No data available |
| Odour      | No data available |

Causes mild skin irritation. May cause damage to organs through prolonged or repeated exposure. Harmful to aquatic life.

GHS Classification
Skin corrosion/irritation : Category 3
Specific target organ toxicity - repeated exposure : Category 2
Short-term (acute) aquatic hazard : Category 3

GHS label elements
Hazard pictograms

Signal word : Warning

Hazard statements : H316 Causes mild skin irritation. H373 May cause damage to organs through prolonged or repeated exposure. H402 Harmful to aquatic life.
Precautionary statements:

**Prevention:**
P260 Do not breathe dust.
P273 Avoid release to the environment.

**Response:**
P314 Get medical advice/attention if you feel unwell.
P332 + P313 If skin irritation occurs: Get medical advice/attention.

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

**Physical and chemical hazards**
Not classified based on available information.

**Health hazards**
Causes mild skin irritation. May cause damage to organs through prolonged or repeated exposure.

**Environmental hazards**
Harmful to aquatic life.

**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.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grazoprevir</td>
<td>Chemical name</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>1350462-55-3</td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>7647-14-5</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>151-21-3</td>
</tr>
<tr>
<td></td>
<td>557-04-0</td>
</tr>
</tbody>
</table>

### 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.
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

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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
Causes mild skin irritation.
May cause damage to organs through prolonged or repeated exposure.
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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media:
Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media:
None known.

Specific hazards during firefighting:
Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
Carbon oxides
Nitrogen oxides (NOx)
Metal oxides
Chlorine compounds
Sulphur oxides

Specific extinguishing methods:
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

Special protective equipment for firefighters:
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:
Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
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.

7. HANDLING AND STORAGE

Handling
Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation: Use only with adequate ventilation.

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.

Avoidance of contact: Oxidizing agents

Storage
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

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
</table>

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Grazoprevir Formulation

9. PHYSICAL AND CHEMICAL PROPERTIES
## Grazoprevir Formulation

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
<td>powder</td>
</tr>
<tr>
<td><strong>Colour</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Odour</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Odour Threshold</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Melting point/freezing point</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Initial boiling point and boiling range</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Flash point</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Flammability (solid, gas)</strong></td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td><strong>Flammability (liquids)</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Upper explosion limit / Upper flammability limit</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Lower explosion limit / Lower flammability limit</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Vapour pressure</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Relative vapour density</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Relative density</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Density</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Solubility(ies)</strong></td>
<td>Water solubility: No data available</td>
</tr>
<tr>
<td><strong>Partition coefficient: n-octanol/water</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Auto-ignition temperature</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Decomposition temperature</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Viscosity</strong></td>
<td>Viscosity, kinematic: Not applicable</td>
</tr>
<tr>
<td><strong>Explosive properties</strong></td>
<td>Not explosive</td>
</tr>
<tr>
<td><strong>Oxidizing properties</strong></td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>

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10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.

Chemical stability: Stable under normal conditions.

Possibility of hazardous reactions:
- May form explosive dust-air mixture during processing, handling or other means.
- Can react with strong oxidizing agents.

Conditions to avoid:
- Heat, flames and sparks.
- Avoid dust formation.

Incompatible materials:
- Oxidizing agents

Incompatible materials:
- Oxidizing agents

Hazardous decomposition products:
- No hazardous decomposition products are known.

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: > 5,000 mg/kg
Method: Calculation method

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

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

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
Grazoprevir Formulation

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
Causes mild skin irritation.

Components:

Grazoprevir:
Result: No skin irritation

Sodium chloride:
Species: Rabbit
Result: No skin irritation

Sodium n-dodecyl sulfate:
Species: Rabbit
Result: Skin irritation

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 chloride:
Species: Rabbit
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 chloride:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Result: negative

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
Species: Guinea pig
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
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</table>

- **Genotoxicity in vivo**
  - Test Type: Chromosome aberration test in vitro
    - Result: negative
  - 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 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 synthesis 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.

- **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

Carcinogenicity
Not classified based on available information.

Components:

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

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
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Application Route: Oral
Fertility: NOAEL: 400 mg/kg body weight
Result: No effects on fertility, No effects on foetal development

Effects on foetal development:
- Test Type: Embryo-foetal development
  - Species: Rat
  - Application Route: Oral
  - Embryo-foetal toxicity: NOAEL: 200 mg/kg body weight
  - Result: No effects on foetal development

  Test Type: Embryo-foetal development
  - Species: Rabbit
  - Application Route: Oral
  - Embryo-foetal toxicity: NOAEL: 200 mg/kg body weight
  - Result: No effects on foetal development

  Test Type: Embryo-foetal development
  - Species: Rabbit
  - Application Route: Intravenous
  - Embryo-foetal toxicity: NOAEL: 100 mg/kg body weight
  - Result: No effects on foetal development

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
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

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STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs through prolonged or repeated exposure.

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
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
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Remarks : No significant adverse effects were reported

**Sodium chloride:**
Species : Rat  
LOAEL : 2,533 mg/kg  
Application Route : Ingestion  
Exposure time : 2 yr

**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

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 toxicity): NOEC (Pimephales promelas (fathead minnow)): 0.98 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 5 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms: EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 1.3 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

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 toxicity): NOEC (Pimephales promelas (fathead minnow)): 252 mg/l
Exposure time: 33 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia pulex (Water flea)): 314 mg/l
Exposure time: 21 d

Toxicity to microorganisms: EC10: > 1,000 mg/l

Sodium n-dodecyl sulfate:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 29 mg/l
Exposure time: 96 h
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</tr>
</tbody>
</table>

**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  
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
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 environmental compartments : log Koc: 4.01

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

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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.

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.

National Regulations

GB 6944/12268
Not regulated as a dangerous good

Special precautions for user
Not applicable

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

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

AICS: not determined

DSL: not determined

IECSC: not determined

16. OTHER INFORMATION

Further information

Date format: yyyy/mm/dd

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
SAFETY DATA SHEET
generated according to GB/T 16483 and GB/T 17519

Grazoprevir Formulation

Version 3.6
Revision Date: 2021/01/29
SDS Number: 402566-00014
Date of last issue: 2020/10/10
Date of first issue: 2016/01/07

ACGIH / TWA : 8-hour, 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 Chemicals and Chemical Substances; 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; SDAT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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

Disclaimer
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.

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