

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Boceprevir Formulation

Version 4.1 Revision Date: 26.09.2023 SDS Number: 9371329-00007 Date of last issue: 20.03.2023
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 Sub-stance/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.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Boceprevir Formulation

Version 4.1 Revision Date: 26.09.2023 SDS Number: 9371329-00007 Date of last issue: 20.03.2023
Date of first issue: 27.08.2021

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. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Boceprevir	394730-60-0	Repr. 2; H361f	>= 50 - < 70
Sodium n-dodecyl sulfate	151-21-3 205-788-1	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Aquatic Chronic 3; H412 specific concentration limit Eye Irrit. 2; H319 10 - < 20 % Eye Dam. 1; H318 >= 20 %	>= 3 - < 10
Substances with a workplace exposure limit :			
Starch	9005-25-8 232-679-6		>= 10 - < 20
Cellulose	9004-34-6		>= 10 - < 20

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
4.1	26.09.2023	9371329-00007	Date of first issue: 27.08.2021

	232-674-9		
--	-----------	--	--

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)
Dry chemical

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
4.1	26.09.2023	9371329-00007	Date of first issue: 27.08.2021

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.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NO_x)
Metal oxides
Sulphur oxides

5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
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.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
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.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
4.1	26.09.2023	9371329-00007	Date of first issue: 27.08.2021

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.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. |
| Local/Total ventilation | : | Use only with adequate ventilation. |
| Advice on safe handling | : | Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment. |
| Hygiene measures | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. |

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:
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/m ³
------------------	----------------------

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Boceprevir Formulation

Version 4.1 Revision Date: 26.09.2023 SDS Number: 9371329-00007 Date of last issue: 20.03.2023
Date of first issue: 27.08.2021

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/m ³ (OEB 1)	Internal
Starch	9005-25-8	TWA (inhalable dust)	10 mg/m ³	GB EH40
		TWA (Respirable dust)	4 mg/m ³	GB EH40
Cellulose	9004-34-6	TWA (inhalable dust)	10 mg/m ³	GB EH40
		TWA (Respirable dust)	4 mg/m ³	GB EH40
		STEL (inhalable dust)	20 mg/m ³	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/m ³
	Workers	Skin contact	Long-term systemic effects	4060 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	85 mg/m ³
	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.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
4.1	26.09.2023	9371329-00007	Date of first issue: 27.08.2021

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: Safety goggles 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. 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. 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.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
4.1	26.09.2023	9371329-00007	Date of first issue: 27.08.2021

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.
---------------------	---	---

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
4.1	26.09.2023	9371329-00007	Date of first issue: 27.08.2021

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
Method: OECD Test Guideline 402
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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
4.1	26.09.2023	9371329-00007	Date of first issue: 27.08.2021

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

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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Boceprevir Formulation

Version 4.1 Revision Date: 26.09.2023 SDS Number: 9371329-00007 Date of last issue: 20.03.2023
Date of first issue: 27.08.2021

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)
Result: negative

Test Type: Chromosomal aberration
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Sodium n-dodecyl sulfate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

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

Starch:

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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Boceprevir Formulation

Version 4.1 Revision Date: 26.09.2023 SDS Number: 9371329-00007 Date of last issue: 20.03.2023
Date of first issue: 27.08.2021

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:

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Boceprevir Formulation

Version 4.1 Revision Date: 26.09.2023 SDS Number: 9371329-00007 Date of last issue: 20.03.2023
Date of first issue: 27.08.2021

- 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
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.

Sodium n-dodecyl sulfate:

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

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

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Boceprevir Formulation

Version 4.1 Revision Date: 26.09.2023 SDS Number: 9371329-00007 Date of last issue: 20.03.2023
Date of first issue: 27.08.2021

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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Boceprevir Formulation

Version 4.1 Revision Date: 26.09.2023 SDS Number: 9371329-00007 Date of last issue: 20.03.2023
Date of first issue: 27.08.2021

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
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

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

Sodium n-dodecyl sulfate:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 29 mg/l

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Boceprevir Formulation

Version 4.1 Revision Date: 26.09.2023 SDS Number: 9371329-00007 Date of last issue: 20.03.2023
Date of first issue: 27.08.2021

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

12.2 Persistence and degradability

Components:

Boceprevir:

- Biodegradability : Result: Not readily biodegradable.
Biodegradation: 0.6 %
Exposure time: 28 d

Sodium n-dodecyl sulfate:

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

Cellulose:

- Biodegradability : Result: Readily biodegradable.

12.3 Bioaccumulative potential

Components:

Boceprevir:

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
4.1	26.09.2023	9371329-00007	Date of first issue: 27.08.2021

Bioaccumulation : Species: *Lepomis macrochirus* (Bluegill sunfish)
Bioconcentration factor (BCF): 2.6
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 3.18

Sodium n-dodecyl sulfate:

Partition coefficient: n-octanol/water : log Pow: 0.83

12.4 Mobility in soil

Components:

Boceprevir:

Distribution among environmental compartments : log Koc: 1.9
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 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Boceprevir Formulation

Version 4.1 Revision Date: 26.09.2023 SDS Number: 9371329-00007 Date of last issue: 20.03.2023
Date of first issue: 27.08.2021

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.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
4.1	26.09.2023	9371329-00007	Date of first issue: 27.08.2021

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) No 1005/2009 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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
4.1	26.09.2023	9371329-00007	Date of first issue: 27.08.2021

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