1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Boceprevir Formulation

Manufacturer or supplier’s details
Company: Merck & Co., Inc
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033

Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

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</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boceprevir</td>
<td>394730-60-0</td>
<td>&gt;= 30 - &lt; 60</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 10 - &lt; 30</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>&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 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 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 advice on safe handling:
- Use only with adequate ventilation.
- 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/PERS ONAL 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>NAB</td>
<td>10 mg/m³</td>
<td>ID OEL</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</td>
<td>10 mg/m³</td>
<td>ID OEL</td>
</tr>
</tbody>
</table>

Further information:
- Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals
- Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals

### 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 rec-
Filter type: Particulates type
Hand protection: Recommended guidelines, use respiratory 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.

Eye protection: Wear the following personal protective equipment: Safety goggles

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).

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
SAFETY DATA SHEET
Boceprevir Formulation

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Date of first issue: 2014/10/21

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
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. 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:**

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

**Starch:**
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

**Cellulose:**
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 5.8 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

**Sodium n-dodecyl sulfate:**
Acute oral toxicity: LD50 (Rat): 1,200 mg/kg
  Method: OECD Test Guideline 401
Acute dermal toxicity: LD50 (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**
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
Remarks : Based on data from similar materials

**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
**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>
<tbody>
<tr>
<td>4.3</td>
<td>2021/04/09</td>
<td>23675-00016</td>
<td>2020/10/16</td>
<td>2014/10/21</td>
</tr>
</tbody>
</table>

**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
SAFETY DATA SHEET

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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
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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

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

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
- **NOEC (Ceriodaphnia dubia (water flea)):** $0.88 \text{ mg/l}$  
  Exposure time: $7 \text{ d}$

### Toxicity to microorganisms
- **EC50:** $135 \text{ mg/l}$  
  Exposure time: $3 \text{ h}$

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

**Toxicity to daphnia and other aquatic invertebrates**:  
- **EL50 (Daphnia magna (Water flea)):** $> 1 \text{ mg/l}$  
  Exposure time: $47 \text{ h}$  
  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)):** $> 1 \text{ mg/l}$  
  Exposure time: $72 \text{ h}$  
  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)):** $> 1 \text{ mg/l}$  
  Exposure time: $72 \text{ h}$  
  Test substance: Water Accommodated Fraction  
  Method: OECD Test Guideline 201  
  Remarks: Based on data from similar materials

**Toxicity to microorganisms**:  
- **EC10 (Pseudomonas putida):** $> 100 \text{ mg/l}$  
  Exposure time: $16 \text{ h}$  
  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: $28 \text{ d}$

**Cellulose:**
SAFETY DATA SHEET

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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.
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

- **Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.**

- **Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health**
  Hazardous substances that must be registered : Not applicable

- **Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances**
  Hazardous substances approved for use : Not applicable
  Prohibited substances : Not applicable
  Restricted substances : Not applicable

- **Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials**
  Type of Hazardous Materials Restricted to Import, Distribution and Supervision : 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: yyyy/mm/dd

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ID OEL: Indonesia. Occupational Exposure Limits
ACGIH / TWA: 8-hour, time-weighted average
ID OEL / NAB: Long term exposure limit

AIIC - 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 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 Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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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