SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Ribavirin Liquid Formulation

SECTION 1. IDENTIFICATION

Product name: Ribavirin Liquid Formulation

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Germ cell mutagenicity: Category 2
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure (Oral): Category 1 (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.
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 and face protection.
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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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
</tr>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
</tr>
<tr>
<td>Ribavirin</td>
<td>36791-04-5</td>
</tr>
</tbody>
</table>

Actual concentration 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.
Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed:
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.
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Date of first issue: 12/10/2015

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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

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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>US WEEL</td>
</tr>
<tr>
<td>Ribavirin</td>
<td>36791-04-5</td>
<td>Wipe limit</td>
<td>400 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>40 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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**: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

- **Hand protection**
  - **Material**: Chemical-resistant gloves
  - **Remarks**: Consider double gloving.

- **Eye protection**
  - **Remarks**: Wear safety glasses with side shields or goggles.
  - **Remarks**: If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
  - **Remarks**: 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**
  - **Remarks**: Work uniform or laboratory coat.
  - **Remarks**: Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
  - **Remarks**: Use appropriate degowning techniques to remove potentially contaminated clothing.

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

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

- **Appearance**: liquid
- **Color**: clear
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<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>4.8 - 5.5</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Particle size</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
# Ribavirin Liquid Formulation

<table>
<thead>
<tr>
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<td>12/10/2015</td>
</tr>
</tbody>
</table>

## SECTION 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Reactivity</th>
<th>Not classified as a reactivity hazard.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>None known.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

## 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: > 5,000 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
Ribavirin Liquid Formulation

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.

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

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
### Ribavirin Liquid Formulation

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)</td>
<td>negative</td>
</tr>
</tbody>
</table>

### 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

#### Ribavirin:

- **Species**: Mouse
- **Application Route**: Oral
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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.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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
Application Route: Ingestion
Result: negative

Glycerine:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative
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</tr>
</tbody>
</table>

### 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  
  - **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.

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
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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

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
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
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

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
SECTION 13. DISPOSAL CONSIDERATIONS

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

SECTION 14. TRANSPORT INFORMATION

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

49 CFR
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards: Germ cell mutagenicity
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Ribavirin Liquid Formulation

US State Regulations

Pennsylvania Right To Know
Sucrose 57-50-1
Water 7732-18-5
Glycerine 56-81-5
Propylene glycol 57-55-6
D-Glucitol 50-70-4
Ribavirin 36791-04-5

California Prop. 65
WARNING: This product can expose you to chemicals including Ribavirin, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances
Ribavirin 36791-04-5

California Permissible Exposure Limits for Chemical Contaminants
Sucrose 57-50-1
Glycerine 56-81-5

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information
SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Ribavirin Liquid Formulation

**NFPA 704:**

- **Flammability:** 1
- **Health:** 0
- **Special hazard:** 0
- **Instability:** 0

**NFPA 704:**

- **Health:** 0
- **Flammability:** 1
- **Physical hazard:** 0

**HMIS® IV:**

- **HEALTH:** *3*
- **FLAMMABILITY:** 1
- **PHYSICAL HAZARD:** 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

**Full text of other abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td>NIOSH REL</td>
<td>USA. NIOSH Recommended Exposure Limits</td>
</tr>
<tr>
<td>OSHA Z-1</td>
<td>USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants</td>
</tr>
<tr>
<td>US WEEL</td>
<td>USA. Workplace Environmental Exposure Levels (WEEL)</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>NIOSH REL / TWA</td>
<td>Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek</td>
</tr>
<tr>
<td>OSHA Z-1 / TWA</td>
<td>8-hour time weighted average</td>
</tr>
<tr>
<td>US WEEL / TWA</td>
<td>8-hr TWA</td>
</tr>
</tbody>
</table>

AIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of
Ribavirin Liquid Formulation

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

Revision Date: 09/30/2023

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.

US / Z8