

Boceprevir Formulation

Version 8.0 Revision Date: 2023/09/26 SDS Number: 23681-00021 Date of last issue: 2023/03/20
Date of first issue: 2014/10/21

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Boceprevir Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.
Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION**GHS classification of chemical product**

Reproductive toxicity : Category 2

Short-term (acute) aquatic hazard : Category 3

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H361f Suspected of damaging fertility.
H402 Harmful to aquatic life.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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Response:

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

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

Important symptoms and out- : Dust contact with the eyes can lead to mechanical irritation.
lines of the emergency as- : May form explosive dust-air mixture during processing, han-
sumed : dling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Boceprevir	394730-60-0	>= 50 - < 60	
Starch	9005-25-8	>= 10 - < 20	8-98
Cellulose	9004-34-6	>= 10 - < 20	
Sodium n-dodecyl sulfate	151-21-3	3	2-1679
Magnesium stearate	557-04-0	>= 1 - < 10	2-611

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.

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Most important symptoms and effects, both acute and delayed	:	Rinse mouth thoroughly with water. Suspected of damaging fertility. Dust contact with the eyes can lead to mechanical irritation.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) 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 _x) 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). Dust deposits should not be allowed to accumulate on surfac-

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es, 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
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. |
| Avoidance of contact | : | Oxidizing agents |
| 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. |

Storage

- | | | |
|-----------------------------|---|--|
| 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 |
| Packaging material | : | Unsuitable material: None known. |

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

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

Engineering measures : Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type
 Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration 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).

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : powder

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Colour	:	white
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Boiling point, initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	Not applicable
Lower explosion limit and upper explosion limit / flammability limit	:	
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Evaporation rate	:	No data available
Auto-ignition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Vapour pressure	:	Not applicable
Density and / or relative density	:	
Relative density	:	No data available
Density	:	No data available

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Relative vapour density	:	Not applicable
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.
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
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Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
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Components:**Boceprevir:**

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg LD50 (Monkey): > 1,000 mg/kg
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Starch:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
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Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Sodium n-dodecyl sulfate:

Acute oral toxicity : LD50 (Rat): 1,200 mg/kg
Method: OECD Test Guideline 401

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials

Magnesium stearate:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Assessment: The substance or mixture has no acute oral toxicity
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

Not classified based on available information.

Components:**Boceprevir:**

Species : Rabbit
Result : No skin irritation

Sodium n-dodecyl sulfate:

Species : Rabbit
Result : Skin irritation

Magnesium stearate:

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

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Serious eye damage/eye irritation

Not classified based on available information.

Components:**Boceprevir:**

Species	: Rabbit
Result	: Mild eye irritation

Starch:

Species	: Rabbit
Result	: No eye irritation

Sodium n-dodecyl sulfate:

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

Magnesium stearate:

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

Respiratory or skin 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 n-dodecyl sulfate:

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

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||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

Sodium n-dodecyl sulfate:

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

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Genotoxicity in vivo	: 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
Genotoxicity in vitro	: Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials
Genotoxicity in vitro	: 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

Sodium n-dodecyl sulfate:

Species	: Rat
Application Route	: Ingestion
Exposure time	: 2 Years

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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
Effects on foetal development	:	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 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

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ment	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
LOAEL	: 75 mg/kg
Application Route	: Oral
Exposure time	: 180 d
Target Organs	: Testis

Species	: Mouse
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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 n-dodecyl sulfate:

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

Magnesium stearate:

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

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Boceprevir:**

Ingestion : Symptoms: Headache, Gastrointestinal disturbance, bitter taste

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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 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
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Sodium n-dodecyl sulfate:

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

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		NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l Exposure time: 72 h
Toxicity to fish (Chronic toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): >= 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:**

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

Cellulose:

Biodegradability : Result: Readily biodegradable.

Sodium n-dodecyl sulfate:

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 n-dodecyl sulfate:

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

Magnesium stearate:

Partition coefficient: n-octanol/water : log Pow: > 4

Mobility in soil**Components:****Boceprevir:**

Distribution among environmental compartments : log Koc: 1.9
Method: OECD Test Guideline 106

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

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13. DISPOSAL CONSIDERATIONS**Disposal methods**

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

- UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

IATA-DGR

- UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : 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
Proper shipping name : Not applicable
Class : 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 Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

Special precautions for user

Not applicable

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15. REGULATORY INFORMATION

Related Regulations**Fire Service Law**

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Priority Assessment Chemical Substance

Chemical name	Number
Sodium alkyl(C=8-18) sulfate	214

Industrial Safety and Health Law**Harmful Substances Prohibited from Manufacture**

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
sodium dodecyl sulphate	>=1 - <10	From April 1st, 2025
Magnesium stearate	>=1 - <10	-

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
sodium dodecyl sulphate	From April 1st, 2025
Magnesium stearate	-

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

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Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**Class I Designated Chemical Substances**

Chemical name	Administration number	Concentration (%)
Sodium dodecyl sulfate	275	3.0

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Not regulated as a dangerous good

Aviation Law

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION**Further information**

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD

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compile the Safety Data Sheet

eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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

Date format : yyyy/mm/dd

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; TECl - 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.

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