Commission Regulation (EU) 2020/878



## **Ribavirin Liquid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
5.1	28.09.2024	406974-00024	Date of first issue: 10.12.2015

#### **SECTION 1:** Identification of the substance/mixture and of the company/undertaking

1.1	Product identifier						
	Trade name	:	Ribavirin Liquid Formulation				
1.2	1.2 Relevant identified uses of the substance or mixture and uses advised against						
	Use of the Sub- stance/Mixture	:	Pharmaceutical				
	Recommended restrictions on use	:	Not applicable				
1.3	Details of the supplier of the	saf	ety data sheet				
	Company	:	MSD Piercetown A86 HD21 Dunboyne, Ireland				
	Telephone	:	908-740-4000				
	E-mail address of person responsible for the SDS	:	EHSDATASTEWARD@msd.com				

#### 1.4 Emergency telephone number

1-908-423-6000

#### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

#### Classification (REGULATION (EC) No 1272/2008)

Germ cell mutagenicity, Category 2 Reproductive toxicity, Category 1B

Specific target organ toxicity - repeated exposure, Category 2

#### 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



Signal word

H341: Suspected of causing genetic defects. H360Df: May damage the unborn child. Suspected of damaging fertility. H373: May cause damage to organs through prolonged or repeated exposure.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Hazar	d statements	: H341 H360Df H373	Suspected of causing genetic defects. May damage the unborn child. Suspected of dam- aging fertility. May cause damage to organs through prolonged or repeated exposure.
Precautionary statements		: Preventio	on:
		P201 P280	Obtain special instructions before use. Wear protective gloves/ protective clothing/ eye protection/ face protection.
		Respons	e:
		P308 + P3	313 IF exposed or concerned: Get medical advice/ attention.
		<b>Storage:</b> P405	Store locked up.

#### Hazardous components which must be listed on the label:

Ribavirin

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

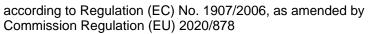
#### **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

#### Components

components			
Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
Ribavirin	36791-04-5	Acute Tox. 4; H302	>= 1 - < 10
		Muta. 2; H341	
		Repr. 1B; H360Df	
		STOT SE 3; H335	
		STOT RE 1; H372	
		(Blood)	

For explanation of abbreviations see section 16.





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#### **SECTION 4: First aid measures**

4.1 Description of 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.		
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).		
If inhaled	:	If inhaled, remove to fresh air. Get medical attention.		
In case of skin contact	:	In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.		
In case of eye contact	:	Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.		
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.		
4.2 Most important symptoms and	d e	effects, both acute and delayed		
Risks	:	Suspected of causing genetic defects. May damage the unborn child. Suspected of damaging fertili- ty. May cause damage to organs through prolonged or repeated exposure.		
4.3 Indication of any immediate medical attention and special treatment needed				
Treatment	:	Treat symptomatically and supportively.		

### **SECTION 5: Firefighting measures**

#### 5.1 Extinguishing media

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.



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#### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire- : Exposure to combustion products may be a hazard to health. fighting

Hazardous combustion prod- : Carbon oxides ucts

#### 5.3 Advice for firefighters

Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
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.

#### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
6.2 Environmental precautions		
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

#### 6.3 Methods and material for containment and cleaning up

ment to keep material from spreading. If of be pumped, store recovered material in a Clean up remaining materials from spill w bent. Local or national regulations may apply to posal of this material, as well as those ma employed in the cleanup of releases. You mine which regulations are applicable. Sections 13 and 15 of this SDS provide in certain local or national reguirements.
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#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

#### **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling **Technical measures** : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. 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 mist or vapours. 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. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment. 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.

