

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Grazoprevir / Elbasvir Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 14.04.2025 |
| 6.3 | 07.08.2025 | 76523-00033 | Date of first issue: 17.03.2015 |

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Grazoprevir / Elbasvir Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Long-term (chronic) aquatic hazard, Category 1

H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Warning

Hazard statements : H410 Very toxic to aquatic life with long lasting effects.

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Precautionary statements : **Prevention:**
P273 Avoid release to the environment.
Response:
P391 Collect spillage.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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

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

Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|---------------|---|--|--------------------------|
| Grazoprevir | 1350462-55-3 | STOT RE 2; H373 (Liver, Testis) | >= 1 - < 10 |
| Elbasvir | 1370468-36-2 | Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 10 | >= 2,5 - < 10 |

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

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vice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : Wash with water and soap.
Get medical attention if symptoms occur.

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Metal oxides
Chlorine compounds

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Nitrogen oxides (NO_x)

5.3 Advice for firefighters

- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- Personal precautions : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

- Environmental precautions : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

- Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Technical measures : Static electricity may accumulate and ignite suspended dust

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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 breathe dust.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

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

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Dust 5 mg/m³
Value type (Form of exposure): TWA (respirable dust)
Basis: FOR-2011-12-06-1358

10 mg/m³
Value type (Form of exposure): TWA (total dust)
Basis: FOR-2011-12-06-1358

| Components | CAS-No. | Value type (Form | Control parameters | Basis |
|------------|---------|------------------|--------------------|-------|
|------------|---------|------------------|--------------------|-------|

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| | | of exposure) | | |
|-------------|--------------|--------------|-------------------------------|----------|
| Grazoprevir | 1350462-55-3 | TWA | 260 µg/m ³ (OEB 2) | Internal |
| Elbasvir | 1370468-36-2 | TWA | 150 µg/m ³ (OEB 2) | Internal |

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|-----------------|-----------|-----------------|----------------------------|---------------------------|
| Sodium chloride | Workers | Inhalation | Long-term systemic effects | 2068,62 mg/m ³ |
| | Workers | Inhalation | Acute systemic effects | 2068,62 mg/m ³ |
| | Workers | Skin contact | Long-term systemic effects | 295,52 mg/kg bw/day |
| | Workers | Skin contact | Acute systemic effects | 295,52 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 443,28 mg/m ³ |
| | Consumers | Inhalation | Acute systemic effects | 443,28 mg/m ³ |
| | Consumers | Skin contact | Long-term systemic effects | 126,65 mg/kg bw/day |
| | Consumers | Skin contact | Acute systemic effects | 126,65 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 126,65 mg/kg bw/day |
| | Consumers | Ingestion | Acute systemic effects | 126,65 mg/kg bw/day |

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

| Substance name | Environmental Compartment | Value |
|-----------------|---------------------------|------------------------------|
| Sodium chloride | Fresh water | 5 mg/l |
| | Sewage treatment plant | 500 mg/l |
| | Soil | 4,86 mg/kg dry weight (d.w.) |

8.2 Exposure controls

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

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.

Hand protection

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| | | |
|--------------------------|---|---|
| Material | : | Chemical-resistant gloves |
| Skin and body protection | : | Work uniform or laboratory coat. |
| Respiratory protection | : | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS EN 143 |
| Filter type | : | Particulates type (P) |

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

| | | |
|--|---|---|
| Physical state | : | powder |
| Colour | : | white |
| Odour | : | No data available |
| Odour Threshold | : | No data available |
| Melting point/freezing point | : | No data available |
| 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) | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Flash point | : | Not applicable |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| pH | : | No data available |
| Viscosity | : | |
| Viscosity, kinematic | : | Not applicable |
| Solubility(ies) | : | |
| Water solubility | : | No data available |

