

## Boceprevir Formulation

Version            Revision Date:            SDS Number:            Date of last issue: 03/20/2023  
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### SECTION 1. IDENTIFICATION

Product name                            : Boceprevir Formulation  
Other means of identification        : No data available

#### Manufacturer or supplier's details

Company name of supplier        : Merck & Co., Inc  
Address                                 : 126 E. Lincoln Avenue  
   : Rahway, New Jersey U.S.A. 07065  
Telephone                             : 908-740-4000  
Emergency telephone               : 1-908-423-6000  
E-mail address                        : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use                    : Pharmaceutical  
Restrictions on use                  : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

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 and face protection.  
**Response:**  
P308 + P313 IF exposed or concerned: Get medical attention.  
**Storage:**  
P405 Store locked up.  
**Disposal:**  
P501 Dispose of contents and container to an approved waste disposal plant.

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### Other hazards

Dust contact with the eyes can lead to mechanical irritation.  
May form explosive dust-air mixture during processing, handling or other means.

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### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture            :    Mixture

#### Components

| Chemical name            | Common Name/Synonym                         | CAS-No.     | Concentration (% w/w) |
|--------------------------|---|-------------|-----------------------|
| Boceprevir               | No data available                           | 394730-60-0 | 50                    |
| Starch                   | Sago starch                                 | 9005-25-8   | 15                    |
| Cellulose                | No data available                           | 9004-34-6   | 10                    |
| Sodium n-dodecyl sulfate | Sulfuric acid monododecyl ester sodium salt | 151-21-3    | 3                     |
| Magnesium stearate       | Octadecanoic acid, magnesium salt (2:1)     | 557-04-0    | 2                     |

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### SECTION 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.

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### SECTION 5. FIRE-FIGHTING MEASURES

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- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.  
Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Metal oxides  
Sulfur 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 fire-fighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.
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### SECTION 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.
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### SECTION 7. HANDLING AND STORAGE

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- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe dust.  
Do not swallow.  
Avoid contact with eyes.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled 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

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

| Components         | CAS-No.     | Value type (Form of exposure)  | Control parameters / Permissible concentration | Basis     |
|--------------------|-------------|--------------------------------|--|-----------|
| Boceprevir         | 394730-60-0 | TWA                            | 2 mg/m <sup>3</sup> (OEB 1)                    | Internal  |
| Starch             | 9005-25-8   | TWA                            | 10 mg/m <sup>3</sup>                           | CA AB OEL |
|                    |             | TWA (Total dust)               | 10 mg/m <sup>3</sup>                           | CA BC OEL |
|                    |             | TWA (respirable dust fraction) | 3 mg/m <sup>3</sup>                            | CA BC OEL |
|                    |             | TWAEV (total dust)             | 10 mg/m <sup>3</sup>                           | CA QC OEL |
|                    |             | TWA                            | 10 mg/m <sup>3</sup>                           | ACGIH     |
| Cellulose          | 9004-34-6   | TWA                            | 10 mg/m <sup>3</sup>                           | CA AB OEL |
|                    |             | TWA (Total dust)               | 10 mg/m <sup>3</sup>                           | CA BC OEL |
|                    |             | TWA (respirable dust fraction) | 3 mg/m <sup>3</sup>                            | CA BC OEL |
|                    |             | TWAEV (total dust)             | 10 mg/m <sup>3</sup>                           | CA QC OEL |
|                    |             | TWA                            | 10 mg/m <sup>3</sup>                           | ACGIH     |
| Magnesium stearate | 557-04-0    | TWA                            | 10 mg/m <sup>3</sup>                           | CA AB OEL |
|                    |             | TWAEV                          | 10 mg/m <sup>3</sup>                           | CA QC OEL |

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|--|--|-------------------------------------|----------------------|-----------|
|  |  | TWA (Inhalable)                     | 10 mg/m <sup>3</sup> | CA BC OEL |
|  |  | TWA (Respirable)                    | 3 mg/m <sup>3</sup>  | CA BC OEL |
|  |  | TWA (Inhalable particulate matter)  | 10 mg/m <sup>3</sup> | ACGIH     |
|  |  | TWA (Respirable particulate matter) | 3 mg/m <sup>3</sup>  | 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

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration 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).

