SECTION 1. IDENTIFICATION

Product name : Grazoprevir Formulation

Manufacturer or supplier's details
Company : MSD
Address : 855 Leandro N. Alem St., 8 Floor
Buenos Aires, Argentina C1001AFB
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Skin irritation : Category 3
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Liver, Testis)
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 (Liver, Testis) through prolonged or repeated exposure if swallowed.
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/ atten-
SAFETY DATA SHEET

Grazoprevir Formulation

Version: 3.6
Revision Date: 27.08.2021
SDS Number: 443538-00015
Date of last issue: 29.01.2021
Date of first issue: 07.01.2016

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

Other hazards which do not result in classification
Dust contact with the eyes can lead to mechanical irritation.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<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; 5</td>
</tr>
</tbody>
</table>

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
- Causes mild skin irritation.
- May cause damage to organs through prolonged or repeated exposure if swallowed.
- Dust contact with the eyes can lead to mechanical irritation.

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

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
**SAFETY DATA SHEET**

**Grazoprevir Formulation**

<table>
<thead>
<tr>
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<th>Date of last issue: 29.01.2021</th>
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<tbody>
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<td>Date of first issue: 07.01.2016</td>
</tr>
</tbody>
</table>

Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

**Unsuitable extinguishing media:** None known.

**Specific hazards during fire fighting:**
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.

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**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.

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**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

<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>CMP</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></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>

Further information: A4 - Not classifiable as a human carcinogen

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

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.
### SECTION 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reac-</td>
<td>May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>tions</td>
<td></td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>Heat, flames and sparks. Avoid dust formation.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

### SECTION 11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Route of exposure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td></td>
</tr>
<tr>
<td>Skin contact</td>
<td></td>
</tr>
<tr>
<td>Ingestion</td>
<td></td>
</tr>
</tbody>
</table>

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: Not applicable

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
Acute toxicity
Not classified based on available information.

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

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

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

Components:

Grazoprevir:
Species: Bovine cornea
Result: No eye irritation

Sodium chloride:
Species: Rabbit
Result: No eye irritation

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

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

Respiratory or skin 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 chloride:
Test Type: Local lymph node assay (LLNA)
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Routes of exposure: Skin contact
Species: Mouse
Result: negative

**Sodium n-dodecyl sulfate:**
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

**Magnesium stearate:**
Test Type: Maximization Test
Routes of exposure: 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
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 chloride:**
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Result: positive
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: Saccharomyces cerevisiae, gene mutation assay (in vitro)
Result: positive
Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: positive
Test Type: Chromosome aberration test in vitro
Result: positive

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Intraperitoneal injection
Result: positive

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

Sodium n-dodecyl sulfate:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Mouse
Application Route: Ingestion
Result: negative

Magnesium stearate:
Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

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

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

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

### Reproductive toxicity
Not classified based on available information.

### Components:

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

  **Test Type**: Multi-generation study
  - **Species**: Rat
  - **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
  - **Result**: No effects on fetal development.

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

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

### Sodium n-dodecyl sulfate:
### Grazoprevir Formulation

<table>
<thead>
<tr>
<th>Version</th>
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</tr>
</tbody>
</table>

**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**:
- **Target Organs**
- **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
### Grazoprevir Formulation

<table>
<thead>
<tr>
<th>NOAEL</th>
<th>400 mg/kg</th>
</tr>
</thead>
<tbody>
<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>
<tr>
<td>Species</td>
<td>Dog</td>
</tr>
<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>NOAEL</th>
<th>15 mg/kg</th>
</tr>
</thead>
<tbody>
<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>NOAEL</th>
<th>20 mg/kg</th>
</tr>
</thead>
<tbody>
<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>NOAEL</th>
<th>10 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>8 Days</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td>Species</td>
<td>Monkey</td>
</tr>
</tbody>
</table>

**Sodium chloride:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>2.533 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 y</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>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>&gt; 100 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
<tr>
<td>Remarks</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:

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
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
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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
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
SAFETY DATA SHEET

Grazoprevir Formulation

Version 3.6  Revision Date: 27.08.2021  SDS Number: 443538-00015  Date of last issue: 29.01.2021  Date of first issue: 07.01.2016

Partition coefficient: n-octanol/water

Sodium n-dodecyl sulfate:
Partition coefficient: n-octanol/water

Magnesium stearate:
Partition coefficient: n-octanol/water

Mobility in soil

Components:

Grazoprevir:
Distribution among environmental compartments

Other adverse effects
No data available

SECTION 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.

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.

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry: Not applicable
Control of precursors and essential chemicals for the preparation of drugs: Not applicable

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

SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
AR OEL: Argentina. Occupational Exposure Limits
ACGIH / TWA: 8-hour, time-weighted average
AR OEL / CMP: TLV (Threshold Limit Value)

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