1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Boceprevir Formulation

Supplier’s company name, address and phone number

Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : 1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Reproductive toxicity : Category 2
Short-term (acute) aquatic hazard : Category 3

GHS label elements
Hazard pictograms :
Signal word : Warning
Hazard statements :
H361f Suspected of damaging fertility.
H402 Harmful to aquatic life.
Precautionary statements :
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.
Storage:
SAFETY DATA SHEET
Boceprevir Formulation

Version 5.0  Revision Date: 2020/03/23  SDS Number: 23681-00014  Date of last issue: 2019/09/13  Date of first issue: 2014/10/21

P405 Store locked up.

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

Other hazards which do not result in classification
Important symptoms and outlines of the emergency assumed:
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>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boceprevir</td>
<td>394730-60-0</td>
<td>&gt;= 50 - &lt; 60</td>
<td></td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 10 - &lt; 20</td>
<td>8-98</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3</td>
<td>3</td>
<td>2-1679</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 10</td>
<td>2-611</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

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO2)</td>
</tr>
<tr>
<td></td>
<td>Dry chemical</td>
</tr>
<tr>
<td>Unsuitable extinguishing media</td>
<td>None known.</td>
</tr>
<tr>
<td>Specific hazards during firefighting</td>
<td>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.</td>
</tr>
<tr>
<td>Hazardous combustion products</td>
<td>Carbon oxides</td>
</tr>
<tr>
<td></td>
<td>Nitrogen oxides (NOx)</td>
</tr>
<tr>
<td></td>
<td>Metal oxides</td>
</tr>
<tr>
<td></td>
<td>Sulphur oxides</td>
</tr>
<tr>
<td>Specific extinguishing methods</td>
<td>Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.</td>
</tr>
<tr>
<td></td>
<td>Use water spray to cool unopened containers.</td>
</tr>
<tr>
<td></td>
<td>Remove undamaged containers from fire area if it is safe to do so.</td>
</tr>
<tr>
<td></td>
<td>Evacuate area.</td>
</tr>
<tr>
<td>Special protective equipment for firefighters</td>
<td>In the event of fire, wear self-contained breathing apparatus.</td>
</tr>
<tr>
<td></td>
<td>Use personal protective equipment.</td>
</tr>
</tbody>
</table>

### 6. ACCIDENTAL RELEASE MEASURES

<table>
<thead>
<tr>
<th>Personal precautions, protective equipment and emergency procedures</th>
<th>Use personal protective equipment.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Follow safe handling advice and personal protective equipment recommendations.</td>
</tr>
<tr>
<td>Environmental precautions</td>
<td>Discharge into the environment must be avoided.</td>
</tr>
<tr>
<td></td>
<td>Prevent further leakage or spillage if safe to do so.</td>
</tr>
<tr>
<td></td>
<td>Retain and dispose of contaminated wash water.</td>
</tr>
<tr>
<td></td>
<td>Local authorities should be advised if significant spillages cannot be contained.</td>
</tr>
<tr>
<td>Methods and materials for containment and cleaning up</td>
<td>Sweep up or vacuum up spillage and collect in suitable container for disposal.</td>
</tr>
<tr>
<td></td>
<td>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.</td>
</tr>
</tbody>
</table>
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

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.

Storage

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

Packaging material:
- Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boceprevir</td>
<td>394730-60-0</td>
<td>TWA</td>
<td>1 mg/m3 (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</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: 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:
  - 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).

