

according to the Hazardous Products Regulations

## **Ribavirin Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
4.1	09/30/2023	402499-00021	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 - single exposure	:	Category 3
Specific target organ toxicity - repeated exposure (Oral)	:	Category 1 (Blood)
GHS label elements		
Hazard pictograms	:	
Signal Word	:	Danger
Hazard Statements	:	<ul> <li>H335 May cause respiratory irritation.</li> <li>H341 Suspected of causing genetic defects.</li> <li>H360Df May damage the unborn child. Suspected of damaging fertility.</li> <li>H372 Causes damage to organs (Blood) through prolonged or repeated exposure if swallowed.</li> </ul>
Precautionary Statements	:	<b>Prevention:</b> P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood.

according to the Hazardous Products Regulations



## **Ribavirin Solid Formulation**

Version 4.1	Revision Date: 09/30/2023	SDS Number: 402499-00021	Date of last issue: 04/04/2023 Date of first issue: 12/11/2015
		P270 Do not e P271 Use only	in thoroughly after handling. at, drink or smoke when using this product. outdoors or in a well-ventilated area. otective gloves, protective clothing, eye protection
		and keep com unwell.	<ul> <li>P312 IF INHALED: Remove person to fresh air fortable for breathing. Call a doctor if you feel</li> <li>F exposed or concerned: Get medical attention.</li> </ul>
		<b>Storage:</b> P405 Store loc	sked up.
		<b>Disposal:</b> P501 Dispose disposal plant.	of contents and container to an approved waste

### 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.

: Mixture

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture

### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Ribavirin	No data availa- ble	36791-04-5	>= 60 - < 80 *
Cellulose	No data availa- ble	9004-34-6	>= 10 - < 30 *
Magnesium stearate	Octadecanoic acid, magnesi- um salt (2:1)	557-04-0	>= 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.





# **Ribavirin Solid Formulation**

Version 4.1	Revision Date: 09/30/2023	SDS Number: 402499-00021	Date of last issue: 04/04/2023 Date of first issue: 12/11/2015			
		Wash clothin	Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.			
In c	ase of eye contact		If in eyes, rinse well with water.			
lfe	wallowed		attention if irritation develops and persists.			
n swallowed		Get medical	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.			
Мо	st important symptoms	: May cause re	May cause respiratory irritation.			
	l effects, both acute and		causing genetic defects.			
delayed		May damage ty.	the unborn child. Suspected of damaging fertili-			
		Causes dama exposure if s	age to organs through prolonged or repeated wallowed.			
		Contact with the skin.	dust can cause mechanical irritation or drying of			
Pro	tection of first-aiders	: First Aid resp and use the r	with the eyes can lead to mechanical irritation. bonders should pay attention to self-protection, recommended personal protective equipment ential for exposure exists (see section 8).			
Not	es to physician	-	matically and supportively.			

### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media		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 fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :		Use personal protective equipment.	
tive equipment and emer-		Follow safe handling advice (see section 7) and personal	
gency procedures		protective equipment recommendations (see section 8).	
Environmental precautions	:	Avoid release to the environment.	



according to the Hazardous Products Regulations

# **Ribavirin Solid Formulation**

Version 4.1	Revision Date: 09/30/2023	SDS Number: 402499-00021	Date of last issue: 04/04/2023 Date of first issue: 12/11/2015
		Retain and disp	e leakage or spillage if safe to do so. bose of contaminated wash water. les should be advised if significant spillages ained.
	ods and materials for inment and cleaning up	over the area to Add excess liqu Soak up with in Avoid dispersa with compresse Dust deposits a surfaces, as the released into th Clean up rema absorbent. Local or nation disposal of this employed in the determine whic Sections 13 an	with absorbents and place a damp covering o minimize entry of the material into the air. uid to allow the material to enter into solution. hert absorbent material. I of dust in the air (i.e., clearing dust surfaces ed air). should not be allowed to accumulate on ese may form an explosive mixture if they are he atmosphere in sufficient concentration. ining materials from spill with suitable al regulations may apply to releases and material, as well as those materials and items e cleanup of releases. You will need to ch regulations are applicable. d 15 of this SDS provide information regarding national requirements.

