Ribavirin Solid Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Ribavirin Solid Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 199 Wenhai North Road, HEDA, Hangzhou - Zhejiang Province - CHINA 310018
Telephone: 908-740-4000
Emergency telephone number: 86-571-87268110
E-mail address: EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Emergency Overview
Appearance: powder
Colour: white
Odour: No data available

May be harmful if swallowed. 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.

GHS Classification
Acute toxicity (Oral): Category 5
Germ cell mutagenicity: Category 2
Reproductive toxicity: Category 1B
Specific target organ toxicity - single exposure: Category 3
Specific target organ toxicity - repeated exposure: Category 1

GHS label elements
Hazard pictograms:

Signal word: Danger
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Hazard statements:
- H303 May be harmful if swallowed.
- 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 through prolonged or repeated exposure.

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/ face protection.

  Response:
  - P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.
  - P312 Call a POISON CENTER/doctor if you feel unwell.

Storage:
- P405 Store locked up.

Disposal:
- P501 Dispose of contents/ container to an approved waste disposal plant.

Physical and chemical hazards
Not classified based on available information.

Health hazards
May be harmful if swallowed. Suspected of causing genetic defects. May damage the unborn child. Suspected of damaging fertility. May cause respiratory irritation. Causes damage to organs through prolonged or repeated exposure.

Environmental hazards
Not classified based on available information.

Other hazards which do not result in classification
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.

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>
</tbody>
</table>

| Chemical name | CAS-No. | Concentration (% w/w) |
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<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ribavirin</td>
<td>36791-04-5</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
</tbody>
</table>

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: 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:

- May be harmful if swallowed.
- 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.
- Contact with dust can cause mechanical irritation or drying of the skin.
- Dust contact with the eyes can lead to mechanical irritation.

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.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: 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 prod-...
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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 firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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. 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: Sweep up or vacuum up spillage and collect in suitable container for disposal. 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. 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.

7. HANDLING AND STORAGE

Handling

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. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Keep container tightly closed. Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers. 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. Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact: Oxidizing agents

Storage

Conditions for safe storage:
- Keep in properly labelled 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:
  - Strong oxidizing agents

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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>TWA</td>
<td>25 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>250 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>PC-TWA</td>
<td>10 mg/m³</td>
<td>GBZ 2.1-2007</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable fraction)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>3 mg/m³</td>
<td>ACGIH</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
Eye/face 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.

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

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>white</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</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>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapour pressure : Not applicable
Relative vapour 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
Auto-ignition 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

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.

11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation
   Skin contact
   Ingestion
   Eye contact
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
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<tbody>
<tr>
<td>3.9</td>
<td>09/13/2019</td>
<td>402534-00012</td>
<td>2019/04/24</td>
<td>2015/12/11</td>
</tr>
</tbody>
</table>

**Acute toxicity**
May be harmful if swallowed.

**Product:**

<table>
<thead>
<tr>
<th>Components</th>
<th>Acute oral toxicity</th>
<th>Acute toxicity estimate: 2,249 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Method: Calculation method</td>
<td></td>
</tr>
</tbody>
</table>

**Components:**

**Ribavirin:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): 4,116 - 5,584 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LD50 (Mouse): &gt; 10,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD50 (Dog): &gt;= 1,500 mg/kg</td>
</tr>
</tbody>
</table>

**Acute inhalation toxicity**: Remarks: No data available

**Acute dermal toxicity**: Remarks: No data available

**Acute toxicity (other routes of administration)**:

<table>
<thead>
<tr>
<th>Application Route: Intraperitoneal</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 (Rat): 1,554 - 1,758 mg/kg</td>
</tr>
<tr>
<td>LD50 (Mouse): 1,268 mg/kg</td>
</tr>
</tbody>
</table>

**Cellulose:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): &gt; 5,000 mg/kg</th>
</tr>
</thead>
</table>

**Acute inhalation toxicity**:

<table>
<thead>
<tr>
<th>LC50 (Rat): &gt; 5.8 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 4 h</td>
</tr>
<tr>
<td>Test atmosphere: dust/mist</td>
</tr>
</tbody>
</table>

