# SAFETY DATA SHEET

# Boceprevir Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 26.09.2023 |
|---|---|---|---|
| 8.0 | 28.09.2024 | 23663-00023 | Date of first issue: 21.10.2014 |

## SECTION 1. IDENTIFICATION

Product identifier : Boceprevir Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : Avenue Comendador Antônio Loureiro Ramos,
nº 1500 – Distrito Industrial
Montes Claros – MG, Brazil 39404-620

Telephone : +55 (38) 3229 7000

Emergency telephone : +55 (38) 3201 5670

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

## SECTION 2. HAZARDS IDENTIFICATION

**GHS Classification in accordance with ABNT NBR 14725 Standard**

Skin irritation : Category 3

Reproductive toxicity : Category 2

Short-term (acute) aquatic hazard : Category 3

**GHS label elements in accordance with ABNT NBR 14725 Standard**

Hazard pictograms :

Signal Word : Warning

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

Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ 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.

**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.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name | CAS-No. | Classification | Concentration (% w/w) |
|---|---|---|---|
| Boceprevir | 394730-60-0 | Repr., 2 | >= 50 -< 70 |
| Starch | 9005-25-8 | | >= 10 -< 20 |
| Cellulose | 9004-34-6 | | >= 10 -< 20 |
| Sodium n-dodecyl sulfate | 151-21-3 | Acute Tox. (Oral), 4<br>Skin Irrit., 2<br>Eye Dam., 1<br>Aquatic Acute, 2<br>Aquatic Chronic, 3 | >= 3 -< 5 |
| Magnesium stearate | 557-04-0 | | >= 1 -< 5 |

## 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<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<br>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.<br>Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon oxides<br>Nitrogen oxides (NOx)<br>Metal oxides<br>Sulfur oxides |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |

## SECTION 6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>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.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).<br>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.<br>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.<br>Do not breathe dust.<br>Do not swallow.<br>Avoid contact with eyes.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>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.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use. |
| Conditions for safe storage | : | Keep in properly labeled containers.<br>Store locked up.<br>Store in accordance with the particular national regulations. |
| Materials to avoid | : | Do not store with the following product types:<br>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/m3 (OEB 1) | Internal |
| Starch | 9005-25-8 | TWA | 10 mg/m³ | ACGIH |
| Cellulose | 9004-34-6 | TWA | 10 mg/m³ | ACGIH |
| Magnesium stearate | 557-04-0 | TWA (Inhalable particulate matter) | 10 mg/m³ | ACGIH |

| | | | | |
|---|---|---|---|---|
| | | TWA (Respirable particulate matter) | 3 mg/m³ | 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).

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|---|---|---|
| Physical state | : | 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) | : | 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. |
| Molecular weight | : | No data available |
| Particle characteristics | | |
| 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 reactions | : | May form explosive dust-air mixture during processing, handling or other means.<br>Can react with strong oxidizing agents. |

| | | |
|---|---|---|
| Conditions to avoid | : | Heat, flames and sparks.<br>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.

**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<br>Remarks: Based on data from similar materials |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2.000 mg/kg<br>Remarks: Based on data from similar materials |

**Skin corrosion/irritation**

Causes mild skin irritation.

**Components:**

**Boceprevir:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | No skin irritation |

**Sodium n-dodecyl sulfate:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | Skin irritation |

**Magnesium stearate:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | No skin irritation |
| Remarks | : | Based on data from similar materials |

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**Boceprevir:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | Mild eye irritation |

**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)<br>Result: negative<br><br>Test Type: Chromosomal aberration<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Micronucleus test<br>Species: Mouse<br>Application Route: Oral<br>Result: negative |

**Starch:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative |

**Cellulose:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |

**Sodium n-dodecyl sulfate:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Method: OECD Test Guideline 471<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Rodent dominant lethal test (germ cell) (in vivo)<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |

**Magnesium stearate:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: In vitro mammalian cell gene mutation test<br>Result: negative<br>Remarks: Based on data from similar materials<br><br>Test Type: Chromosome aberration test in vitro<br>Method: OECD Test Guideline 473<br>Result: negative<br>Remarks: Based on data from similar materials<br><br>Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br>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<br>Species: Rat, male<br>Fertility: LOAEL: 75 mg/kg body weight<br>Symptoms: Effects on fertility.<br>Result: positive<br><br>Test Type: Fertility/early embryonic development<br>Species: Rat, female<br>Fertility: LOAEL: 150 mg/kg body weight<br>Symptoms: Effects on fertility.<br>Result: positive |
| Effects on fetal development | : | Test Type: Development<br>Species: Rabbit, male and female<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 300 mg/kg body weight<br>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<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |
| Effects on fetal development | : | Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |

