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

Grazoprevir Formulation

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>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grazoprevir</td>
<td>1350462-55-3</td>
<td>&gt;= 10 &lt; 20</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>&gt;= 10 &lt; 20</td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3</td>
<td>&gt;= 1 &lt; 2.5</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 &lt; 10</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.
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 and personal protective equipment recommendations.

Environmental precautions:
- Discharge into the environment must be avoided.
- 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>

4 / 19
Grazoprevir Formulation

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>TWA</th>
<th>Internal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grazoprevir</td>
<td>1350462-55-3</td>
<td>25 µg/m3 (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable fraction) 10 mg/m3 ACGIH</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction) 3 mg/m3 ACGIH</td>
<td></td>
</tr>
</tbody>
</table>

**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.

**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
- **Eye/face protection**: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**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.

**Hand protection**

- **Material**: Chemical-resistant gloves

**Remarks**: Consider double gloving.

**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.

9. PHYSICAL AND CHEMICAL PROPERTIES
Grazoprevir Formulation

According to GB/T 16483 and GB/T 17519

Version: 3.3  Revision Date: 09/13/2019  SDS Number: 402566-00011  Date of last issue: 2019/04/24  Date of first issue: 2016/01/07

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

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

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
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
  - 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
Test Type: Chromosome aberration test in vitro
Results:

**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 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)
Grazoprevir Formulation

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
    - Application Route: Oral
Grazoprevir Formulation

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

STOT - single exposure
Not classified based on available information.
## Grazoprevir Formulation

### 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, Testis, Blood, Bone marrow, gallbladder, spleen

- **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**: Testis, Blood

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

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
Grazoprevir Formulation

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

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
Grazoprevir Formulation

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.
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
according to GB/T 16483 and GB/T 17519

Grazoprevir Formulation

Version 3.3
Revision Date: 09/13/2019
SDS Number: 402566-00011
Date of last issue: 2019/04/24
Date of first issue: 2016/01/07

ACGIH / TWA : 8-hour, time-weighted average

AICS - Australian Inventory of Chemical Substances; 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; SATD - 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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