1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Boceprevir Formulation

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

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

2. HAZARDS IDENTIFICATION

GHS Classification
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 which do not result in classification
Dust contact with the eyes can lead to mechanical irritation.
May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boceprevir</td>
<td>394730-60-0</td>
<td>&gt;= 50 &lt; 70</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 10 &lt; 20</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 10 &lt; 20</td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3</td>
<td>&gt;= 3 &lt; 10</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 &lt; 10</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: 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: 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.

5. FIREFIGHTING 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 potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides, Nitrogen oxides (NOx), Metal oxides, Sulphur oxides

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

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

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

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

7. HANDLING AND STORAGE

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

Local/Total ventilation: Use only with adequate ventilation.

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

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

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>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>PEL (long term)</td>
<td>10 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>PEL (long term)</td>
<td>10 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>PEL (long term)</td>
<td>10 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable 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).

Personal protective equipment

Respiratory protection:
- If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type:
- Particulates type
Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and 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:

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Colour : white

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : 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) : No data available

Upper explosion limit / Upper flammability limit : No data available
10. STABILITY AND REACTIVITY

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

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

Incompatible materials: Oxidizing agents

Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact
### 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>
</table>

#### Acute toxicity
Not classified based on available information.

**Product:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>Acute toxicity estimate: &gt; 2,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Method: Calculation method</td>
</tr>
</tbody>
</table>

**Components:**

**Boceprevir:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): &gt; 2,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LD50 (Monkey): &gt; 1,000 mg/kg</td>
</tr>
</tbody>
</table>

**Starch:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): &gt; 5,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rabbit): &gt; 2,000 mg/kg</td>
</tr>
</tbody>
</table>

**Cellulose:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): &gt; 5,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute inhalation toxicity</td>
<td>LC50 (Rat): &gt; 5.8 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 4 h</td>
</tr>
<tr>
<td></td>
<td>Test atmosphere: dust/mist</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rabbit): &gt; 2,000 mg/kg</td>
</tr>
</tbody>
</table>

**Sodium n-dodecyl sulfate:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): 1,200 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Method: OECD Test Guideline 401</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 402</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): &gt; 2,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Method: OECD Test Guideline 423</td>
</tr>
<tr>
<td></td>
<td>Assessment: The substance or mixture has no acute oral toxicity</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rabbit): &gt; 2,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Skin corrosion/irritation**

Not classified based on available information.
SAFETY DATA SHEET
Boceprevir Formulation

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 sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:
Boceprevir:
Test Type: Maximisation Test
Species: Guinea pig
**SAFETY DATA SHEET**

**Boceprevir Formulation**

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<tr>
<th>Version</th>
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</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Starch:</strong></td>
<td>Maximisation Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td><strong>Sodium n-dodecyl sulfate:</strong></td>
<td>Maximisation Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td><strong>Magnesium stearate:</strong></td>
<td>Maximisation Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>negative</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

- **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
SAFETY DATA SHEET

Boceprevir Formulation

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

STOT - single exposure
Not classified based on available information.

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

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

Sodium n-dodecyl sulfate:
- **Toxicity to fish**: LC50 (Pimephales promelas (fathead minnow)): 29 mg/l
  Exposure time: 96 h

- **Toxicity to daphnia and other aquatic invertebrates**: EC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l
  Exposure time: 48 h

- **Toxicity to algae/aquatic plants**: ErC50 (Desmodesmus subspicatus (green algae)): > 120 mg/l
  Exposure time: 72 h

  NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l
  Exposure time: 72 h
Toxicity to fish (Chronic toxicity):

- **Boceprevir**: NOEC (Pimephales promelas (fathead minnow)): $\geq 1.357$ mg/l
  - Exposure time: 42 d

- **Magnesium stearate**: 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 (Chronic toxicity):

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

Toxicity to microorganisms:

- **Boceprevir**: EC50: 135 mg/l
  - Exposure time: 3 h

Magnesium stearate:

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

Toxicity to algae/aquatic plants:

- **Boceprevir**: 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

- **Magnesium stearate**: 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
  - No toxicity at the limit of solubility

Toxicity to microorganisms:

- **Boceprevir**: 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

**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.
SAFETY DATA SHEET

Boceprevir Formulation

Version 4.1 Revision Date: 23.03.2020 SDS Number: 23691-00014 Date of last issue: 13.09.2019 Date of first issue: 21.10.2014

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

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

15. REGULATORY INFORMATION

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

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

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

Fire Safety (Petroleum and Flammable Materials) Regulations
: Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Further information

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
SG OEL : Singapore. Workplace Safety and Health Act - First Schedule Permissible Exposure Limits of Toxic Substances
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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