

# SAFETY DATA SHEET



## Ribavirin Solid Formulation

Version  
5.1

Revision Date:  
14.04.2025

SDS Number:  
402487-00022

Date of last issue: 28.09.2024  
Date of first issue: 11.12.2015

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### SECTION 1. IDENTIFICATION

Product identifier : Ribavirin Solid Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : Avenida Tanner de Melo, Quadra 10 Lote 4A, Galpão A  
Parque Industrial Vice Presidente José Alencar Aparecida de  
Goiás – GO, Brazil

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification in accordance with ABNT NBR 14725 Standard

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 in accordance with ABNT NBR 14725 Standard

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

# SAFETY DATA SHEET



## Ribavirin Solid Formulation

|                |                              |                             |                                                                   |
|----------------|------------------------------|-----------------------------|-------------------------------------------------------------------|
| Version<br>5.1 | Revision Date:<br>14.04.2025 | SDS Number:<br>402487-00022 | Date of last issue: 28.09.2024<br>Date of first issue: 11.12.2015 |
|----------------|------------------------------|-----------------------------|-------------------------------------------------------------------|

fertility.

H372 Causes damage to organs (Blood) through prolonged or repeated exposure if swallowed.

### Precautionary Statements

#### : Prevention:

P201 Obtain special instructions before use.

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.

### 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.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

| Chemical name      | CAS-No.    | Classification                                                                               | Concentration (% w/w) |
|--------------------|------------|----------------------------------------------------------------------------------------------|-----------------------|
| Ribavirin          | 36791-04-5 | Acute Tox. (Oral), 4<br>Muta., 2<br>Repr., 1B<br>STOT SE, 3<br>STOT RE,<br>(Oral)(Blood) , 1 | >= 50 -< 70           |
| Cellulose          | 9004-34-6  |                                                                                              | >= 10 -< 20           |
| Magnesium stearate | 557-04-0   |                                                                                              | >= 1 -< 5             |

## SECTION 4. FIRST AID MEASURES

|                |                                                                                                                                                          |
|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| General advice | : In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice. |
| If inhaled     | : If inhaled, remove to fresh air.                                                                                                                       |

# SAFETY DATA SHEET



## Ribavirin Solid Formulation

|                |                              |                             |                                                                   |
|----------------|------------------------------|-----------------------------|-------------------------------------------------------------------|
| Version<br>5.1 | Revision Date:<br>14.04.2025 | SDS Number:<br>402487-00022 | Date of last issue: 28.09.2024<br>Date of first issue: 11.12.2015 |
|----------------|------------------------------|-----------------------------|-------------------------------------------------------------------|

|                                                             |                                                                                                                                                                                                                                                                                                                                                                                                            |
|-------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| In case of skin contact                                     | Get medical attention.<br>: In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse.                                                                                                                                                          |
| In case of eye contact                                      | : If in eyes, rinse well with water.<br>Get medical attention if irritation develops and persists.                                                                                                                                                                                                                                                                                                         |
| If swallowed                                                | : If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>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.<br>Dust contact with the eyes can lead to mechanical irritation.<br>May be harmful if swallowed.<br>May cause respiratory irritation.<br>Suspected of causing genetic defects.<br>May damage the unborn child. Suspected of damaging fertility.<br>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<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>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.<br>Exposure to combustion products may be a hazard to health.                   |
| Hazardous combustion products                  | : Carbon oxides<br>Metal oxides                                                                                                                                                                                                                   |
| Specific extinguishing methods                 | : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.                                                                                                                                            |

**Ribavirin Solid Formulation**Version  
5.1Revision Date:  
14.04.2025SDS Number:  
402487-00022Date of last issue: 28.09.2024  
Date of first issue: 11.12.2015**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.

# SAFETY DATA SHEET



## Ribavirin Solid Formulation

|                |                              |                             |                                                                   |
|----------------|------------------------------|-----------------------------|-------------------------------------------------------------------|
| Version<br>5.1 | Revision Date:<br>14.04.2025 | SDS Number:<br>402487-00022 | Date of last issue: 28.09.2024<br>Date of first issue: 11.12.2015 |
|----------------|------------------------------|-----------------------------|-------------------------------------------------------------------|