#### 7.2 Conditions for safe storage, including any incompatibilities

The optimitions for sale storage, i	nordanig any moonpationales
Requirements for storage areas and containers	: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Advice on common storage	: Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases
7.3 Specific end use(s)	
Specific use(s)	: No data available



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#### **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

#### **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sucrose	57-50-1	OELV - 8 hrs (TWA)	10 mg/m3	IE OEL
		OELV - 15 min (STEL)	20 mg/m3	IE OEL
Propylene glycol	57-55-6	OELV - 8 hrs (TWA) (particles)	10 mg/m3	IE OEL
		OELV - 8 hrs (TWA) (total (va- pour and parti- cles))	150 ppm 470 mg/m3	IE OEL
Ribavirin	36791-04-5	Wipe limit	400 µg/100 cm <sup>2</sup>	Internal
		TWA	40 µg/m3 (OEB 3)	Internal

#### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health ef- fects	Value
Propylene glycol	Workers	Inhalation	Long-term local ef- fects	10 mg/m3
	Workers	Inhalation	Long-term systemic effects	168 mg/m3
	Consumers	Inhalation	Long-term local ef- fects	10 mg/m3
	Consumers	Inhalation	Long-term systemic effects	50 mg/m3
Glycerine	Workers	Inhalation	Long-term local ef- fects	56 mg/m3
	Consumers	Ingestion	Long-term systemic effects	229 mg/kg bw/day
	Consumers	Inhalation	Long-term local ef- fects	33 mg/m3

#### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Propylene glycol	Fresh water	260 mg/l
	Freshwater - intermittent	183 mg/l
	Marine water	26 mg/l
	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg dry weight (d.w.)
	Marine sediment	57.2 mg/kg dry weight (d.w.)
	Soil	50 mg/kg dry weight (d.w.)

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Glyce	erine	Fresh water		0.885 mg/l
		Marine water		0.0885 mg/l
		Intermittent u	se/release	8.85 mg/l
		Sewage treat	ment plant	1000 mg/l
		Fresh water s	sediment	3.3 mg/kg dry weight (d.w.)
		Marine sedim	nent	0.33 mg/kg dry weight (d.w.)
		Soil		0.141 mg/kg dry weight (d.w.)

#### 8.2 Exposure controls

#### **Engineering measures**

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

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

Eye/face protection : Hand 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.
Material :	Chemical-resistant gloves
Remarks : Skin and body protection :	Consider double gloving. 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.
Respiratory protection    :      Filter type    :	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 14387 Combined particulates and organic vapour type (A-P)

#### **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

Physical state	:	liquid
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Colour

: clear

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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	Odour		:	No data available	
	Odour 7	Fhreshold	:	No data available	
	Melting	point/freezing point	:	No data available	
	Initial bo range	oiling point and boiling	:	No data available	
	Flamma	ability (solid, gas)	:	Not applicable	
	Flamma	ability (liquids)	:	No data available	
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Flash p	oint	:	No data available	
	Auto-igi	nition temperature	:	No data available	
	Decom	position temperature	:	No data available	
	рН		:	4.8 - 5.5	
	Viscosit Visc	ty osity, kinematic	:	No data available	
	Solubilit Wate	ty(ies) er solubility	:	No data available	
	Partitior octanol	n coefficient: n- /water	:	Not applicable	
	Vapour	pressure	:	No data available	
	Relative	e density	:	No data available	
	Density		:	No data available	
	Relative	e vapour density	:	No data available	
		characteristics icle size	:	Not applicable	