### SECTION 7. HANDLING AND STORAGE

Technical measures	:	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation	:	If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	:	Do not get on skin or clothing. Do not breathe dust. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers. Minimize dust generation and accumulation. Keep container closed when not in use. 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
Conditions for safe storage	:	environment. Keep in properly labeled containers. Store locked up.



according to the Hazardous Products Regulations

## **Ribavirin Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
4.1	09/30/2023	402499-00021	Date of first issue: 12/11/2015
Mate	rials to avoid	Store in accord Do not store w Strong oxidizir	, well-ventilated place. dance with the particular national regulations. ith the following product types: ig agents ubstances and mixtures

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

ingredients with workplag	Ingredients with workplace control parameters					
Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis		
Ribavirin	36791-04-5	Wipe limit	400 µg/100 cm <sup>2</sup>	Internal		
		TWA	40 µg/m3 (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 (respir- able dust fraction)	3 mg/m³	CA BC OEL		
		TWAEV (to- tal 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		
		TWAEV	10 mg/m <sup>3</sup>	CA QC OEL		
		TWA (Inhal- able)	10 mg/m³	CA BC OEL		
		TWA (Res- pirable)	3 mg/m³	CA BC OEL		
		TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH		
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH		

### Ingredients with workplace control parameters

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.



according to the Hazardous Products Regulations

# **Ribavirin Solid Formulation**

Version 4.1	Revision Date: 09/30/2023	SDS Number: 402499-00021	Date of last issue: 04/04/2023 Date of first issue: 12/11/2015
Pers	onal protective equip	nent	
Respiratory protection		exposure ass	cal exhaust ventilation is not available or essment demonstrates exposures outside the d guidelines, use respiratory protection.
	Iter type I protection	: Particulates t	
М	aterial	: Chemical-res	istant gloves
	emarks protection	If the work en mists or aeros Wear a faces	ble gloving. glasses with side shields or goggles. vironment or activity involves dusty conditions, sols, wear the appropriate goggles. hield or other full face protection if there is a lirect contact to the face with dusts, mists, or
Skin	and body protection	: Work uniform Additional boo task being pe disposable su	or laboratory coat. dy garments should be used based upon the rformed (e.g., sleevelets, apron, gauntlets, its) to avoid exposed skin surfaces. ate degowning techniques to remove potentially clothing.
Hygie	ene measures	: If exposure to eye flushing s working place When using o Wash contam The effective engineering o appropriate d industrial hyg	chemical is likely during typical use, provide systems and safety showers close to the

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	white
Odor	:	No data available
Odor Threshold	:	No data available
рН	:	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



according to the Hazardous Products Regulations

## **Ribavirin Solid Formulation**

Vers 4.1	sion	Revision Date: 09/30/2023		S Number: 2499-00021	Date of last issue: 04/04/2023 Date of first issue: 12/11/2015
	Flammability (solid, gas)		:	May form explosi handling or other	ve dust-air mixture during processing, means.
	Flamma	ability (liquids)	:	No data available	•
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapor p	oressure	:	Not applicable	
	Relative	e vapor density	:	Not applicable	
	Relative density		:	No data available	)
	Density		:	No data available	)
	Solubility(ies) Water solubility		:	No data available	9
	Partition coefficient: n- octanol/water		:	Not applicable	
		ition temperature	:	No data available	
	Decomp	position temperature	:	No data available	
	Viscosit Visc	y osity, kinematic	:	Not applicable	
	Explosiv	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance of	mixture is not classified as oxidizing.
	Particle	size	:	No data available	)

### SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. 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 Hazardous decomposition products	:	Oxidizing agents



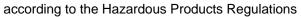
according to the Hazardous Products Regulations

Version 4.1	Revision Date: 09/30/2023	SDS Number: 402499-00021		Date of last issue: 04/04/2023 Date of first issue: 12/11/2015
SECTION	N 11. TOXICOLOGICAL I	NF	ORMATION	
Inha Skin Inge	rmation on likely routes lation contact stion contact	of	exposure	
	te toxicity			
	classified based on availa	ble	information.	
	<u>duct:</u> te oral toxicity	:	Acute toxicity es Method: Calcula	stimate: > 2,000 mg/kg ation method
Con	<u>iponents:</u>			
Riba	avirin:			
Acut	e oral toxicity	:	LD50 (Rat): 4,1	16 - 5,584 mg/kg
			LD50 (Mouse):	> 10,000 mg/kg
			LD50 (Dog): >=	1,500 mg/kg
Acut	e inhalation toxicity	:	Remarks: No da	ata available
Acut	e dermal toxicity	:	Remarks: No da	ata available
	te toxicity (other routes of inistration)	:		54 - 1,758 mg/kg ite: Intraperitoneal
			LD50 (Mouse): Application Rou	1,268 mg/kg ite: Intraperitoneal
Cell	ulose:			
Acut	e oral toxicity	:	LD50 (Rat): > 5	,000 mg/kg
Acut	e inhalation toxicity	:	LC50 (Rat): > 5 Exposure time: Test atmospher	4 h
Acut	e dermal toxicity	:	LD50 (Rabbit):	> 2,000 mg/kg
Man	nesium stearate:			
-	te oral toxicity	:	Assessment: Thicity	,000 mg/kg Test Guideline 423 ne substance or mixture has no acute oral tox d on data from similar materials
Acut	e dermal toxicity	:	LD50 (Rabbit):	> 2,000 mg/kg
			. /	



