SAFETY DATA SHEET

Grazoprevir Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Grazoprevir Formulation

Manufacturer or supplier's details
Company name of supplier: MSD
Address: Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone: 52 55 57284444
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATATESTEWARD@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)

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.

Precautionary Statements: Prevention:
P260 Do not breathe dust.

Response:
P314 Get medical advice/ attention if you feel unwell. P332 + P313 If skin irritation occurs: Get medical advice/ attention.

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

Other hazards
Dust contact with the eyes can lead to mechanical irritation. May form explosive dust-air mixture during processing, handling or other means.
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SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grazoprevir</td>
<td>Mixture</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td></td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grazoprevir</td>
<td>1350462-55-3</td>
<td>&gt;= 10 -&lt; 20</td>
</tr>
<tr>
<td>Sodium 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; 3</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


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

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 and personal protective equipment recommendations.

Environmental precautions:
- Discharge into the environment must be avoided.
- Prevent further leakage or spillage if safe to do so.
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up:
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
- Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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.

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.

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>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>VLE-PPT</td>
<td>10 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable fraction)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Engineering measures:
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

Personal protective equipment
Respiratory protection:
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, mist 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder

Color: No data available

Odor: No data available

Odor Threshold: No data available

pH: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: Not applicable

Evaporation rate: Not applicable

Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids): No data available

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapor pressure: Not applicable

Relative vapor density: Not applicable
Relative density : No data available
Density : No data available
Solubility(ies) : No data available
   Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity : Not applicable
   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 reac-
tions : May form explosive dust-air mixture during processing, handling or other means.
   Can react with strong oxidizing agents.
Conditions to avoid : Heat, flames and sparks.
   Avoid dust formation.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
   Method: Calculation method
Components:

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

Sodium 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 (Rabbit): > 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
### Serious eye damage/eye irritation
Not classified based on available information.

### Components:

#### Grazoprevir:
<table>
<thead>
<tr>
<th>Species</th>
<th>Bovine cornea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>

#### Sodium chloride:
<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>

#### Sodium n-dodecyl sulfate:
<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Irreversible effects on the eye</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 405</td>
</tr>
</tbody>
</table>

#### Magnesium stearate:
<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Respiratory or skin sensitization

#### Skin sensitization
Not classified based on available information.

#### Respiratory sensitization
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>Routes of exposure</td>
<td>Dermal</td>
</tr>
<tr>
<td>Result</td>
<td>Not a skin sensitizer.</td>
</tr>
</tbody>
</table>

#### Sodium chloride:
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Local lymph node assay (LLNA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

#### Sodium n-dodecyl sulfate:
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximization Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
</tbody>
</table>
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</tr>
</thead>
</table>

| **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:**

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

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

**Germ cell mutagenicity - Assessment**

Weight of evidence does not support classification as a germ cell mutagen.

**Sodium chloride:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: In vitro mammalian cell gene mutation test Result: positive</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: Bacterial reverse mutation assay (AMES) Result: negative</td>
</tr>
<tr>
<td></td>
<td>Test Type: Saccharomyces cerevisiae, gene mutation assay (in vitro) Result: positive</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Result: positive</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: Chromosome aberration test in vitro Result: positive</td>
</tr>
<tr>
<td></td>
<td>Test Type: Chromosome aberration test in vitro Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: In vivo micronucleus test Species: Mouse</th>
</tr>
</thead>
</table>
### 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

- **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

- **Genotoxicity in vivo**
  - Test Type: Chromosome aberration test in vitro
  - Method: OECD Test Guideline 473
  - 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:**
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  
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
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Species : Mouse
NOAEL : 200 mg/kg
LOAEL : 500 mg/kg
Application Route : Oral
Exposure time : 90 Days
Target Organs : Liver, Kidney, Blood

Species : Dog
NOAEL : 20 mg/kg
LOAEL : 600 mg/kg
Application Route : Oral
Exposure time : 30 Days
Target Organs : Testis, Blood

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

**Sodium chloride:**
Species : Rat
LOAEL : 2,533 mg/kg
Application Route : Ingestion
Exposure time : 2 y

**Sodium n-dodecyl sulfate:**
Species : Rat
NOAEL : 488 mg/kg
Application Route : Ingestion
Exposure time : 90 Days
Remarks : Based on data from similar materials

**Magnesium stearate:**
Species : Rat
NOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 90 Days
Remarks : Based on data from similar materials

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

**Experience with human exposure**

**Components:**

**Grazoprevir:**
Ingestion : Symptoms: Headache, Gastrointestinal disturbance
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.

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

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

Exposure time: 48 h

Toxicity to algae/aquatic plants: EC50: > 2,000 mg/l
Exposure time: 96 h

Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 252 mg/l
Exposure time: 33 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia pulex (Water flea)): 314 mg/l
Exposure time: 21 d

Toxicity to microorganisms: EC10: > 1,000 mg/l

Sodium n-dodecyl sulfate:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 29 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: ErC50 (Desmodesmus subspicatus (green algae)): > 120 mg/l
Exposure time: 72 h
NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l
Exposure time: 72 h

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

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

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

Magnesium stearate:
Toxicity to fish: LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l
Exposure time: 48 h
Method: DIN 38412
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EL50 (Daphnia magna (Water flea)): > 1 mg/l
Exposure time: 47 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials
No toxicity at the limit of solubility.

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

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (Pseudomonas putida): > 100 mg/l
Exposure time: 16 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Persistence and degradability
Components:

Grazoprevir:
Biodegradability : Result: Not readily biodegradable.
Biodegradation: 66 %
Exposure time: 28 d

Sodium n-dodecyl sulfate:
Biodegradability : Result: Readily biodegradable.
Biodegradation: 95 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Magnesium stearate:
Biodegradability : Result: Not biodegradable.
Remarks: Based on data from similar materials

Bioaccumulative potential
Components:

Grazoprevir:
Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 7.62

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

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

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

**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.

**Domestic regulation**

- **NOM-002-SCT**: Not regulated as a dangerous good

**Special precautions for user**
Not applicable

### SECTION 15. REGULATORY INFORMATION

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

- Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills: Not applicable

**The ingredients of this product are reported in the following inventories:**

- **AICS**: not determined
SAFETY DATA SHEET

Grazoprevir Formulation

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA : 8-hour, time-weighted average
NOM-010-STPS-2014 / VLE-PPT : Time weighted average limit value

DSL : not determined
IECSC : not determined

Sources of key data used to compile the Material Safety Data Sheet


Revision Date : 09/13/2019
The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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