SECTION 1. IDENTIFICATION

Product name: Ribavirin Solid 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

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 - single exposure: Category 3
Specific target organ toxicity - repeated exposure (Oral): Category 1 (Blood)

GHS label elements
Hazard pictograms:

Signal Word: Danger
Hazard Statements:
H335 May cause respiratory irritation.
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 dust.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

**Response:**
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a doctor if you feel unwell.
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**
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ribavirin</td>
<td>No data available</td>
<td>36791-04-5</td>
<td>&gt;= 60 - &lt; 80 *</td>
</tr>
<tr>
<td>Cellulose</td>
<td>No data available</td>
<td>9004-34-6</td>
<td>&gt;= 10 - &lt; 30 *</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
</tbody>
</table>

* 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.
In case of eye contact:
If in eyes, rinse well with water. 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:
Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation. May cause respiratory irritation. 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 (CO2)
Dry chemical

Unsuitable extinguishing media:
None known.

Specific hazards during fire fighting:
Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
Carbon oxides
Metal 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. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages
Methods and materials for containment and cleaning up cannot be contained.

Surround spill with absorbents and place a damp covering over the area to minimize entry of the material into the air.
Add excess liquid to allow the material to enter into solution.
Soak up with inert absorbent material.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
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 : Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

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 dust.
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.
Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
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.
Keep in a cool, well-ventilated place.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
SAFETY DATA SHEET

Ribavirin Solid Formulation

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>Ribavirin</td>
<td>36791-04-5</td>
<td>Wipe limit</td>
<td>400 µg/100 cm² Internal</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>40 µg/m³ (OEB 3) Internal</td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³ CA AB OEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³ CA BC OEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>3 mg/m³ CA BC OEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (total dust)</td>
<td>10 mg/m³ CA QC OEL</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA</td>
<td>10 mg/m³ CA AB OEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV</td>
<td>10 mg/m³ CA QC OEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable)</td>
<td>10 mg/m³ CA BC OEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>3 mg/m³ CA BC OEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³ ACGIH</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³ ACGIH</td>
<td></td>
</tr>
</tbody>
</table>

Engineering measures: 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: Particulates 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.

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: powder
Color: white
Odor: No data available
Odor Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: No data available
Evaporation rate: Not applicable
Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids): No data available
Upper explosion limit / Upper: No data available
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Version 4.0  Revision Date: 04/04/2023  SDS Number: 402499-00020  Date of last issue: 07/22/2022  Date of first issue: 12/11/2015

flammability limit
Lower explosion limit / Lower flammability limit: No data available
Vapor pressure: Not applicable
Relative vapor density: Not applicable
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: Not applicable
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Particle size: No data available

SECTION 10. STABILITY AND REACTIVITY
Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions:
  May form explosive dust-air mixture during processing, handling or other means.
  Can react with strong oxidizing agents.
Conditions to avoid: Heat, flames and sparks.
  Avoid dust formation.
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
SAFETY DATA SHEET

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Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Components:
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

Cellulose:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Magnesium stearate:
Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Assessment: The substance or mixture has no acute oral toxicity
Remarks: Based on data from similar materials
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Remarks: Based on data from similar materials

Skin corrosion/irritation
Not classified based on available information.

Components:
Ribavirin:
Remarks : No data available
May irritate skin.
Magnesium stearate:
Species: Rabbit
Result: No skin irritation
Remarks: Based on data from similar materials

Serious eye damage/eye irritation
Not classified based on available information.

Components:
Ribavirin:
Remarks: No data available
      May irritate eyes.

Magnesium stearate:
Species: Rabbit
Result: No eye irritation
Remarks: Based on data from similar materials

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

Magnesium stearate:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

Germ cell mutagenicity
Suspected of causing genetic defects.

Components:
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
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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.

Cellulose:

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

  Test Type: In vitro mammalian cell gene mutation test
  Result: negative

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

Magnesium stearate:

Genotoxicity in vitro:
: Test Type: In vitro mammalian cell gene mutation test
  Result: negative
  Remarks: Based on data from similar materials

  Test Type: Chromosome aberration test in vitro
  Method: OECD Test Guideline 473
  Result: negative
  Remarks: Based on data from similar materials

  Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
  Remarks: Based on data from similar materials

Carcinogenicity
Not classified based on available information.
Components:

Ribavirin:

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>6 Months</td>
</tr>
<tr>
<td>LOAEL</td>
<td>75 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Blood, Testes</td>
</tr>
<tr>
<td>Remarks</td>
<td>The mechanism or mode of action may not be relevant in humans.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>NOAEL</td>
<td>10 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>The mechanism or mode of action may not be relevant in humans.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>18 Months</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>The mechanism or mode of action may not be relevant in humans.</td>
</tr>
</tbody>
</table>

Cellulose:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>72 weeks</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

Reproductive toxicity

May damage the unborn child. Suspected of damaging fertility.

Components:

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.

