1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Grazoprevir Formulation

Manufacturer or supplier’s details
Company : MSD
Address : 50 Tuas West Drive
          Singapore - Singapore 638408
Telephone : 908-740-4000
Emergency telephone number : 65 6697 2111 (24/7/365)
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

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

2. HAZARDS IDENTIFICATION

GHS Classification
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Liver, Testis)

GHS label elements
Hazard pictograms : Warning

Signal word : Warning
Hazard statements : 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.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification
Dust contact with the eyes can lead to mechanical irritation.
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>Grazoprevir</td>
<td>1350462-55-3</td>
<td>&gt;= 10 -&lt; 20</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3</td>
<td>&gt;= 1 -&lt; 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 -&lt; 10</td>
<td></td>
</tr>
</tbody>
</table>

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 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.

5. FIREFIGHTING 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), Metal oxides, Chlorine compounds, Sulphur 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 firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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.

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 as-
Assessment
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
Keep in properly labelled containers.
Store in accordance with the particular national regulations.

Materials to avoid:
Do not store with the following product types:
Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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>PEL (long term)</td>
<td>10 mg/m³</td>
<td>SG OEL</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

Eye protection:
Remarks: Consider double gloving.
Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a
potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling</td>
<td>No data available</td>
</tr>
<tr>
<td>range</td>
<td></td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper</td>
<td>No data available</td>
</tr>
<tr>
<td>flammability limit</td>
<td></td>
</tr>
<tr>
<td>Lower explosion limit / Lower</td>
<td>No data available</td>
</tr>
<tr>
<td>flammability limit</td>
<td></td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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.

Particle size : No data available

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.

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: > 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

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
Not classified based on available information.

Components:
Grazoprevir:
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 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 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

Magnesium stearate:
Test Type: Maximisation Test
Exposure routes: 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.
SAFETY DATA SHEET

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>
</table>

**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: In vitro mammalian cell gene mutation test
  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

- 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 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
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Embryo-foetal toxicity: NOAEL</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multi-generation study</td>
<td>Rat</td>
<td>Oral</td>
<td>400 mg/kg body weight</td>
<td>No effects on fertility, No effects on foetal development</td>
<td></td>
</tr>
<tr>
<td>Two-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Ingestion</td>
<td></td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test</td>
<td>Rat</td>
<td>Ingestion</td>
<td>100 mg/kg body weight</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Sodium n-dodecyl sulfate:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo-foetal development</td>
<td>Rat</td>
<td>Oral</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>Two-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo-foetal development</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
Grazoprevir Formulation

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
SAFETY DATA SHEET

Grazoprevir Formulation

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

**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

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
### Toxicity to fish (Chronic toxicity)

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC (Pimephales promelas (fathead minnow))</th>
<th>Exposure time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>0.98 mg/l</td>
<td>32 d</td>
<td>OECD Test Guideline 210</td>
<td>No toxicity at the limit of solubility</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>1.357 mg/l</td>
<td>42 d</td>
<td>OECD Test Guideline 210</td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC (Daphnia magna (Water flea))</th>
<th>Exposure time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>5 mg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>0.88 mg/l</td>
<td>7 d</td>
<td>OECD Test Guideline 210</td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Test Type</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>&gt; 1,000 mg/l</td>
<td>3 h</td>
<td>Respiration inhibition</td>
<td>OECD Test Guideline 209</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>135 mg/l</td>
<td>3 h</td>
<td>Respiration inhibition</td>
<td>OECD Test Guideline 209</td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Test Type</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>&gt; 120 mg/l</td>
<td>72 h</td>
<td>Respiration inhibition</td>
<td>OECD Test Guideline 209</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>30 mg/l</td>
<td>72 h</td>
<td>Respiration inhibition</td>
<td>OECD Test Guideline 209</td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
Grazoprevir Formulation

aquatic invertebrates

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
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.

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.

15. REGULATORY INFORMATION

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable
Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable

The components of this product are reported in the following inventories:

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Reporting Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Further information


Date format: dd.mm.yyyy

Full text of other abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td>SG OEL</td>
<td>Singapore. Workplace Safety and Health Act - First Schedule Permissible Exposure Limits of Toxic Substances</td>
</tr>
</tbody>
</table>

AICS - Australian Inventory of Chemical Substances; 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 - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; ICS0 - 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; KECl - 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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 Substanc-
SAFETY DATA SHEET

Grazoprevir Formulation

Version | Revision Date: | SDS Number: | Date of last issue: | Date of first issue:
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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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