

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Grazoprevir Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2025/04/14 |
| 6.1 | 2025/08/07 | 402566-00023 | Date of first issue: 2016/01/07 |

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Grazoprevir 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 | : No data available |
| Odour | : No data available |

Causes mild skin irritation. May cause damage to organs through prolonged or repeated exposure. Harmful to aquatic life.

GHS Classification

Skin corrosion/irritation : Category 3

Specific target organ toxicity - repeated exposure : Category 2

Short-term (acute) aquatic hazard : Category 3

GHS label elements

Hazard pictograms :



Signal word : Warning

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Hazard statements : H316 Causes mild skin irritation.
H373 May cause damage to organs through prolonged or repeated exposure.
H402 Harmful to aquatic life.

Precautionary statements : **Prevention:**
P260 Do not breathe dust.
P273 Avoid release to the environment.
Response:
P319 Get medical help if you feel unwell.
P332 + P317 If skin irritation occurs: Get medical help.
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. May cause damage to organs through prolonged or repeated exposure.

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) |
|-------------------------|--------------|-----------------------|
| Grazoprevir | 1350462-55-3 | >= 10 -< 20 |
| Sodium chloride | 7647-14-5 | >= 10 -< 20 |
| Sodium dodecyl sulphate | 151-21-3 | >= 1 -< 2.5 |
| 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 advice.

If inhaled : If inhaled, remove to fresh air.

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|-------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| In case of skin contact | : Get medical attention if symptoms occur. 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 if symptoms occur. Rinse mouth thoroughly with water. |
| Most important symptoms and effects, both acute and delayed | : Headache Gastrointestinal discomfort Dust contact with the eyes can lead to mechanical irritation. Causes mild skin irritation. May cause damage to organs through prolonged or repeated exposure. |
| 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 Chlorine compounds 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.

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Avoidance of contact : Oxidizing agents

Storage

Conditions for safe storage : Keep in properly labelled containers.
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 |
|--------------------|--------------|-------------------------------------|------------------------------------------------|----------|
| Grazoprevir | 1350462-55-3 | TWA | 260 µg/m ³ (OEB 2) | Internal |
| 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 : Use feasible engineering controls to minimize exposure to compound.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

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 safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.

Hand protection

Material : Chemical-resistant gloves

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.

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When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|--------------------------------------------------|---|---------------------------------------------------------------------------------|
| Appearance | : | powder |
| Colour | : | No data available |
| 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 | : | Not applicable |
| Evaporation rate | : | Not applicable |
| Flammability (solid, gas) | : | May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids) | : | No data available |
| 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 |
| Partition coefficient: n- | : | Not applicable |

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octanol/water

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

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.

Product:

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

Components:

Grazoprevir:

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

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Sodium chloride:

| | |
|---------------------------|-----------------------------------------------------------------------------|
| Acute oral toxicity | : LD50 (Rat): 3,550 mg/kg |
| Acute inhalation toxicity | : LC50 (Rat): > 42 mg/l Exposure time: 1 h Test atmosphere: dust/mist |
| Acute dermal toxicity | : LD50 (Rabbit): > 5,000 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.

Components:

Grazoprevir:

| | |
|--------|----------------------|
| Result | : No skin irritation |
|--------|----------------------|

Sodium chloride:

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

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Serious eye damage/eye irritation

Not classified based on available information.

Components:

Grazoprevir:

| | | |
|---------|---|-------------------|
| Species | : | Bovine cornea |
| Result | : | No eye irritation |

Sodium chloride:

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

Grazoprevir:

| | | |
|-----------------|---|-------------------------------|
| Test Type | : | Local lymph node assay (LLNA) |
| Exposure routes | : | Dermal |
| Result | : | Not a skin sensitizer. |

Sodium chloride:

| | | |
|-----------------|---|-------------------------------|
| Test Type | : | Local lymph node assay (LLNA) |
| Exposure routes | : | Skin contact |
| Species | : | Mouse |
| Result | : | negative |

Sodium dodecyl sulphate:

| | | |
|-----------|---|-------------------|
| Test Type | : | Maximisation Test |
|-----------|---|-------------------|

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

Grazoprevir:

| | | |
|-------------------------------------|---|--------------------------------------------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: Chromosome aberration test in vitro Result: negative |
| Genotoxicity in vivo | : | Test Type: In vivo micronucleus test Application Route: Oral Result: negative |
| Germ cell mutagenicity - Assessment | : | Weight of evidence does not support classification as a germ cell mutagen. |

