SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Ribavirin Solid Formulation

Version 3.11  Revision Date: 2020/10/02  SDS Number: 402534-00014  Date of last issue: 2020/03/23  Date of first issue: 2015/12/11

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>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
</tbody>
</table>
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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 products: Carbon oxides
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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**: 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. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-
sessment
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.
Do not eat, drink or smoke when using this product.
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>CN OEL</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 particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</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 expo-
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Filter type
- 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.

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>
</tbody>
</table>
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**Flammability (liquids)** : No data available

**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

Acute toxicity
May be harmful if swallowed.

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
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.
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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 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.
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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)
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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
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
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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 foetal 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.

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.

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.

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 - As:

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 foetal 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.

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.

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.

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 - As:
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**Assessment**  
Clear evidence of adverse effects on development, based on animal experiments.

**Cellulose:**  
Effects on fertility: Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

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

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.
Remarks: Based on Human Evidence
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<thead>
<tr>
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</tr>
</tbody>
</table>

**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

## 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
- 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
Ribavirin Solid Formulation

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.

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
Sources of key data used to compile the Safety Data Sheet
Ribavirin Solid Formulation

Date format: yyyy/mm/dd

**Full text of other abbreviations**

ACGIH: USA. ACGIH Threshold Limit Values (TLV)
CN OEL: Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.

ACGIH / TWA: 8-hour, time-weighted average
CN OEL / PC-TWA: Permissible concentration - time weighted average

**Disco**

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.

CN / EN