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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

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|  |   |   |
|--|---|---|
| Color  | : | white   |
| Odor   | : | No data available   |
| Odor 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)                           | : | Not applicable  |
| Upper explosion limit / Upper flammability limit | : | No data available   |
| Lower explosion limit / Lower flammability limit | : | No data available   |
| Vapor pressure                                   | : | Not applicable  |
| Relative vapor density                           | : | Not applicable  |
| Relative 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           | : | Not applicable  |
| Autoignition 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.                        |

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Molecular weight : No data available

Particle size : No data available

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### SECTION 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.

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### SECTION 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

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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

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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 sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

### Components:

#### Boceprevir:

Test Type : Maximization Test  
Species : Guinea pig  
Result : negative

#### Starch:

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative

#### Sodium n-dodecyl sulfate:

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative  
Remarks : Based on data from similar materials

#### Magnesium stearate:

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative  
Remarks : Based on data from similar materials

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### **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

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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.

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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 fetal 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 fetal 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 fetal development : Test Type: Embryo-fetal 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 fetal development : Test Type: Embryo-fetal development

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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 : Testis, Prostate

Species : Rat  
NOAEL : 15 mg/kg  
LOAEL : 75 mg/kg  
Application Route : Oral  
Exposure time : 180 d  
Target Organs : 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 :  $\geq 2,000$  mg/kg  
Application Route : Skin contact  
Exposure time : 28 Days  
Method : OECD Test Guideline 410

##### **Cellulose:**

Species : Rat

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NOAEL :  $\geq 9,000$  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

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## SECTION 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) : 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      :    EC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l  
aquatic invertebrates      Exposure time: 48 h

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

NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l  
Exposure time: 72 h

Toxicity to fish (Chronic tox-      :    NOEC (Pimephales promelas (fathead minnow)): >= 1.357  
icity)      mg/l  
Exposure time: 42 d

Toxicity to daphnia and other      :    NOEC (Ceriodaphnia dubia (water flea)): 0.88 mg/l  
aquatic invertebrates (Chron-      Exposure time: 7 d  
ic toxicity)

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      :    EL50 (Daphnia magna (Water flea)): > 1 mg/l  
aquatic invertebrates      Exposure time: 47 h  
Test substance: Water Accommodated Fraction  
Method: Directive 67/548/EEC, Annex V, C.2.  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubility.

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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

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### SECTION 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
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.

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### SECTION 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.

**Domestic regulation**

**TDG**

Not regulated as a dangerous good

**Special precautions for user**

Not applicable

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### SECTION 15. REGULATORY INFORMATION

**The ingredients of this product are reported in the following inventories:**

|       |   |                |
|-------|---|----------------|
| AICS  | : | not determined |
| DSL   | : | not determined |
| IECSC | : | not determined |

### SECTION 16. OTHER INFORMATION

#### Full text of other abbreviations

|                   |   |   |
|-------------------|---|---|
| ACGIH             | : | USA. ACGIH Threshold Limit Values (TLV)   |
| CA AB OEL         | : | Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)   |
| CA BC OEL         | : | Canada. British Columbia OEL  |
| CA QC OEL         | : | Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants |
| ACGIH / TWA       | : | 8-hour, time-weighted average   |
| CA AB OEL / TWA   | : | 8-hour Occupational exposure limit  |
| CA BC OEL / TWA   | : | 8-hour time weighted average  |
| CA QC OEL / TWAEV | : | Time-weighted average exposure value  |

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 Standardization; KECl - 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 - Transporta-

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tion of Dangerous Goods; TECL - Thailand Existing Chemicals Inventory; 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

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 09/26/2023  
Date format : mm/dd/yyyy

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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