according to the Hazardous Products Regulations

rsion I	Revision Date: 09/30/2023	SDS Number: 402499-00021	Date of last issue: 04/04/2023 Date of first issue: 12/11/2015
		Remarks: Bas	ed on data from similar materials
Skin	corrosion/irritation		
Not c	lassified based on av	ailable information.	
<u>Com</u>	oonents:		
Riba	/irin:		
Rema	arks	: No data availa May irritate sk	
Magn	esium stearate:		
Speci	es	: Rabbit	
Resu		: No skin irritati	***
Rema	arks	: Based on data	a from similar materials
Serio	us eye damage/eye	irritation	
Not c	lassified based on av	ailable information.	
<u>Com</u>	oonents:		
Riba	/irin:		
Rema	arks	: No data availa	able
		May irritate ey	Yes.
Magn	esium stearate:		
Speci	es	: Rabbit	
Resu		: No eye irritatio	วท
Rema	arks	: Based on data	a from similar materials
Resp	iratory or skin sens	itization	
	sensitization		
Not c	assified based on av	ailable information.	
Resp	iratory sensitizatior	1	
Not c	lassified based on av	ailable information.	
<u>Com</u>	<u>oonents:</u>		
Riba	/irin:		
Rema	arks	: No data availa	able
Magn	esium stearate:		
Test <sup>-</sup>		: Maximization	Test
	es of exposure	: Skin contact	
Speci	es	: Guinea pig	
Metho		: OECD Test G	uideline 406
Resu		: negative	a from similar materials
Rema		Based on data	





ersion 1	Revision Date: 09/30/2023	SDS Number: 402499-00021	Date of last issue: 04/04/2023 Date of first issue: 12/11/2015		
Germ	cell mutagenicity				
Suspec	cted of causing gene	tic defects.			
<u>Compo</u>	onents:				
Ribavi	rin:				
Genoto	oxicity in vitro	: Test Type: Result: neg	Bacterial reverse mutation assay (AMES) gative		
			In vitro mammalian cell gene mutation test m: Rodent cell line sitive		
			Chromosomal aberration m: Human lymphocytes gative		
Genoto	oxicity in vivo	: Test Type: Species: R Result: ne			
		Test Type: Species: M Result: pos			
		Test Type: Species: M Result: pos			
Germ o Assess	cell mutagenicity - ment		Positive result(s) from in vivo mammalian somatic cell muta- genicity tests.		
Cellulo	ose:				
	oxicity in vitro	: Test Type: Result: neg	Bacterial reverse mutation assay (AMES) gative		
		Test Type: Result: neg	In vitro mammalian cell gene mutation test gative		
Genoto	oxicity in vivo	cytogeneti Species: M	Iouse n Route: Ingestion		
Magne	sium stearate:				
-	oxicity in vitro	Result: neg	In vitro mammalian cell gene mutation test gative Based on data from similar materials		
			Chromosome aberration test in vitro ECD Test Guideline 473 gative		



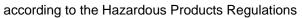
according to the Hazardous Products Regulations

ersion 1	Revision Date: 09/30/2023	SDS Number: 402499-00021	Date of last issue: 04/04/2023 Date of first issue: 12/11/2015
		Remarks: Base	d on data from similar materials
			terial reverse mutation assay (AMES)
		Result: negative Remarks: Base	e d on data from similar materials
	<b>nogenicity</b> assified based on av	ailable information.	
<u>Comp</u>	onents:		
Ribav	irin:		
Specie	es	: Mouse	
	ation Route	: Oral	
	ure time	: 6 Months	
LOAE		: 75 mg/kg body	weight
Result		: negative : Blood, Testes	
Rema	t Organs rks	,	n or mode of action may not be relevant in hu
rtoma		mans.	
Specie		: Rat	
	ation Route	: Oral	
	ure time	: 2 Years	weight
NOAE Result		: 10 mg/kg body : negative	weight
Rema			n or mode of action may not be relevant in hu
		mans.	,
Specie		: Mouse	
	ation Route	: Oral	
Expos Result	ure time	: 18 Months	
Rema		: negative · The mechanism	n or mode of action may not be relevant in hu
Rema		mans.	
Cellul	ose:		
Specie		: Rat	
	ation Route	: Ingestion	
	ure time	: 72 weeks	
Result	t	: negative	
Repro	ductive toxicity		
-	-	hild. Suspected of dama	aging fertility.
	onents:	·	
Ribav	irin:		
Effects	s on fertility	: Test Type: Fert	ility
	,	Species: Rat, n	nale
			ite: Intraperitoneal injection
			.: < 20 mg/kg body weight
		Symptoms: Red	aucea lenility