Sodium chloride:

| | | |
|-----------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vitro | : | Test Type: In vitro mammalian cell gene mutation test Result: positive Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: Saccharomyces cerevisiae, gene mutation assay (in vitro) Result: positive Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Result: positive Test Type: Chromosome aberration test in vitro Result: positive |
|-----------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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| | |
|----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | Test Type: Chromosome aberration test in vitro Result: negative |
| Genotoxicity in vivo | : Test Type: In vivo micronucleus test Species: Mouse Application Route: Intraperitoneal injection Result: negative |
| | Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Rat Application Route: Intraperitoneal injection Result: positive |
| Germ cell mutagenicity - Assessment | : Weight of evidence does not support classification as a germ cell mutagen. |

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.

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Components:

Sodium chloride:

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

Not classified based on available information.

Components:

Grazoprevir:

| | | |
|-------------------------------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility | : | Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 400 mg/kg body weight Result: negative Test Type: Multi-generation study Species: Rat Application Route: Oral Fertility: NOAEL: 400 mg/kg body weight Result: No effects on fertility, No effects on foetal development |
| Effects on foetal development | : | Test Type: Embryo-foetal development Species: Rat Application Route: Oral Embryo-foetal toxicity: NOAEL: 200 mg/kg body weight Result: No effects on foetal development Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Embryo-foetal toxicity: NOAEL: 200 mg/kg body weight Result: No effects on foetal development Test Type: Embryo-foetal development Species: Rabbit Application Route: Intravenous Embryo-foetal toxicity: NOAEL: 100 mg/kg body weight |

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Result: No effects on foetal development

Sodium dodecyl sulphate:

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

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

Magnesium stearate:

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

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

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Grazoprevir:

Target Organs : Liver, Testis
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Grazoprevir:

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Species : Rat
NOAEL : 400 mg/kg
Application Route : Oral
Exposure time : 30 Days
Remarks : No significant adverse effects were reported

Species : Rat
NOAEL : 400 mg/kg
Application Route : Oral
Exposure time : 180 Days
Remarks : No significant adverse effects were reported

Species : Dog
NOAEL : 15 mg/kg
LOAEL : 100 mg/kg
Application Route : Oral
Exposure time : 270 Days
Target Organs : Liver, Blood, Bone marrow, gallbladder, spleen, Testis

Species : Mouse
NOAEL : 200 mg/kg
LOAEL : 500 mg/kg
Application Route : Oral
Exposure time : 90 Days
Target Organs : Liver, Kidney, Blood

Species : Dog
NOAEL : 20 mg/kg
LOAEL : 600 mg/kg
Application Route : Oral
Exposure time : 30 Days
Target Organs : Blood, Testis

Species : Monkey
NOAEL : 10 mg/kg
Exposure time : 8 Days
Remarks : No significant adverse effects were reported

Sodium chloride:

Species : Rat
LOAEL : 2,533 mg/kg
Application Route : Ingestion
Exposure time : 2 yr

Sodium dodecyl sulphate:

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

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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:

Grazoprevir:

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Grazoprevir:

| | | |
|-----------------------------------------------------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish | : | LC50 (Cyprinodon variegatus (sheepshead minnow)): > 10 mg/l Exposure time: 96 h Remarks: No toxicity at the limit of solubility |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 10 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility LC50 (Americamysis): 8.9 mg/l Exposure time: 96 h |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 10 mg/l Exposure time: 72 hrs Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility NOEC (Pseudokirchneriella subcapitata (green algae)): 10 mg/l Exposure time: 72 hrs Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility |

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Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.98 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 5 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 1.3 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Sodium chloride:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 5,840 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 4,136 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50: > 2,000 mg/l
Exposure time: 96 h

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 252 mg/l
Exposure time: 33 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia pulex (Water flea)): 314 mg/l
Exposure time: 21 d

Toxicity to microorganisms : EC10: > 1,000 mg/l

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

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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:

Grazoprevir:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 66 %

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Exposure time: 28 d

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:

Grazoprevir:

Bioaccumulation : Species: *Lepomis macrochirus* (Bluegill sunfish)
Bioconcentration factor (BCF): 7.62

Partition coefficient: n-octanol/water : log Pow: 3.72

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:

Grazoprevir:

Distribution among environmental compartments : log Koc: 4.01

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.

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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 |
| 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

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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

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

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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 : 2025/08/07

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 : 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; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recom-

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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. 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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