SAFETY DATA SHEET

Ribavirin Liquid Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Ribavirin Liquid Formulation

Manufacturer or supplier’s details

Company: MSD
Address: 855 Leandro N. Alem St., 8 Floor
         Buenos Aires, Argentina  C1001AFB
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Germ cell mutagenicity: Category 2
Reproductive toxicity: Category 1B
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.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapors.
Ribavirin Liquid Formulation

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sucrose</td>
<td>57-50-1</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td></td>
<td>Glycerine</td>
<td>56-81-5</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td></td>
<td>Ribavirin</td>
<td>36791-04-5</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

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. 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.
SAFETY DATA SHEET

Ribavirin Liquid Formulation

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 firefighting: 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 and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided.
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
SAFETY DATA SHEET

Ribavirin Liquid Formulation

Version 4.2  Revision Date: 09/13/2019  SDS Number: 406963-00012
Date of last issue: 24.04.2019  Date of first issue: 10.12.2015

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 vapors or spray mist.
- Do not swallow.
- Avoid contact with eyes.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- 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
  - 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>CMP</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td>CMP (Mist)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Ribavirin</td>
<td>36791-04-5</td>
<td>TWA</td>
<td>25 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information:
- A4 - Not classifiable as a human carcinogen: Agents which cause concern that they could be carcinogenic for humans but which cannot be assessed conclusively because of a lack of data. In vitro or animal studies do not provide indications of carcinogenicity which are sufficient to classify the agent into one of the other categories., lung
- TWA 10 mg/m³ ACGIH
- Wipe limit 250 µg/100 cm² 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 vapor type

Hand protection: Chemical-resistant gloves

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.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

**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
Ribavirin Liquid Formulation

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
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 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

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

**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:**

**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.
Ribavirin Liquid Formulation

Components:

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:

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

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
SAFETY DATA SHEET

Ribavirin Liquid Formulation

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:

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:

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  
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  
May cause 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:

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

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Ribavirin:
Inhalation: Symptoms: Headache, Dizziness
SAFETY DATA SHEET

Ribavirin Liquid Formulation

Sanofi-Genzyme

Version 4.2  Revision Date: 09/13/2019  SDS Number: 406963-00012  Date of last issue: 24.04.2019  Date of first issue: 10.12.2015

Remarks: Based on Human Evidence

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

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

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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:

Glycerine:
SAFETY DATA SHEET

Ribavirin Liquid Formulation

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

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.
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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Argentina. Carcinogenic Substances and Agents
Registry. : Not applicable

Control of precursors and essential chemicals for the
preparation of drugs. : Not applicable

**International Regulations**

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

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

**SECTION 16. OTHER INFORMATION**

**Further information**


**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>AR OEL</td>
<td>Argentina. Occupational Exposure Limits</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>AR OEL / CMP</td>
<td>TLV (Threshold Limit Value)</td>
</tr>
</tbody>
</table>

AICS - Australian Inventory of Chemical Substances; 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 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 Chemical 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, Bioaccumu-
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