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: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
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)

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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS
**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 firefighting**: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

**Hazardous combustion products**: Carbon oxides. Nitrogen oxides (NOx).
SAFETY DATA SHEET

Grazoprevir Formulation

Version 4.6  Revision Date: 27.08.2021  SDS Number: 402644-00015  Date of last issue: 29.01.2021

Date of first issue: 07.01.2016

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.

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>85 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>850 µg/100 cm²</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 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>

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.
SAFETY DATA SHEET

Grazoprevir Formulation

Filter type: Particulates type
Hand protection: Chemical-resistant gloves

Material: Consider double gloving.
Remarks: 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.

Eye protection: 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):
  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 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:
| 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
SAFETY DATA SHEET

Grazoprevir Formulation

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
Grazoprevir Formulation

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
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, Blood, Bone marrow, gallbladder, spleen, Testis
SAFETY DATA SHEET

Grazoprevir Formulation

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 : Blood, Testis

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.

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
SAFETY DATA SHEET
Grazoprevir Formulation

| 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 |
SAFETY DATA SHEET
Grazoprevir Formulation

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- : 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 : Time weighted average
NOM-010-STPS-2014 / VLE-PPT : Time weighted average limit value

All abbreviations are referred to in the full text


Revision Date : 27.08.2021
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.

MX / Z8