# SAFETY DATA SHEET

# Ribavirin Liquid Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
|---|---|---|---|
| 5.1 | 30.09.2023 | 402761-00019 | Date of first issue: 10.12.2015 |

## Section 1: Identification

Product name : Ribavirin Liquid Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800 CHEMCALL)

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: Hazard identification

**GHS Classification**

Germ cell mutagenicity : Category 2

Reproductive toxicity : Category 1

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

**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.
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 -< 50 |
| Glycerine | 56-81-5 | >= 20 -< 30 |
| Propylene glycol | 57-55-6 | >= 20 -< 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 : Suspected of causing genetic defects.

| | | |
|---|---|---|
| and effects, both acute and delayed | | May damage the unborn child. Suspected of damaging fertility.<br>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: Fire-fighting measures

| | | |
|---|---|---|
| Suitable extinguishing media | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<br>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.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |

## Section 6: Accidental release measures

| | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g. by containment or oil barriers).<br>Retain and dispose of contaminated wash water.<br>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.<br>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.<br>Clean up remaining materials from spill with suitable absorbent.<br>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.

## 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.<br>Do not breathe mist or vapours.<br>Do not swallow.<br>Avoid contact with eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Do not eat, drink or smoke when using this product.<br>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.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>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.<br>Store locked up.<br>Keep tightly closed.<br>Store in accordance with the particular national regulations. |
| Materials to avoid | : | Do not store with the following product types:<br>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 | WES-TWA | 10 mg/m3 | NZ OEL |
| | | TWA | 10 mg/m3 | ACGIH |
| Propylene glycol | 57-55-6 | WES-TWA (particulate) | 10 mg/m3 | NZ OEL |

| | | | | |
|---|---|---|---|---|
| | | WES-TWA (Vapour and particulates) | 150 ppm<br>474 mg/m3 | NZ OEL |
| Glycerine | 56-81-5 | WES-TWA (Mist) | 10 mg/m3 | NZ OEL |
| Ribavirin | 36791-04-5 | Wipe limit | 400 µg/100 cm² | Internal |
| | | TWA | 40 µg/m3 (OEB 3) | Internal |

**Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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

| | | |
|---|---|---|
| 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 size | : | Not applicable |

**Section 10: Stability and reactivity**

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

**Glycerine:**

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

Acute dermal toxicity : LD50 (Guinea pig): > 5,000 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

**Ribavirin:**

Acute oral toxicity : LD50 (Rat): 4,116 - 5,584 mg/kg

LD50 (Mouse): > 10,000 mg/kg

LD50 (Dog): >= 1,500 mg/kg

| | | |
|---|---|---|
| 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<br>Application Route: Intraperitoneal<br><br>LD50 (Mouse): 1,268 mg/kg<br>Application Route: Intraperitoneal |

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**Glycerine:**

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

**Propylene glycol:**

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

**Ribavirin:**

| | | |
|---|---|---|
| Remarks | : | No data available<br>May irritate skin. |

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**Glycerine:**

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

**Propylene glycol:**

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

**Ribavirin:**

| | | |
|---|---|---|
| Remarks | : | No data available<br>May irritate eyes. |

**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<br>Result: negative |

**Glycerine:**

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

**Propylene glycol:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: Chromosome aberration test in vitro<br>Method: OECD Test Guideline 473<br>Result: negative |

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

**Ribavirin:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Test system: Rodent cell line<br>Result: positive<br><br>Test Type: Chromosomal aberration<br>Test system: Human lymphocytes<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: dominant lethal test<br>Species: Rat<br>Result: negative<br><br>Test Type: Mouse Lymphoma<br>Species: Mouse<br>Result: positive<br><br>Test Type: Micronucleus test<br>Species: Mouse<br>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:**

**Glycerine:**

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

**Propylene glycol:**

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

**Ribavirin:**

| | | |
|---|---|---|
| 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:**

**Glycerine:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Two-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |

**Propylene glycol:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Two-generation reproduction toxicity study<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |

**Ribavirin:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Fertility<br>Species: Rat, male<br>Application Route: Intraperitoneal injection<br>Fertility: LOAEL: < 20 mg/kg body weight<br>Symptoms: Reduced fertility<br>Result: positive<br><br>Test Type: Fertility<br>Species: Mouse, male<br>Application Route: Oral<br>Fertility: LOAEL: 35 mg/kg body weight<br>Symptoms: Reduced fertility<br>Result: positive<br><br>Test Type: Fertility<br>Species: Rat, females<br>Application Route: Oral<br>Fertility: NOAEL: 10 mg/kg body weight<br>Result: Animal testing did not show any effects on fertility.<br><br>Test Type: Fertility<br>Species: Rat, male<br>Application Route: Oral<br>Fertility: NOAEL: 160 mg/kg body weight<br>Result: Animal testing did not show any effects on fertility. |
| Effects on foetal development | : | Test Type: Development<br>Species: Rat, female<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: <= 1 mg/kg body weight<br>Symptoms: Reduced body weight, Reduced number of viable fetuses, Skeletal malformations<br>Result: Embryotoxic effects and adverse effects on the offspring were detected.<br><br>Test Type: Development<br>Species: Rabbit, female<br>Application Route: Oral<br>General Toxicity Maternal: LOAEL: 1 mg/kg body weight<br>Developmental Toxicity: LOAEL: 1 mg/kg body weight<br>Symptoms: Reduced body weight, Skeletal malformations<br>Result: Embryotoxic effects and adverse effects on the offspring were detected.<br><br>Test Type: Development<br>Species: Hamster<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 2.5 mg/kg body weight<br>Symptoms: Skeletal and visceral variations, Total Resorptions / resorption rate |

Result: Embryotoxic effects and adverse effects on the off-spring 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:**

**Glycerine:**

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

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 |

**Propylene glycol:**

| | | |
|---|---|---|
| Species | : | Rat, male |
| NOAEL | : | >= 1,700 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 2 yr |

**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<br>Remarks: Based on Human Evidence |
| Skin contact | : | Remarks: May cause eye irritation.<br>Based on Human Evidence |
| Eye contact | : | Remarks: May cause eye irritation.<br>Based on Human Evidence |
| Ingestion | : | Symptoms: blood effects, immune system effects, anorexia, Dizziness, insomnia, Fatigue, Headache, Itching, Rash, liver function change, Gastrointestinal disturbance |

## Section 12: Ecological information

### Ecotoxicity

**Components:**

**Glycerine:**

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

**Propylene glycol:**

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

**Ribavirin:**

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

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:**

**Glycerine:**

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

**Propylene glycol:**

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

**Bioaccumulative potential**

**Components:**

**Sucrose:**

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

**Glycerine:**

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

**Propylene glycol:**

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

**Ribavirin:**

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

**Mobility in soil**

No data available

**Other adverse effects**

No data available

## Section 13: Disposal considerations

### Disposal methods

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

**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

**NZS 5433**

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

**HSNO Approval Number**

not allocated

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

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

## Section 16: Other information

| | | |
|---|---|---|
| Revision Date | : | 30.09.2023 |

**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 | : | dd.mm.yyyy |

**Full text of other abbreviations**

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| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| NZ OEL | : | New Zealand. Workplace Exposure Standards for Atmospheric Contaminants |
| ACGIH / TWA | : | 8-hour, time-weighted average |
| NZ OEL / WES-TWA | : | Workplace 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 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 con-

centration; 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.

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