# Boceprevir Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
|---|---|---|---|
| 4.3 | 28.09.2024 | 9371329-00009 | Date of first issue: 27.08.2021 |

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier

Trade name : Boceprevir Formulation

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

### 1.3 Details of the supplier of the safety data sheet

Company : MSD
120 Moorgate
EC2M 6UR London, United Kingdom

Telephone : +44 (0) 2081548000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

### 1.4 Emergency telephone number

1-908-423-6000

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

Reproductive toxicity, Category 2 H361f: Suspected of damaging fertility.

### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

Hazard pictograms :

Signal word : Warning

Hazard statements : H361f Suspected of damaging fertility.

Precautionary statements : **Prevention:**

P201 Obtain special instructions before use.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

**Storage:**

P405 Store locked up.

Hazardous components which must be listed on the label:
Boceprevir

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
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

### 3.2 Mixtures

**Components**

| Chemical name | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification | Concentration (% w/w) |
|---|---|---|---|
| Boceprevir | 394730-60-0 | Repr. 2; H361f | >= 50 - < 70 |
| Sodium n-dodecyl sulfate | 151-21-3<br>205-788-1 | Acute Tox. 4; H302<br>Skin Irrit. 2; H315<br>Eye Dam. 1; H318<br>Aquatic Chronic 3; H412<br>_____<br>specific concentration limit<br>Eye Irrit. 2; H319<br>10 - < 20 %<br>Eye Dam. 1; H318<br>>= 20 %<br>Eye Irrit. 2; H319<br>10 - < 20 %<br>Eye Dam. 1; H318<br>>= 20 % | >= 3 - < 10 |
| Substances with a workplace exposure limit : | | | |

| | | | |
|---|---|---|---|
| Starch | 9005-25-8<br>232-679-6 | | >= 10 - < 20 |
| Cellulose | 9004-34-6<br>232-674-9 | | >= 10 - < 20 |

For explanation of abbreviations see section 16.

## SECTION 4: First aid measures

### 4.1 Description of 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.

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).

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.

### 4.2 Most important symptoms and effects, both acute and delayed

Risks : Suspected of damaging fertility.

Dust contact with the eyes can lead to mechanical irritation.

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam

| | | |
|---|---|---|
| | | Carbon dioxide (CO2)<br>Dry chemical |
| Unsuitable extinguishing media | : | None known. |

### 5.2 Special hazards arising from the substance or mixture

| | | |
|---|---|---|
| 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>Sulphur oxides |

### 5.3 Advice for firefighters

| | | |
|---|---|---|
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |
| 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. |

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

| | | |
|---|---|---|
| Personal precautions | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |

### 6.2 Environmental precautions

| | | |
|---|---|---|
| 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>If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060). |

### 6.3 Methods and material for containment and cleaning up

| | | |
|---|---|---|
| Methods for 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 re- |

leased 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.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

| | | |
|---|---|---|
| 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. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. |

### 7.2 Conditions for safe storage, including any incompatibilities

| | | |
|---|---|---|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations. |
| Advice on common storage | : | Do not store with the following product types:<br>Strong oxidizing agents |

### 7.3 Specific end use(s)

| | | |
|---|---|---|
| Specific use(s) | : | No data available |

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

**Occupational Exposure Limits**

dust of any kind

10 mg/m3
Value type (Form of exposure): TWA (Inhalable)
Basis: GB EH40

4 mg/m3
Value type (Form of exposure): TWA (Respirable fraction)
Basis: GB EH40

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|---|---|---|---|---|
| Boceprevir | 394730-60-0 | TWA | 2 mg/m3 (OEB 1) | Internal |
| Starch | 9005-25-8 | TWA (inhalable dust) | 10 mg/m3 | GB EH40 |
| | | TWA (Respirable dust) | 4 mg/m3 | GB EH40 |
| Cellulose | 9004-34-6 | TWA (inhalable dust) | 10 mg/m3 | GB EH40 |
| | | TWA (Respirable dust) | 4 mg/m3 | GB EH40 |
| | | STEL (inhalable dust) | 20 mg/m3 | GB EH40 |

**Derived No Effect Level (DNEL)**

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|---|---|---|---|---|
| Sodium n-dodecyl sulfate | Workers | Inhalation | Long-term systemic effects | 285 mg/m3 |
| | Workers | Skin contact | Long-term systemic effects | 4060 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 85 mg/m3 |
| | Consumers | Skin contact | Long-term systemic effects | 2440 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 24 mg/kg bw/day |