**Acute dermal toxicity**: LD50 (Rabbit): > 2,000 mg/kg
Remarks: Based on data from similar materials

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): &gt; 2,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method: OECD Test Guideline 423</td>
<td></td>
</tr>
<tr>
<td>Assessment: The substance or mixture has no acute oral toxicity</td>
<td></td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

**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:**

<table>
<thead>
<tr>
<th>Remarks</th>
<th>No data available</th>
</tr>
</thead>
</table>
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</tbody>
</table>

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 sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

**Ribavirin:**
- **Remarks:** No data available

**Magnesium stearate:**
- **Test Type:** Maximisation Test
- **Exposure routes:** 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
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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
Type: Test Type: dominant lethal test
Species: Rat
Result: negative

Type: Test Type: Mouse Lymphoma
Species: Mouse
Result: positive

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

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

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

Magnesium stearate:

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

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

Type: 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:**
- **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.

**Cellulose:**
- **Species:** Rat
- **Application Route:** Ingestion
- **Exposure time:** 72 weeks
- **Result:** negative

**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
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Fertility</th>
<th>Species: Rat, females</th>
<th>Application Route: Oral</th>
<th>Fertility: NOAEL: 10 mg/kg body weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result:</td>
<td>Animal testing did not show any effects on fertility.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Fertility</th>
<th>Species: Rat, male</th>
<th>Application Route: Oral</th>
<th>Fertility: NOAEL: 160 mg/kg body weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result:</td>
<td>Animal testing did not show any effects on fertility.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Effects on foetal 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-foetal development
  - **Species:** Rat
  - **Application Route:** Oral
  - **General Toxicity Maternal:** NOAEL: 0.3 mg/kg body weight
  - **Embryo-foetal toxicity:** LOAEL: 1 mg/kg body weight
  - **Symptoms:** Skeletal malformations
  - **Result:** positive

### Reproductive toxicity - Assessment:

- Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments.

### Cellulose:

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

**Effects on foetal 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 foetal development**
- Test Type: Embryo-foetal 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 through prolonged or repeated exposure.

**Components:**

**Ribavirin:**
- Exposure routes: 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
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Species: Rat  
NOAEL: 7.6 mg/kg  
Application Route: Inhalation  
Exposure time: 90 d  
Target Organs: Blood, Lungs

Species: Dog  
NOAEL: 5 mg/kg  
Application Route: Oral  
Exposure time: 1 yr  
Target Organs: Blood, Gastrointestinal tract

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

Cellulose:
Species: Rat  
NOAEL: >= 9,000 mg/kg  
Application Route: Ingestion  
Exposure time: 90 Days

Magnesium stearate:
Species: Rat  
NOAEL: > 100 mg/kg  
Application Route: Ingestion  
Exposure time: 90 Days  
Remarks: Based on data from similar materials

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 function change, Gastrointestinal disturbance
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12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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

Cellulose:
- Toxicity to fish: LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
  Exposure time: 48 h
  Remarks: Based on data from similar materials

Magnesium stearate:
- Toxicity to fish: LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l
  Exposure time: 48 h
  Method: DIN 38412
  Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates: EL50 (Daphnia magna (Water flea)): > 1 mg/l
  Exposure time: 47 h
  Test substance: Water Accommodated Fraction
  Remarks: Based on data from similar materials
  No toxicity at the limit of solubility
- Toxicity to algae/aquatic plants: EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
  Exposure time: 72 h
  Test substance: Water Accommodated Fraction
  Method: OECD Test Guideline 201
### Toxicity to microorganisms

**EC10** (Pseudomonas putida): > 100 mg/l  
**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

### 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.
Ribavirin Solid Formulation

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.

National Regulations

GB 6944/12268
Not regulated as a dangerous good

Special precautions for user
Not applicable

15. REGULATORY INFORMATION

National regulatory information

Law on the Prevention and Control of Occupational Diseases

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Further information


Date format: yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)


ACGIH / TWA : 8-hour, time-weighted average

GBZ 2.1-2007 / PC-TWA : Permissible concentration - time weighted average
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 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; 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

Disclaimer
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

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