SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Grazoprevir Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name: Grazoprevir Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Pharmaceutical

1.3 Details of the supplier of the safety data sheet
Company: MSD
Innishannon
County Cork - Ireland

Telephone: 353 214329300
Telefax: 908-735-1496
E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Specific target organ toxicity - repeated exposure, Category 2
H373: May cause damage to organs through prolonged or repeated exposure.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms:

Signal word: Warning

Hazard statements: H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements: Prevention:
P260 Do not breathe dust.
Response:
Hazardous components which must be listed on the label:
Grazoprevir

2.3 Other hazards
Dust contact with the eyes can lead to mechanical irritation.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grazoprevir</td>
<td>1350462-55-3</td>
<td>STOT RE 2; H373</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3 205-788-1</td>
<td>Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Aquatic Chronic 3; H412</td>
<td>&gt;= 1 - &lt; 2.5</td>
<td></td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

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

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).

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.

4.2 Most important symptoms and effects, both acute and delayed
Symptoms: Headache
Gastrointestinal discomfort

Risks: May cause damage to organs through prolonged or repeated exposure.
Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed
Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

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

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
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

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

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.
SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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.
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.

7.2 Conditions for safe storage, including any incompatibilities
- Requirements for storage areas and containers: Keep in properly labelled containers. Store in accordance with the particular national regulations.
- Advice on common storage: Do not store with the following product types: Strong oxidizing agents

7.3 Specific end use(s)
- Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grazoprevir</td>
<td>1350462-55-3</td>
<td>TWA</td>
<td>25 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>250 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>OELV - 8 hrs (TWA)</td>
<td>10 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td></td>
<td>Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used</td>
<td></td>
</tr>
</tbody>
</table>

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>2068.62 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>2068.62 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>295.52 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>295.52 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic</td>
<td>443.28 mg/m³</td>
</tr>
</tbody>
</table>
Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride</td>
<td>Fresh water</td>
<td>5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>500 mg/l</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>4.86 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>Fresh water</td>
<td>0.176 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.018 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1.35 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>6.97 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.697 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>1.29 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

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
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 face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or
aerosols.

Hand protection
Material : Chemical-resistant gloves
Remarks : Consider double gloving.
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.
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 (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : powder
Colour : No data available
Odour : No data available
Odour Threshold : No data available
pH : No data available
Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flash point : Not applicable
Evaporation rate : Not applicable
Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapour pressure : Not applicable
Relative vapour density : Not applicable
Relative density : No data available
Density : No data available
Solubility(ies) :
**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>
</table>

- **Water solubility**: No data available
- **Partition coefficient: n-octanol/water**: Not applicable
- **Auto-ignition temperature**: No data available
- **Decomposition temperature**: No data available
- **Viscosity**: Not applicable
- **EXPLOSIVE PROPERTIES**: Not explosive
- **OXIDIZING PROPERTIES**: The substance or mixture is not classified as oxidizing.

### 9.2 Other information

- **Flammability (liquids)**: No data available
- **Particle size**: No data available

### SECTION 10: Stability and reactivity

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

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

#### 10.4 Conditions to avoid

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

#### 10.5 Incompatible materials

- **Materials to avoid**: Oxidizing agents

#### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

### SECTION 11: Toxicological information

#### 11.1 Information on toxicological effects

- **Information on likely routes of exposure**: Inhalation, Skin contact, Ingestion, Eye contact
Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity :  Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

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

Sodium n-dodecyl sulfate:
Acute oral toxicity :  LD50 (Rat): 1,200 mg/kg
Method: OECD Test Guideline 401
Acute dermal toxicity :  LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials

Skin corrosion/irritation
Not classified based on available information.

Components:
Grazoprevir:
Result :  No skin irritation

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

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

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.
**Respiratory sensitisation**
Not classified based on available information.