**Predicted No Effect Concentration (PNEC)**

| Substance name | Environmental Compartment | Value |
|---|---|---|
| Sodium n-dodecyl sulfate | Fresh water | 0.176 mg/l |
| | Marine water | 0.018 mg/l |
| | Sewage treatment plant | 1.35 mg/l |
| | Fresh water sediment | 6.97 mg/kg dry weight (d.w.) |
| | Marine sediment | 0.697 mg/kg dry |

| | | |
|---|---|---|
| | | weight (d.w.) |
| | Soil | 1.29 mg/kg dry weight (d.w.) |

### 8.2 Exposure controls

**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**

| | | |
|---|---|---|
| Eye/face protection | : | Wear the following personal protective equipment:<br>Safety goggles<br>Equipment should conform to BS EN 166 |
| Hand protection | | |
| Material | : | Chemical-resistant gloves |
| Remarks | : | Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday. |
| Skin and body protection | : | Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.<br>Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc). |
| Respiratory protection | : | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.<br>Equipment should conform to BS EN 143 |
| Filter type | : | Particulates type (P) |

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

| | | |
|---|---|---|
| Appearance | : | powder |
| Colour | : | white |
| Odour | : | No data available |
| Odour Threshold | : | No data available |
| pH | : | No data available |
| Melting point/freezing point | : | No data available |

| | | |
|---|---|---|
| Initial boiling point and boiling range | : | No data available |
| Flash point | : | No data available |
| Evaporation rate | : | No data available |
| Flammability (solid, gas) | : | May form explosive dust-air mixture during processing, handling or other means. |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapour pressure | : | Not applicable |
| Relative vapour 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 |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity | | |
| Viscosity, kinematic | : | No data available |
| Explosive properties | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |

**9.2 Other information**

| | | |
|---|---|---|
| Flammability (liquids) | : | Not applicable |
| Molecular weight | : | No data available |
| Particle size | : | No data available |

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

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

**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<br>Method: OECD Test Guideline 402<br>Remarks: Based on data from similar materials |

**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<br>Exposure time: 4 h<br>Test atmosphere: dust/mist |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg |

**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 |

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**Boceprevir:**

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

**Sodium n-dodecyl sulfate:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Method | : | OECD Test Guideline 405 |
| Result | : | Irreversible effects on the eye |

**Starch:**

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

**Respiratory or skin sensitisation**

**Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:**

**Boceprevir:**

| | | |
|---|---|---|
| Test Type | : | Maximisation Test |
| Species | : | Guinea pig |
| Result | : | negative |

**Sodium n-dodecyl sulfate:**

| | | |
|---|---|---|
| Test Type | : | Maximisation Test |
| Exposure routes | : | Skin contact |
| Species | : | Guinea pig |
| Result | : | negative |
| Remarks | : | Based on data from similar materials |

**Starch:**

| | | |
|---|---|---|
| Test Type | : | Maximisation Test |
| Exposure routes | : | Skin contact |
| Species | : | Guinea pig |
| Result | : | negative |

**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 |

**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 |

Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Mouse
Application Route: Ingestion
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

**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

**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

**Cellulose:**

| | | |
|---|---|---|
| Species | : | Rat |
| Application Route | : | Ingestion |
| Exposure time | : | 72 weeks |
| Result | : | negative |

**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 foetal 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. |

**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 foetal development | : | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative<br>Remarks: Based on data from similar materials |

**Cellulose:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion |

| | | |
|---|---|---|
| | | Result: negative |
| Effects on foetal development | : | Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |

**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 |

**Sodium n-dodecyl sulfate:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 488 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 90 Days |
| Remarks | : | Based on data from similar materials |

**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 |

**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

### 12.1 Toxicity

**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 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 |

| | | |
|---|---|---|
| Toxicity to fish (Chronic toxicity) | : | NOEC: > 9 mg/l<br>Exposure time: 28 d<br>Species: Pimephales promelas (fathead minnow)<br>Method: OECD Test Guideline 210 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: 7.2 mg/l<br>Exposure time: 21 d<br>Species: Daphnia magna (Water flea)<br>Method: OECD Test Guideline 211 |

