

## Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
5.2	14.04.2025	23678-00022	Date of first issue: 21.10.2014

---

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Boceprevir Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road  
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

---

### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

##### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

##### GHS Classification

Skin corrosion/irritation : Category 3

Reproductive toxicity : Category 2

Short-term (acute) aquatic hazard : Category 3

##### GHS label elements

Hazard pictograms :



Signal word : Warning

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

## Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
5.2	14.04.2025	23678-00022	Date of first issue: 21.10.2014

Precautionary statements : **Prevention:**  
P203 Obtain, read and follow all safety instructions before use.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**  
P318 IF exposed or concerned, get medical advice.  
P332 + P317 If skin irritation occurs: Get medical help.

**Storage:**  
P405 Store locked up.

**Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

### Other hazards which do not result in classification

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

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Boceprevir	394730-60-0	$\geq 50$ - $< 70$
Starch	9005-25-8	$\geq 10$ - $< 20$
Cellulose	9004-34-6	$\geq 10$ - $< 20$
Sodium dodecyl sulphate	151-21-3	$\geq 3$ - $< 5$
Magnesium stearate	557-04-0	$\geq 1$ - $< 5$

## 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 : Dust contact with the eyes can lead to mechanical irritation.

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
5.2	14.04.2025	23678-00022	Date of first issue: 21.10.2014

and effects, both acute and delayed		Causes mild skin irritation.
Protection of first-aiders	:	Suspected of damaging fertility.
	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

### 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire-fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Nitrogen oxides (NO <sub>x</sub> ) Metal oxides Sulphur oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Boceprevir Formulation

Version 5.2      Revision Date: 14.04.2025      SDS Number: 23678-00022      Date of last issue: 26.09.2023  
Date of first issue: 21.10.2014

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 7. HANDLING AND STORAGE

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

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components 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

## Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
5.2	14.04.2025	23678-00022	Date of first issue: 21.10.2014

		ter)		
--	--	------	--	--

**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 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.

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

**Skin and body protection** : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.  
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

**Hygiene measures** : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance** : powder

**Colour** : white

**Odour** : No data available

**Odour Threshold** : No data available

**pH** : No data available

**Melting point/freezing point** : No data available

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
5.2	14.04.2025	23678-00022	Date of first issue: 21.10.2014

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
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.
Molecular weight	:	No data available
Particle characteristics		
Particle size	:	No data available

### 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
------------	---	--

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
5.2	14.04.2025	23678-00022	Date of first issue: 21.10.2014

Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure :

- Inhalation
- Skin contact
- Ingestion
- Eye contact

#### Acute toxicity

Not classified based on available information.

#### Product:

Acute oral toxicity : Acute toxicity estimate: > 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 dodecyl sulphate:**

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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
5.2	14.04.2025	23678-00022	Date of first issue: 21.10.2014

---

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

#### Sodium dodecyl sulphate:

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 dodecyl sulphate:

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

#### Magnesium stearate:



# SAFETY DATA SHEET

according to the Globally Harmonized System



## Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
5.2	14.04.2025	23678-00022	Date of first issue: 21.10.2014

---

Species	:	Rabbit
Result	:	No eye irritation
Remarks	:	Based on data from similar materials

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### Boceprevir:

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

##### Starch:

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

##### Sodium dodecyl sulphate:

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

##### Magnesium stearate:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative
Remarks	:	Based on data from similar materials

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### Boceprevir:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: Chromosomal aberration Result: negative

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
5.2	14.04.2025	23678-00022	Date of first issue: 21.10.2014

---

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 dodecyl sulphate:**

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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
5.2	14.04.2025	23678-00022	Date of first issue: 21.10.2014

### 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 dodecyl sulphate:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	2 Years
Method	:	OECD Test Guideline 453
Result	:	negative
Remarks	:	Based on data from similar materials

### Reproductive toxicity

Suspected of damaging fertility.

### Components:

#### Boceprevir:

Effects on fertility	:	Test Type: Fertility/early embryonic development Species: Rat, male Fertility: LOAEL: 75 mg/kg body weight Symptoms: Effects on fertility Result: positive
----------------------	---	--

	:	Test Type: Fertility/early embryonic development Species: Rat, female Fertility: LOAEL: 150 mg/kg body weight Symptoms: Effects on fertility Result: positive
--	---	---

Effects on foetal development	:	Test Type: Development Species: Rabbit, male and female
-------------------------------	---	--

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
5.2	14.04.2025	23678-00022	Date of first issue: 21.10.2014

Application Route: Oral  
Developmental Toxicity: NOAEL: 300 mg/kg body weight  
Result: negative

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments.

### Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on foetal development : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative

### Sodium dodecyl sulphate:

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 416  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

### Magnesium stearate:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

### STOT - single exposure

Not classified based on available information.

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
5.2	14.04.2025	23678-00022	Date of first issue: 21.10.2014

### STOT - repeated exposure

Not classified based on available information.

### Repeated dose toxicity

#### Components:

##### **Boceprevir:**

Species	: Monkey
NOAEL	: > 200 mg/kg
Application Route	: Oral
Exposure time	: 365 d
Remarks	: No significant adverse effects were reported

Species	: Rat
NOAEL	: 75 mg/kg
LOAEL	: 100 mg/kg
Application Route	: Oral
Exposure time	: 90 d
Target Organs	: Testis, Prostate

Species	: Rat
NOAEL	: 15 mg/kg
LOAEL	: 75 mg/kg
Application Route	: Oral
Exposure time	: 180 d
Target Organs	: Testis

Species	: Mouse
NOAEL	: 250 mg/kg
LOAEL	: 500 mg/kg
Application Route	: Oral
Exposure time	: 90 d
Target Organs	: Kidney

##### **Starch:**

Species	: Rat
NOAEL	: $\geq 2,000$ mg/kg
Application Route	: Skin contact
Exposure time	: 28 Days
Method	: OECD Test Guideline 410

##### **Cellulose:**

Species	: Rat
NOAEL	: $\geq 9,000$ mg/kg
Application Route	: Ingestion
Exposure time	: 90 Days

##### **Sodium dodecyl sulphate:**

Species	: Rat
NOAEL	: 488 mg/kg

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
5.2	14.04.2025	23678-00022	Date of first issue: 21.10.2014

Application Route : Ingestion  
Exposure time : 90 Days  
Remarks : Based on data from similar materials

### Magnesium stearate:

Species : Rat  
NOAEL : > 100 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days  
Remarks : Based on data from similar materials

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### Boceprevir:

Ingestion : Symptoms: Headache, Gastrointestinal disturbance, bitter taste

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### Boceprevir:

Toxicity to algae/aquatic plants : EC50 ( Pseudokirchneriella subcapitata (green algae)): > 9.5 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC ( Pseudokirchneriella subcapitata (green algae)): 9.5 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50: > 959 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

NOEC: 959 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity) : NOEC: > 9 mg/l  
Exposure time: 28 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
5.2	14.04.2025	23678-00022	Date of first issue: 21.10.2014

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 7.2 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

### Cellulose:

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

### Sodium dodecyl sulphate:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 29 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l  
Exposure time: 48 h

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

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

Toxicity to microorganisms : EC50: 135 mg/l  
Exposure time: 3 h

Toxicity to fish (Chronic toxicity) : NOEC:  $\geq$  1.357 mg/l  
Exposure time: 42 d  
Species: Pimephales promelas (fathead minnow)

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

### 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  
Method: Directive 67/548/EEC, Annex V, C.2.  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubility

Toxicity to algae/aquatic plants : EL50 ( Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
Exposure time: 72 h

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
5.2	14.04.2025	23678-00022	Date of first issue: 21.10.2014

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 dodecyl sulphate:**

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



# SAFETY DATA SHEET

according to the Globally Harmonized System



## Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
5.2	14.04.2025	23678-00022	Date of first issue: 21.10.2014

### Sodium dodecyl sulphate:

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 K<sub>oc</sub>: 1.9  
Method: OECD Test Guideline 106

### Other adverse effects

No data available

## 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

## 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 IMO instruments

Not applicable for product as supplied.

### Special precautions for user

Not applicable

## 15. REGULATORY INFORMATION

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

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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
5.2	14.04.2025	23678-00022	Date of first issue: 21.10.2014

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

### 16. OTHER INFORMATION

Revision Date : 14.04.2025

#### 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/>

Date format : dd.mm.yyyy

#### 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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
5.2	14.04.2025	23678-00022	Date of first issue: 21.10.2014

---

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.

IN / EN