SAFETY DATA SHEET

Boceprevir Formulation

SECTION 1. IDENTIFICATION

Product name : Boceprevir Formulation

Manufacturer or supplier’s details
Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
          Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Combustible dust
Reproductive toxicity : Category 2

GHS label elements
Hazard pictograms : ![Warning Symbol]

Signal Word : Warning
Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air. 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 and face protection.

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

Storage:
P405 Store locked up.

Disposal:
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**Boceprevir Formulation**

**Version** 10.0  
**Revision Date:** 03/20/2023  
**SDS Number:** 23692-00021  
**Date of last issue:** 10/01/2022  
**Date of first issue:** 10/21/2014

P501 Dispose of contents and container to an approved waste disposal plant.

**Other hazards**
Dust contact with the eyes can lead to mechanical irritation.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boceprevir</td>
<td>394730-60-0</td>
<td>50</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>15</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>10</td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3</td>
<td>3</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>2</td>
</tr>
</tbody>
</table>

### 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.

**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. Rinse mouth thoroughly with water.

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

**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:** Avoid generating dust; fine dust dispersed in air in sufficient
fighting 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
Sulfur oxides

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

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

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

SECTION 7. HANDLING AND STORAGE

Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation Advice on safe handling: Use only with adequate ventilation. Do not get on skin or clothing. Do not breathe dust. Do not swallow.
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Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.

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>inert or nuisance dust</th>
<th>50 Million particles per cubic foot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value type (Form of exposure): TWA (total dust)</td>
<td></td>
</tr>
<tr>
<td>Basis: OSHA Z-3</td>
<td></td>
</tr>
</tbody>
</table>

| 15 mg/m³ |
| Value type (Form of exposure): TWA (total dust) |
| Basis: OSHA Z-3 |

| 5 mg/m³ |
| Value type (Form of exposure): TWA (respirable fraction) |
| Basis: OSHA Z-3 |

| 15 Million particles per cubic foot |
| Value type (Form of exposure): TWA (respirable fraction) |
| Basis: OSHA Z-3 |

| Dust, nuisance dust and particulates | 10 mg/m³ |
| Value type (Form of exposure): PEL (Total dust) |
| Basis: CAL PEL |

| 5 mg/m³ |
| Value type (Form of exposure): PEL (respirable dust fraction) |
| Basis: CAL PEL |

<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>2 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>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</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).

**Personal protective equipment**

**Respiratory protection**

General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**Hand protection**

Material: 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.
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Hygiene measures: Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc). 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
Odor Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: No data available
Evaporation rate: No data available
Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids): Not applicable
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapor pressure: Not applicable
Relative vapor density: Not applicable
Relative density: No data available
Density: No data available
Solubility(ies)
Water solubility: No data available
Solubility in other solvents: No data available
Partition coefficient: n-
SECTION 10. STABILITY AND REACTIVITY

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

Conditions to avoid: Heat, flames and sparks. Avoid dust formation.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity
Not classified based on available information.

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

Components:
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 (Rabbit): > 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:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximization Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</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>

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
  - Result: negative

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
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

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

IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
OSHA  No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP  No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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
Remark: Based on data from similar materials

Effects on fetal development:
Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remark: 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:

