1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Boceprevir Formulation

Manufacturer or supplier’s details
Company : MSD
Address : 199 Wenhai North Road
          HEDA, Hangzhou - Zhejiang Province - CHINA 310018
Telephone : 908-740-4000
Emergency telephone number : 86-571-87268110
E-mail address : EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Emergency Overview

<table>
<thead>
<tr>
<th>Appearance</th>
<th>powder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>white</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
</tbody>
</table>

Causes mild skin irritation. Suspected of damaging fertility. Harmful to aquatic life.

GHS Classification

- Skin corrosion/irritation : Category 3
- Reproductive toxicity : Category 2
- Short-term (acute) aquatic hazard : Category 3

GHS label elements

Signal word : Warning


Precautionary statements : Prevention:
P201 Obtain special instructions before use.
Boceprevir Formulation

Physical and chemical hazards
Not classified based on available information.

Health hazards
Causes mild skin irritation. Suspected of damaging fertility.

Environmental hazards
Harmful to aquatic life.

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>Mixture</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Components</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:
- Causes mild skin irritation.
- 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 firefighting:
Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon oxides
- Nitrogen oxides (NOx)
- Metal oxides
- 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 (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...
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 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.
- Avoidance of contact: Oxidizing agents

Storage
- Conditions for safe storage: Keep in properly labelled containers. Store locked up.
- 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

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</th>
<th>Control parameter</th>
<th>Basis</th>
</tr>
</thead>
</table>


Boceprevir Formulation

| Substance            | Form of exposure | Permissible concentration | OEL  
|----------------------|------------------|---------------------------|------
| Boceprevir           | TWA              | 1 mg/m³ (OEB 1)           | Internal |
| Starch               | TWA              | 10 mg/m³                  | ACGIH |
| Cellulose            | PC-TWA           | 10 mg/m³                  | CN OEL |
| Magnesium stearate   | TWA (Inhalable particulate matter) | 10 mg/m³ | ACGIH |
| Magnesium stearate   | TWA (Respirable particulate matter) | 3 mg/m³ | ACGIH |

**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

**Eye/face 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).

**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.

**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.
Boceprevir Formulation

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>white</td>
</tr>
<tr>
<td>Odour</td>
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</tr>
<tr>
<td>Odour Threshold</td>
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</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
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</tr>
<tr>
<td>Initial boiling point and boiling</td>
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</tr>
<tr>
<td>range</td>
<td></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</td>
</tr>
<tr>
<td></td>
<td>processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
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</tr>
<tr>
<td>Upper explosion limit / Upper</td>
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</tr>
<tr>
<td>flammability limit</td>
<td></td>
</tr>
<tr>
<td>Lower explosion limit / Lower</td>
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</tr>
<tr>
<td>flammability limit</td>
<td></td>
</tr>
<tr>
<td>Vapour pressure</td>
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<tr>
<td>Relative vapour density</td>
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<tr>
<td>Density</td>
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<tr>
<td>Solubility(ies)</td>
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<tr>
<td>Water solubility</td>
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<tr>
<td>Solubility in other solvents</td>
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<tr>
<td>Partition coefficient: n-octanol/water</td>
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<tr>
<td>Auto-ignition temperature</td>
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<tr>
<td>Decomposition temperature</td>
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</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>
</tbody>
</table>
Boceprevir Formulation

Oxidizing properties: The substance or mixture is not classified as oxidizing.
Molecular weight: No data available
Particle size: No data available

10. STABILITY AND REACTIVITY

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

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

11. TOXICOLOGICAL INFORMATION

Exposure routes:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity:
Not classified based on available information.

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

Components:
Boceprevir:
Acute oral toxicity:

Starch:
Acute oral toxicity:
Acute dermal toxicity:

Cellulose:
Acute oral toxicity:
Acute inhalation toxicity:
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**
Causes mild skin irritation.

**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
Boceprevir Formulation

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
Result: negative

Starch:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

Sodium n-dodecyl sulfate:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

Magnesium stearate:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials
Germ cell mutagenicity
Not classified based on available information.

Components:

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
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
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Boceprevir Formulation

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
<table>
<thead>
<tr>
<th>Substance</th>
<th>Type</th>
<th>Route</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>LOAEL</th>
<th>Result</th>
<th>Symptoms</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boceprevir</td>
<td>Fertility/early embryonic development</td>
<td>Ingestion</td>
<td>Test Type: Fertility/early embryonic development</td>
<td>Species: Rat, female</td>
<td>LOAEL: 150 mg/kg body weight</td>
<td>Result: positive</td>
<td>Effects on fertility</td>
<td>Based on animal experiments.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Development</td>
<td>Oral</td>
<td>Test Type: Development</td>
<td>Species: Rabbit, male and female</td>
<td>Developmental Toxicity: NOAEL: 300 mg/kg body weight</td>
<td>Result: negative</td>
<td>Some evidence of adverse effects on sexual function and fertility.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td>One-generation reproduction toxicity study</td>
<td>Ingestion</td>
<td>Test Type: One-generation reproduction toxicity study</td>
<td>Species: Rat</td>
<td>Result: negative</td>
<td>Effects on fertility</td>
<td>Based on data from similar materials.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>Two-generation reproduction toxicity study</td>
<td>Ingestion</td>
<td>Test Type: Two-generation reproduction toxicity study</td>
<td>Species: Rat</td>
<td>Method: OECD Test Guideline 416</td>
<td>Result: negative</td>
<td>Effects on foetal development</td>
<td>Based on data from similar materials.</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Embryo-foetal development</td>
<td>Ingestion</td>
<td>Test Type: Embryo-foetal development</td>
<td>Species: Rat</td>
<td>Result: negative</td>
<td>Effects on foetal development</td>
<td>Based on data from similar materials.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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>4.2</td>
<td>2020/10/16</td>
<td>23670-00015</td>
<td>2020/03/23</td>
<td>2014/10/21</td>
</tr>
</tbody>
</table>

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
## Boceprevir Formulation

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingestion</td>
<td>90 Days</td>
</tr>
</tbody>
</table>

### Sodium n-dodecyl sulfate:

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL (mg/kg)</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>488</td>
<td>Ingestion</td>
<td>90 Days</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Magnesium stearate:

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL (mg/kg)</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt; 100</td>
<td>Ingestion</td>
<td>90 Days</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### 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
Boceprevir Formulation

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): 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:
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
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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.

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.

National Regulations

GB 6944/12268
Not regulated as a dangerous good

Special precautions for user
Not applicable
SAFETY DATA SHEET
generated by MSD

Boceprevir Formulation

Version: 4.2
Revision Date: 2020/10/16
SDS Number: 23670-00015
Date of last issue: 2020/03/23
Date of first issue: 2014/10/21

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

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

Date format: yyyy/mm/dd

Full text of other abbreviations
ACGIH / TWA : USA. ACGIH Threshold Limit Values (TLV)
ACGIH / OEL : Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.
CN OEL / PC-TWA : 8-hour, time-weighted average
CN OEL / TWA : Permissible concentration - time weighted average

AIC - 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, Bioaccumu-
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Boceprevir Formulation

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Disclaimer
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.

CN / EN