SECTION 1. IDENTIFICATION

Product name: Boceprevir Formulation
Other means of identification: No data available

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road, Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Reproductive toxicity: Category 2

GHS label elements
Hazard pictograms:

Signal Word: Warning
Hazard Statements: H361f Suspected of damaging fertility.
Precautionary Statements:

Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.
Other hazards
Dust contact with the eyes can lead to mechanical irritation.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td>Boceprevir</td>
<td>394730-60-0</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
</tr>
</tbody>
</table>

Actual concentration or concentration range is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice
In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled
If inhaled, remove to fresh air.
Get medical attention.

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.

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

Most important symptoms and effects, both acute and delayed
Suspected of damaging fertility.
Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders
First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician
Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media
None known.

Specific hazards during fire fighting
Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a
### SAFETY DATA SHEET

**Boceprevir 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>4.3</td>
<td>03/23/2020</td>
<td>23664-00014</td>
<td>09/13/2019</td>
<td>10/21/2014</td>
</tr>
</tbody>
</table>

- **Potential dust explosion hazard.** Exposure to combustion products may be a hazard to health.

<table>
<thead>
<tr>
<th>Hazardous combustion products</th>
<th>Carbon oxides</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Nitrogen oxides (NOx)</td>
</tr>
<tr>
<td></td>
<td>Metal oxides</td>
</tr>
<tr>
<td></td>
<td>Sulfur oxides</td>
</tr>
</tbody>
</table>

| Specific extinguishing methods | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area. |

| Special protective equipment for fire-fighters | In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. |

### SECTION 6. ACCIDENTAL RELEASE MEASURES

<table>
<thead>
<tr>
<th>Personal precautions, protective equipment and emergency procedures</th>
<th>Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environmental precautions</td>
<td>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.</td>
</tr>
</tbody>
</table>

| Methods and materials for containment and cleaning up | Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

### SECTION 7. HANDLING AND STORAGE

<table>
<thead>
<tr>
<th>Technical measures</th>
<th>Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local/Total ventilation</td>
<td>Use only with adequate ventilation. Do not get on skin or clothing. Do not breathe dust. Do not swallow. Avoid contact with eyes.</td>
</tr>
<tr>
<td>Advice on safe handling</td>
<td></td>
</tr>
</tbody>
</table>

---

3 / 19
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.

**Conditions for safe storage**: Keep in properly labeled containers.
Store locked up.
Store in accordance with the particular national regulations.

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

---

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Ingredients with workplace control parameters**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boceprevir</td>
<td>394730-60-0</td>
<td>TWA</td>
<td>1 mg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (Total dust)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

**Engineering measures**: Ensure adequate ventilation, especially in confined areas.
Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Dust formation may be relevant in the processing of this product. In addition to substance-specific OELs, general limitations of concentrations of particulates in the air at workplaces have to be considered in workplace risk assessment. Relevant limits include: OSHA PEL for Particulates Not Otherwise Regulated of 15 mg/m³ - total dust, 5 mg/m³ - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m³ - respirable particles, 10 mg/m³ - inhalable particles.

**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**
- Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

**Eye protection**
- Wear the following personal protective equipment:
  - Safety goggles

**Skin and body protection**
- Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
- Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

**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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**
- Powder

**Color**
- White

**Odor**
- No data available
<table>
<thead>
<tr>
<th>Property</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor 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 range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</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 flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility in other solvents</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>
SECTION 10. STABILITY AND REACTIVITY

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

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

Incompatible materials:
- Oxidizing agents

Hazardous decomposition products:
- No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity:
Not classified based on available information.

Product:
Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

**Boceprevir:**
- Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
- LD50 (Monkey): > 1,000 mg/kg

**Starch:**
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
- Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

**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

**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:

Boceprevir:
Species: Rabbit
Result: No skin irritation

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

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

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

Components:

Boceprevir:
Species: Rabbit
Result: Mild eye irritation

Starch:
Species: Rabbit
Result: No eye irritation

Sodium n-dodecyl sulfate:
Species: Rabbit
Result: Irreversible effects on the eye
Method: OECD Test Guideline 405
Magnesium stearate:
Species: Rabbit
Result: No eye irritation
Remarks: Based on data from similar materials

Respiratory or skin sensitization
Skin sensitization
Not classified based on available information.
Respiratory sensitization
Not classified based on available information.

Components:

Boceprevir:
Test Type: Maximization Test
Species: Guinea pig
Result: negative

Starch:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative

Sodium n-dodecyl sulfate:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

Magnesium stearate:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Test Type: Chromosomal aberration
Genotoxicity in vivo:
Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

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

Cellulose:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
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

Magnesium stearate:
Genotoxicity in vitro:
Test Type: In vitro mammalian cell gene mutation test
Result: negative
Remarks: Based on data from similar materials
Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials
Carcinogenicity
Not classified based on available information.

Components:

Boceprevir:
Species: Mouse
Application Route: Oral
Exposure time: 72 Weeks
Dose: 650 mg/kg body weight
Result: negative

Species: Rat
Application Route: Oral
Exposure time: 104 Weeks
Dose: 125 mg/kg body weight
Result: negative

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

Sodium n-dodecyl sulfate:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Method: OECD Test Guideline 453
Result: negative
Remarks: Based on data from similar materials

Reproductive toxicity
Suspected of damaging fertility.

