SAFETY DATA SHEET

Ribavirin Solid Formulation

Version 2.2  Revision Date: 09/13/2019  SDS Number: 413002-00012  Date of last issue: 24.04.2019

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Ribavirin Solid Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

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 (Oral) : Category 1 (Blood)

GHS label elements
Hazard pictograms : ☢️ ⚠️
Signal word : Danger
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 (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/ face protection.

Response:
P301 + P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:
P405 Store locked up.

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

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

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</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; 5</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 immediately.
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 if swallowed. 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
                                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 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

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.

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

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>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
- **Hand protection**: Chemical-resistant gloves
- **Remarks**: Consider double gloving.
- **Eye protection**: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- **Skin and body protection**: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
- **Hygiene measures**: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder
Colour : white
Odour : No data available
Odour 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
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
Information on likely routes of exposure : 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.

**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.

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
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: 24.04.2019</th>
<th>Date of first issue: 11.12.2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.2</td>
<td>09/13/2019</td>
<td>413002-00012</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

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 : 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
## Reproductive toxicity - Assessment

<table>
<thead>
<tr>
<th>Reproductive toxicity - Assessment</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Toxicity Maternal: LOAEL: 1 mg/kg body weight</td>
<td>Development</td>
<td>Rat</td>
<td>Oral</td>
<td>positive</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 1 mg/kg body weight</td>
<td>Development</td>
<td>Rat</td>
<td>Oral</td>
<td>positive</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Symptoms: Reduced body weight, Skeletal malformations</td>
<td></td>
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<tr>
<td>Result: Embryotoxic effects and adverse effects on the offspring were detected.</td>
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<tr>
<td>Test Type: Development</td>
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<tr>
<td>Species: Hamster</td>
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</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 2.5 mg/kg body weight</td>
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<tr>
<td>Symptoms: Skeletal and visceral variations, Total Resorptions / resorption rate</td>
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<tr>
<td>Result: Embryotoxic effects and adverse effects on the offspring were detected.</td>
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<tr>
<td>Test Type: Embryo-foetal development</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species: Rat</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>General Toxicity Maternal: NOAEL: 0.3 mg/kg body weight</td>
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<tr>
<td>Embryo-foetal toxicity: LOAEL: 1 mg/kg body weight</td>
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<tr>
<td>Symptoms: Skeletal malformations</td>
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<tr>
<td>Result: positive</td>
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</tbody>
</table>

### Cellulose:

**Effects on fertility**

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

**Effects on foetal development**

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type: Fertility/early embryonic development</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Species: Rat</td>
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<tr>
<td>Application Route: Ingestion</td>
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<tr>
<td>Result: negative</td>
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</tbody>
</table>

### Magnesium stearate:

**Effects on fertility**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test</td>
<td></td>
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<tr>
<td>Species: Rat</td>
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</tr>
<tr>
<td>Application Route: Ingestion</td>
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<tr>
<td>Method: OECD Test Guideline 422</td>
<td></td>
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<tr>
<td>Result: negative</td>
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<tr>
<td>Remarks: Based on data from similar materials</td>
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</tr>
</tbody>
</table>

**Effects on foetal development**

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type: Embryo-foetal development</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Species: Rat</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
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<tr>
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<td></td>
</tr>
</tbody>
</table>
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:
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
SAFETY DATA SHEET

Ribavirin Solid Formulation

Version 2.2  Revision Date: 09/13/2019  SDS Number: 413002-000012  Date of last issue: 24.04.2019  Date of first issue: 11.12.2015

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

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
**SAFETY DATA SHEET**

**Ribavirin Solid Formulation**

<table>
<thead>
<tr>
<th>component</th>
<th>Toxicity to fish</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cellulose</strong></td>
<td>LC50 (Oryzias latipes (Japanese medaka)): &gt; 100 mg/l</td>
<td>48 h</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Magnesium stearate</strong></td>
<td>LC50 (Leuciscus idus (Golden orfe)): &gt; 100 mg/l</td>
<td>48 h</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>No toxicity at the limit of solubility</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
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<td></td>
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<td>Remarks: Based on data from similar materials</td>
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<tr>
<td></td>
<td>NOELR (Pseudokirchneriella subcapitata (green algae)): &gt; 1 mg/l</td>
<td>72 h</td>
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<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
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<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
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<td>Method: OECD Test Guideline 201</td>
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<td>Remarks: Based on data from similar materials</td>
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<tr>
<td></td>
<td>EC10 (Pseudomonas putida): &gt; 100 mg/l</td>
<td>16 h</td>
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<tr>
<td>Persistence and degradability</td>
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</tbody>
</table>

**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: \( \log \text{ Pow} = 0.971 \)

Magnesium stearate:
Partition coefficient: n-octanol/water: \( \log \text{ Pow} > 4 \)

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.

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 IMO instruments
Not applicable for product as supplied.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

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

AICS: not determined

DSL: not determined
SAFETY DATA SHEET

Ribavirin Solid Formulation

Version 2.2  Revision Date: 09/13/2019  SDS Number: 413002-00012  Date of last issue: 24.04.2019
Date of first issue: 11.12.2015

IECSC : not determined

16. OTHER INFORMATION

Further information

Date format: dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA : 8-hour, time-weighted average

AICCS - 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; LDI50 - 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

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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