according to the Hazardous Products Regulations



Version 4.1	Revision Date: 09/30/2023	SDS Number: 402499-00021	Date of last issue: 04/04/2023 Date of first issue: 12/11/2015
		Result: positive Test Type: Fer Species: Mous Application Ro Fertility: LOAE Symptoms: Re Result: positive	tility se, male ute: Oral L: 35 mg/kg body weight sduced fertility
		Test Type: Fer Species: Rat, 1 Application Ro Fertility: NOAE	tility emales
			male
Effects on fetal development		Symptoms: Re fetuses., Skele	emale ute: Oral I Toxicity: LOAEL: <= 1 mg/kg body weight educed body weight, Reduced number of viable etal malformations. otoxic effects and adverse effects on the
		Developmenta Symptoms: Re	it, female ute: Oral ty Maternal: LOAEL: 1 mg/kg body weight I Toxicity: LOAEL: 1 mg/kg body weight educed body weight, Skeletal malformations. otoxic effects and adverse effects on the
		Symptoms: Sk tions / resorption	ster ute: Oral I Toxicity: LOAEL: 2.5 mg/kg body weight eletal and visceral variations ., Total Resorp- on rate. otoxic effects and adverse effects on the
		Species: Rat Application Ro General Toxici Embryo-fetal to	bryo-fetal development ute: Oral ty Maternal: NOAEL: 0.3 mg/kg body weight oxicity.: LOAEL: 1 mg/kg body weight eletal malformations.





ersion 1	Revision Date: 09/30/2023		9S Number: 2499-00021	Date of last issue: 04/04/2023 Date of first issue: 12/11/2015
			Result: positive	
Reproductive toxicity - As- sessment		:	: Some evidence of adverse effects on sexual functio fertility, based on animal experiments., Clear eviden adverse effects on development, based on animal experiments.	
Cellu	lose:			
Effect	Effects on fertility		Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative	
Effect	Effects on fetal development		Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative	
Magn	esium stearate:			
Effect	ts on fertility	:	reproduction/deve Species: Rat Application Route Method: OECD T Result: negative	
Effect	Effects on fetal development		Species: Rat Application Route Result: negative	vo-fetal development e: Ingestion on data from similar materials
	-single exposure			
-	cause respiratory irritatio ponents:	n.		
Ribay Asses	ssment	:	May cause respire	atory irritation.
STO	-repeated exposure			
Caus	es damage to organs (B	lood	) through prolonge	d or repeated exposure if swallowed.
<u>Com</u>	ponents:			
Ribay				
Targe	es of exposure et Organs ssment	:	Ingestion Blood Causes damage t exposure.	to organs through prolonged or repeated



according to the Hazardous Products Regulations

ted dose toxicity onents: irin: es	:		
rin: es			
9S -			
_			
	•	Monkey	
ure time	:	30 mg/kg 10 d	
ure time Organs	:	Blood, Gastroii	ntestinal tract
Ū			
	:		
	:		
	:	Blood, Lungs	
S	:	Dog	
L	:	5 mg/kg	
	:	Oral	
	:		
Organs	-	Blood, Gastroli	ntestinal tract
	:	Mouse	
	:		
	:		
	:		vascular system
organo	•	Biood, Caralo	
ose:			
	:	Rat	
	:		g
	:		
		90 Days	
esium stearate:			
	:	Rat	
	:	> 100 mg/kg	
	:		
			from similar materials
es L ation Route ure time ks		> 100 mg/kg Ingestion 90 Days	from similar materials
assified based on av	vailable	information.	
ience with human	exposu	ire	
onents:			
rin:			
tion		Symptoms: He	adache, Dizziness
	•		ed on Human Evidence
ontact	:	Remarks: May	cause eye irritation.
		L : : : : : : : : : : : : : : : : : : :	L : 7.6 mg/kg ation Route : Inhalation Organs : Blood, Lungs es : Dog L : 5 mg/kg ation Route : Oral ure time : 1 y Organs : Blood, Gastroin es : Mouse L : 20 mg/kg ation Route : Oral ure time : 18 Months Organs : Blood, Cardio- es : 20 mg/kg ation Route : Oral ure time : 18 Months Organs : Blood, Cardio- es : Rat L : >= 9,000 mg/kg ation Route : Ingestion ure time : 90 Days esium stearate: es : Rat L : > 100 mg/kg ation Route : Ingestion ure time : 90 Days esium stearate: es : Rat L : > 100 mg/kg ation Route : Ingestion ure time : 90 Days ks : Based on data ation toxicity assified based on available information. ience with human exposure onents: frin: ition : Symptoms: He Remarks: Based