|                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                             | <p>Keep away from heat and sources of ignition.<br/>Take precautionary measures against static discharges.<br/>Do not eat, drink or smoke when using this product.<br/>Take care to prevent spills, waste and minimize release to the environment.</p> <p>Hygiene measures</p> <p>: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.<br/>When using do not eat, drink or smoke.<br/>Wash contaminated clothing before re-use.<br/>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.</p> |
| Conditions for safe storage | <p>: Keep in properly labeled containers.<br/>Store locked up.<br/>Keep tightly closed.<br/>Keep in a cool, well-ventilated place.<br/>Store in accordance with the particular national regulations.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Materials to avoid          | <p>: Do not store with the following product types:<br/>Strong oxidizing agents<br/>Self-reactive substances and mixtures<br/>Organic peroxides<br/>Explosives<br/>Gases</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Ingredients with workplace control parameters

| Components         | CAS-No.    | Value type<br>(Form of<br>exposure)          | Control parame-<br>ters / Permissible<br>concentration | Basis    |
|--------------------|------------|----------------------------------------------|--------------------------------------------------------|----------|
| Ribavirin          | 36791-04-5 | Wipe limit                                   | 400 µg/100 cm <sup>2</sup>                             | Internal |
|                    |            | TWA                                          | 40 µg/m <sup>3</sup> (OEB 3)                           | Internal |
| Cellulose          | 9004-34-6  | TWA                                          | 10 mg/m <sup>3</sup>                                   | ACGIH    |
| Magnesium stearate | 557-04-0   | TWA<br>(Inhalable<br>particulate<br>matter)  | 10 mg/m <sup>3</sup>                                   | ACGIH    |
|                    |            | TWA<br>(Respirable<br>particulate<br>matter) | 3 mg/m <sup>3</sup>                                    | ACGIH    |

|                      |                                                                                                                                                                                                                                                                                                                                                                                                                  |
|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Engineering measures | <p>: All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.<br/>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).<br/>Minimize open handling.</p> |
|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

# SAFETY DATA SHEET



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Version  
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Revision Date:  
14.04.2025

SDS Number:  
402487-00022

Date of last issue: 28.09.2024  
Date of first issue: 11.12.2015

### Personal protective equipment

|                          |                                                                                                                                                                                                                                                                                                                  |
|--------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Respiratory protection   | : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.                                                                                                                                           |
| Filter type              | : Particulates type                                                                                                                                                                                                                                                                                              |
| Hand protection          |                                                                                                                                                                                                                                                                                                                  |
| Material                 | : Chemical-resistant gloves                                                                                                                                                                                                                                                                                      |
| Remarks                  | : Consider double gloving.                                                                                                                                                                                                                                                                                       |
| Eye protection           | : Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>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.<br>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.<br>Use appropriate degowning techniques to remove potentially contaminated clothing.                    |

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

|                                                  |                                                                                   |
|--------------------------------------------------|-----------------------------------------------------------------------------------|
| Physical state                                   | : powder                                                                          |
| Color                                            | : white                                                                           |
| Odor                                             | : No data available                                                               |
| Odor Threshold                                   | : No data available                                                               |
| pH                                               | : No data available                                                               |
| Melting point/freezing point                     | : No data available                                                               |
| Initial boiling point and boiling range          | : No data available                                                               |
| Flash point                                      | : No data available                                                               |
| Evaporation rate                                 | : Not applicable                                                                  |
| Flammability (solid, gas)                        | : May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids)                           | : No data available                                                               |
| Upper explosion limit / Upper flammability limit | : No data available                                                               |
| Lower explosion limit / Lower flammability limit | : No data available                                                               |

# SAFETY DATA SHEET



## Ribavirin Solid Formulation

Version 5.1 Revision Date: 14.04.2025 SDS Number: 402487-00022 Date of last issue: 28.09.2024 Date of first issue: 11.12.2015

---

|                                        |                                                            |
|----------------------------------------|------------------------------------------------------------|
| 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 characteristics               |                                                            |
| Particle size                          | : No data available                                        |

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## 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.<br>Can react with strong oxidizing agents. |
| Conditions to avoid                | : Heat, flames and sparks.<br>Avoid dust formation.                                                                          |
| Incompatible materials             | : Oxidizing agents                                                                                                           |
| Hazardous decomposition products   | : No hazardous decomposition products are known.                                                                             |

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## SECTION 11. TOXICOLOGICAL INFORMATION

|                                          |                                                          |
|------------------------------------------|----------------------------------------------------------|
| Information on likely routes of exposure | : Inhalation<br>Skin contact<br>Ingestion<br>Eye contact |
|------------------------------------------|----------------------------------------------------------|

### Acute toxicity

May be harmful if swallowed.

