Grazoprevir Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name: Grazoprevir Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture: Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company: MSD
   Shotton Lane
   NE23 3JU Cramlington NU - Great Britain
   Telephone: 44 1 670 59 30 00
   Telefax: 908-735-1496
   E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Specific target organ toxicity - repeated exposure, Category 2
   H373: May cause damage to organs through prolonged or repeated exposure.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms:
   Signal word: Warning
   Hazard statements: H373 May cause damage to organs through prolonged or repeated exposure.
   Precautionary statements: Prevention:
   P260 Do not breathe dust.

Response:
Hazardous components which must be listed on the label:
Grazoprevir

2.3 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

#### 3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grazoprevir</td>
<td>1350462-55-3</td>
<td>STOT RE 2; H373 (Liver, Testis)</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3 205-788-1</td>
<td>Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Aquatic Chronic 3; H412</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of 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.

**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).

**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.
**SAFETY DATA SHEET**
according to Regulation (EC) No. 1907/2006

**Grazoprevir Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.4</td>
<td>10.10.2020</td>
<td>443808-00013</td>
<td>23.03.2020</td>
<td>07.01.2016</td>
</tr>
</tbody>
</table>

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

### 4.2 Most important symptoms and effects, both acute and delayed

**Symptoms**: Headache, Gastrointestinal discomfort

**Risks**: May cause damage to organs through prolonged or repeated exposure. Dust contact with the eyes can lead to mechanical irritation.

### 4.3 Indication of any immediate medical attention and special treatment needed

**Treatment**: Treat symptomatically and supportively.

---

**SECTION 5: Firefighting measures**

#### 5.1 Extinguishing media

**Suitable extinguishing media**: Water spray, Alcohol-resistant foam, Carbon dioxide (CO2), Dry chemical

**Unsuitable extinguishing media**: None known.

#### 5.2 Special hazards arising from the substance or mixture

**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), Metal oxides, Chlorine compounds, Sulphur oxides

#### 5.3 Advice for firefighters

**Special protective equipment for firefighters**: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

**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.
SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:
- Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage:
- Do not store with the following product types: Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s):
- No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</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>
</tbody>
</table>

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>2068.62 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>2068.62 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>295.52 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>295.52 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>443.28 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>443.28 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>126.65 mg/kg bw/day</td>
</tr>
</tbody>
</table>
Consumers  | Skin contact  | Acute systemic effects  | 126.65 mg/kg bw/day  
--- | --- | --- | ---  
Consumers  | Ingestion  | Long-term systemic effects  | 126.65 mg/kg bw/day  
Consumers  | Ingestion  | Acute systemic effects  | 126.65 mg/kg bw/day  
Sodium n-dodecyl sulfate  | Workers  | Inhalation  | Long-term systemic effects  | 285 mg/m³  
Workers  | Skin contact  | Long-term systemic effects  | 4060 mg/kg bw/day  
Consumers  | Inhalation  | Long-term systemic effects  | 85 mg/m³  
Consumers  | Skin contact  | Long-term systemic effects  | 2440 mg/kg bw/day  
Consumers  | Ingestion  | Long-term systemic effects  | 24 mg/kg bw/day  

### 8.2 Exposure controls

#### 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

**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 face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Hand protection**

- Material: Chemical-resistant gloves
Remarks: Consider double gloving.

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.

Respiratory protection:
If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to BS EN 143
Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: powder

Colour: No data available

Odour: No data available

Odour 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.

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapour pressure: Not applicable

Relative vapour 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

Auto-ignition 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.

9.2 Other information
  Flammability (liquids) : No data available
  Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
  Not classified as a reactivity hazard.

10.2 Chemical stability
  Stable under normal conditions.

10.3 Possibility of hazardous reactions
  Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
  Can react with strong oxidizing agents.

10.4 Conditions to avoid
  Conditions to avoid : Heat, flames and sparks.
  Avoid dust formation.

10.5 Incompatible materials
  Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
  No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
  Information on likely routes of exposure : Inhalation
  Skin contact
  Ingestion
  Eye contact

  Acute toxicity
  Not classified based on available information.