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| | | |
|---|---|-------------------|
| Partition coefficient: n-octanol/water | : | Not applicable |
| Vapour pressure | : | Not applicable |
| Relative density | : | No data available |
| Density | : | No data available |
| Relative vapour density | : | Not applicable |
| Particle characteristics Particle size | : | No data available |

9.2 Other information

| | | |
|----------------------|---|--|
| Explosives | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Evaporation rate | : | Not applicable |

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

| | | |
|---------------------|---|--|
| Hazardous reactions | : | May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents. |
|---------------------|---|--|

10.4 Conditions to avoid

| | | |
|---------------------|---|---|
| Conditions to avoid | : | Heat, flames and sparks. Avoid dust formation. |
|---------------------|---|---|

10.5 Incompatible materials

| | | |
|--------------------|---|------------------|
| Materials to avoid | : | Oxidizing agents |
|--------------------|---|------------------|

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation

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| | |
|----------|--------------|
| exposure | Skin contact |
| | Ingestion |
| | Eye contact |

Acute toxicity

Not classified based on available information.

Components:

Grazoprevir:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg

Elbasvir:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg

LD50 (Mouse): > 1.000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Grazoprevir:

Result : No skin irritation

Elbasvir:

Species : reconstructed human epidermis (RhE)

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Grazoprevir:

Species : Bovine cornea

Result : No eye irritation

Elbasvir:

Species : Bovine cornea

Result : No eye irritation

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:

Grazoprevir:

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

Elbasvir:

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

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

Elbasvir:

| | |
|-----------------------|--|
| 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 Species: Rat Application Route: Oral Result: negative |
|----------------------|---|

| | |
|------------------------------------|--|
| Germ cell mutagenicity- Assessment | : Weight of evidence does not support classification as a germ cell mutagen. |
|------------------------------------|--|

Carcinogenicity

Not classified based on available information.

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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
Result: No effects on foetal development

Elbasvir:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat, male and female
Application Route: Oral
Fertility: NOAEL: 1.000 mg/kg body weight
Result: No effects on fertility

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 1.000 mg/kg body weight
Result: No effects on early embryonic development

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 1.000 mg/kg body weight

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Result: No effects on early embryonic development

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

Grazoprevir:

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

Repeated dose toxicity

Components:

Grazoprevir:

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

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

Elbasvir:

Species : Rat
NOAEL : 1.000 mg/kg
Application Route : Oral
Exposure time : 180 d
Remarks : No significant adverse effects were reported

Species : Dog
NOAEL : 1.000 mg/kg
Application Route : Oral
Exposure time : 270 d
Remarks : No significant adverse effects were reported

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Not classified based on available information.

Product:

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

Experience with human exposure

Components:

Grazoprevir:

Ingestion : Symptoms: Headache, Gastrointestinal disturbance

Elbasvir:

Ingestion : Symptoms: Headache, Abdominal pain, constipation, Nausea, Fatigue, muscle pain, joint pain, Dizziness, Cough, Skin irritation, rhinitis, Drowsiness, nasal congestion

SECTION 12: Ecological information

12.1 Toxicity

Components:

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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

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

Toxicity to fish (Chronic toxicity) : NOEC: 0,98 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210
Remarks: No toxicity at the limit of solubility

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

Elbasvir:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 10 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: No toxicity at the limit of solubility

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| | | LC50 (Menidia beryllina (Silverside)): > 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): 7,7 mg/l Exposure time: 96 h Method: US-EPA OPPTS 850.1035 Remarks: No toxicity at the limit of solubility |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (algae)): > 0,081 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility |
| | | NOEC (Pseudokirchneriella subcapitata (green algae)): 0,081 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility |
| Toxicity to microorganisms | : | EC50 : > 1.000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 |
| | | NOEC : 271,9 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 |
| Toxicity to fish (Chronic toxicity) | : | NOEC: 0,0023 mg/l Exposure time: 32 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: 0,84 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211 Remarks: No toxicity at the limit of solubility |
| M-Factor (Chronic aquatic toxicity) | : | 10 |

