1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Grazoprevir / Elbasvir Formulation

Supplier’s company name, address and phone number
Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : +1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Short-term (acute) aquatic hazard : Category 3
Long-term (chronic) aquatic hazard : Category 1

GHS label elements
Hazard pictograms : 
Signal word : Warning
Hazard statements : H402 Harmful to aquatic life. H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements : Prevention:
P273 Avoid release to the environment.
Response:
P391 Collect spillage.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.
Other hazards which do not result in classification

Important symptoms and outlines of the emergency assumed:
- Dust contact with the eyes can lead to mechanical irritation.
- Contact with dust can cause mechanical irritation or drying of the skin.
- May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>1 - 10</td>
<td></td>
</tr>
<tr>
<td>Grazoprevir</td>
<td>1350462-55-3</td>
<td>2.5 - 10</td>
<td></td>
</tr>
<tr>
<td>Elbasvir</td>
<td>1370468-36-2</td>
<td>2.5 - 10</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>1 - 10</td>
<td>2-611</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>0.1 - 1</td>
<td>1-558, 5-5225</td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3</td>
<td>0.25 - 1</td>
<td>2-1679</td>
</tr>
<tr>
<td>Silicon, amorphous</td>
<td>112945-52-5</td>
<td>0.1 - 1</td>
<td>1-548</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td>0.0025 - 0.025</td>
<td>3-540, 9-1805</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.

In case of skin contact: Wash with water and soap. Get medical attention if symptoms occur.

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: Contact with dust can cause mechanical irritation or drying of the skin. 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
SAFETY DATA SHEET

Grazoprevir / Elbasvir 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>11.0</td>
<td>2021/08/27</td>
<td>76213-00020</td>
<td>2021/04/09</td>
<td>2015/03/17</td>
</tr>
</tbody>
</table>

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
Metal oxides
Chlorine compounds
Nitrogen oxides (NOx)

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 (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.

7. HANDLING AND STORAGE

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 breathe dust. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. 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.

Avoidance of contact: Oxidizing agents

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.

Storage

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

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Reference concentration / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<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>Wipe limit</td>
<td>850 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Elbasvir</td>
<td>1370468-36-2</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhal)</td>
<td>10 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 : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : powder

Colour : white
<table>
<thead>
<tr>
<th><strong>Odour</strong></th>
<th>No data available</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Odour Threshold</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Melting point/freezing point</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Boiling point, initial boiling point and boiling range</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Flammability (solid, gas)</strong></td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td><strong>Flammability (liquids)</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Lower explosion limit and upper explosion limit / flammability limit</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Upper explosion limit / Upper flammability limit</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Lower explosion limit / Lower flammability limit</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Flash point</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Decomposition temperature</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Auto-ignition temperature</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Viscosity</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Viscosity, kinematic</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Solubility(ies)</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Water solubility</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Partition coefficient: n-octanol/water</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Vapour pressure</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Density and / or relative density</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Relative density</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Density</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Relative vapour density</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Explosive properties</strong></td>
<td>Not explosive</td>
</tr>
<tr>
<td><strong>Oxidizing properties</strong></td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td><strong>Particle characteristics</strong></td>
<td></td>
</tr>
</tbody>
</table>
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.

Components:

Cellulose:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity:
LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

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

Elbasvir:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
LD50 (Mouse): > 1,000 mg/kg

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

Titanium dioxide:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 6.82 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Assessment: The substance or mixture has no acute inhalation toxicity

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

Silicon, amorphous:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
  Method: OECD Test Guideline 401
  Remarks: Based on data from similar materials
Acute inhalation toxicity: LC50 (Rat): > 2.08 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Assessment: The substance or mixture has no acute inhalation toxicity
  Remarks: Based on data from similar materials
Acute dermal toxicity: LD50 (Rabbit): > 5,000 mg/kg
  Remarks: Based on data from similar materials

2,6-Di-tert-butyl-p-cresol:
Acute oral toxicity: LD50 (Rat): > 6,000 mg/kg
  Method: OECD Test Guideline 401
Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
  Method: OECD Test Guideline 402
  Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation:
Not classified based on available information.

