SAFETY DATA SHEET
Grazoprevir Formulation

SECTION 1. IDENTIFICATION

Product name: Grazoprevir Formulation

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue
          Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Combustible dust
Specific target organ toxicity - repeated exposure (Oral): Category 2 (Liver, Testis)

GHS label elements
Hazard pictograms: 

Signal Word: Warning

Hazard Statements: If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
                  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 attention if you feel unwell.
Disposal: P501 Dispose of contents and container to an approved waste disposal plant.
SAFETY DATA SHEET
Grazoprevir Formulation

Other hazards
Dust contact with the eyes can lead to mechanical irritation.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grazoprevir</td>
<td>Mixture</td>
</tr>
</tbody>
</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 n-dodecyl sulfate</td>
<td>151-21-3</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret.

SECTION 4. FIRST AID MEASURES

General advice:
In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled:
If inhaled, remove to fresh air. Get medical attention if symptoms occur.

In case of skin contact:
In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact:
If in eyes, rinse well with water. Get medical attention if irritation develops and persists.

If swallowed:
If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed:
Headache
Gastrointestinal discomfort
Dust contact with the eyes can lead to mechanical irritation. May cause damage to organs through prolonged or repeated exposure if swallowed.

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. FIRE-FIGHTING 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
- Sulfur 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 fire-fighters:**
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

**SECTION 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.

**SECTION 7. HANDLING AND STORAGE**

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

**Local/Total ventilation**
Use only with adequate ventilation.

**Advice on safe handling**
- Do not get on skin or clothing.
- Do not breathe dust.
- Do not swallow.
- Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage: Keep in properly labeled containers. Store in accordance with the particular national regulations.

Materials to avoid: Do not store with the following product types: Strong oxidizing agents.

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Ingredients with workplace control parameters**

- **inert or nuisance dust**
  - 50 Million particles per cubic foot
  - Value type (Form of exposure): TWA (total dust)
  - Basis: OSHA Z-3
  - 15 mg/m³
  - Value type (Form of exposure): TWA (total dust)
  - Basis: OSHA Z-3
  - 5 mg/m³
  - Value type (Form of exposure): TWA (respirable fraction)
  - Basis: OSHA Z-3
  - 15 Million particles per cubic foot
  - Value type (Form of exposure): TWA (respirable fraction)
  - Basis: OSHA Z-3

- **Dust, nuisance dust and particulates**
  - 10 mg/m³
  - Value type (Form of exposure): PEL (Total dust)
  - Basis: CAL PEL
  - 5 mg/m³
  - Value type (Form of exposure): PEL (respirable dust fraction)
  - Basis: CAL PEL

<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>
<tbody>
<tr>
<td>Grazoprevir</td>
<td>1350462-55-3</td>
<td>TWA</td>
<td>85 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>850 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</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: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

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

Skin and body protection: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder
Color : No data available
Odor : No data available
Odor Threshold : No data available
pH : No data available
Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flash point : Not applicable
Evaporation rate : Not applicable
Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids) : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapor pressure : Not applicable
Relative vapor density : Not applicable
Relative density : No data available
Density : No data available
Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity
Viscosity, kinematic : Not applicable
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Particle size : No data available
SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous 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.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure
Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 5,000 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

Magnesium stearate:
Species : Rabbit
Result : No skin irritation
Remarks : Based on data from similar materials

Serious eye damage/eye irritation
Not classified based on available information.

Components:
Grazoprevir:
Species : Bovine cornea
Result : No eye irritation

Sodium n-dodecyl sulfate:
Species : Rabbit
Result : Irreversible effects on the eye
Method : OECD Test Guideline 405

Magnesium stearate:
Species : Rabbit
Result : No eye irritation
Remarks : Based on data from similar materials

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:
Grazoprevir:
Test Type : Local lymph node assay (LLNA)
Routes of exposure : Dermal
Result : Not a skin sensitizer.
### Sodium n-dodecyl sulfate:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximization Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Magnesium stearate:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximization Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### 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

#### 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 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

IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
Not classified based on available information.

Components:
Grazoprevir:
Effects on fertility: Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: NOAEL: 400 mg/kg body weight
Result: negative

Test Type: Multi-generation study
Species: Rat
Application Route: Oral
Fertility: NOAEL: 400 mg/kg body weight
Result: No effects on fertility., No effects on fetal development.

