Boceprevir Formulation

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
Appearance: powder
Colour: white
Odour: No data available

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
Hazard pictograms: 

Signal word: Warning

Hazard statements: H316 Causes mild skin irritation.
                  H361f Suspected of damaging fertility.
                  H402 Harmful to aquatic life.

Precautionary statements: Prevention:
                          P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

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

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>&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.
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

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<thead>
<tr>
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<th>Date of last issue: 2019/09/13</th>
<th>Date of first issue: 2014/10/21</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1</td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

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 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
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>

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## Boceprevir Formulation

<table>
<thead>
<tr>
<th>Material</th>
<th>(Form of exposure)</th>
<th>(TWA)</th>
<th>Permissible concentration</th>
<th>Source</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>ACGIH</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>PC-TWA</td>
<td>10 mg/m³</td>
<td>GBZ 2.1-2007</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</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
- **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.
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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
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapour pressure**: No data available
- **Relative vapour 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-octanol/water**: No data available
- **Auto-ignition temperature**: No data available
- **Decomposition temperature**: No data available
- **Viscosity**
  - Viscosity, kinematic: No data available
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Explosive properties : Not explosive

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

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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
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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:
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 foetal 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 foetal development:
Test Type: Embryo-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:

- **Test Type:** Embryo-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:** 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
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<table>
<thead>
<tr>
<th>Component</th>
<th>Application Route</th>
<th>NOAEL</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>Ingestion</td>
<td>488 mg/kg</td>
<td>90 Days</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Ingestion</td>
<td>&gt; 100 mg/kg</td>
<td>90 Days</td>
</tr>
</tbody>
</table>

**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
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ic toxicity) 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) : 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
  - 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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<thead>
<tr>
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<th>Partition coefficient: n-octanol/water</th>
<th>log Pow</th>
</tr>
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<tr>
<td>Sodium n-dodecyl sulfate:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td></td>
<td>log Pow: 0.83</td>
</tr>
<tr>
<td>Magnesium stearate:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td></td>
<td>log Pow: &gt; 4</td>
</tr>
</tbody>
</table>

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
according to GB/T 16483 and GB/T 17519

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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:

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Status</th>
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<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
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<tr>
<td>DSL</td>
<td>not determined</td>
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<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
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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:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full text</th>
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</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>GBZ 2.1-2007 / PC-TWA</td>
<td>Permissible concentration - time weighted average</td>
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</table>

AICS - Australian Inventory of Chemical Substances; 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 Organization 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

<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>
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<td>4.1</td>
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<td>23670-00014</td>
<td>2019/09/13</td>
<td>2014/10/21</td>
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Disclaimer

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