

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Boceprevir Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2024/09/28 |
| 7.0 | 2025/04/14 | 23670-00024 | Date of first issue: 2014/10/21 |

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Boceprevir Formulation

Manufacturer or supplier's details

Company : MSD

Address : 199 Wenhai North Road
HEDA, Hangzhou - Zhejiang Province - CHINA 310018

Telephone : +1-908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Emergency Overview

| | |
|------------|---------------------|
| Appearance | : powder |
| Colour | : white |
| Odour | : No data available |

Causes mild skin irritation. Suspected of damaging fertility. Harmful to aquatic life.

GHS Classification

Skin corrosion/irritation : Category 3

Reproductive toxicity : Category 2

Short-term (acute) aquatic hazard : Category 3

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H316 Causes mild skin irritation.

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

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

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

Storage:
P405 Store locked up.

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

Physical and chemical hazards

Not classified based on available information.

Health hazards

Causes mild skin irritation. Suspected of damaging fertility.

Environmental hazards

Harmful to aquatic life.

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.

May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|-------------------------|-------------|-----------------------|
| Boceprevir | 394730-60-0 | >= 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 |

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

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| If inhaled | : advice. 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 | : Dust contact with the eyes can lead to mechanical irritation. Causes mild skin 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). |
| 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. |

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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 surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

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

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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

Components with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|--------------------|-------------|-------------------------------------|--|----------|
| Boceprevir | 394730-60-0 | TWA | 2 mg/m ³ (OEB 1) | Internal |
| Starch | 9005-25-8 | TWA | 10 mg/m ³ | ACGIH |
| Cellulose | 9004-34-6 | PC-TWA | 10 mg/m ³ | CN OEL |
| | | 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

Eye/face 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).

Hand protection

Material : Chemical-resistant gloves

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

9. PHYSICAL AND CHEMICAL PROPERTIES

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

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| | | |
|--|---|--|
| Density | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Solubility in other solvents | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity | | |
| Viscosity, kinematic | : | No data available |
| Explosive properties | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight | : | No data available |
| Particle characteristics | | |
| Particle size | : | No data available |

10. STABILITY AND REACTIVITY

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

| | | |
|-----------------|---|--|
| Exposure routes | : | Inhalation Skin contact Ingestion Eye contact |
|-----------------|---|--|

Acute toxicity

Not classified based on available information.

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Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

Boceprevir:

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

Starch:

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

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Sodium dodecyl sulphate:

Acute oral toxicity : LD50 (Rat): 1,200 mg/kg
Method: OECD Test Guideline 401
Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials

Magnesium stearate:

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

Skin corrosion/irritation

Causes mild skin irritation.

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Components:

Boceprevir:

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

Sodium dodecyl sulphate:

| | |
|---------|-------------------|
| Species | : Rabbit |
| Result | : Skin irritation |

Magnesium stearate:

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

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Boceprevir:

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

Starch:

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

Sodium dodecyl sulphate:

| | |
|---------|-----------------------------------|
| Species | : Rabbit |
| 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.

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Components:

Boceprevir:

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

Starch:

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

Sodium dodecyl sulphate:

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

Magnesium stearate:

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

Germ cell mutagenicity

Not classified based on available information.

Components:

Boceprevir:

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

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II

Cellulose:

| | |
|-----------------------|---|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Result: negative |
| Genotoxicity in vivo | : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative |

Sodium dodecyl sulphate:

| | |
|-----------------------|--|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative Test Type: In vitro mammalian cell gene mutation test Result: negative |
| Genotoxicity in vivo | : Test Type: Rodent dominant lethal test (germ cell) (in vivo) Species: Mouse Application Route: Ingestion Result: negative |

Magnesium stearate:

| | |
|-----------------------|---|
| Genotoxicity in vitro | : Test Type: In vitro mammalian cell gene mutation test Result: negative Remarks: Based on data from similar materials Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials |
|-----------------------|---|

Carcinogenicity

Not classified based on available information.

Components:

Boceprevir:

| | |
|-------------------|---------|
| Species | : Mouse |
| Application Route | : Oral |

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| | |
|---------------|-------------------------|
| Exposure time | : 72 Weeks |
| Dose | : 650 mg/kg body weight |
| Result | : negative |

| | |
|-------------------|-------------------------|
| Species | : Rat |
| Application Route | : Oral |
| Exposure time | : 104 Weeks |
| Dose | : 125 mg/kg body weight |
| Result | : negative |

Cellulose:

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

Sodium dodecyl sulphate:

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

Reproductive toxicity

Suspected of damaging fertility.

Components:

Boceprevir:

| | |
|------------------------------------|---|
| Effects on fertility | : Test Type: Fertility/early embryonic development Species: Rat, male Fertility: LOAEL: 75 mg/kg body weight Symptoms: Effects on fertility Result: positive Test Type: Fertility/early embryonic development Species: Rat, female Fertility: LOAEL: 150 mg/kg body weight Symptoms: Effects on fertility Result: positive |
| Effects on foetal development | : Test Type: Development Species: Rabbit, male and female 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. |

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II

Cellulose:

| | |
|-------------------------------|---|
| Effects on fertility | : Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative |
| Effects on foetal development | : Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative |

Sodium dodecyl sulphate:

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

Magnesium stearate:

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|-------------------------------|--|
| 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.

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Repeated dose toxicity

Components:

Boceprevir:

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

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

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

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

Starch:

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

Cellulose:

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

Sodium dodecyl sulphate:

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|---------|-------------|
| Species | : Rat |
| NOAEL | : 488 mg/kg |

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|-------------------|--|
| 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:

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| Ingestion | : Symptoms: Headache, Gastrointestinal disturbance, bitter taste |
|-----------|--|

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Boceprevir:

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|--|--|
| 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 |

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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

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 : EL50 (*Pseudokirchneriella subcapitata* (green algae)): > 1

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| | | |
|----------------------------|---|---|
| plants | | 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:

| | | |
|------------------|---|--|
| 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 |
|-----------------|---|---|

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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

13. DISPOSAL CONSIDERATIONS

Disposal methods

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

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

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable

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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 : no

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

GB 6944/12268

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Marine pollutant : no

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

National regulatory information

Law on the Prevention and Control of Occupational Diseases

Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals : This product is not listed in the catalogue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of determination.

Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218) : Not listed

Hazardous Chemicals for Priority Management under SAWS : Not listed

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Catalogue of Specially Controlled Hazardous Chemicals : Not listed

List of Explosive Precursors : Not listed

Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals : Not listed

Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import and Export : Not listed

Regulation on the Administration of Precursor Chemicals

Catalogue and Classification of Precursor Chemicals : Not listed

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

Regulations of Ozone Depleting Substances Management

List of Controlled Ozone Depleting Substances Import and Export : Not listed

List of Controlled Ozone Depleting Substances : Not listed

Environmental Protection Law

List of Priority Controlled Chemicals : Not listed

List of Key Controlled New Pollutants : Not listed

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 2025/04/14

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/>

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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)
CN OEL : Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.

ACGIH / TWA : 8-hour, time-weighted average
CN OEL / PC-TWA : Permissible concentration - time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Disclaimer

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.

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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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