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>&gt; 200 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>365 d</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>75 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>100 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 d</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Testis, Prostate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>15 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>75 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>180 d</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Testis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>250 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>500 mg/kg</td>
</tr>
</tbody>
</table>
### Application Route
- **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
<table>
<thead>
<tr>
<th>Substance/Property</th>
<th>Test Type</th>
<th>Method</th>
<th>NOEC/EC50/LC50</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
</table>
| **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  
NOEC (Pimephales promelas (fathead minnow)): > 9 mg/l | | | | | |
| **Exposure time:** 28 d Method: OECD Test Guideline 210  
NOEC (Daphnia magna (Water flea)): 7.2 mg/l | | | | | |
| **Exposure time:** 21 d Method: OECD Test Guideline 211  
NOEC (Daphnia magna (Water flea)): 7.2 mg/l | | | | | |
| **Exposure time:** 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209  
EC50: > 959 mg/l | | | | | |
| **Exposure time:** 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209  
NOEC: 959 mg/l | | | | | |
| **Exposure time:** 48 h | | | | | |
| Remarks: Based on data from similar materials | | | | | |
| **Exposure time:** 48 h | | | | | |
| **Exposure time:** 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209  
NOEC: 959 mg/l | | | | | |
| **Exposure time:** 42 d | | | | | |
| **Exposure time:** 7 d | | | | | |
| **Exposure time:** 3 h | | | | | |
| **Exposure time:** 72 h  
NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l | | | | | |
| **Exposure time:** 72 h  
NOEC (Desmodesmus subspicatus (green algae)): > 120 mg/l | | | | | |
| **Exposure time:** 29 d  
Pimephales promelas (fathead minnow)): 29 mg/l | | | | | |
| **Exposure time:** 96 h | | | | | |
| **Exposure time:** 48 h  
Ceriodaphnia dubia (water flea)): 5.55 mg/l | | | | | |
| **Exposure time:** 72 h  
Desmodesmus subspicatus (green algae)): > 120 mg/l | | | | | |
| **Exposure time:** 72 h  
Pimephales promelas (fathead minnow)): >= 1.357 mg/l | | | | | |
| **Exposure time:** 42 d  
Pimephales promelas (fathead minnow)): 0.88 mg/l | | | | | |
| **Exposure time:** 7 d  
Pimephales promelas (fathead minnow)): 0.88 mg/l | | | | | |
| **Exposure time:** 3 h  
Pimephales promelas (fathead minnow)): 0.88 mg/l | | | | | |
### Magnesium stearate:

**Toxicity to fish**: LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l  
Exposure time: 48 h  
Method: DIN 38412  
Remarks: Based on data from similar materials

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

**Toxicity to algae/aquatic plants**: EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
Exposure time: 72 h  
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:

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.
Do not dispose of waste into sewer.

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

49 CFR
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards
- Combustible dust
- Reproductive toxicity

SARA 313
- This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
- Boceprevir 394730-60-0
- Starch 9005-25-8
- D-Glucose, 4-O-β-D-galactopyranosyl-, monohydrate 64044-51-5
- Cellulose 9004-34-6
- Croscarmellose sodium 74811-65-7
- Sodium n-dodecyl sulfate 151-21-3

California Permissible Exposure Limits for Chemical Contaminants
- Starch 9005-25-8
- Cellulose 9004-34-6
- Magnesium stearate 557-04-0

The ingredients of this product are reported in the following inventories:
- AICS: not determined
- DSL: not determined
- IECSC: not determined
**SECTION 16. OTHER INFORMATION**

**Further information**

**NFPA 704:**

- **Flammability:** 1
- **Health:** 1
- **Special hazard:** 0
- **Instability:** 0

**HMIS® IV:**

- **HEALTH:** *
- **FLAMMABILITY:** 3
- **PHYSICAL HAZARD:** 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The *"* represents a chronic hazard, while the */" represents the absence of a chronic hazard.

**Full text of other abbreviations**

- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **CAL PEL**: California permissible exposure limits for chemical contaminants (Title 8, Article 107)
- **NIOSH REL**: USA. NIOSH Recommended Exposure Limits
- **OSHA Z-1**: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- **OSHA Z-3**: USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
- **ACGIH / TWA**: 8-hour, time-weighted average
- **CAL PEL / PEL**: Permissible exposure limit
- **NIOSH REL / TWA**: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
- **OSHA Z-1 / TWA**: 8-hour time weighted average
- **OSHA Z-3 / TWA**: 8-hour time weighted average

**Abbreviations:**

- AIIC - Australian Inventory of Industrial Chemicals
- ASTM - American Society for the Testing of Materials
- bw - Body weight
- CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act
- CMR - Carcinogen, Mutagen or Reproductive Toxicant
- DIN - Standard of the German Institute for Standardisation
- DOT - Department of Transportation
- DSL - Domestic Substances List
- ECx - Concentration associated with x% response
- EHS - Extremely Hazardous Substance
- 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
SAFETY DATA SHEET
Boceprevir Formulation

Revision Date: 03/20/2023
SDS Number: 23692-00021
Date of last issue: 10/01/2022
Date of first issue: 10/21/2014

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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 03/20/2023

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

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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