#### 9.2 Other information

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Explo	osives	:	Not explosive	
Oxidi	zing properties	:	The substance of	or mixture is not classified as oxidizing.
Evap	oration rate	:	No data availabl	e
SECTION	N 10: Stability and re	eactiv	vity	
<b>10.1 Reac</b> Not c	t <b>ivity</b> lassified as a reactivity	, hazaı	rd.	
	nical stability			
	e under normal conditio			
	<b>ibility of hazardous r</b> oord			trong oxidizing agents.
	ditions to avoid		Nevelo	
Cond	itions to avoid	:	None known.	
10.5 Inco	mpatible materials			
Mate	rials to avoid	:	Oxidizing agents	3
	rdouo docomposition		lueto	
	rdous decompositior azardous decompositio	-		
SECTION	N 11: Toxicological	infor	mation	
0201101				
11.1 Infor	mation on hazard cla	sses	as defined in Reg	gulation (EC) No 1272/2008
	nation on likely routes	of :	<b>A 1 1 1</b>	
expo	Sule		Skin contact Ingestion	
			Eye contact	
	e toxicity			
	lassified based on avai	ilable i	information.	
Prod			• • • • • •	· / 0.000 //
Acute	e oral toxicity	:	Acute toxicity est Method: Calculat	imate: > 2,000 mg/kg ion method
<u>Com</u>	ponents:			
Riba	virin:			
Acute	e oral toxicity	:	LD50 (Rat): 4,11	6 - 5,584 mg/kg
			LD50 (Mouse): >	10,000 mg/kg
			LD50 (Dog): >= 1	I,500 mg/kg

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	Acute ir	nhalation toxicity	:	Remarks: No data	available
	Acute d	lermal toxicity	:	Remarks: No data	available
	Acute to adminis	oxicity (other routes of stration)	:	LD50 (Rat): 1,554 Application Route	
				LD50 (Mouse): 1,2 Application Route	
		orrosion/irritation	hle	information	
	Compo		DIC	intornation.	
	Ribavir				
	Remark	s	:	No data available May irritate skin.	
		s eye damage/eye irri ssified based on availa			
	Compo	onents:			
	<b>Ribavir</b> Remark		:	No data available May irritate eyes.	
	Respira	atory or skin sensitis	atio	'n	
	Skin se	ensitisation			
	Not clas	ssified based on availa	ble	information.	
		atory sensitisation ssified based on availa	ble	information.	
	Compo	onents:			
	Ribavir	in:			
	Remark	(S	:	No data available	
		<b>cell mutagenicity</b> ted of causing genetic	def	ects.	
	<u>Compo</u>	onents:			
	<b>Ribavir</b> Genoto	<b>in:</b> xicity in vitro	:	Test Type: Bacter Result: negative	ial reverse mutation assay (AMES)
				Test Type: In vitro	mammalian cell gene mutation test

