

**Ribavirin Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue:
2.2	2025/04/14	402579-00021	2023/09/30
			Date of first issue: 2015/12/11

---

**1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Ribavirin Solid Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065

Telephone : +1-908-740-4000

Emergency telephone number : +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

---

**2. HAZARDS IDENTIFICATION****GHS Classification**

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.

## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
2.2	2025/04/14	402579-00021	Date of first issue: 2015/12/11

## Precautionary statements

: **Prevention:**

P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe dust.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P271 Use only outdoors or in a well-ventilated area.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

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

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards which do not result in classification**

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

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Ribavirin	36791-04-5	$\geq 60$ - $\leq 100$
Cellulose	9004-34-6	$\geq 10$ - $< 30$
Magnesium stearate	557-04-0	$< 10$

**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.

**Ribavirin Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
2.2	2025/04/14	402579-00021	Date of first issue: 2015/12/11

---

In case of eye contact	: Remove contaminated clothing and shoes. Get medical attention. 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.

---

**5. FIREFIGHTING 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 firefighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

---

**6. ACCIDENTAL RELEASE MEASURES**

**Ribavirin Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue:
2.2	2025/04/14	402579-00021	2023/09/30
			Date of first issue: 2015/12/11

---

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 minimise 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.

---

**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 sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.  
Minimize dust generation and accumulation.  
Keep container closed when not in use.

## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
2.2	2025/04/14	402579-00021	2023/09/30
			Date of first issue: 2015/12/11

Keep away from heat and sources of ignition.  
 Take precautionary measures against static discharges.  
 Do not eat, drink or smoke when using this product.  
 Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labelled containers.  
 Store locked up.  
 Keep tightly closed.  
 Keep in a cool, well-ventilated place.

Materials to avoid : Store in accordance with the particular national regulations.  
 Do not store with the following product types:  
 Strong oxidizing agents

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Components 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	NAB	10 mg/m <sup>3</sup>	ID OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Magnesium stearate	557-04-0	NAB	10 mg/m <sup>3</sup>	ID OEL
Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals				
		TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH

**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

**Ribavirin Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue:
2.2	2025/04/14	402579-00021	2023/09/30
			Date of first issue: 2015/12/11

---

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.

---

**9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	:	powder
Colour	:	white
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available

**Ribavirin Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
2.2	2025/04/14	402579-00021	Date of first issue: 2015/12/11

---

Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Particle characteristics Particle size	:	No data available

---

**10. STABILITY AND REACTIVITY**

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

---

**11. TOXICOLOGICAL INFORMATION**

Information on likely routes of	:	Inhalation
---------------------------------	---	------------

## Ribavirin Solid Formulation

Version 2.2	Revision Date: 2025/04/14	SDS Number: 402579-00021	Date of last issue: 2023/09/30 Date of first issue: 2015/12/11
----------------	------------------------------	-----------------------------	---

---

exposure

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

**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



**Ribavirin Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
2.2	2025/04/14	402579-00021	Date of first issue: 2015/12/11

---

**Skin corrosion/irritation**

Not classified based on available information.

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

Remarks : No data available  
May irritate skin.

**Magnesium stearate:**

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

**Serious eye damage/eye irritation**

Not classified based on available information.

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

Remarks : No data available  
May irritate eyes.

**Magnesium stearate:**

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

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

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

Remarks : No data available

**Magnesium stearate:**

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative  
Remarks : Based on data from similar materials

**Ribavirin Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
2.2	2025/04/14	402579-00021	Date of first issue: 2015/12/11

---

**Germ cell mutagenicity**

Suspected of causing genetic defects.

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

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

**Cellulose:**

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative  Test Type: In vitro mammalian cell gene mutation test Result: negative
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative

**Magnesium stearate:**

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

**Ribavirin Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
2.2	2025/04/14	402579-00021	Date of first issue: 2015/12/11

---

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

**Reproductive toxicity**

May damage the unborn child. Suspected of damaging fertility.

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

Effects on fertility	:	Test Type: Fertility
----------------------	---	----------------------

## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
2.2	2025/04/14	402579-00021	Date of first issue: 2015/12/11

---

Species: Rat, male  
Application Route: Intraperitoneal injection  
Fertility: LOAEL: < 20 mg/kg body weight  
Symptoms: Reduced fertility  
Result: positive

Test Type: Fertility  
Species: Mouse, male  
Application Route: Oral  
Fertility: LOAEL: 35 mg/kg body weight  
Symptoms: Reduced fertility  
Result: positive

Test Type: Fertility  
Species: Rat, females  
Application Route: Oral  
Fertility: NOAEL: 10 mg/kg body weight  
Result: Animal testing did not show any effects on fertility.

