SECTION 1. IDENTIFICATION

Product name : Ribavirin Solid 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)

Combustible dust
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 : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
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.

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>Ribavirin</td>
<td>36791-04-5</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</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 : If in eyes, rinse well with water.
SAFETY DATA SHEET

Ribavirin Solid Formulation

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 cannot be contained.
Methods and materials for containment and cleaning up:

- 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:
  - Strong oxidizing agents
  - Self-reactive substances and mixtures
SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>inert or nuisance dust</th>
<th>Value type (Form of exposure): TWA (total dust)</th>
<th>Basis: OSHA Z-3</th>
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<td>5 mg/m³</td>
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<tr>
<td></td>
<td>Value type (Form of exposure): TWA (respirable fraction)</td>
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<td>Dust, nuisance dust and particulates</td>
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<tr>
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<td>5 mg/m³</td>
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<table>
<thead>
<tr>
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<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
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<tr>
<td>Ribavirin</td>
<td>36791-04-5</td>
<td>Wipe limit</td>
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<td>TWA</td>
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<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
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<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>
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<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>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
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<tr>
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<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
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</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

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

**Material**: 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

**Material**: 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

**Material**: powder

### Color

**Material**: 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 flammability limit : No data available
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.
Incompatible materials : Oxidizing agents
Incompatible materials : Avoid dust formation.
Incompatible materials : 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: 2,249 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
### SAFETY DATA SHEET

**Ribavirin Solid Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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<td>6.0</td>
<td>04/04/2023</td>
<td>402657-00019</td>
<td>07/22/2022</td>
<td>12/11/2015</td>
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</table>

#### Test atmosphere:
dust/mist

#### Acute dermal toxicity
LD50 (Rabbit): > 2,000 mg/kg

#### Magnesium stearate:

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Value</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Assessment</td>
<td>OECD Test Guideline 423</td>
<td></td>
</tr>
<tr>
<td>Result</td>
<td>No skin irritation</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Species</td>
<td>Rabbit</td>
<td></td>
</tr>
<tr>
<td>Remarks</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Skin corrosion/irritation
Not classified based on available information.

#### Components:

**Ribavirin**

<table>
<thead>
<tr>
<th>Remarks</th>
<th>Value</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No data available</td>
<td>Based on data from similar materials</td>
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**Magnesium stearate**

<table>
<thead>
<tr>
<th>Species</th>
<th>Value</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>No skin irritation</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

#### Serious eye damage/eye irritation

#### Components:

**Ribavirin**

<table>
<thead>
<tr>
<th>Remarks</th>
<th>Value</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>Based on data from similar materials</td>
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</tbody>
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**Magnesium stearate**

<table>
<thead>
<tr>
<th>Species</th>
<th>Value</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>No eye irritation</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

#### 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
  - **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:
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

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:

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:

Cellulose:
Effects on fertility: Test Type: One-generation reproduction toxicity study
Species: Rat
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:

<table>
<thead>
<tr>
<th>Routes of exposure</th>
<th>Ingestion</th>
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<tbody>
<tr>
<td>Target Organs</td>
<td>Blood</td>
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<tr>
<td>Assessment</td>
<td>Causes damage to organs through prolonged or repeated exposure.</td>
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Repeated dose toxicity

Components:
Ribavirin:

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<tr>
<th>Species</th>
<th>Monkey</th>
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<tbody>
<tr>
<td>LOAEL</td>
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<tr>
<td>Exposure time</td>
<td>10 d</td>
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<tr>
<td>Target Organs</td>
<td>Blood, Gastrointestinal tract</td>
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<table>
<thead>
<tr>
<th>Species</th>
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<td>Target Organs</td>
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<td>Application Route</td>
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<td>Exposure time</td>
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<tr>
<td>Target Organs</td>
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Cellulose:

<table>
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<tr>
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<td>Ingestion</td>
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</table>
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. |
|Remarks: Based on Human Evidence |
|Eye contact | Remarks: May cause eye irritation. |
|Remarks: 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:

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 |
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Date of first issue: 12/11/2015

**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

**Exposure time:**
- 48 h

**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
  - Remarks: Based on data from similar materials
  - 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

**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

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.
SAFETY DATA SHEET

Ribavirin Solid Formulation

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
- Combustible dust
- 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.

US State Regulations

Pennsylvania Right To Know
Ribavirin 36791-04-5
Cellulose 9004-34-6
D-Glucose, 4-O-β-D-galactopyranosyl-, monohydrate 64044-51-5

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
Cellulose 9004-34-6
Magnesium stearate 557-04-0

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
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NFPA 704:

<table>
<thead>
<tr>
<th>Flammability</th>
<th>Instability</th>
<th>Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS® IV:

| HEALTH       | * 3 |
| FLAMMABILITY | 3   |
| 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
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CAL PEL : California permissible exposure limits for chemical contaminants (Title 8, Article 107)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA : 8-hour, time-weighted average
CAL PEL / PEL : Permissible exposure limit
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA : 8-hour time weighted average
OSHA Z-3 / TWA : 8-hour time weighted average

AIIC - 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; IECS - 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 Other-

Revision Date: 04/04/2023

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.

US / Z8