SAFETY DATA SHEET

Grazoprevir Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Grazoprevir Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Rua Treze de Maio, 1161, Campinas, São Paulo, Brazil 13106-054
Telephone: 908-740-4000
Emergency telephone: 55 19 3758 2000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
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 in accordance with ABNT NBR 14725 Standard
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-
tion.

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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grazoprevir</td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Grazoprevir</td>
</tr>
<tr>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>Sodium chloride</td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>Sodium n-dodecyl sulfate</td>
</tr>
<tr>
<td></td>
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<td></td>
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<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Magnesium stearate</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.
SAFETY DATA SHEET
Grazoprevir Formulation

Version  4.1  Revision Date: 10.10.2020  SDS Number: 402533-00013  Date of last issue: 23.03.2020

Date of first issue: 07.01.2016

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) Internal</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>250 µg/100 cm² Internal</td>
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<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³ ACGIH</td>
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<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³ ACGIH</td>
<td></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**

- **Material**: Wear safety glasses with side shields or goggles.
- **Remarks**: 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**

- **Material**: Work uniform or laboratory coat.
- **Remarks**: 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
### Grazoprevir Formulation

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

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

Conditions to avoid: Heat, flames and sparks. Avoid dust formation.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity:
Not classified based on available information.

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

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

Sodium 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)
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:**

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

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.
  - 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
### Sodium chloride:

<table>
<thead>
<tr>
<th>Toxicity Type</th>
<th>Toxicity Parameter</th>
<th>Exposure Time</th>
<th>Method Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50</td>
<td>96 h</td>
<td>(Lepomis macrochirus (Bluegill sunfish)) 5.840 mg/l</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50</td>
<td>48 h</td>
<td>(Daphnia magna (Water flea)) 4.136 mg/l</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>EC50</td>
<td>96 h</td>
<td>&gt; 2.000 mg/l</td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>NOEC</td>
<td>33 d</td>
<td>(Pimephales promelas (fathead minnow)) 252 mg/l</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>NOEC</td>
<td>21 d</td>
<td>(Daphnia pulex (Water flea)) 314 mg/l</td>
</tr>
<tr>
<td>Toxicity to microorganisms</td>
<td>EC10</td>
<td>&gt; 1.000 mg/l</td>
<td></td>
</tr>
</tbody>
</table>

### Sodium n-dodecyl sulfate:

<table>
<thead>
<tr>
<th>Toxicity Type</th>
<th>Toxicity Parameter</th>
<th>Exposure Time</th>
<th>Method Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50</td>
<td>96 h</td>
<td>(Pimephales promelas (fathead minnow)) 29 mg/l</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50</td>
<td>48 h</td>
<td>(Ceriodaphnia dubia (water flea)) 5.55 mg/l</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>ErC50</td>
<td>&gt; 120 mg/l</td>
<td>(Desmodesmus subspicatus (green algae))</td>
</tr>
<tr>
<td></td>
<td>NOEC</td>
<td>72 h</td>
<td>(Desmodesmus subspicatus (green algae)) 30 mg/l</td>
</tr>
</tbody>
</table>
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

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**

**ANTT**
Not regulated as a dangerous good

### SECTION 15. REGULATORY INFORMATION

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

- National List of Carcinogenic Agents for Humans - (LINACH): Not applicable
- Brazil. List of chemicals controlled by the Federal Police: Not applicable

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