Effects on fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Embryo-fetal toxicity.: NOAEL: 200 mg/kg body weight
### 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 fetal development:**
- Test Type: Embryo-fetal development
- Species: Rat
- Application Route: Ingestion
- Result: negative
- Remarks: Based on data from similar materials

### Magnesium stearate

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

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

### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

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

**Grazoprevir:**

<table>
<thead>
<tr>
<th>Target Organs</th>
<th>Liver, Testis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment</td>
<td>May cause damage to organs through prolonged or repeated exposure.</td>
</tr>
</tbody>
</table>

### Repeated dose toxicity

**Components:**

**Grazoprevir:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>400 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>30 Days</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>400 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>180 Days</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>15 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>100 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>270 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver, Blood, Bone marrow, gallbladder, spleen, Testis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>200 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>500 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver, Kidney, Blood</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>20 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>600 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>30 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Blood, Testis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>10 mg/kg</td>
</tr>
<tr>
<td>Exposure time</td>
<td>8 Days</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

**Sodium n-dodecyl sulfate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>488 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
</tbody>
</table>
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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity
Components:
Grazoprevir:
Toxicity to fish: LC50 (Cyprinodon variegatus (sheepshead minnow)): > 10 mg/l
Exposure time: 96 h
Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 10 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility.

LC50 (Americamysis): 8.9 mg/l
Exposure time: 96 h

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): > 10 mg/l
Exposure time: 72 hrs
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility.

NOEC (Pseudokirchneriella subcapitata (green algae)): 10 mg/l
Exposure time: 72 hrs
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility.

Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 0.98 mg/l
Exposure time: 32 d
### Grazoprevir Formulation

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>OECD Test Guideline 210</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

#### 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 n-dodecyl sulfate:

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>OECD Test Guideline 210</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

#### 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:

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIN 38412</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

#### 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
- EL50 (Pseudokirchneriella subcapitata (green algae)): > 1
plants

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:
## SAFETY DATA SHEET

### Grazoprevir Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.0</td>
<td>04/04/2023</td>
<td>402662-00020</td>
<td>10/01/2022</td>
<td>01/07/2016</td>
</tr>
</tbody>
</table>

### 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

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods
- Waste from residues: Dispose of in accordance with local regulations. Do not dispose of waste into sewer.
- Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG
- Not regulated as a dangerous good

#### IATA-DGR
- Not regulated as a dangerous good

#### IMDG-Code
- Not regulated as a dangerous good

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
- Not applicable for product as supplied.

### Domestic regulation

#### 49 CFR
- Not regulated as a dangerous good

### Special precautions for user
- Not applicable

## SECTION 15. REGULATORY INFORMATION

### CERCLA Reportable Quantity
- This material does not contain any components with a CERCLA RQ.

### SARA 304 Extremely Hazardous Substances Reportable Quantity
- This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
- This material does not contain any components with a section 302 EHS TPQ.
SAFETY DATA SHEET
Grazoprevir Formulation

Version 9.0
Revision Date: 04/04/2023
SDS Number: 402662-00020
Date of last issue: 10/01/2022
Date of first issue: 01/07/2016

SARA 311/312 Hazards: Combustible dust
Specific target organ toxicity (single or repeated exposure)

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations
Pennsylvania Right To Know
D-mannitol 69-65-8
Polyvinylpyrrolidone / Vinyl Acetate Copolymer 25086-89-9
Sodium chloride 7647-14-5
Croscarmellose sodium 74811-65-7
Grazoprevir 1350462-55-3

California Permissible Exposure Limits for Chemical Contaminants
Magnesium stearate 557-04-0

The ingredients of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECS: not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:
Flammability
1
Health
1
Special hazard
Instability
0

HMIS® IV:

HEALTH
*
2
FLAMMABILITY
3
PHYSICAL HAZARD
0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
Grazoprevir Formulation

SAFETY DATA SHEET

Version 9.0 | Revision Date: 04/04/2023 | SDS Number: 402662-00020 | Date of last issue: 10/01/2022

Date of first issue: 01/07/2016

CAL PEL : California permissible exposure limits for chemical contaminants (Title 8, Article 107)

OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts

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

CAL PEL / PEL : Permissible exposure limit

OSHA Z-3 / TWA : 8-hour time weighted average

All - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECS - Inventory of Existing Chemicals 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; MSHA - Mine Safety and Health Administration; n.o.s - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance 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


Revision Date : 04/04/2023

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

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

18 / 19
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.

US / Z8