

Ribavirin Liquid Formulation

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| Version | Revision Date: | SDS Number: | Date of last issue: 30.09.2023 |
| 3.5 | 06.04.2024 | 402728-00020 | Date of first issue: 10.12.2015 |

SECTION 1: IDENTIFICATION

Product name : Ribavirin Liquid Formulation

Manufacturer or supplier's details

Company : MSD

Address : Building A - Level 1/26 Talavera Rd
Macquarie Park NSW, Australia 2113

Telephone : 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Germ cell mutagenicity : Category 2

Reproductive toxicity : Category 1B

Specific target organ toxicity - : Category 2 (Blood)
repeated exposure (Oral)

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H341 Suspected of causing genetic defects.
H360Df May damage the unborn child. Suspected of damaging fertility.
H373 May cause damage to organs (Blood) through prolonged or repeated exposure if swallowed.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read

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and understood.

P260 Do not breathe mist or vapours.

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

Response:

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

Storage:

P405 Store locked up.

Disposal:

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

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|------------------|------------|-----------------------|
| Sucrose | 57-50-1 | >= 30 -< 60 |
| Propylene glycol | 57-55-6 | >= 10 -< 30 |
| Glycerine | 56-81-5 | >= 10 -< 30 |
| Ribavirin | 36791-04-5 | >= 1 -< 10 |

SECTION 4. FIRST AID MEASURES

| | |
|---|---|
| General advice | : In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice. |
| If inhaled | : If inhaled, remove to fresh air. Get medical attention. |
| In case of skin contact | : In case of contact, immediately flush skin with soap and 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 | : Flush eyes with water as a precaution. 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 | : Suspected of causing genetic defects. May damage the unborn child. Suspected of damaging fertili- |

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| delayed | ty. |
| | May cause damage to organs through prolonged or repeated exposure if swallowed. |
| 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. |

SECTION 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 | : Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : Carbon 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. |

SECTION 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. Prevent spreading over a wide area (e.g. by containment or oil barriers). 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 | : Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items |

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

SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.
Do not breathe mist or vapours.
Do not swallow.
Avoid contact with eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Do not eat, drink or smoke when using this product.
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.
- Conditions for safe storage : Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Components with workplace control parameters**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|------------------|---------|----------------------------------|--|--------|
| Sucrose | 57-50-1 | TWA | 10 mg/m ³ | AU OEL |
| | | TWA | 10 mg/m ³ | ACGIH |
| Propylene glycol | 57-55-6 | TWA (particulate) | 10 mg/m ³ | AU OEL |

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|-----------|------------|------------------------------------|----------------------------------|----------|
| | | TWA (Total (vapour and particles)) | 150 ppm 474 mg/m ³ | AU OEL |
| Glycerine | 56-81-5 | TWA (Mist) | 10 mg/m ³ | AU OEL |
| Ribavirin | 36791-04-5 | Wipe limit | 400 µg/100 cm ² | Internal |
| | | TWA | 40 µg/m ³ (OEB 3) | Internal |

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

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 : Combined particulates and organic vapour type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye 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.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : clear

Odour : No data available

Odour Threshold : No data available

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|--|---|--|
| pH | : | 4.8 - 5.5 |
| 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) | : | Not applicable |
| 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 | : | No data available |
| Relative vapour density | : | No data available |
| Relative density | : | No data available |
| Density | : | No data available |
| Solubility(ies) Water solubility | : | 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. |
| Particle characteristics Particle size | : | Not applicable |

SECTION 10. STABILITY AND REACTIVITY

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| Reactivity | : | Not classified as a reactivity hazard. |
| Chemical stability | : | Stable under normal conditions. |
| Possibility of hazardous reactions | : | Can react with strong oxidizing agents. |
| Conditions to avoid | : | None known. |
| Incompatible materials | : | Oxidizing agents |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

SECTION 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: > 2,000 mg/kg Method: Calculation method |
|---------------------|---|--|