**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 microorganisms | : | EC50 : 135 mg/l<br>Exposure time: 3 h |
| Toxicity to fish (Chronic toxicity) | : | NOEC: >= 1.357 mg/l<br>Exposure time: 42 d<br>Species: Pimephales promelas (fathead minnow) |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: 0.88 mg/l<br>Exposure time: 7 d<br>Species: Ceriodaphnia dubia (water flea) |

**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 |

### 12.2 Persistence and degradability

**Components:**

**Boceprevir:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 0.6 %<br>Exposure time: 28 d |

**Sodium n-dodecyl sulfate:**

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

**Cellulose:**

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

### 12.3 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 |

### 12.4 Mobility in soil

**Components:**

**Boceprevir:**

| | | |
|---|---|---|
| Distribution among environmental compartments | : | log Koc: 1.9<br>Method: OECD Test Guideline 106 |

### 12.5 Results of PBT and vPvB assessment

**Product:**

| | | |
|---|---|---|
| Assessment | : | This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. |

### 12.6 Other adverse effects

**Product:**

| | | |
|---|---|---|
| Endocrine disrupting potential | : | This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f). |

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

| | | |
|---|---|---|
| Product | : | Dispose of in accordance with local regulations.<br>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.<br>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.<br>Do not dispose of waste into sewer. |
| 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

### 14.1 UN number

| | | |
|---|---|---|
| **ADN** | : | Not regulated as a dangerous good |
| **ADR** | : | Not regulated as a dangerous good |
| **RID** | : | Not regulated as a dangerous good |
| **IMDG** | : | Not regulated as a dangerous good |
| **IATA** | : | Not regulated as a dangerous good |

### 14.2 UN proper shipping name

| | | |
|---|---|---|
| **ADN** | : | Not regulated as a dangerous good |
| **ADR** | : | Not regulated as a dangerous good |
| **RID** | : | Not regulated as a dangerous good |
| **IMDG** | : | Not regulated as a dangerous good |
| **IATA** | : | Not regulated as a dangerous good |

### 14.3 Transport hazard class(es)

| | | |
|---|---|---|
| **ADN** | : | Not regulated as a dangerous good |
| **ADR** | : | Not regulated as a dangerous good |
| **RID** | : | Not regulated as a dangerous good |
| **IMDG** | : | Not regulated as a dangerous good |
| **IATA** | : | Not regulated as a dangerous good |

### 14.4 Packing group

| | | |
|---|---|---|
| **ADN** | : | Not regulated as a dangerous good |
| **ADR** | : | Not regulated as a dangerous good |
| **RID** | : | Not regulated as a dangerous good |
| **IMDG** | : | Not regulated as a dangerous good |
| **IATA (Cargo)** | : | Not regulated as a dangerous good |
| **IATA (Passenger)** | : | Not regulated as a dangerous good |

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Relevant EU provisions transposed through retained EU law

| | | |
|---|---|---|
| UK REACH List of restrictions (Annex 17) | : | Not applicable |
| UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation | : | Not applicable |
| The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) | : | Not applicable |
| Regulation (EC) on substances that deplete the ozone layer | : | Not applicable |
| UK REACH List of substances subject to authorisation (Annex XIV) | : | Not applicable |
| GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation | : | Not applicable |

Control of Major Accident Hazards Regulations 2015 (COMAH)
Not applicable

**Other regulations:**

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

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

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

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

Other information : 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 H-Statements**

| | | |
|---|---|---|
| H302 | : | Harmful if swallowed. |
| H315 | : | Causes skin irritation. |
| H318 | : | Causes serious eye damage. |
| H361f | : | Suspected of damaging fertility. |
| H412 | : | Harmful to aquatic life with long lasting effects. |

**Full text of other abbreviations**

| | | |
|---|---|---|
| Acute Tox. | : | Acute toxicity |
| Aquatic Chronic | : | Long-term (chronic) aquatic hazard |
| Eye Dam. | : | Serious eye damage |
| Repr. | : | Reproductive toxicity |
| Skin Irrit. | : | Skin irritation |
| GB EH40 | : | UK. EH40 WEL - Workplace Exposure Limits |
| GB EH40 / TWA | : | Long-term exposure limit (8-hour TWA reference period) |
| GB EH40 / STEL | : | Short-term exposure limit (15-minute reference period) |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

**Further information**

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

| **Classification of the mixture:** | | **Classification procedure:** |
|---|---|---|
| Repr. 2 | H361f | Calculation method |

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.

GB / EN