### Product:

Acute oral toxicity : Acute toxicity estimate: 2.249 mg/kg

# SAFETY DATA SHEET



## Ribavirin Solid Formulation

Version  
5.1

Revision Date:  
14.04.2025

SDS Number:  
402487-00022

Date of last issue: 28.09.2024  
Date of first issue: 11.12.2015

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

**Ribavirin Solid Formulation**

|                |                              |                             |                                                                   |
|----------------|------------------------------|-----------------------------|-------------------------------------------------------------------|
| Version<br>5.1 | Revision Date:<br>14.04.2025 | SDS Number:<br>402487-00022 | Date of last issue: 28.09.2024<br>Date of first issue: 11.12.2015 |
|----------------|------------------------------|-----------------------------|-------------------------------------------------------------------|

---

Remarks : Based on data from similar materials

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Ribavirin:**

Remarks : No data available  
May irritate eyes.

**Magnesium stearate:**

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

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Ribavirin:**

Remarks : No data available

**Magnesium stearate:**

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

**Germ cell mutagenicity**

Suspected of causing genetic defects.

**Components:****Ribavirin:**

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

Test Type: In vitro mammalian cell gene mutation test  
Test system: Rodent cell line  
Result: positive

Test Type: Chromosomal aberration  
Test system: Human lymphocytes  
Result: negative

**Ribavirin Solid Formulation**

Version 5.1

Revision Date: 14.04.2025

SDS Number: 402487-00022

Date of last issue: 28.09.2024  
Date of first issue: 11.12.2015

|                                                |                                                                                                                                                        |
|------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vivo                           | : Test Type: dominant lethal test<br>Species: Rat<br>Result: negative                                                                                  |
|                                                | Test Type: Mouse Lymphoma<br>Species: Mouse<br>Result: positive                                                                                        |
|                                                | Test Type: Micronucleus test<br>Species: Mouse<br>Result: positive                                                                                     |
| Germ cell mutagenicity - Assessment            | : Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.                                                                           |
| <b>Cellulose:</b>                              |                                                                                                                                                        |
| Genotoxicity in vitro                          | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative                                                                               |
|                                                | Test Type: In vitro mammalian cell gene mutation test<br>Result: negative                                                                              |
| Genotoxicity in vivo                           | : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |
| <b>Magnesium stearate:</b>                     |                                                                                                                                                        |
| Genotoxicity in vitro                          | : Test Type: In vitro mammalian cell gene mutation test<br>Result: negative<br>Remarks: Based on data from similar materials                           |
|                                                | Test Type: Chromosome aberration test in vitro<br>Method: OECD Test Guideline 473<br>Result: negative<br>Remarks: Based on data from similar materials |
|                                                | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br>Remarks: Based on data from similar materials                                |
| <b>Carcinogenicity</b>                         |                                                                                                                                                        |
| Not classified based on available information. |                                                                                                                                                        |
| <b>Components:</b>                             |                                                                                                                                                        |
| <b>Ribavirin:</b>                              |                                                                                                                                                        |
| Species                                        | : Mouse                                                                                                                                                |
| Application Route                              | : Oral                                                                                                                                                 |
| Exposure time                                  | : 6 Months                                                                                                                                             |
| LOAEL                                          | : 75 mg/kg body weight                                                                                                                                 |

**Ribavirin Solid Formulation**

|                |                              |                             |                                                                   |
|----------------|------------------------------|-----------------------------|-------------------------------------------------------------------|
| Version<br>5.1 | Revision Date:<br>14.04.2025 | SDS Number:<br>402487-00022 | Date of last issue: 28.09.2024<br>Date of first issue: 11.12.2015 |
|----------------|------------------------------|-----------------------------|-------------------------------------------------------------------|

|                   |   |                                                                |
|-------------------|---|----------------------------------------------------------------|
| Result            | : | negative                                                       |
| Target Organs     | : | Blood, Testes                                                  |
| Remarks           | : | The mechanism or mode of action may not be relevant in humans. |
| Species           | : | Rat                                                            |
| Application Route | : | Oral                                                           |
| Exposure time     | : | 2 Years                                                        |
| NOAEL             | : | 10 mg/kg body weight                                           |
| Result            | : | negative                                                       |
| Remarks           | : | The mechanism or mode of action may not be relevant in humans. |
| Species           | : | Mouse                                                          |
| Application Route | : | Oral                                                           |
| Exposure time     | : | 18 Months                                                      |
| Result            | : | negative                                                       |
| Remarks           | : | The mechanism or mode of action may not be relevant in humans. |

**Cellulose:**

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

**Reproductive toxicity**

May damage the unborn child. Suspected of damaging fertility.