Components:**Sucrose:**

| | | |
|---------------------|---|--------------------------|
| Acute oral toxicity | : | LD50 (Rat): 29,700 mg/kg |
|---------------------|---|--------------------------|

Propylene glycol:

| | | |
|---------------------|---|--------------------------|
| Acute oral toxicity | : | LD50 (Rat): 22,000 mg/kg |
|---------------------|---|--------------------------|

| | | |
|---------------------------|---|---|
| Acute inhalation toxicity | : | LC50 (Rat): > 44.9 mg/l Exposure time: 4 h Test atmosphere: dust/mist |
|---------------------------|---|---|

| | | |
|-----------------------|---|---|
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg Assessment: The substance or mixture has no acute dermal toxicity |
|-----------------------|---|---|

Glycerine:

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

| | | |
|-----------------------|---|----------------------------------|
| Acute dermal toxicity | : | LD50 (Guinea pig): > 5,000 mg/kg |
|-----------------------|---|----------------------------------|

Ribavirin:

| | | |
|---------------------|---|---|
| Acute oral toxicity | : | LD50 (Rat): 4,116 - 5,584 mg/kg LD50 (Mouse): > 10,000 mg/kg LD50 (Dog): >= 1,500 mg/kg |
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Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : LD50 (Rat): 1,554 - 1,758 mg/kg
Application Route: Intraperitoneal

LD50 (Mouse): 1,268 mg/kg
Application Route: Intraperitoneal

Skin corrosion/irritation

Not classified based on available information.

Components:**Propylene glycol:**

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Glycerine:

Species : Rabbit
Result : No skin irritation

Ribavirin:

Remarks : No data available
May irritate skin.

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Propylene glycol:**

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

Glycerine:

Species : Rabbit
Result : No eye irritation

Ribavirin:

Remarks : No data available
May irritate eyes.

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Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Propylene glycol:**

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

Ribavirin:

| | | |
|---------|---|-------------------|
| Remarks | : | No data available |
|---------|---|-------------------|

Chronic toxicity**Germ cell mutagenicity**

Suspected of causing genetic defects.

Components:**Sucrose:**

| | | |
|-----------------------|---|---|
| Genotoxicity in vitro | : | Test Type: In vitro mammalian cell gene mutation test |
| | | Result: negative |

Propylene glycol:

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

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

| | | |
|----------------------|---|--|
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) |
| | | Species: Mouse |
| | | Application Route: Intraperitoneal injection |
| | | Result: negative |

Glycerine:

| | | |
|-----------------------|---|---|
| Genotoxicity in vitro | : | Test Type: In vitro mammalian cell gene mutation test |
| | | Result: negative |

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

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Test Type: Chromosome aberration test in vitro

Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)

Result: negative

Ribavirin:

Genotoxicity in vitro

: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: Rodent cell line

Result: positive

Test Type: Chromosomal aberration

Test system: Human lymphocytes

Result: negative

Genotoxicity in vivo

: Test Type: dominant lethal test
Species: Rat
Result: negative

Test Type: Mouse Lymphoma

Species: Mouse

Result: positive

Test Type: Micronucleus test

Species: Mouse

Result: positive

Germ cell mutagenicity -
Assessment

: Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

Carcinogenicity

Not classified based on available information.

Components:**Propylene glycol:**

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

Glycerine:

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

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Ribavirin:

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|-------------------|--|
| Species | : Mouse |
| Application Route | : Oral |
| Exposure time | : 6 Months |
| LOAEL | : 75 mg/kg body weight |
| Result | : negative |
| Target Organs | : Blood, Testes |
| Remarks | : The mechanism or mode of action may not be relevant in humans. |

| | |
|-------------------|--|
| Species | : Rat |
| Application Route | : Oral |
| Exposure time | : 2 Years |
| NOAEL | : 10 mg/kg body weight |
| Result | : negative |
| Remarks | : The mechanism or mode of action may not be relevant in humans. |

| | |
|-------------------|--|
| Species | : Mouse |
| Application Route | : Oral |
| Exposure time | : 18 Months |
| Result | : negative |
| Remarks | : The mechanism or mode of action may not be relevant in humans. |

Reproductive toxicity

May damage the unborn child. Suspected of damaging fertility.