Components:

Grazoprevir:
Result: No skin irritation
Elbasvir:
Species: reconstructed human epidermis (RhE)
Result: No skin irritation

Magnesium stearate:
Species: Rabbit
Result: No skin irritation
Remarks: Based on data from similar materials

Titanium dioxide:
Species: Rabbit
Result: No skin irritation

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

Silicon, amorphous:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

2,6-Di-tert-butyl-p-cresol:
Species: Rabbit
Method: OECD Test Guideline 404
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

Elbasvir:
Species: Bovine cornea
Result: No eye irritation

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

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

Silicon, amorphous:
<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 405</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

2,6-Di-tert-butyl-p-cresol:
<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 405</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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. |

Elbasvir:
| Test Type       | Local lymph node assay (LLNA) |
| Exposure routes | Dermal |
| Species         | Mouse |
| Result          | negative |

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 |
Titanium dioxide:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Local lymph node assay (LLNA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

Sodium n-dodecyl sulfate:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximisation Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

2,6-Di-tert-butyl-p-cresol:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Human repeat insult patch test (HRIPT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Humans</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

Germ cell mutagenicity
Not classified based on available information.

Components:

Cellulose:

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

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

Grazoprevir:

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

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

| Germ cell mutagenicity - Assessment | Weight of evidence does not support classification as a germ cell mutagen. |

Elbasvir:
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
Species: Rat
Application Route: Oral
Result: negative

Germ cell mutagenicity assessment: Weight of evidence does not support classification as a germ cell mutagen.

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

Titanium dioxide:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo: Test Type: In vivo micronucleus test
Species: Mouse
Result: negative

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

Silicon, amorphous:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
SAFETY DATA SHEET

Grazoprevir / Elbasvir Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
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<th>Date of last issue:</th>
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</thead>
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<td>2021/08/27</td>
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<td>2021/04/09</td>
<td>2015/03/17</td>
</tr>
</tbody>
</table>

**Genotoxicity in vivo**
- Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative
  - Remarks: Based on data from similar materials

**2,6-Di-tert-butyl-p-cresol**
- Genotoxicity in vitro
  - Test Type: Bacterial reverse mutation assay (AMES)
    - Result: negative
- Test Type: In vitro mammalian cell gene mutation test
  - Result: negative
- Test Type: Chromosome aberration test in vitro
  - Result: negative

**Genotoxicity in vivo**
- Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

**Carcinogenicity**
- Not classified based on available information.

**Components:**

**Cellulose**
- Species: Rat
- Application Route: Ingestion
- Exposure time: 72 weeks
- Result: negative

**Titanium dioxide**
- Species: Rat
- Application Route: Inhalation (dust/mist/fume)
- Exposure time: 2 Years
- Method: OECD Test Guideline 453
- Result: positive
- Remarks: The mechanism or mode of action may not be relevant in humans.

**Carcinogenicity - Assessment**
- Limited evidence of carcinogenicity in inhalation studies with animals.

**Sodium n-dodecyl sulfate**
- Species: Rat
- Application Route: Ingestion
## Exposure time

<table>
<thead>
<tr>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>OECD Test Guideline 453</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Silicon, amorphous:

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Ingestion</td>
<td>103 weeks</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### 2,6-Di-tert-butyl-p-cresol:

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Ingestion</td>
<td>22 Months</td>
<td>negative</td>
<td></td>
</tr>
</tbody>
</table>

### Reproductive toxicity

Not classified based on available information.

### Components:

#### Cellulose:

- **Effects on fertility**
  - Test Type: One-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

- **Effects on foetal development**
  - Test Type: Fertility/early embryonic development
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

#### 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**
  - Test Type: Embryo-foetal development
  - Species: Rat
  - Application Route: Oral
  - Embryo-foetal toxicity: NOAEL: 200 mg/kg body weight
  - Result: No effects on foetal development
Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Oral  
Embryo-foetal toxicity: NOAEL: 200 mg/kg body weight  
Result: No effects on foetal development  

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Intravenous  
Embryo-foetal toxicity: NOAEL: 100 mg/kg body weight  
Result: No effects on foetal development  

Elbasvir:  
Effects on fertility: Test Type: Fertility/early embryonic development  
Species: Rat, male and female  
Application Route: Oral  
Fertility: NOAEL: 1,000 mg/kg body weight  
Result: No effects on fertility  

Effects on foetal development: Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 1,000 mg/kg body weight  
Result: No effects on early embryonic development  

