

Ribavirin Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.1 30.09.2023 402650-00020 Date of first issue: 11.12.2015

Section 1: Identification

Product name : Ribavirin Solid Formulation

Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908

Upper Hutt - New Zealand

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

Section 2: Hazard identification

GHS Classification

Germ cell mutagenicity : Category 2

Reproductive toxicity : Category 1

Specific target organ toxicity - :

single exposure

Category 3

Specific target organ toxicity - :

repeated exposure (Oral)

Category 1 (Blood)

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : H335 May cause respiratory irritation.

H341 Suspected of causing genetic defects.

H360Df May damage the unborn child. Suspected of damaging

ertility.

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: 04.04.2023 5.1 30.09.2023 402650-00020 Date of first issue: 11.12.2015

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P261 Avoid breathing 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 protec-

tion/ 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.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Ribavirin	36791-04-5	>= 50 -< 70
Cellulose	9004-34-6	>= 10 -< 20
Magnesium stearate	557-04-0	>= 1 -< 10

Section 4: First-aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice 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.



Ribavirin Solid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.1
 30.09.2023
 402650-00020
 Date of first issue: 11.12.2015

Get medical attention.
Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact : If in eyes, rinse well with water.

Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

May cause respiratory irritation.

and effects, both acute and Suspected of causing genetic defects. delayed May damage the unborn child. Suspected of causing genetic defects.

May damage the unborn child. Suspected of damaging fertili-

ty.

Causes damage to organs through prolonged or repeated

exposure if swallowed.

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation. 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

Protection of first-aiders

Most important symptoms

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

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 prod: :

ucts

Carbon oxides

Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

Section 6: Accidental release measures

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).



Ribavirin Solid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.1
 30.09.2023
 402650-00020
 Date of first issue: 11.12.2015

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 deter-

mine 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 as-

sessment

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 respira-

tory irritants or sensitisers.

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.



Ribavirin Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.1 30.09.2023 402650-00020 Date of first issue: 11.12.2015

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.

Conditions for safe storage : Keep in properly labelled containers.

Store locked up. Keep tightly closed.

Keep in a cool, well-ventilated place.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis
		exposure)	concentration	
Ribavirin	36791-04-5	Wipe limit	400 μg/100 cm ²	Internal
		TWA	40 μg/m3 (OEB 3)	Internal
Cellulose	9004-34-6	WES-TWA	10 mg/m3	NZ OEL
		TWA	10 mg/m3	ACGIH
Magnesium stearate	557-04-0	WES-TWA	10 mg/m3	NZ OEL
		TWA (Inhal-	10 mg/m3	ACGIH
		able particu- late matter)		
		TWA (Res-	3 mg/m3	ACGIH
		pirable par-		
		ticulate mat-		
		ter)		

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 con-

tainment devices). Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.



Ribavirin Solid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.1
 30.09.2023
 402650-00020
 Date of first issue: 11.12.2015

Filter type
Hand protection

: Particulates type

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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Section 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, han-

dling or other means.

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : Not applicable



Ribavirin Solid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.1
 30.09.2023
 402650-00020
 Date of first issue: 11.12.2015

Relative vapour density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Particle size : No data available

Section 10: Stability and reactivity

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

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Hazardous decomposition

products

Oxidizing agents

No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes : 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



Ribavirin Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.1 30.09.2023 402650-00020 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 tox-

icity

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.



Ribavirin Solid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.1
 30.09.2023
 402650-00020
 Date of first issue: 11.12.2015

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

Chronic toxicity

Germ cell mutagenicity

Suspected of causing genetic defects.

Components:

Ribavirin:

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

Result: negative



Ribavirin Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.1 30.09.2023 402650-00020 Date of first issue: 11.12.2015

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 muta-

genicity tests.

Cellulose:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Result: negative

Magnesium stearate:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials



Ribavirin Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.1 30.09.2023 402650-00020 Date of first issue: 11.12.2015

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 hu-

mans.

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 hu-

mans.

Species : Mouse
Application Route : Oral
Exposure time : 18 Months
Result : negative

Remarks : The mechanism or mode of action may not be relevant in hu-

mans.