Components:**Propylene glycol:**

| | |
|----------------------|---|
| Effects on fertility | : Test Type: Two-generation reproduction toxicity study Species: Mouse Application Route: Ingestion Result: negative |
|----------------------|---|

| | |
|-------------------------------|--|
| Effects on foetal development | : Test Type: Embryo-foetal development Species: Mouse Application Route: Ingestion Result: negative |
|-------------------------------|--|

Glycerine:

| | |
|----------------------|---|
| Effects on fertility | : Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative |
|----------------------|---|

| | |
|-------------------------------|--|
| Effects on foetal development | : Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative |
|-------------------------------|--|

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Ribavirin:

Effects on fertility

- : Test Type: Fertility
Species: Rat, male
Application Route: Intraperitoneal injection
Fertility: LOAEL: < 20 mg/kg body weight
Symptoms: Reduced fertility
Result: positive
- Test Type: Fertility
Species: Mouse, male
Application Route: Oral
Fertility: LOAEL: 35 mg/kg body weight
Symptoms: Reduced fertility
Result: positive
- Test Type: Fertility
Species: Rat, females
Application Route: Oral
Fertility: NOAEL: 10 mg/kg body weight
Result: Animal testing did not show any effects on fertility.
- Test Type: Fertility
Species: Rat, male
Application Route: Oral
Fertility: NOAEL: 160 mg/kg body weight
Result: Animal testing did not show any effects on fertility.

Effects on foetal development

- : Test Type: Development
Species: Rat, female
Application Route: Oral
Developmental Toxicity: LOAEL: <= 1 mg/kg body weight
Symptoms: Reduced body weight, Reduced number of viable fetuses, Skeletal malformations
Result: Embryotoxic effects and adverse effects on the offspring were detected.
- Test Type: Development
Species: Rabbit, female
Application Route: Oral
General Toxicity Maternal: LOAEL: 1 mg/kg body weight
Developmental Toxicity: LOAEL: 1 mg/kg body weight
Symptoms: Reduced body weight, Skeletal malformations
Result: Embryotoxic effects and adverse effects on the offspring were detected.
- Test Type: Development
Species: Hamster
Application Route: Oral
Developmental Toxicity: LOAEL: 2.5 mg/kg body weight
Symptoms: Skeletal and visceral variations, Total Resorptions / resorption rate

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Result: Embryotoxic effects and adverse effects on the offspring were detected.

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
General Toxicity Maternal: NOAEL: 0.3 mg/kg body weight
Embryo-foetal toxicity: LOAEL: 1 mg/kg body weight
Symptoms: Skeletal malformations
Result: positive

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments.

STOT - single exposure

Not classified based on available information.

Components:**Ribavirin:**

Assessment : May cause respiratory irritation.

STOT - repeated exposure

May cause damage to organs (Blood) through prolonged or repeated exposure if swallowed.

Components:**Ribavirin:**

Exposure routes : Ingestion
Target Organs : Blood
Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Components:****Propylene glycol:**

Species : Rat, male
NOAEL : $\geq 1,700$ mg/kg
Application Route : Ingestion
Exposure time : 2 yr

Glycerine:

Species : Rat
NOAEL : 0.167 mg/l
LOAEL : 0.622 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 13 Weeks

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Species : Rat
NOAEL : 8,000 - 10,000 mg/kg
Application Route : Ingestion
Exposure time : 2 yr

Species : Rabbit
NOAEL : 5,040 mg/kg
Application Route : Skin contact
Exposure time : 45 Weeks

Ribavirin:

Species : Monkey
LOAEL : 30 mg/kg
Exposure time : 10 d
Target Organs : Blood, Gastrointestinal tract