Test Type: Fertility  
Species: Rat, male  
Application Route: Oral  
Fertility: NOAEL: 160 mg/kg body weight  
Result: Animal testing did not show any effects on fertility.

Effects on foetal development : Test Type: Development  
Species: Rat, female  
Application Route: Oral  
Developmental Toxicity: LOAEL: <= 1 mg/kg body weight  
Symptoms: Reduced body weight, Reduced number of viable fetuses, Skeletal malformations  
Result: Embryotoxic effects and adverse effects on the 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.

## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
2.2	2025/04/14	402579-00021	2023/09/30
			Date of first issue: 2015/12/11

---

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
General Toxicity Maternal: NOAEL: 0.3 mg/kg body weight  
Embryo-foetal toxicity: LOAEL: 1 mg/kg body weight  
Symptoms: Skeletal malformations  
Result: positive

Reproductive toxicity - 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 foetal development : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative

**Magnesium stearate:**

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

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

**STOT - single exposure**

May cause respiratory irritation.

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

Assessment : May cause respiratory irritation.

**STOT - repeated exposure**

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

**Ribavirin Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
2.2	2025/04/14	402579-00021	Date of first issue: 2015/12/11

---

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

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

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

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

Species	: Rat
NOAEL	: 7.6 mg/kg
Application Route	: Inhalation
Exposure time	: 90 d
Target Organs	: Blood, Lungs

Species	: Dog
NOAEL	: 5 mg/kg
Application Route	: Oral
Exposure time	: 1 yr
Target Organs	: Blood, Gastrointestinal tract

Species	: Mouse
NOAEL	: 20 mg/kg
Application Route	: Oral
Exposure time	: 18 Months
Target Organs	: Blood, Cardio-vascular system

**Cellulose:**

Species	: Rat
NOAEL	: $\geq 9,000$ 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

## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
2.2	2025/04/14	402579-00021	2023/09/30
			Date of first issue: 2015/12/11

---

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Ribavirin:**

Inhalation	:	Symptoms: Headache, Dizziness Remarks: Based on Human Evidence
Skin contact	:	Remarks: May cause eye irritation. Based on Human Evidence
Eye contact	:	Remarks: May cause eye irritation. Based on Human Evidence
Ingestion	:	Symptoms: blood effects, immune system effects, anorexia, Dizziness, insomnia, Fatigue, Headache, Itching, Rash, liver function change, Gastrointestinal disturbance

---

**12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Ribavirin:**

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

**Cellulose:**

Toxicity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
------------------	---	--

## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
2.2	2025/04/14	402579-00021	2023/09/30
			Date of first issue: 2015/12/11

---

**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

**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



## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
2.2	2025/04/14	402579-00021	Date of first issue: 2015/12/11

**Magnesium stearate:**

Partition coefficient: n-octanol/water : log Pow: > 4

**Mobility in soil**

No data available

**Other adverse effects**

No data available

**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.

**14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

UN number : Not applicable

Proper shipping name : Not applicable

Class : Not applicable

Subsidiary risk : Not applicable

Packing group : Not applicable

Labels : Not applicable

Environmentally hazardous : no

**IATA-DGR**

UN/ID No. : Not applicable

Proper shipping name : Not applicable

Class : Not applicable

Subsidiary risk : Not applicable

Packing group : Not applicable

Labels : Not applicable

Packing instruction (cargo aircraft) : Not applicable

Packing instruction (passenger aircraft) : Not applicable

**IMDG-Code**

UN number : Not applicable

Proper shipping name : Not applicable

Class : Not applicable

Subsidiary risk : Not applicable

Packing group : Not applicable

Labels : Not applicable

EmS Code : Not applicable

Marine pollutant : Not applicable

## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
2.2	2025/04/14	402579-00021	Date of first issue: 2015/12/11

---

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

Not applicable for product as supplied.

**Special precautions for user**

Not applicable

---

**15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture****Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.****Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health**

Hazardous substances that must be registered : Not applicable

**Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances**

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

**Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials**

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

---

**16. OTHER INFORMATION**

Revision Date : 2025/04/14

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

Date format : yyyy/mm/dd

**Full text of other abbreviations**

**Ribavirin Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
2.2	2025/04/14	402579-00021	Date of first issue: 2015/12/11

---

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
ID OEL	:	Indonesia. Occupational Exposure Limits
ACGIH / TWA	:	8-hour, time-weighted average
ID OEL / NAB	:	Long term exposure limit

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; 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.

ID / EN