according to the Hazardous Products Regulations

ersion .1	Revision Date: 09/30/2023		9S Number: 2499-00021	Date of last issue: 04/04/2023 Date of first issue: 12/11/2015
Eye contact Ingestion		:	Dizziness, insomr	use eye irritation.
	12. ECOLOGICAL INFO	ORN	IATION	
	oxicity			
	oonents:			
<b>Ribav</b> Toxici	r <b>irin:</b> ty to fish	:	LC50 (Oncorhync Exposure time: 96	hus mykiss (rainbow trout)): > 119 mg/l ን h
	ty to daphnia and other ic invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD Te	
Toxici plants	ty to algae/aquatic	:	EC50 (Pseudokiro mg/l Exposure time: 96 Method: OECD Te	
			NOEC (Pseudokir mg/l Exposure time: 96 Method: OECD Te	
Toxici	ty to microorganisms	:	EC50: > 1,000 mg Exposure time: 3 Test Type: Respir Method: OECD To	h ation inhibition
Cellul	lose:			
Toxici	ty to fish	:	Exposure time: 48	ipes (Japanese medaka)): > 100 mg/l 3 h on data from similar materials
Magn	esium stearate:			
Toxici	ty to fish	:	Exposure time: 48 Method: DIN 384	
	ty to daphnia and other ic invertebrates	:	Exposure time: 47 Test substance: V Method: Directive	agna (Water flea)): > 1 mg/l 7 h Vater Accommodated Fraction 67/548/EEC, Annex V, C.2. on data from similar materials



according to the Hazardous Products Regulations

ersion .1	Revision Date: 09/30/2023		2499-00021	Date of last issue: 04/04/2023 Date of first issue: 12/11/2015
			No toxicity at th	e limit of solubility.
	Toxicity to algae/aquatic plants		mg/l Exposure time: Test substance Method: OECD Remarks: Base	irchneriella subcapitata (green algae)): > 1 72 h : Water Accommodated Fraction Test Guideline 201 d on data from similar materials e limit of solubility.
			mg/l Exposure time: Test substance Method: OECD	lokirchneriella subcapitata (green algae)): > 1 72 h : Water Accommodated Fraction Test Guideline 201 d on data from similar materials
Toxic	ity to microorganisms	:	Exposure time: Test substance	nonas putida): > 100 mg/l 16 h : Water Accommodated Fraction d on data from similar materials
Persi	stence and degradabi	ility		
Com	ponents:			
Cellu	lose:			
Biode	egradability	:	Result: Readily	biodegradable.
Magn	nesium stearate:			
Biode	egradability	:	Result: Not bio Remarks: Base	degradable d on data from similar materials
Bioad	ccumulative potential			
Com	ponents:			
	<b>virin:</b> ion coefficient: n- ol/water	:	log Pow: 0.971	
Magn	nesium stearate:			
	ion coefficient: n- ol/water	:	log Pow: > 4	
	<b>lity in soil</b> ata available			
Othe	r adverse effects			



according to the Hazardous Products Regulations

## **Ribavirin Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
4.1	09/30/2023	402499-00021	Date of first issue: 12/11/2015

### **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 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

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 safe- ty, Schedule 1, Part 1: Permissible exposure values for air-

according to the Hazardous Products Regulations



## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
4.1	09/30/2023	402499-00021	Date of first issue: 12/11/2015

	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; 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 - Verv Persistent and Verv 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 Date format	:	09/30/2023 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 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



according to the Hazardous Products Regulations

## **Ribavirin Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
4.1	09/30/2023	402499-00021	Date of first issue: 12/11/2015

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