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Developmental Toxicity</th>
<th>Symptoms</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development</td>
<td>Rat, female</td>
<td>Oral</td>
<td>LOAEL: &lt;= 1 mg/kg body weight</td>
<td>Reduced body weight, Reduced number of viable fetuses, Skeletal malformations</td>
<td>Embryotoxic effects and adverse effects on the offspring were detected.</td>
</tr>
<tr>
<td>Development</td>
<td>Rabbit, female</td>
<td>Oral</td>
<td>LOAEL: 1 mg/kg body weight</td>
<td>Reduced body weight, Skeletal malformations</td>
<td>Embryotoxic effects and adverse effects on the offspring were detected.</td>
</tr>
<tr>
<td>Development</td>
<td>Hamster</td>
<td>Oral</td>
<td>LOAEL: 2.5 mg/kg body weight</td>
<td>Skeletal and visceral variations, Total Resorptions / resorption rate</td>
<td>Embryotoxic effects and adverse effects on the offspring were detected.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>General Toxicity Maternal</th>
<th>Developmental Toxicity</th>
<th>Symptoms</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo-fetal development</td>
<td>Rat</td>
<td>Oral</td>
<td>NOAEL: 0.3 mg/kg body weight</td>
<td>LOAEL: 1 mg/kg body weight</td>
<td>Skeletal malformations</td>
<td>positive</td>
</tr>
</tbody>
</table>

### 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.

### Cellulose
<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>One-generation reproduction toxicity study</td>
<td>Rat</td>
</tr>
</tbody>
</table>
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Application Route: Ingestion
Result: negative

Effects on fetal development:
Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative

Magnesium stearate:
Effects on fertility:
Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development:
Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

STOT-single exposure
May cause respiratory irritation.

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:
Ribavirin:
Species: Monkey
LOAEL: 30 mg/kg
Exposure time: 10 d
Target Organs: Blood, Gastrointestinal tract
Species: Rat
SAFETY DATA SHEET

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<table>
<thead>
<tr>
<th>NOAEL</th>
<th>7.6 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Inhalation</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 d</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Blood, Lungs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>5 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>1 y</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Blood, Gastrointestinal tract</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>20 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>18 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Blood, Cardio-vascular system</td>
</tr>
</tbody>
</table>

**Cellulose:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>&gt;= 9,000 mg/kg</td>
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<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
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</table>

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>&gt; 100 mg/kg</td>
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<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure**

**Components:**

**Ribavirin:**

<table>
<thead>
<tr>
<th>Inhalation</th>
<th>Symptoms: Headache, Dizziness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin contact</td>
<td>Remarks: May cause eye irritation.</td>
</tr>
<tr>
<td>Eye contact</td>
<td>Remarks: May cause eye irritation.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Symptoms: blood effects, immune system effects, anorexia, Dizziness, insomnia, Fatigue, Headache, Itching, Rash, liver function change, Gastrointestinal disturbance</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Remarks</th>
<th>Based on Human Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Based on Human Evidence</td>
</tr>
<tr>
<td></td>
<td>Based on Human Evidence</td>
</tr>
</tbody>
</table>
### SECTION 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

**Components:**

**Ribavirin:**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to fish</strong></td>
<td>LC50 (Oncorhynchus mykiss (rainbow trout)): &gt; 119 mg/l</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>96 h</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 117 mg/l</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>48 h</td>
</tr>
<tr>
<td><strong>Method</strong></td>
<td>OECD Test Guideline 202</td>
</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EC50 (Pseudokirchneriella subcapitata (green algae)):</strong></td>
<td>&gt; 119 mg/l</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>96 h</td>
</tr>
<tr>
<td><strong>Method</strong></td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

**NOEC (Pseudokirchneriella subcapitata (green algae)):**

<table>
<thead>
<tr>
<th>Value</th>
<th>mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>6.9</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Exposure time:**

| 96 h |

**Method:**

| OECD Test Guideline 201 |

**Toxicity to microorganisms**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EC50:</strong></td>
<td>&gt; 1,000 mg/l</td>
</tr>
<tr>
<td><strong>Exposure time:</strong></td>
<td>3 h</td>
</tr>
<tr>
<td><strong>Test Type:</strong></td>
<td>Respiration inhibition</td>
</tr>
<tr>
<td><strong>Method:</strong></td>
<td>OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

**Cellulose:**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to fish</strong></td>
<td>LC50 (Oryzias latipes (Japanese medaka)): &gt; 100 mg/l</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>48 h</td>
</tr>
<tr>
<td><strong>Remarks:</strong></td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to fish</strong></td>
<td>LC50 (Leuciscus idus (Golden orfe)): &gt; 100 mg/l</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>48 h</td>
</tr>
<tr>
<td><strong>Remarks:</strong></td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EL50</strong></td>
<td>&gt; 1 mg/l</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>47 h</td>
</tr>
<tr>
<td><strong>Test substance:</strong></td>
<td>Water Accommodated Fraction</td>
</tr>
<tr>
<td><strong>Remarks:</strong></td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td><strong>No toxicity at the limit of solubility.</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EL50</strong></td>
<td>&gt; 1 mg/l</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>72 h</td>
</tr>
<tr>
<td><strong>Test substance:</strong></td>
<td>Water Accommodated Fraction</td>
</tr>
<tr>
<td><strong>Method:</strong></td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td><strong>Remarks:</strong></td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
Ribavirin Solid Formulation

No toxicity at the limit of solubility.

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Exposure time: 72 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Exposure time: 16 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Persistence and degradability

Components:

Cellulose:
Biodegradability: Result: Readily biodegradable.

Magnesium stearate:
Biodegradability: Result: Not biodegradable
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

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

Magnesium stearate:
Partition coefficient: n-octanol/water: log Pow: > 4

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

TDG
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)


CA BC OEL : Canada. British Columbia OEL

CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne 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 QC OEL / TWA EV : Time-weighted average exposure value

AICL - 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;
SAFETY DATA SHEET

Ribavirin Solid Formulation

Version 4.0  Revision Date: 04/04/2023  SDS Number: 402499-00020  Date of last issue: 07/22/2022  Date of first issue: 12/11/2015

ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System


Revision Date: 04/04/2023
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