12.2 Persistence and degradability

Components:

Grazoprevir:

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Biodegradability : Result: Not readily biodegradable.
Biodegradation: 66 %
Exposure time: 28 d

Elbasvir:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 37 %
Exposure time: 28 d

12.3 Bioaccumulative potential

Components:

Grazoprevir:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 7,62

Partition coefficient: n-octanol/water : log Pow: 3,72

Elbasvir:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 82
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 6,54

12.4 Mobility in soil

Components:

Grazoprevir:

Distribution among environmental compartments : log Koc: 4,01

Elbasvir:

Distribution among environmental compartments : log Koc: 5,24

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to

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REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

| | |
|------------------------|---|
| Product | : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer. |
| Contaminated packaging | : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product. |

SECTION 14: Transport information

14.1 UN number or ID number

| | |
|------|-----------|
| ADN | : UN 3077 |
| ADR | : UN 3077 |
| RID | : UN 3077 |
| IMDG | : UN 3077 |
| IATA | : UN 3077 |

14.2 UN proper shipping name

| | |
|------|---|
| ADN | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Elbasvir) |
| ADR | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Elbasvir) |
| RID | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Elbasvir) |
| IMDG | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Elbasvir) |
| IATA | : Environmentally hazardous substance, solid, n.o.s. (Elbasvir) |

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14.3 Transport hazard class(es)

| | Class | Subsidiary risks |
|-------------|-------|------------------|
| ADN | : 9 | |
| ADR | : 9 | |
| RID | : 9 | |
| IMDG | : 9 | |
| IATA | : 9 | |

14.4 Packing group

| | |
|--|-----------------|
| ADN | |
| Packing group | : III |
| Classification Code | : M7 |
| Hazard Identification Number | : 90 |
| Labels | : 9 |
| ADR | |
| Packing group | : III |
| Classification Code | : M7 |
| Hazard Identification Number | : 90 |
| Labels | : 9 |
| Tunnel restriction code | : (-) |
| RID | |
| Packing group | : III |
| Classification Code | : M7 |
| Hazard Identification Number | : 90 |
| Labels | : 9 |
| IMDG | |
| Packing group | : III |
| Labels | : 9 |
| EmS Code | : F-A, S-F |
| IATA (Cargo) | |
| Packing instruction (cargo aircraft) | : 956 |
| Packing instruction (LQ) | : Y956 |
| Packing group | : III |
| Labels | : Miscellaneous |
| IATA (Passenger) | |
| Packing instruction (passenger aircraft) | : 956 |
| Packing instruction (LQ) | : Y956 |
| Packing group | : III |
| Labels | : Miscellaneous |

14.5 Environmental hazards

| | |
|---------------------------|-------|
| ADN | |
| Environmentally hazardous | : yes |
| ADR | |

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

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

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| | | | |
|----|--------------------------|---------------------|---------------------|
| E1 | ENVIRONMENTAL HAZARDS | Quantity 1 100 t | Quantity 2 200 t |
|----|--------------------------|---------------------|---------------------|

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

| | |
|-------|------------------|
| AICS | : not determined |
| DSL | : not determined |
| IECSC | : not determined |

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

| | |
|------|---|
| H373 | : May cause damage to organs through prolonged or repeated exposure if swallowed. |
| H410 | : Very toxic to aquatic life with long lasting effects. |

Full text of other abbreviations

| | |
|---------------------------|--|
| Aquatic Chronic | : Long-term (chronic) aquatic hazard |
| STOT RE | : Specific target organ toxicity - repeated exposure |
| FOR-2011-12-06-1358 | : Norway. Occupational Exposure limits |
| FOR-2011-12-06-1358 / TWA | : Long term exposure limit |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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;

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NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

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/>

Classification of the mixture:

Aquatic Chronic 1 H410

Classification procedure:

Calculation method

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.

NO / EN