SAFETY DATA SHEET

Boceprevir Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Boceprevir Formulation

Manufacturer or supplier's details
Company name of supplier : MSD
Address : 2000 Galloping Hill Road
          Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Skin irritation : Category 3
Reproductive toxicity : Category 2

GHS label elements
Hazard pictograms :

Signal Word : Warning

Hazard Statements : H316 Causes mild skin irritation.
                   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.
P332 + P313 IF skin irritation occurs: Get medical advice/ attention.

Storage:
P405 Store locked up.

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

Boceprevir Formulation

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bocceprevir</td>
<td>CAS-No. 394730-60-0 Concentration (% w/w) &gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>Starch</td>
<td>CAS-No. 9005-25-8 Concentration (% w/w) &gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Cellulose</td>
<td>CAS-No. 9004-34-6 Concentration (% w/w) &gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>CAS-No. 151-21-3 Concentration (% w/w) &gt;= 3 - &lt; 5</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>CAS-No. 557-04-0 Concentration (% w/w) &gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

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: Causes mild skin irritation. Suspected of damaging fertility. Dust contact with the eyes can lead to mechanical irritation.
Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
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 (NOx)
- 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.

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.

SECTION 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:
- 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.

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.

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

<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>VLE-PPT</td>
<td>10 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>VLE-PPT</td>
<td>10 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>VLE-PPT</td>
<td>10 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></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

Material: 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.

Remarks: 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

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).

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder
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): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
SAFETY DATA SHEET
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Vapor pressure : No data available
Relative vapor 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
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.
Molecular weight : No data available
Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY
Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reac-
tions : 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.

SECTION 11. TOXICOLOGICAL INFORMATION
Information on likely routes of exposure
   Inhalation
   Skin contact
   Ingestion
   Eye contact
Acute toxicity
   Not classified based on available information.
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Product:
Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
   Method: Calculation method

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

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

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

Sodium n-dodecyl sulfate:
Acute oral toxicity: LD50 (Rat): 1,200 mg/kg
   Method: OECD Test Guideline 401
Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
   Method: OECD Test Guideline 402
   Remarks: Based on data from similar materials

Magnesium stearate:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
   Method: OECD Test Guideline 423
   Assessment: The substance or mixture has no acute oral toxicity
   Remarks: Based on data from similar materials
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
   Remarks: Based on data from similar materials

Skin corrosion/irritation
Causes mild skin irritation.

Components:
Boceprevir:
Species: Rabbit
Result: No skin irritation
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Boceprevir Formulation

Version 5.4
Revision Date: 16.10.2020
SDS Number: 23683-00015
Date of last issue: 23.03.2020
Date of first issue: 21.10.2014

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 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

**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 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
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
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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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:
Boceprevir:
Toxicity to algae/aquatic : EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.5
plants

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration</th>
<th>Exposure Time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC (Pseudokirchneriella subcapitata (green algae))</td>
<td>9.5 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>NOEC (Pimephales promelas (fathead minnow))</td>
<td>&gt; 9 mg/l</td>
<td>28 d</td>
<td>OECD Test Guideline 210</td>
</tr>
<tr>
<td>NOEC (Daphnia magna (Water flea))</td>
<td>7.2 mg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
</tr>
<tr>
<td>EC50: &gt; 959 mg/l</td>
<td>3 h</td>
<td>Respiration inhibition</td>
<td>OECD Test Guideline 209</td>
</tr>
<tr>
<td>LC50 (Oryzias latipes (Japanese medaka))</td>
<td>&gt; 100 mg/l</td>
<td>48 h</td>
<td></td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOEC (Pimephales promelas (fathead minnow))</td>
<td>&gt;= 1.357 mg/l</td>
<td>42 d</td>
<td></td>
</tr>
<tr>
<td>EC50 (Ceriodaphnia dubia (water flea))</td>
<td>0.88 mg/l</td>
<td>7 d</td>
<td></td>
</tr>
<tr>
<td>EC50: 135 mg/l</td>
<td>3 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cellulose:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOEC (Desmodesmus subspicatus (green algae))</td>
<td>30 mg/l</td>
<td>72 h</td>
<td></td>
</tr>
<tr>
<td>NOEC (Desmodesmus subspicatus (green algae))</td>
<td>&gt; 120 mg/l</td>
<td>72 h</td>
<td></td>
</tr>
</tbody>
</table>

**Toxicity to fish (Chronic toxicity):**

- NOEC (Pimephales promelas (fathead minnow)): > 9 mg/l
- NOEC (Ceriodaphnia dubia (water flea)): 0.88 mg/l
- EC50: > 959 mg/l

**Toxicity to microorganisms:**

- EC50: > 959 mg/l
- NOEC: 959 mg/l

**Remarks:** Based on data from similar materials.
Magnesium stearate:

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

**Toxicity to daphnia and other aquatic invertebrates**: EL50 (Daphnia magna (Water flea)): > 1 mg/l
- Exposure time: 47 h
- Test substance: Water Accommodated Fraction
- Remarks: Based on data from similar materials

**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

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

SECTION 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.

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

NOM-002-SCT
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills.

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)
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA : 8-hour, time-weighted average
NOM-010-STPS-2014 / VLE-PPT : Time weighted average limit 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; 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

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

Revision Date : 16.10.2020

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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