

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.2	04/14/2025	402499-00022	Date of first issue: 12/11/2015

### SECTION 1. IDENTIFICATION

Product name : Ribavirin Solid Formulation  
Other means of identification : No data available

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

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

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

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

#### GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : 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.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Ribavirin Solid Formulation

Version 4.2      Revision Date: 04/14/2025      SDS Number: 402499-00022      Date of last issue: 09/30/2023  
Date of first issue: 12/11/2015

P260 Do not breathe dust.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P271 Use only outdoors or in a well-ventilated area.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.

### Response:

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

### Storage:

P405 Store locked up.

### Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

### Other hazards

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Ribavirin	No data available	36791-04-5	$\geq 60 - < 80$ *
Cellulose	No data available	9004-34-6	$\geq 10 - < 30$ *
Magnesium stearate	Octadecanoic acid, magnesium salt (2:1)	557-04-0	$\geq 1 - < 5$ *

\* Actual concentration or concentration range is withheld as a trade secret

## SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.  
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.2	04/14/2025	402499-00022	Date of first issue: 12/11/2015

In case of eye contact	: Wash clothing before reuse. Thoroughly clean shoes before reuse.
If swallowed	: If in eyes, rinse well with water. Get medical attention if irritation develops and persists. If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	: Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation. May cause respiratory irritation. Suspected of causing genetic defects. May damage the unborn child. Suspected of damaging fertility. Causes damage to organs through prolonged or repeated exposure if swallowed.
Protection of first-aiders	: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	: Treat symptomatically and supportively.

### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire fighting	: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Carbon oxides Metal oxides
Specific extinguishing methods	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency measures	: Use personal protective equipment. Follow safe handling advice (see section 7) and personal
---	--

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.2	04/14/2025	402499-00022	Date of first issue: 12/11/2015

- |   |  |
|---|--|
| gency procedures                                      | protective equipment recommendations (see section 8).  |
| Environmental precautions                             | :<br>Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained.   |
| Methods and materials for containment and cleaning up | :<br>Surround spill with absorbents and place a damp covering over the area to minimize entry of the material into the air.<br>Add excess liquid to allow the material to enter into solution.<br>Soak up with inert absorbent material.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).<br>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.<br>Clean up remaining materials from spill with suitable absorbent.<br>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.<br>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

### SECTION 7. HANDLING AND STORAGE

- |                         |   |
|-------------------------|---|
| Technical measures      | :<br>Static electricity may accumulate and ignite suspended dust causing an explosion.<br>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.   |
| Local/Total ventilation | :<br>If sufficient ventilation is unavailable, use with local exhaust ventilation.  |
| Advice on safe handling | :<br>Do not get on skin or clothing.<br>Do not breathe dust.<br>Do not swallow.<br>Avoid contact with eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>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.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>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. |

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Ribavirin Solid Formulation

Version 4.2      Revision Date: 04/14/2025      SDS Number: 402499-00022      Date of last issue: 09/30/2023  
Date of first issue: 12/11/2015

- Conditions for safe storage : Take care to prevent spills, waste and minimize release to the environment.  
Keep in properly labeled containers.  
Store locked up.  
Keep tightly closed.  
Keep in a cool, well-ventilated place.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible 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>	CA AB OEL
		TWA (Total dust)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m <sup>3</sup>	CA BC OEL
		TWAEV (total dust)	10 mg/m <sup>3</sup>	CA QC OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Magnesium stearate	557-04-0	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWA (Inhalable)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (Respirable)	3 mg/m <sup>3</sup>	CA BC OEL
		TWAEV (inhalable dust)	10 mg/m <sup>3</sup>	CA QC OEL
		TWAEV (respirable aerosol fraction)	3 mg/m <sup>3</sup>	CA QC OEL
		TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.2	04/14/2025	402499-00022	Date of first issue: 12/11/2015

**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**

**Material** : 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.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance** : powder

**Color** : white

**Odor** : No data available

**Odor Threshold** : No data available

**pH** : No data available

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Ribavirin Solid Formulation

Version 4.2	Revision Date: 04/14/2025	SDS Number: 402499-00022	Date of last issue: 09/30/2023 Date of first issue: 12/11/2015
----------------	------------------------------	-----------------------------	---

Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flash point	: No data available
Evaporation rate	: Not applicable
Flammability (solid, gas)	: May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	: No data available
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapor pressure	: Not applicable
Relative vapor density	: Not applicable
Relative density	: No data available
Density	: No data available
Solubility(ies) Water solubility	: No data available
Partition coefficient: n-octanol/water	: Not applicable
Autoignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity Viscosity, kinematic	: Not applicable
Explosive properties	: Not explosive
Oxidizing properties	: The substance or mixture is not classified as oxidizing.
Particle characteristics Particle size	: No data available

### SECTION 10. STABILITY AND REACTIVITY

Reactivity	: Not classified as a reactivity hazard.
Chemical stability	: Stable under normal conditions.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.2	04/14/2025	402499-00022	Date of first issue: 12/11/2015

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.

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 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



# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.2	04/14/2025	402499-00022	Date of first issue: 12/11/2015

---

### 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 sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

### Components:

#### Ribavirin:

Remarks : No data available

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.2	04/14/2025	402499-00022	Date of first issue: 12/11/2015

---

### Magnesium stearate:

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

### Germ cell mutagenicity

Suspected of causing genetic defects.