**Sodium n-dodecyl sulfate:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Two-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Method: OECD Test Guideline 416<br>Result: negative<br>Remarks: Based on data from similar materials |
| Effects on fetal development | : | Test Type: Embryo-fetal development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative<br>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<br>Species: Rat<br>Application Route: Ingestion<br>Method: OECD Test Guideline 422<br>Result: negative<br>Remarks: Based on data from similar materials |
| Effects on fetal development | : | Test Type: Embryo-fetal development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative<br>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 | : | >= 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 plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 9,5 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 9,5 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Pimephales promelas (fathead minnow)): > 9 mg/l<br>Exposure time: 28 d<br>Method: OECD Test Guideline 210 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 7,2 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211 |
| Toxicity to microorganisms | : | EC50: > 959 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209<br><br>NOEC: 959 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209 |

**Cellulose:**

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

**Sodium n-dodecyl sulfate:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): 29 mg/l<br>Exposure time: 96 h |

| | | |
|---|---|---|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Ceriodaphnia dubia (water flea)): 5,55 mg/l<br>Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | ErC50 (Desmodesmus subspicatus (green algae)): > 120 mg/l<br>Exposure time: 72 h<br><br>NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l<br>Exposure time: 72 h |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Pimephales promelas (fathead minnow)): >= 1,357 mg/l<br>Exposure time: 42 d |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Ceriodaphnia dubia (water flea)): 0,88 mg/l<br>Exposure time: 7 d |
| Toxicity to microorganisms | : | EC50: 135 mg/l<br>Exposure time: 3 h |

**Magnesium stearate:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l<br>Exposure time: 48 h<br>Method: DIN 38412<br>Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates | : | EL50 (Daphnia magna (Water flea)): > 1 mg/l<br>Exposure time: 47 h<br>Test substance: Water Accommodated Fraction<br>Method: Directive 67/548/EEC, Annex V, C.2.<br>Remarks: Based on data from similar materials<br>No toxicity at the limit of solubility. |
| Toxicity to algae/aquatic plants | : | EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l<br>Exposure time: 72 h<br>Test substance: Water Accommodated Fraction<br>Method: OECD Test Guideline 201<br>Remarks: Based on data from similar materials<br>No toxicity at the limit of solubility.<br><br>NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l<br>Exposure time: 72 h<br>Test substance: Water Accommodated Fraction<br>Method: OECD Test Guideline 201<br>Remarks: Based on data from similar materials |
| Toxicity to microorganisms | : | EC10 (Pseudomonas putida): > 100 mg/l<br>Exposure time: 16 h<br>Test substance: Water Accommodated Fraction<br>Remarks: Based on data from similar materials |

**Persistence and degradability**

**Components:**

**Boceprevir:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 0,6 %<br>Exposure time: 28 d |

**Cellulose:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Readily biodegradable. |

**Sodium n-dodecyl sulfate:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Readily biodegradable.<br>Biodegradation: 95 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301B |

**Magnesium stearate:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Not biodegradable<br>Remarks: Based on data from similar materials |

**Bioaccumulative potential**

**Components:**

**Boceprevir:**

| | | |
|---|---|---|
| Bioaccumulation | : | Species: Lepomis macrochirus (Bluegill sunfish)<br>Bioconcentration factor (BCF): 2,6<br>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<br>Method: OECD Test Guideline 106 |

**Other adverse effects**

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

| | | |
|---|---|---|
| Waste from residues | : | Do not dispose of waste into sewer.<br>Dispose of in accordance with local regulations. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>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**

**ANTT**
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**

| | | |
|---|---|---|
| National List of Carcinogenic Agents for Humans - (LINACH) | : | Not applicable |
| Brazil. List of chemicals controlled by the Federal Police | : | Not applicable |

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

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

## SECTION 16. OTHER INFORMATION

| | | |
|---|---|---|
| Revision Date | : | 28.09.2024 |
| Date format | : | dd.mm.yyyy |

**Further information**

| | | |
|---|---|---|
| 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/ |

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

**Full text of other abbreviations**

| | | |
|---|---|---|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| ACGIH / TWA | : | 8-hour, time-weighted average |

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; TECI - 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

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.

BR / Z8