Components:

Boceprevir:
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat, male
Fertility: LOAEL: 75 mg/kg body weight
Symptoms: Effects on fertility.
Result: positive

Test Type: Fertility/early embryonic development
Species: Rat, female
Fertility: LOAEL: 150 mg/kg body weight
Symptoms: Effects on fertility.
Result: positive

Effects on fetal development: Test Type: Development
Species: Rabbit, male and female
Application Route: Oral
Developmental Toxicity: NOAEL: 300 mg/kg body weight
Result: negative

Reproductive toxicity - Assessment:
Some evidence of adverse effects on sexual function and fertility, based on animal experiments.

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

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

Sodium n-dodecyl sulfate:
- Effects on fertility: Test Type: Two-generation reproduction toxicity study
  Species: Rat
  Application Route: Ingestion
  Method: OECD Test Guideline 416
  Result: negative
  Remarks: Based on data from similar materials

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

Magnesium stearate:
- Effects on fertility: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
  Species: Rat
  Application Route: Ingestion
  Method: OECD Test Guideline 422
  Result: negative
  Remarks: Based on data from similar materials

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

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Not classified based on available information.
Repeated dose toxicity

**Components:**

**Boceprevir:**

- **Species**: Monkey
- **NOAEL**: > 200 mg/kg
- **Application Route**: Oral
- **Exposure time**: 365 d
- **Remarks**: No significant adverse effects were reported

- **Species**: Rat
  - **NOAEL**: 75 mg/kg
  - **LOAEL**: 100 mg/kg
  - **Application Route**: Oral
  - **Exposure time**: 90 d
  - **Target Organs**: Prostate, Testis

- **Species**: Rat
  - **NOAEL**: 15 mg/kg
  - **LOAEL**: 75 mg/kg
  - **Application Route**: Oral
  - **Exposure time**: 180 d
  - **Target Organs**: Liver, Testis

- **Species**: Mouse
  - **NOAEL**: 250 mg/kg
  - **LOAEL**: 500 mg/kg
  - **Application Route**: Oral
  - **Exposure time**: 90 d
  - **Target Organs**: Kidney

**Starch:**

- **Species**: Rat
  - **NOAEL**: >= 2,000 mg/kg
  - **Application Route**: Skin contact
  - **Exposure time**: 28 Days
  - **Method**: OECD Test Guideline 410

**Cellulose:**

- **Species**: Rat
  - **NOAEL**: >= 9,000 mg/kg
  - **Application Route**: Ingestion
  - **Exposure time**: 90 Days

**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:

Boceprevir:
Ingestion: Symptoms: Headache, Gastrointestinal disturbance, bitter taste

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Boceprevir:
Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.5 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
NOEC (Pseudokirchneriella subcapitata (green algae)): 9.5 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): > 9 mg/l
Exposure time: 28 d
Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 7.2 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
Toxicity to microorganisms: EC50: > 959 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
NOEC: 959 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Cellulose:
### Sodium n-dodecyl sulfate:

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to fish</strong></td>
<td>LC50 (Pimephales promelas (fathead minnow)): 29 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</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>
</tr>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>ErC50 (Desmodesmus subspicatus (green algae)): &gt; 120 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
</tbody>
</table>

NOEC (Pimephales promelas (fathead minnow)): >= 1.357 mg/l
Exposure time: 42 d

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

NOEC (Ceriodaphnia dubia (water flea)): 0.88 mg/l
Exposure time: 7 d

**Toxicity to microorganisms**

EC50: 135 mg/l
Exposure time: 3 h

### Magnesium stearate:

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to fish</strong></td>
<td>LC50 (Leuciscus idus (Golden orfe)): &gt; 100 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
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<tr>
<td>Method: DIN 38412</td>
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<tr>
<td>Remarks: Based on data from similar materials</td>
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**Toxicity to daphnia and other aquatic invertebrates**

EL50 (Daphnia magna (Water flea)): > 1 mg/l
Exposure time: 47 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials
No toxicity at the limit of solubility.

**Toxicity to algae/aquatic plants**

EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
No toxicity at the limit of solubility.

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
Toxicity to microorganisms

EC10 (Pseudomonas putida): > 100 mg/l
Exposure time: 16 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Persistence and degradability

Components:

Boceprevir:
Biodegradability
Result: Not readily biodegradable.
Biodegradation: 0.6 %
Exposure time: 28 d

Cellulose:
Biodegradability
Result: Readily biodegradable.

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:

Boceprevir:
Bioaccumulation
Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 2.6
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water
log Pow: 3.18

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

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

Mobility in soil

Components:

Boceprevir:
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Distribution among environmental compartments: log Koc: 1.9
Method: OECD Test Guideline 106

Other adverse effects:
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods:
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

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

Domestic regulation

TDG
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
CA BC OEL: Canada. British Columbia OEL
CA QC OEL: Québec. Regulation respecting occupational health and safe-
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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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CA / Z8