Cellulose:

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

Reproductive toxicity

May damage the unborn child. Suspected of damaging fertility.

Components:

Ribavirin:

Effects on fertility : Test Type: Fertility

Species: Rat, male

Application Route: Intraperitoneal injection Fertility: LOAEL: < 20 mg/kg body weight

Symptoms: Reduced fertility

Result: positive

Test Type: Fertility Species: Mouse, male Application Route: Oral



Ribavirin Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.1 30.09.2023 402650-00020 Date of first issue: 11.12.2015

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 develop-

ment

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-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 - As-

Some evidence of adverse effects on sexual function and



Ribavirin Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.1 30.09.2023 402650-00020 Date of first issue: 11.12.2015

sessment fertility, based on animal experiments., Clear evidence of ad-

verse 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 develop-

ment

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 develop-

ment

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.

Components:

Ribavirin:

Exposure routes : Ingestion Target Organs : Blood

Assessment : Causes damage to organs through prolonged or repeated

exposure.



Ribavirin Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.1 30.09.2023 402650-00020 Date of first issue: 11.12.2015

Repeated dose toxicity

Components:

Ribavirin:

Species : Monkey LOAEL : 30 mg/kg Exposure time : 10 d

Target Organs : Blood, Gastrointestinal tract

Species : Rat
NOAEL : 7.6 mg/kg
Application Route : Inhalation
Exposure time : 90 d

Target Organs : Blood, Lungs

Species : Dog NOAEL : 5 mg/kg Application Route : Oral Exposure time : 1 yr

Target Organs : Blood, Gastrointestinal tract

Species : Mouse
NOAEL : 20 mg/kg
Application Route : Oral
Exposure time : 18 Months

Target Organs : Blood, Cardio-vascular system

Cellulose:

Species : Rat

NOAEL : >= 9,000 mg/kg

Application Route : Ingestion Exposure time : 90 Days

Magnesium stearate:

Species : Rat

NOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Remarks : Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Ribavirin:

Inhalation : Symptoms: Headache, Dizziness

Remarks: Based on Human Evidence



Ribavirin Solid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.1
 30.09.2023
 402650-00020
 Date of first issue: 11.12.2015

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:

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



Ribavirin Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.1 30.09.2023 402650-00020 Date of first issue: 11.12.2015

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-

: log Pow: > 4

octanol/water

Mobility in soil
No data available

Other adverse effects

No data available



Ribavirin Solid Formulation

Version Date of last issue: 04.04.2023 Revision Date: SDS Number: 5.1 30.09.2023 402650-00020 Date of first issue: 11.12.2015

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

Section 14: Transport information

International Regulations

UNRTDG

UN number Not applicable Not applicable Proper shipping name Not applicable Class Subsidiary risk Not applicable Not applicable Packing group Labels Not applicable

IATA-DGR

UN/ID No. Not applicable Proper shipping name Not applicable Class Not applicable Not applicable Subsidiary risk Packing group Not applicable Labels Not applicable Packing instruction (cargo Not applicable

aircraft)

Packing instruction (passen-

ger aircraft)

Not applicable

IMDG-Code

UN number Not applicable Proper shipping name Not applicable Class Not applicable Not applicable Subsidiary risk Not applicable Packing group Labels Not applicable **EmS Code** Not applicable Not applicable Marine pollutant

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

Not applicable for product as supplied.

National Regulations

NZS 5433

UN number Not applicable Proper shipping name Not applicable Not applicable Class Not applicable Subsidiary risk



Ribavirin Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.1 30.09.2023 402650-00020 Date of first issue: 11.12.2015

Packing group : Not applicable Labels : Not applicable Hazchem Code : Not applicable

Special precautions for user

Not applicable

Section 15: Regulatory information

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

HSNO Approval Number

not allocated

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

AICS : not determined

DSL : not determined

IECSC : not determined

Section 16: Other information

Revision Date : 30.09.2023

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 Agen-

cy, http://echa.europa.eu/

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospher-

ic Contaminants

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

NZ OEL / WES-TWA : Workplace Exposure Standard - 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 con-



Ribavirin Solid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.1
 30.09.2023
 402650-00020
 Date of first issue: 11.12.2015

centration; 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.

NZ / EN