### Components:

#### Ribavirin:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: In vitro mammalian cell gene mutation test Test system: Rodent cell line Result: positive
	Test Type: Chromosomal aberration Test system: Human lymphocytes Result: negative
Genotoxicity in vivo	: Test Type: dominant lethal test Species: Rat Result: negative
	Test Type: Mouse Lymphoma Species: Mouse Result: positive
	Test Type: Micronucleus test Species: Mouse Result: positive
Germ cell mutagenicity - Assessment	: Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.
<b>Cellulose:</b>	
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

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.2	04/14/2025	402499-00022	Date of first issue: 12/11/2015

---

Result: negative

### Magnesium stearate:

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

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

Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

### Carcinogenicity

Not classified based on available information.

### Components:

#### Ribavirin:

Species : Mouse  
Application Route : Oral  
Exposure time : 6 Months  
LOAEL : 75 mg/kg body weight  
Result : negative  
Target Organs : Blood, Testes  
Remarks : The mechanism or mode of action may not be relevant in humans.

Species : Rat  
Application Route : Oral  
Exposure time : 2 Years  
NOAEL : 10 mg/kg body weight  
Result : negative  
Remarks : The mechanism or mode of action may not be relevant in humans.

Species : Mouse  
Application Route : Oral  
Exposure time : 18 Months  
Result : negative  
Remarks : The mechanism or mode of action may not be relevant in humans.

#### Cellulose:

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

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.2	04/14/2025	402499-00022	Date of first issue: 12/11/2015

### Reproductive toxicity

May damage the unborn child. Suspected of damaging fertility.

### Components:

#### Ribavirin:

Effects on fertility	: Test Type: Fertility Species: Rat, male Application Route: Intraperitoneal injection Fertility: LOAEL: < 20 mg/kg body weight Symptoms: Reduced fertility Result: positive  Test Type: Fertility Species: Mouse, male Application Route: Oral Fertility: LOAEL: 35 mg/kg body weight Symptoms: Reduced fertility Result: positive  Test Type: Fertility Species: Rat, females Application Route: Oral Fertility: NOAEL: 10 mg/kg body weight Result: Animal testing did not show any effects on fertility.  Test Type: Fertility Species: Rat, male Application Route: Oral Fertility: NOAEL: 160 mg/kg body weight Result: Animal testing did not show any effects on fertility.
Effects on fetal development	: Test Type: Development Species: Rat, female Application Route: Oral Developmental Toxicity: LOAEL: <= 1 mg/kg body weight Symptoms: Reduced body weight, Reduced number of viable fetuses., Skeletal malformations. Result: Embryotoxic effects and adverse effects on the offspring were detected.  Test Type: Development Species: Rabbit, female Application Route: Oral General Toxicity Maternal: LOAEL: 1 mg/kg body weight Developmental Toxicity: LOAEL: 1 mg/kg body weight Symptoms: Reduced body weight, Skeletal malformations. Result: Embryotoxic effects and adverse effects on the offspring were detected.  Test Type: Development Species: Hamster Application Route: Oral Developmental Toxicity: LOAEL: 2.5 mg/kg body weight

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.2	04/14/2025	402499-00022	Date of first issue: 12/11/2015

Symptoms: Skeletal and visceral variations ., Total Resorptions / resorption rate.

Result: Embryotoxic effects and adverse effects on the offspring were detected.

Test Type: Embryo-fetal development

Species: Rat

Application Route: Oral

General Toxicity Maternal: NOAEL: 0.3 mg/kg body weight

Embryo-fetal toxicity.: LOAEL: 1 mg/kg body weight

Symptoms: Skeletal malformations.

Result: positive

Reproductive toxicity - Assessment : 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

### 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.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.2	04/14/2025	402499-00022	Date of first issue: 12/11/2015

### 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
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	: $\geq 9,000$ 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

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.2	04/14/2025	402499-00022	Date of first issue: 12/11/2015

### 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

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### **Ribavirin:**

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 119 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 117 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 119 mg/l Exposure time: 96 h Method: OECD Test Guideline 201  NOEC (Pseudokirchneriella subcapitata (green algae)): 6.9 mg/l Exposure time: 96 h Method: OECD Test Guideline 201
Toxicity to microorganisms	:	EC50: > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

#### **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:**

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.2	04/14/2025	402499-00022	Date of first issue: 12/11/2015

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

### 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



# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.2	04/14/2025	402499-00022	Date of first issue: 12/11/2015

octanol/water

### **Mobility in soil**

No data available

### **Other adverse effects**

No data available

## 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.

## SECTION 14. TRANSPORT INFORMATION

### **International Regulations**

#### **UNRTDG**

Not regulated as a dangerous good

#### **IATA-DGR**

Not regulated as a dangerous good

#### **IMDG-Code**

Not regulated as a dangerous good

### **Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

### **Domestic regulation**

#### **TDG**

Not regulated as a dangerous good

### **Special precautions for user**

Not applicable

## SECTION 15. REGULATORY INFORMATION

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

## SECTION 16. OTHER INFORMATION

### **Full text of other abbreviations**

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.2	04/14/2025	402499-00022	Date of first issue: 12/11/2015

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	:	Canada. British Columbia OEL
CA QC OEL	:	Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for air-borne contaminants
ACGIH / TWA	:	8-hour, time-weighted average
CA AB OEL / TWA	:	8-hour Occupational exposure limit
CA BC OEL / TWA	:	8-hour time weighted average
CA QC OEL / TWAEV	:	Time-weighted average exposure value

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 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; TECL - 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

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/>

Revision Date : 04/14/2025  
Date format : mm/dd/yyyy

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

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.2	04/14/2025	402499-00022	Date of first issue: 12/11/2015

---

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.

CA / Z8