Species : Rat
NOAEL : 7.6 mg/kg
Application Route : Inhalation
Exposure time : 90 d
Target Organs : Blood, Lungs

Species : Dog
NOAEL : 5 mg/kg
Application Route : Oral
Exposure time : 1 yr
Target Organs : Blood, Gastrointestinal tract

Species : Mouse
NOAEL : 20 mg/kg
Application Route : Oral
Exposure time : 18 Months
Target Organs : Blood, Cardio-vascular system

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Ribavirin:**

Inhalation : Symptoms: Headache, Dizziness
Remarks: Based on Human Evidence

Skin contact : Remarks: May cause eye irritation.
Based on Human Evidence

Eye contact : Remarks: May cause eye irritation.
Based on Human Evidence

Ingestion : Symptoms: blood effects, immune system effects, anorexia,
Dizziness, insomnia, Fatigue, Headache, Itching, Rash, liver
function change, Gastrointestinal disturbance

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SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:**Propylene glycol:**

| | | |
|--|---|---|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l Exposure time: 7 d |
| Toxicity to microorganisms | : | NOEC (Pseudomonas putida): > 20,000 mg/l Exposure time: 18 h |

Glycerine:

| | | |
|---|---|--|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 1,955 mg/l Exposure time: 48 h |
| Toxicity to microorganisms | : | NOEC (Pseudomonas putida): > 10,000 mg/l Exposure time: 16 h Method: DIN 38 412 Part 8 |

Ribavirin:

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): > 119 mg/l Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 117 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 119 mg/l Exposure time: 96 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 6.9 mg/l Exposure time: 96 h |

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Method: OECD Test Guideline 201

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

Persistence and degradability**Components:****Propylene glycol:**

Biodegradability : Result: Readily biodegradable.
Biodegradation: 98.3 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

Glycerine:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 %
Exposure time: 30 d
Method: OECD Test Guideline 301D

Bioaccumulative potential**Components:****Sucrose:**

Partition coefficient: n-octanol/water : Pow: < 1

Propylene glycol:

Partition coefficient: n-octanol/water : log Pow: -1.07
Method: Regulation (EC) No. 440/2008, Annex, A.8

Glycerine:

Partition coefficient: n-octanol/water : log Pow: -1.75

Ribavirin:

Partition coefficient: n-octanol/water : log Pow: 0.971

Mobility in soil

No data available

Other adverse effects

No data available

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| | | | |
|---------|----------------|--------------|---------------------------------|
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SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

| | | |
|------------------------|---|---|
| Waste from residues | : | Do not dispose of waste into sewer. Dispose of in accordance with local regulations. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product. |

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

| | | |
|---------------------------|---|----------------|
| UN number | : | Not applicable |
| 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 | : | Not applicable |

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

Not applicable for product as supplied.

National Regulations**ADG**

| | | |
|----------------------|---|----------------|
| UN number | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class | : | Not applicable |

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| | | |
|-----------------|---|----------------|
| Subsidiary risk | : | Not applicable |
| Packing group | : | Not applicable |
| Labels | : | Not applicable |
| Hazchem Code | : | Not applicable |

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

| | | |
|---|---|--|
| Therapeutic Goods (Poisons Standard) Instrument | : | No poison schedule number allocated (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical) |
|---|---|--|

| | | |
|------------------------------------|---|---|
| Prohibition/Licensing Requirements | : | There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations. |
|------------------------------------|---|---|

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

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

SECTION 16: ANY OTHER RELEVANT INFORMATION**Further information**

| | | |
|---|---|---|
| Revision Date | : | 06.04.2024 |
| Sources of key data used to compile the Safety Data Sheet | : | Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/ |
| Date format | : | dd.mm.yyyy |

Full text of other abbreviations

| | | |
|--------------|---|--|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| AU OEL | : | Australia. Workplace Exposure Standards for Airborne Contaminants. |
| ACGIH / TWA | : | 8-hour, time-weighted average |
| AU OEL / TWA | : | Exposure standard - 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

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

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.

AU / EN