

Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
6.1	14.04.2025	23691-00024	Date of first issue: 21.10.2014

Section 1: Identification

Product identifier : Boceprevir Formulation

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

Manufacturer or supplier's details

Company : MSD
Address : 50 Tuas West Drive
Singapore - Singapore 638408
Telephone : +1-908-740-4000
Emergency telephone number : 65 6697 2111 (24/7/365)
E-mail address : EHSDATASTEWARD@msd.com

Section 2: Hazard identification

Classification of the substance or mixture

Reproductive toxicity : Category 2

GHS Label elements, including precautionary statements

Hazard pictograms :



Signal word : Warning

Hazard statements : H361f Suspected of damaging fertility.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.

Response:

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

Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
6.1	14.04.2025	23691-00024	Date of first issue: 21.10.2014

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.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

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

Section 4: First-aid measures**Description of necessary first-aid measures**

General advice	: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	: If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	: In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	: If in eyes, rinse well with water. Get medical attention if irritation develops and persists.
If swallowed	: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed

Risks	: Dust contact with the eyes can lead to mechanical irritation. Suspected of damaging fertility.
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).

Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
6.1	14.04.2025	23691-00024	Date of first issue: 21.10.2014

Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

Section 5: Fire-fighting measures**Extinguishing media**

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

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

Special protective actions for fire-fighters

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**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).

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.
Local authorities should be advised if significant spillages cannot be contained.

Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
6.1	14.04.2025	23691-00024	06.04.2024
			Date of first issue: 21.10.2014

Methods and materials 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 employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

Section 7: Handling and storage**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.

Conditions for safe storage, including any incompatibilities

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

Boceprevir Formulation

Version 6.1 Revision Date: 14.04.2025 SDS Number: 23691-00024 Date of last issue: 06.04.2024
 Date of first issue: 21.10.2014

Section 8: Exposure controls/personal protection

Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Boceprevir	394730-60-0	TWA	2 mg/m ³ (OEB 1)	Internal
Starch	9005-25-8	PEL (long term)	10 mg/m ³	SG OEL
		TWA	10 mg/m ³	ACGIH
Cellulose	9004-34-6	PEL (long term)	10 mg/m ³	SG OEL
		TWA	10 mg/m ³	ACGIH
Magnesium stearate	557-04-0	PEL (long term)	10 mg/m ³	SG OEL
		TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m ³	ACGIH

Appropriate engineering control 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).

Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection : Wear the following personal protective equipment:
Safety goggles

Skin 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.

Filter type : Particulates type

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending

Boceprevir Formulation

Version 6.1	Revision Date: 14.04.2025	SDS Number: 23691-00024	Date of last issue: 06.04.2024 Date of first issue: 21.10.2014
----------------	------------------------------	----------------------------	---

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.

Section 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
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

Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
6.1	14.04.2025	23691-00024	Date of first issue: 21.10.2014

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

Section 10: Stability and reactivity

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

Section 11: Toxicological information

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
--	---	--

Acute toxicity

Not classified based on available information.

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
---------------------	---	---------------------------

Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
6.1	14.04.2025	23691-00024	Date of first issue: 21.10.2014

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 401Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials**Magnesium stearate:**Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Assessment: The substance or mixture has no acute oral toxicity
Remarks: Based on data from similar materialsAcute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Remarks: Based on data from similar materials**Skin corrosion/irritation**

Not classified based on available information.

Components:**Boceprevir:**Species : Rabbit
Result : No skin irritation**Sodium dodecyl sulphate:**Species : Rabbit
Result : Skin irritation

Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
6.1	14.04.2025	23691-00024	Date of first issue: 21.10.2014

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

Magnesium stearate:

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

Respiratory or skin 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

Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
6.1	14.04.2025	23691-00024	Date of first issue: 21.10.2014

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
--	---

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
----------------------	--

Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
6.1	14.04.2025	23691-00024	Date of first issue: 21.10.2014

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

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

Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
6.1	14.04.2025	23691-00024	Date of first issue: 21.10.2014

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 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
----------------------	---

Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
6.1	14.04.2025	23691-00024	06.04.2024
			Date of first issue: 21.10.2014

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.

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

Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
6.1	14.04.2025	23691-00024	Date of first issue: 21.10.2014

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
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

Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
6.1	14.04.2025	23691-00024	06.04.2024
			Date of first issue: 21.10.2014

taste

Section 12: Ecological information

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

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

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

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

Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
6.1	14.04.2025	23691-00024	06.04.2024
			Date of first issue: 21.10.2014

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

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

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

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

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
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:**

Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
6.1	14.04.2025	23691-00024	Date of first issue: 21.10.2014

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

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 Koc: 1.9
Method: OECD Test Guideline 106

Other adverse effects

No data available

Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
6.1	14.04.2025	23691-00024	Date of first issue: 21.10.2014

Section 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.

Section 14: Transport information**International Regulations****UNRTDG**

UN number	:	Not applicable
UN proper shipping name	:	Not applicable
Transport hazard class(es)	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Environmentally hazardous	:	no

IATA-DGR

UN/ID No.	:	Not applicable
UN proper shipping name	:	Not applicable
Transport hazard class(es)	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Packing instruction (cargo aircraft)	:	Not applicable
Packing instruction (passenger aircraft)	:	Not applicable

IMDG-Code

UN number	:	Not applicable
UN proper shipping name	:	Not applicable
Transport hazard class(es)	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
EmS Code	:	Not applicable
Marine pollutant	:	Not applicable

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
6.1	14.04.2025	23691-00024	Date of first issue: 21.10.2014

Section 15: Regulatory information**Safety, health and environmental regulations specific for the product in question**

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subject to the requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable
Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable
Regulations

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

AICS : not determined

DSL : not determined

IECSC : not determined

Section 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)
SG OEL : Singapore. Workplace Safety and Health (General Provisions) Regulations - First Schedule Permissible Exposure Limits of Toxic Substances.

ACGIH / TWA : 8-hour, time-weighted average
SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

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

Boceprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
6.1	14.04.2025	23691-00024	Date of first issue: 21.10.2014

Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

SG / EN