

## Ribavirin Liquid Formulation

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### SECTION 1. IDENTIFICATION

Product name : Ribavirin Liquid Formulation  
Other means of identification : No data available

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable


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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Germ cell mutagenicity : Category 2  
Reproductive toxicity : Category 1B  
Specific target organ toxicity : Category 1 (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.  
H372 Causes 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 and understood.  
P260 Do not breathe mist or vapors.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P280 Wear protective gloves, protective clothing, eye protection

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and face protection.

**Response:**

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

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards**

None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name    | Common Name/Synonym                                 | CAS No./Unique ID | Concentration (% w/w) | Trade secret |
|------------------|---|-------------------|-----------------------|--------------|
| Sucrose          | .alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl | 57-50-1*          | >= 15 - <= 40         | TSC          |
| Propylene glycol | 1,2-Propanediol                                     | 57-55-6*          | >= 10 - <= 30         | TSC          |
| Glycerine        | 1,2,3-Propanetriol                                  | 56-81-5*          | >= 10 - <= 30         | TSC          |
| Ribavirin        | No data available                                   | 36791-04-5*       | >= 3 - <= 7           | TSC          |

\* Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

### 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.

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- Most important symptoms and effects, both acute and delayed : Get medical attention.  
Rinse mouth thoroughly with water.  
Suspected of causing genetic defects.  
May damage the unborn child. Suspected of damaging fertility.  
Causes 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  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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 fire-fighters : 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.

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Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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 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 vapors.  
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.

Conditions for safe storage : Keep in properly labeled 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  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients 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 <sup>3</sup>                           | CA AB OEL |
|            |         | TWA (Total                    | 10 mg/m <sup>3</sup>                           | CA BC OEL |

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|                  |            |                                |                                 |           |
|------------------|------------|--------------------------------|---------------------------------|-----------|
|                  |            | dust)                          |                                 |           |
|                  |            | TWA (respirable dust fraction) | 3 mg/m <sup>3</sup>             | CA BC OEL |
|                  |            | TWAEV                          | 10 mg/m <sup>3</sup>            | CA QC OEL |
|                  |            | TWA                            | 10 mg/m <sup>3</sup>            | ACGIH     |
| Propylene glycol | 57-55-6    | TWA (Vapour and aerosols)      | 50 ppm<br>155 mg/m <sup>3</sup> | CA ON OEL |
|                  |            | TWA (aerosol)                  | 10 mg/m <sup>3</sup>            | CA ON OEL |
| Glycerine        | 56-81-5    | TWA (Mist)                     | 10 mg/m <sup>3</sup>            | CA AB OEL |
|                  |            | TWA (Mist)                     | 10 mg/m <sup>3</sup>            | CA BC OEL |
|                  |            | TWA (Respirable mist)          | 3 mg/m <sup>3</sup>             | CA BC OEL |
|                  |            | TWAEV (Mist)                   | 10 mg/m <sup>3</sup>            | CA QC OEL |
| Ribavirin        | 36791-04-5 | Wipe limit                     | 400 µg/100 cm <sup>2</sup>      | Internal  |
|                  |            | TWA                            | 40 µg/m <sup>3</sup> (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 vapor 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

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Hygiene measures : contaminated clothing.  
: 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.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : clear

Odor : No data available

Odor 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

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)  
Water solubility : No data available

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|  |   |  |
|--|---|--|
| Partition coefficient: n-octanol/water | : | Not applicable   |
| Autoignition 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   |

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### 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. |

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### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

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<br>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 |
|---------------------|---|--------------------------|

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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

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.

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### 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.

### **Respiratory or skin sensitization**

#### **Skin sensitization**

Not classified based on available information.

#### **Respiratory sensitization**

Not classified based on available information.

### Components:

#### **Propylene glycol:**

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative

#### **Ribavirin:**

Remarks : No data available

### **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

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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

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.

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### 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

#### **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:

#### **Propylene glycol:**

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

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Mouse

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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 fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

### 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 fetal 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

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

Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
General Toxicity Maternal: NOAEL: 0.3 mg/kg body weight  
Embryo-fetal 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

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

### Components:

#### Ribavirin:

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

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### Repeated dose toxicity

#### Components:

##### **Propylene glycol:**

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

##### **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 y

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 y  
Target Organs : Blood, Gastrointestinal tract

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

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### 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,<br>Dizziness, insomnia, Fatigue, Headache, Itching, Rash, liver<br>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<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   |

#### 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 |

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|   |   |  |
|---|---|--|
| 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<br>Method: OECD Test Guideline 201 |
| Toxicity to microorganisms                          | : | EC50: > 1,000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209   |

### Persistence and degradability

#### Components:

##### **Propylene glycol:**

|                  |   |   |
|------------------|---|---|
| Biodegradability | : | Result: Readily biodegradable.<br>Biodegradation: 98.3 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301F |
|------------------|---|---|

##### **Glycerine:**

|                  |   |   |
|------------------|---|---|
| Biodegradability | : | Result: Readily biodegradable.<br>Biodegradation: 92 %<br>Exposure time: 30 d<br>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<br>Method: Regulation (EC) No. 440/2008, Annex, A.8 |
|--|---|--|

##### **Glycerine:**

|                           |   |                |
|---------------------------|---|----------------|
| Partition coefficient: n- | : | log Pow: -1.75 |
|---------------------------|---|----------------|

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|| octanol/water

**Ribavirin:**

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

**Mobility in soil**

No data available

**Other adverse effects**

No data available

**Endocrine disrupting properties**

No data available

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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.

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### SECTION 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**

Not regulated as a dangerous good

**IATA-DGR**

Not regulated as a dangerous good

**IMDG-Code**

Not regulated as a dangerous good

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

Not applicable for product as supplied.

**Domestic regulation**

**TDG**

Not regulated as a dangerous good

**Special precautions for user**

Not applicable

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### SECTION 15. REGULATORY INFORMATION

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

AICS : not determined

CA. DSL : not determined

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CN IECSC : not determined

### Canadian lists

No substances are subject to CEPA Section 84 Ministerial Conditions.

## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

|                   |   |  |
|-------------------|---|--|
| ACGIH             | : | USA. ACGIH Threshold Limit Values (TLV)  |
| CA AB OEL         | : | Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)  |
| CA BC OEL         | : | Canada. British Columbia OEL   |
| CA ON OEL         | : | Ontario Table of Occupational Exposure Limits made under the Occupational Health and Safety Act.   |
| CA QC OEL         | : | Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for air-borne contaminants |
| ACGIH / TWA       | : | 8-hour, time-weighted average  |
| CA AB OEL / TWA   | : | 8-hour Occupational exposure limit   |
| CA BC OEL / TWA   | : | 8-hour time weighted average   |
| CA ON OEL / TWA   | : | Time-Weighted Average Limit (TWA)  |
| CA QC OEL / TWAEV | : | Time-weighted average exposure value   |

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 Standardization; 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 Organization 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; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; 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, Authorization and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances

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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

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 05/09/2026  
Date format : mm/dd/yyyy

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

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.

CA / Z8