SECTION 1. PRODUCT AND COMPANY 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-
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
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.

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

<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>Magnesium stearate</td>
<td>557-04-0</td>
<td>CMP</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
</tbody>
</table>

Further information: A4 - Not classifiable as a human carcinogen, irritation

<table>
<thead>
<tr>
<th>Components</th>
<th></th>
<th>TWA (Inhalable particulate matter)</th>
<th>10 mg/m³</th>
<th>ACGIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</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.
SAFETY DATA SHEET

Grazoprevir Formulation

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: 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,
SAFETY DATA SHEET

Grazoprevir Formulation

<table>
<thead>
<tr>
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<tr>
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<td>443538-00014</td>
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</tr>
</tbody>
</table>

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 : 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

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 : Inhalation
exposure
Skin contact
Ingestion
Eye contact

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

**Product:**
Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg
Method: Calculation method

**Components:**
**Grazoprevir:**
Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg

**Sodium chloride:**
Acute oral toxicity : LD50 (Rat): 3.550 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 42 mg/l
Exposure time: 1 h
Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Rabbit): > 5.000 mg/kg

**Sodium n-dodecyl sulfate:**
Acute oral toxicity : LD50 (Rat): 1.200 mg/kg
Method: OECD Test Guideline 401
Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials

**Magnesium stearate:**
Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 423
Assessment: The substance or mixture has no acute oral toxicity
Remarks: Based on data from similar materials
Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg
Remarks: Based on data from similar materials

**Skin corrosion/irritation**
Causes mild skin irritation.

**Components:**
**Grazoprevir:**
Result : No skin irritation

**Sodium chloride:**
SAFETY DATA SHEET

Grazoprevir Formulation

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)
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 syn-
thesis 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:
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:
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: 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>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
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<tr>
<td>3.5</td>
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<td>10.10.2020</td>
<td>07.01.2016</td>
</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:** 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
<table>
<thead>
<tr>
<th>Substance</th>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grazoprevir Formulation</td>
<td>Dog</td>
<td>400 mg/kg</td>
<td></td>
<td>Oral</td>
<td>180 Days</td>
<td>Liver, Blood, Bone marrow, gallbladder, spleen, Testis</td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td>15 mg/kg</td>
<td>100 mg/kg</td>
<td>Oral</td>
<td>270 Days</td>
<td>Liver, Blood, Bone marrow, gallbladder, spleen, Testis</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>200 mg/kg</td>
<td>500 mg/kg</td>
<td>Oral</td>
<td>90 Days</td>
<td>Liver, Kidney, Blood</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>Rat</td>
<td>2.533 mg/kg</td>
<td></td>
<td>Ingestion</td>
<td>2 y</td>
<td></td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>Rat</td>
<td>488 mg/kg</td>
<td></td>
<td>Ingestion</td>
<td>90 Days</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Rat</td>
<td>&gt; 100 mg/kg</td>
<td></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:
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
Sodium chloride:
- **Toxicity to fish**: LC50 (Lepomis macrochirus (Bluegill sunfish)): 5.840 mg/l
- Exposure time: 96 h
- Test Type: Respiration inhibition
- Method: OECD Test Guideline 209

- **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
- NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l
- Exposure time: 72 h

- **Toxicity to fish (Chronic toxicity)**: NOEC (Pimephales promelas (fathead minnow)): >= 1,357 mg/l
- Exposure time: 42 d

- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**: NOEC (Ceriodaphnia dubia (water flea)): 0,88 mg/l
- Exposure time: 7 d

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

Magnesium stearate:
- **Toxicity to fish**: LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l
- Exposure time: 48 h
- Method: DIN 38412
- Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates
EL50 (Daphnia magna (Water flea)): > 1 mg/l
Exposure time: 47 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials
No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants
EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
No toxicity at the limit of solubility.

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
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
Grazoprevir Formulation

Partition coefficient: n-octanol/water: log Pow: 3.72

**Sodium n-dodecyl sulfate**
Partition coefficient: n-octanol/water: log Pow: 0.83

**Magnesium stearate**
Partition coefficient: n-octanol/water: log Pow: > 4

**Mobility in soil**

**Components:**

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

**Other adverse effects**
No data available

---

**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.

---

**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
  : Not applicable
preparation of drugs.

International Regulations

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)

Abbreviations:

- **AIC**: Australian Inventory of 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)
- **EC**: Concentration associated with % response
- **EL**: Loading rate associated with % response
- **EmS**: Emergency Schedule
- **EN**: Existing New Chemical Substances (Japan)
- **ER**: Emergency Response Guideline
- **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
- **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
- **SADT**: Self-Accelerating Decomposition Temperature
- **SDS**: Safety Data Sheet
- **TCSI**: Taiwan Chemical Substance Inventory
- **TDG**: Transportation of Dangerous Goods
- **TSCA**: Toxic Substances Control Act (United States)
- **UN**: United Na-
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