Developmental Toxicity: NOAEL: 1,000 mg/kg body weight  
Result: No effects on early embryonic development  

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 foetal development: Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials  

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
SAFETY DATA SHEET

Grazoprevir / Elbasvir Formulation

Version: 11.0  Revision Date: 2021/08/27  SDS Number: 76213-00020  Date of last issue: 2021/04/09  Date of first issue: 2015/03/17

Effects on foetal development:
- Test Type: Embryo-foetal development
- Species: Rat
- Application Route: Ingestion
- Result: negative
- Remarks: Based on data from similar materials

Silicon, amorphous:
- Test Type: Embryo-foetal development
- Species: Rat
- Application Route: Ingestion
- Result: negative
- Remarks: Based on data from similar materials

2,6-Di-tert-butyl-p-cresol:
- Test Type: Two-generation reproduction toxicity study
- 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
Not classified based on available information.

Components:

Grazoprevir:
- Target Organs: Liver, Testis
- Assessment: May cause damage to organs through prolonged or repeated exposure.

2,6-Di-tert-butyl-p-cresol:
- Assessment: No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Repeated dose toxicity

Components:

Cellulose:
- Species: Rat
- NOAEL: >= 9,000 mg/kg
- Application Route: Ingestion
- Exposure time: 90 Days
<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL (mg/kg)</th>
<th>Application Route</th>
<th>Exposure time (days)</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>400</td>
<td>Oral</td>
<td>30</td>
<td>Liver, Blood, Bone marrow, gallbladder, spleen, Testis</td>
</tr>
<tr>
<td>Rat</td>
<td>400</td>
<td>Oral</td>
<td>180</td>
<td></td>
</tr>
<tr>
<td>Dog</td>
<td>15</td>
<td>Oral</td>
<td>270</td>
<td>Liver, Blood, Bone marrow, gallbladder, spleen, Testis</td>
</tr>
<tr>
<td>Mouse</td>
<td>200</td>
<td>Oral</td>
<td>90</td>
<td>Liver, Kidney, Blood</td>
</tr>
<tr>
<td>Dog</td>
<td>20</td>
<td>Oral</td>
<td>30</td>
<td>Blood, Testis</td>
</tr>
<tr>
<td>Monkey</td>
<td>10</td>
<td></td>
<td>8</td>
<td></td>
</tr>
</tbody>
</table>

**Elbasvir:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL (mg/kg)</th>
<th>Application Route</th>
<th>Exposure time (days)</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>1,000</td>
<td>Oral</td>
<td>180</td>
<td></td>
</tr>
<tr>
<td>Dog</td>
<td>1,000</td>
<td>Oral</td>
<td>270</td>
<td></td>
</tr>
</tbody>
</table>
Magnesium stearate:
- **Species**: Rat
- **NOAEL**: > 100 mg/kg
- **Application Route**: Ingestion
- **Exposure time**: 90 Days
- **Remarks**: Based on data from similar materials

Titanium dioxide:
- **Species**: Rat
- **NOAEL**: 24,000 mg/kg
- **Application Route**: Ingestion
- **Exposure time**: 28 Days
- **Species**: Rat
- **NOAEL**: 10 mg/m3
- **Application Route**: inhalation (dust/mist/fume)
- **Exposure time**: 2 yr

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

Silicon, amorphous:
- **Species**: Rat
- **NOAEL**: 1.3 mg/l
- **Application Route**: inhalation (dust/mist/fume)
- **Exposure time**: 13 Weeks
- **Remarks**: Based on data from similar materials

2,6-Di-tert-butyl-p-cresol:
- **Species**: Rat
- **NOAEL**: 25 mg/kg
- **Application Route**: Ingestion
- **Exposure time**: 22 Months

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

**Experience with human exposure**

**Components:**

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

**Elbasvir:**
- **Ingestion**: Symptoms: Headache, Abdominal pain, constipation, Nausea, Fatigue, muscle pain, joint pain, Dizziness, Cough, Skin irrita-
12. ECOLOGICAL INFORMATION

Ecotoxicity

**Components:**

**Cellulose:**
- **Toxicity to fish**: LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
  - Exposure time: 48 h
  - Remarks: Based on data from similar materials

**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
  - 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
### Elbasvir:

**Toxicity to fish**
- NOEC: 1.3 mg/l
- Exposure time: 3 h
- Test Type: Respiration inhibition
- Method: OECD Test Guideline 209

**Toxicity to daphnia and other aquatic invertebrates**
- LC50 (Lepomis macrochirus (Bluegill sunfish)): > 10 mg/l
- Exposure time: 96 h
- Remarks: No toxicity at the limit of solubility

- LC50 (Menidia beryllina (Silverside)): > 10 mg/l
- Exposure time: 96 h
- Remarks: No toxicity at the limit of solubility

**Toxicity to algae/aquatic plants**
- 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): 7.7 mg/l
- Exposure time: 96 h
- Remarks: No toxicity at the limit of solubility

**Toxicity to fish (Chronic toxicity)**
- NOEC (Pimephales promelas (fathead minnow)): 0.0023 mg/l
- Exposure time: 32 d
- Method: OECD Test Guideline 210

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**
- NOEC (Daphnia magna (Water flea)): 0.84 mg/l
- Exposure time: 21 d
- Method: OECD Test Guideline 211
- Remarks: No toxicity at the limit of solubility

**M-Factor (Chronic aquatic toxicity)**
- 10

**Toxicity to microorganisms**
- EC50: > 1,000 mg/l
- Exposure time: 3 h
- Test Type: Respiration inhibition
- Method: OECD Test Guideline 209

- NOEC: 271.9 mg/l
- Exposure time: 3 h
Magnesium stearate:

- **Toxicity to fish**: LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l  
  Exposure time: 48 h  
  Method: OECD Test Guideline 209

- **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

- **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

Titanium dioxide:

- **Toxicity to fish**: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
  Exposure time: 96 h  
  Method: OECD Test Guideline 203

- **Toxicity to daphnia and other aquatic invertebrates**: EC50 (Daphnia magna (Water flea)): > 100 mg/l  
  Exposure time: 48 h

- **Toxicity to algae/aquatic plants**: EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l  
  Exposure time: 72 h

- **Toxicity to microorganisms**: EC50: > 1,000 mg/l  
  Exposure time: 3 h  
  Method: OECD Test Guideline 209

Sodium n-dodecyl sulfate:

- **Toxicity to fish**: LC50 (Pimephales promelas (fathead minnow)): 29 mg/l
<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>Toxicity to algae/aquatic plants</th>
<th>Toxicity to fish (Chronic toxicity)</th>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>Toxicity to microorganisms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicon, amorphous:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>ErC50 (Desmodesmus subspicatus (green algae)): &gt; 120 mg/l</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l</td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>NOEC (Pimephales promelas (fathead minnow)): &gt;= 1.357 mg/l</td>
<td></td>
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<td></td>
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<tr>
<td></td>
<td>Exposure time: 42 d</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>NOEC (Ceriodaphnia dubia (water flea)): 0.88 mg/l</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Exposure time: 7 d</td>
<td></td>
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<tr>
<td></td>
<td>EC50: 135 mg/l</td>
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<tr>
<td></td>
<td>Exposure time: 3 h</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol:</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LC50 (Danio rerio (zebra fish)): &gt; 10,000 mg/l</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 203</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Exposition time: 24 h</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 1,000 mg/l</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 202</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOEC (Desmodesmus subspicatus (green algae)): 10,000 mg/l</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>LC50 (Danio rerio (zebra fish)): &gt; 0.57 mg/l</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposition time: 96 h</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposition time: 48 h</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EC50 (Daphnia magna (Water flea)): 0.48 mg/l</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 202</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposition time: 48 h</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ErC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 0.24</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
plants

<table>
<thead>
<tr>
<th>Plants</th>
<th>mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 72 h</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
</tbody>
</table>

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.24 mg/l
| Exposure time: 72 h |
| Method: OECD Test Guideline 201 |

M-Factor (Acute aquatic toxicity): 1

Toxicity to fish (Chronic toxicity): NOEC (Oryzias latipes (Japanese medaka)): 0.053 mg/l
| Exposure time: 30 d |
| Method: OECD Test Guideline 210 |

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 0.316 mg/l
| Exposure time: 21 d |

M-Factor (Chronic aquatic toxicity): 1

Toxicity to microorganisms: EC50: > 10,000 mg/l
| Exposure time: 3 h |
| Method: OECD Test Guideline 209 |

Persistence and degradability

Components:

Cellulose:

| Biodegradability | Result: Readily biodegradable. |

Grazoprevir:

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

Elbasvir:

| Biodegradability | Result: Not readily biodegradable. |
| Biodegradation: 37 % |
| Exposure time: 28 d |

Magnesium stearate:

| Biodegradability | Result: Not biodegradable |
| Remarks: Based on data from similar materials |

Sodium n-dodecyl sulfate:

| Biodegradability | Result: Readily biodegradable. |
| Biodegradation: 95 % |
| Exposure time: 28 d |
| Method: OECD Test Guideline 301B |
2,6-Di-tert-butyl-p-cresol:

**Biodegradability**: Result: Not readily biodegradable.
- Biodegradation: 4.5%
- Exposure time: 28 d
- Method: OECD Test Guideline 301C

**Bioaccumulative potential**

**Components:**

**Grazoprevir:**
- **Bioaccumulation**: Species: *Lepomis macrochirus* (Bluegill sunfish)
  - Bioconcentration factor (BCF): 7.62
- **Partition coefficient: n-octanol/water**: log Pow: 3.72

**Elbasvir:**
- **Bioaccumulation**: Species: *Lepomis macrochirus* (Bluegill sunfish)
  - Bioconcentration factor (BCF): 82
  - Method: OECD Test Guideline 305
- **Partition coefficient: n-octanol/water**: log Pow: 6.54

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

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

**2,6-Di-tert-butyl-p-cresol:**
- **Bioaccumulation**: Species: *Cyprinus carpio* (Carp)
  - Bioconcentration factor (BCF): 330 - 1,800
- **Partition coefficient: n-octanol/water**: log Pow: 5.1

**Mobility in soil**

**Components:**

**Grazoprevir:**
- **Distribution among environmental compartments**: log Koc: 4.01

**Elbasvir:**
- **Distribution among environmental compartments**: log Koc: 5.24

**Hazardous to the ozone layer**
- Not applicable

**Other adverse effects**
- No data available
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**
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Elbasvir)
- Class: 9
- Packing group: III
- Labels: 9

**IATA-DGR**
- UN/ID No.: UN 3077
- Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Elbasvir)
- Class: 9
- Packing group: III
- Labels: Miscellaneous
- Packing instruction (cargo aircraft): 956
- Packing instruction (passenger aircraft): 956
- Environmentally hazardous: yes

**IMDG-Code**
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Elbasvir)
- Class: 9
- Packing group: III
- Labels: 9
- EmS Code: F-A, S-F
- Marine pollutant: yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations
Refer to section 15 for specific national regulation.

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet.
15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium alkyl(C=8-18) sulfate</td>
<td>214</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-4-methylphenol</td>
<td>64</td>
</tr>
</tbody>
</table>

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
<td>&gt;=1 - &lt;10</td>
</tr>
<tr>
<td>Titanium(IV) oxide</td>
<td>191</td>
<td>&gt;=0.1 - &lt;1</td>
</tr>
<tr>
<td>Crystalline silica</td>
<td>165</td>
<td>&gt;=0.1 - &lt;1</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
</tr>
<tr>
<td>Crystalline silica</td>
<td>165</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable
Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law
Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

<table>
<thead>
<tr>
<th>Bulk transportation</th>
<th>Not classified as noxious liquid substance</th>
</tr>
</thead>
</table>

Marine Pollution and Sea Disaster Prevention etc Law

<table>
<thead>
<tr>
<th>Pack transportation</th>
<th>Classified as marine pollutant</th>
</tr>
</thead>
</table>

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

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

<table>
<thead>
<tr>
<th>AICS</th>
<th>not determined</th>
</tr>
</thead>
<tbody>
<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
Sources of key data used to compile the Safety Data: Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-
SAFETY DATA SHEET

Grazoprevir / Elbasvir Formulation

Version 11.0 Revision Date: 2021/08/27 SDS Number: 76213-00020 Date of last issue: 2021/04/09

Date format: yyyy/mm/dd

Full text of other abbreviations

ACGIH / TWA: USA. ACGIH Threshold Limit Values (TLV)
ACGIH / OEL-M: 8-hour, time-weighted average
JP OEL JSOH / OEL-M: Occupational Exposure Limit-Mean

AIIIC - 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 - 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; 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 Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transport of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.