Product:
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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Date of first issue: 07.01.2016

Acute oral toxicity: Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Components:
Grazoprevir:
Acute oral toxicity: LD50 (Rat): > 2,000 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

Skin corrosion/irritation
Not classified based on available information.

Components:
Grazoprevir:
Result: No skin irritation

Sodium n-dodecyl sulfate:
Species: Rabbit
Result: Skin irritation

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

Components:
Grazoprevir:
Species: Bovine cornea
Result: No eye irritation

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

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.
Components:

Grazoprevir:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Dermal
Result: Not a skin sensitizer.

Sodium n-dodecyl sulfate:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
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 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

Carcinogenicity
Not classified based on available information.
Components:

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 foetal development

Effects on foetal development:
Species: Rat
Application Route: Oral
Embryo-foetal toxicity: NOAEL: 200 mg/kg body weight
Result: No effects on foetal 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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Grazoprevir Formulation

Version 3.4    Revision Date: 10.10.2020    SDS Number: 443808-00013    Date of last issue: 23.03.2020    Date of first issue: 07.01.2016

Effects on foetal development:
- Test Type: Embryo-foetal 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 through prolonged or repeated exposure.

**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
Grazoprevir Formulation

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 n-dodecyl sulfate:
Species: Rat
NOAEL: 488 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

12.1 Toxicity

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
<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>mg/l</td>
<td>Exposure time: 72 hrs</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility</td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to microorganisms</strong></td>
<td>EC50 : &gt; 1,000 mg/l</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
<td>Test Type: Respiration inhibition</td>
</tr>
<tr>
<td></td>
<td>Test Type: Respiration inhibition</td>
<td>Method: OECD Test Guideline 209</td>
</tr>
<tr>
<td></td>
<td>NOEC : 1.3 mg/l</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
<td>Test Type: Respiration inhibition</td>
</tr>
<tr>
<td></td>
<td>Test Type: Respiration inhibition</td>
<td>Method: OECD Test Guideline 209</td>
</tr>
<tr>
<td><strong>Toxicity to fish (Chronic toxicity)</strong></td>
<td>NOEC: 0.98 mg/l</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 32 d</td>
<td>Species: Pimephales promelas (fathead minnow)</td>
</tr>
<tr>
<td></td>
<td>Species: Pimephales promelas (fathead minnow)</td>
<td>Method: OECD Test Guideline 210</td>
</tr>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility</td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</strong></td>
<td>NOEC: 5 mg/l</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
<td>Species: Daphnia magna (Water flea)</td>
</tr>
<tr>
<td></td>
<td>Species: Daphnia magna (Water flea)</td>
<td>Method: OECD Test Guideline 211</td>
</tr>
<tr>
<td><strong>Sodium n-dodecyl sulfate:</strong></td>
<td>LC50 (Pimephales promelas (fathead minnow)): 29 mg/l</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
<td>EC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>ErC50 (Desmodesmus subspicatus (green algae)): &gt; 120 mg/l</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to microorganisms</strong></td>
<td>EC50 : 135 mg/l</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to fish (Chronic toxicity)</strong></td>
<td>NOEC: &gt;= 1.357 mg/l</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 42 d</td>
<td>Species: Pimephales promelas (fathead minnow)</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</strong></td>
<td>NOEC: 0.88 mg/l</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 7 d</td>
<td>Species: Ceriodaphnia dubia (water flea)</td>
</tr>
</tbody>
</table>
12.2 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

12.3 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

12.4 Mobility in soil

Components:

Grazoprevir:
Distribution among environmental compartments: log Koc: 4.01

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product: Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
SECTION 14: Transport information

14.1 UN number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
REACH - List of substances subject to authorisation (Annex XIV): Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

Other regulations:
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:
AICS: not determined
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Grazoprevir Formulation

Version 3.4
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DSL : not determined
IECSC : not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements
H302 : Harmful if swallowed.
H315 : Causes skin irritation.
H318 : Causes serious eye damage.
H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.
H412 : Harmful to aquatic life with long lasting effects.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Dam. : Serious eye damage
Skin Irrit. : Skin irritation
STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 - (Quantit-
Further information


Classification of the mixture: STOT RE 2 H373

Classification procedure: Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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