**Components:**

**Grazoprevir:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Local lymph node assay (LLNA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Dermal</td>
</tr>
<tr>
<td>Result</td>
<td>Not a skin sensitizer.</td>
</tr>
</tbody>
</table>

**Sodium n-dodecyl sulfate:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximisation Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</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>

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Grazoprevir:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Chromosome aberration test in vitro</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: In vivo micronucleus test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

| Germ cell mutagenicity-Assessment | Weight of evidence does not support classification as a germ cell mutagen. |

**Sodium n-dodecyl sulfate:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Method: OECD Test Guideline 471</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: In vitro mammalian cell gene mutation test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Rodent dominant lethal test (germ cell) (in vivo)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Carcinogenicity**
Not classified based on available information.
Components:

Sodium n-dodecyl sulfate:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Method: OECD Test Guideline 453
Result: negative
Remarks: Based on data from similar materials

Reproductive toxicity
Not classified based on available information.

Components:

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

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

**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, 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
**Grazoprevir Formulation**

**Application Route**: Oral  
**Exposure time**: 30 Days  
**Target Organs**: Testis, Blood

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

**Sodium n-dodecyl sulfate**:

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>488 mg/kg</td>
<td>Ingestion</td>
<td>90 Days</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Aspiration toxicity**  
Not classified based on available information.

**Experience with human exposure**

**Components**

**Grazoprevir**:

<table>
<thead>
<tr>
<th>Ingestion</th>
<th>Symptoms: Headache, Gastrointestinal disturbance</th>
</tr>
</thead>
</table>

### SECTION 12: Ecological information

**12.1 Toxicity**

**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 |
### Grazoprevir Formulation

**Toxicity to microorganisms**
- **EC50:** > 1,000 mg/l
- **Exposure time:** 3 h
- **Test Type:** Respiration inhibition
- **Method:** OECD Test Guideline 201
- **Remarks:** No toxicity at the limit of solubility

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

### Toxicity to fish (Chronic toxicity)
- **NOEC:** 0.98 mg/l
- **Exposure time:** 32 d
- **Species:** Pimephales promelas (fathead minnow)
- **Method:** OECD Test Guideline 210
- **Remarks:** No toxicity at the limit of solubility

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

### 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 microorganisms
- **EC50:** 135 mg/l
- **Exposure time:** 3 h

#### Toxicity to fish (Chronic toxicity)
- **NOEC:** >= 1.357 mg/l
- **Exposure time:** 42 d
- **Species:** Pimephales promelas (fathead minnow)

#### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
- **NOEC:** 0.88 mg/l
- **Exposure time:** 7 d
- **Species:** Ceriodaphnia dubia (water flea)
12.2 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

12.3 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

12.4 Mobility in soil

**Components:**

**Grazoprevir:**
- Distribution among environmental compartments: log Koc: 4.01

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other adverse effects

No data available

**SECTION 13: Disposal considerations**

13.1 Waste treatment methods

- **Product:** Dispose of in accordance with local regulations.
  According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
  Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

- **Contaminated packaging:** Empty containers should be taken to an approved waste handling site for recycling or disposal.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Grazoprevir Formulation

Version 3.2 Revision Date: 09/13/2019 SDS Number: 443809-00011 Date of last issue: 24.04.2019

If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
REACH - List of substances subject to authorisation (Annex XIV): Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EC) No 850/2004 on persistent organic pollutants: Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable

Other regulations:
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:
AICS: not determined
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<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>
</table>

- DSL : not determined
- IECSC : not determined

#### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

**Other information**

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

### Full text of H-statements

- **H302**: Harmful if swallowed.
- **H315**: Causes skin irritation.
- **H318**: Causes serious eye damage.
- **H373**: May cause damage to organs through prolonged or repeated exposure if swallowed.
- **H412**: Harmful to aquatic life with long lasting effects.

### Full text of other abbreviations

- **Acute Tox.**: Acute toxicity
- **Aquatic Chronic**: Long-term (chronic) aquatic hazard
- **Eye Dam.**: Serious eye damage
- **Skin Irrit.**: Skin irritation
- **STOT RE**: Specific target organ toxicity - repeated exposure
- **IE OEL**: Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
- **IE OEL / OELV - 8 hrs (TWA)**: Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals.
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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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture: STOT RE 2  Classification procedure: H373  Calculation method

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.

IE / EN