**Components:****Ribavirin:**

|                      |   |                                                                                                                                                                                           |
|----------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility | : | Test Type: Fertility<br>Species: Rat, male<br>Application Route: Intraperitoneal injection<br>Fertility: LOAEL: < 20 mg/kg body weight<br>Symptoms: Reduced fertility<br>Result: positive |
|                      | : | Test Type: Fertility<br>Species: Mouse, male<br>Application Route: Oral<br>Fertility: LOAEL: 35 mg/kg body weight<br>Symptoms: Reduced fertility<br>Result: positive                      |
|                      | : | Test Type: Fertility<br>Species: Rat, females<br>Application Route: Oral<br>Fertility: NOAEL: 10 mg/kg body weight<br>Result: Animal testing did not show any effects on fertility.       |
|                      | : | Test Type: Fertility<br>Species: Rat, male                                                                                                                                                |

# SAFETY DATA SHEET



## Ribavirin Solid Formulation

Version  
5.1

Revision Date:  
14.04.2025

SDS Number:  
402487-00022

Date of last issue: 28.09.2024  
Date of first issue: 11.12.2015

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

### Cellulose:

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

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

**Ribavirin Solid Formulation**Version  
5.1Revision Date:  
14.04.2025SDS Number:  
402487-00022Date of last issue: 28.09.2024  
Date of first issue: 11.12.2015**Magnesium stearate:**

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

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

**STOT-single exposure**

May cause respiratory irritation.

**Components:****Ribavirin:**

Assessment : May cause respiratory irritation.

**STOT-repeated exposure**

Causes damage to organs (Blood) through prolonged or repeated exposure if swallowed.

**Components:****Ribavirin:**

Routes of exposure : Ingestion  
Target Organs : Blood  
Assessment : Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****Ribavirin:**

Species : Monkey  
LOAEL : 30 mg/kg  
Exposure time : 10 d  
Target Organs : Blood, Gastrointestinal tract

Species : Rat  
NOAEL : 7,6 mg/kg  
Application Route : Inhalation  
Exposure time : 90 d  
Target Organs : Blood, Lungs

Species : Dog  
NOAEL : 5 mg/kg

# SAFETY DATA SHEET



## Ribavirin Solid Formulation

Version 5.1      Revision Date: 14.04.2025      SDS Number: 402487-00022      Date of last issue: 28.09.2024  
Date of first issue: 11.12.2015

---

|                   |   |                               |
|-------------------|---|-------------------------------|
| Application Route | : | Oral                          |
| Exposure time     | : | 1 y                           |
| 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<br>Remarks: Based on Human Evidence                                                                                                    |
| Skin contact | : | Remarks: May cause eye irritation.<br>Based on Human Evidence                                                                                                        |
| Eye contact  | : | Remarks: May cause eye irritation.<br>Based on Human Evidence                                                                                                        |
| Ingestion    | : | Symptoms: blood effects, immune system effects, anorexia, Dizziness, insomnia, Fatigue, Headache, Itching, Rash, liver function change, Gastrointestinal disturbance |

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## SECTION 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

#### **Components:**

##### **Ribavirin:**

|                                                     |   |                                                                               |
|-----------------------------------------------------|---|-------------------------------------------------------------------------------|
| Toxicity to fish                                    | : | LC50 (Oncorhynchus mykiss (rainbow trout)): > 119 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 117 mg/l<br>Exposure time: 48 h          |

**Ribavirin Solid Formulation**Version  
5.1Revision Date:  
14.04.2025SDS Number:  
402487-00022Date of last issue: 28.09.2024  
Date of first issue: 11.12.2015

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  
Method: Directive 67/548/EEC, Annex V, C.2.  
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

# SAFETY DATA SHEET



## Ribavirin Solid Formulation

Version  
5.1

Revision Date:  
14.04.2025

SDS Number:  
402487-00022

Date of last issue: 28.09.2024  
Date of first issue: 11.12.2015

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### 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

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## SECTION 13. DISPOSAL CONSIDERATIONS

#### **Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
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.

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## 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.

# SAFETY DATA SHEET



## Ribavirin Solid Formulation

Version 5.1 Revision Date: 14.04.2025 SDS Number: 402487-00022 Date of last issue: 28.09.2024 Date of first issue: 11.12.2015

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### Domestic regulation

#### ANTT

Not regulated as a dangerous good

#### Special precautions for user

Not applicable

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## SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

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## SECTION 16. OTHER INFORMATION

Revision Date : 14.04.2025  
Date format : dd.mm.yyyy

### Further information

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

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

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; 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

# SAFETY DATA SHEET



## Ribavirin Solid Formulation

Version  
5.1

Revision Date:  
14.04.2025

SDS Number:  
402487-00022

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Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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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