9. PHYSICAL AND CHEMICAL PROPERTIES

- Physical state: powder
- Colour: white
- Odour: No data available
- Odour Threshold: No data available
- Melting point/freezing point: No data available
- Boiling point, initial boiling point and boiling range: No data available
- Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.
### 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.</td>
</tr>
</tbody>
</table>

---

**Flammability (liquids):** No data available

**Lower explosion limit and upper explosion limit / flammability limit**

**Upper explosion limit / Upper flammability limit:** No data available

**Lower explosion limit / Lower flammability limit:** No data available

**Flash point:** No data available

**Decomposition temperature:** No data available

**pH:** No data available

**Evaporation rate:** No data available

**Auto-ignition temperature:** No data available

**Viscosity**

**Viscosity, kinematic:** 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

**Vapour pressure:** No data available

**Density and / or relative density**

**Density:** No data available

**Relative vapour density:** No data available

**Explosive properties:** Not explosive

**Oxidizing properties:** The substance or mixture is not classified as oxidizing.

**Molecular weight:** No data available

**Particle characteristics**

**Particle size:** No data available
## 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

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

**Product:**
- **Acute oral toxicity**: Acute toxicity estimate: > 2,000 mg/kg
  - Method: Calculation method

#### Components:

<table>
<thead>
<tr>
<th>Component</th>
<th>Acute oral toxicity</th>
<th>Acute dermal toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boceprevir</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Monkey): &gt; 1,000 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Starch</td>
<td>LD50 (Rat): &gt; 5,000 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td>LD50 (Rat): &gt; 5,000 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>LD50 (Rat): 1,200 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 401</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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 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
  - 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:  
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
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
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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:

| LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l |
| Exposure time: 48 h |
| Remarks: Based on data from similar materials |

Sodium n-dodecyl sulfate:

<p>| LC50 (Pimephales promelas (fathead minnow)): 29 mg/l |</p>
<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity</th>
<th>Exposure Time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate:</td>
<td>Toxicity to fish</td>
<td>LC50 (Leuciscus idus (Golden orfe)): &gt; 100 mg/l</td>
<td>Conference 38412</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EL50 (Daphnia magna (Water flea)): &gt; 1 mg/l</td>
<td>Directive 67/548/EEC, Annex V, C.2.</td>
<td>No toxicity at the limit of solubility</td>
</tr>
<tr>
<td></td>
<td>Toxicity to algae/aquatic plants</td>
<td>EL50 (Pseudokirchneriella subcapitata (green algae)): &gt; 1 mg/l</td>
<td>OECD Test Guideline 201</td>
<td>No toxicity at the limit of solubility</td>
</tr>
<tr>
<td></td>
<td>Toxicity to microorganisms</td>
<td>EC10 (Pseudomonas putida): &gt; 100 mg/l</td>
<td>OECD Test Guideline 201</td>
<td>No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>
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

Hazardous to the ozone layer
Not applicable
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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
Refer to section 15 for specific national regulation.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium alkyl(C=8-18) sulfate</td>
<td>214</td>
</tr>
</tbody>
</table>

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable
Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

**Substances Subject to be Notified Names**
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
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<th>Concentration (%)</th>
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<tr>
<td>Magnesium stearate</td>
<td>327</td>
<td>&gt;=1 - &lt;10</td>
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**Substances Subject to be Indicated Names**
Article 57 (Enforcement Order Article 18)

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<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
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</tbody>
</table>

**Ordinance on Prevention of Hazards Due to Specified Chemical Substances**
Not applicable

**Ordinance on Prevention of Lead Poisoning**
Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**
Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning**
Not applicable

**Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**
Not applicable

**Poisonous and Deleterious Substances Control Law**
Not applicable

**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

**Class I Designated Chemical Substances**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
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</thead>
<tbody>
<tr>
<td>Sodium Lauryl Sulfate</td>
<td>275</td>
<td>3.0</td>
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</table>

**High Pressure Gas Safety Act**
Not applicable

**Explosive Control Law**
Not applicable

**Vessel Safety Law**
Not regulated as a dangerous good

**Aviation Law**
Not regulated as a dangerous good

**Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation : Not classified as noxious liquid substance
Pack transportation : Not classified as marine pollutant
19. Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

10. Waste Disposal and Public Cleansing Law
Industrial waste

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:

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

Date format : yyyy/mm/dd

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA : 8-hour, time-weighted average

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 Organisation for Standardisation; 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 Develop-
<table>
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<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>5.0</td>
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<td>23681-00014</td>
<td>2019/09/13</td>
<td>2014/10/21</td>
</tr>
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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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