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rsion	Revision Date: 28.09.2024	SDS Number: 406974-00024	Date of last issue: 06.04.2024 Date of first issue: 10.12.2015
		Test system: F Result: positive	Rodent cell line e
			romosomal aberration Iuman lymphocytes /e
Geno	toxicity in vivo	: Test Type: dor Species: Rat Result: negativ	minant lethal test /e
		Test Type: Mo Species: Mous Result: positive	
		Test Type: Mic Species: Mous Result: positive	
Germ sessn	cell mutagenicity- As- nent	: Positive result genicity tests.	(s) from in vivo mammalian somatic cell muta-
Not cl	nogenicity assified based on avail	able information.	
Not cl	assified based on availa	able information.	
Not cl <u>Comp</u> Ribav Speci	assified based on availa <u>conents:</u> <b>/irin:</b> es	able information.	
Not cl <u>Comp</u> Ribav Speci Applic	assified based on availa <u>conents:</u> ririn: es cation Route	: Mouse : Oral	
Not cl Comp Ribav Speci Applic Expos	assified based on availa <u>conents:</u> virin: es cation Route sure time	: Mouse : Oral : 6 Months	weight
Not cl Comp Ribav Speci Applic Expos LOAE	assified based on availa <u>conents:</u> virin: es cation Route sure time L	: Mouse : Oral : 6 Months : 75 mg/kg body	v weight
Not cl Comp Ribav Speci Applic Expos LOAE Resul	assified based on availa <u>conents:</u> virin: es cation Route sure time L	: Mouse : Oral : 6 Months	v weight
Not cl Comp Ribav Speci Applic Expos LOAE Resul	assified based on availa <u>conents:</u> <u>virin:</u> es cation Route sure time iL t t organs	: Mouse : Oral : 6 Months : 75 mg/kg body : negative : Blood, Testes	r weight m or mode of action may not be relevant in hu
Not cl Comp Ribav Speci Applic Expos LOAE Resul Targe	assified based on availa <u>conents:</u> <u>virin:</u> es cation Route sure time L t t ot Organs arks	: Mouse : Oral : 6 Months : 75 mg/kg body : negative : Blood, Testes : The mechanis	
Not cl Comp Ribav Speci Applic Expos LOAE Resul Targe Rema Speci Applic	assified based on availa <u>ponents:</u> <u>virin:</u> es cation Route sure time L t of Organs arks es cation Route	<ol> <li>Mouse</li> <li>Oral</li> <li>6 Months</li> <li>75 mg/kg body</li> <li>negative</li> <li>Blood, Testes</li> <li>The mechanis mans.</li> <li>Rat</li> <li>Oral</li> </ol>	
Not cl Comp Ribav Speci Applic Expos LOAE Resul Targe Rema Speci Applic Expos	assified based on availa <u>ponents:</u> <u>virin:</u> es cation Route sure time L t of Organs urks es cation Route sure time	<ol> <li>Mouse</li> <li>Oral</li> <li>6 Months</li> <li>75 mg/kg body</li> <li>negative</li> <li>Blood, Testes</li> <li>The mechanis mans.</li> <li>Rat</li> <li>Oral</li> <li>2 Years</li> </ol>	m or mode of action may not be relevant in hu
Not cl Comp Ribav Speci Applic Expos LOAE Resul Targe Rema Speci Applic	assified based on availa <u>ponents:</u> <u>virin:</u> es cation Route sure time L t t Organs arks es cation Route sure time EL	<ul> <li>Mouse</li> <li>Oral</li> <li>6 Months</li> <li>75 mg/kg body</li> <li>negative</li> <li>Blood, Testes</li> <li>The mechanis mans.</li> <li>Rat</li> <li>Oral</li> <li>2 Years</li> <li>10 mg/kg body</li> </ul>	m or mode of action may not be relevant in hu
Not cl Comp Ribav Speci Applic Expos LOAE Resul Targe Rema Speci Applic Expos NOAE	assified based on availa <u>ponents:</u> <u>virin:</u> es cation Route sure time L t or Organs arks es cation Route sure time L t t	<ul> <li>Mouse</li> <li>Oral</li> <li>6 Months</li> <li>75 mg/kg body</li> <li>negative</li> <li>Blood, Testes</li> <li>The mechanis mans.</li> <li>Rat</li> <li>Oral</li> <li>2 Years</li> <li>10 mg/kg body</li> <li>negative</li> </ul>	m or mode of action may not be relevant in hu
Not cl Comp Ribav Speci Applic Expos LOAE Resul Targe Rema Speci Applic Expos NOAE Resul Resul Resul Resul Resul Speci	assified based on availa <u>ponents:</u> <u>virin:</u> es cation Route sure time L t Organs arks es cation Route sure time L t t arks es	<ul> <li>Mouse</li> <li>Oral</li> <li>6 Months</li> <li>75 mg/kg body</li> <li>negative</li> <li>Blood, Testes</li> <li>The mechanis mans.</li> <li>Rat</li> <li>Oral</li> <li>2 Years</li> <li>10 mg/kg body</li> <li>negative</li> <li>The mechanis mans.</li> </ul>	m or mode of action may not be relevant in hu
Not cl Comp Ribav Speci Applic Expos LOAE Resul Targe Rema Speci Applic Expos NOAE Resul Resul Resul Speci Applic Expos NOAE Resul Resul Resul Speci Applic Expos	assified based on availa <u>ponents:</u> <u>virin:</u> es cation Route sure time L t Organs arks es cation Route sure time L t arks es cation Route	<ol> <li>Mouse</li> <li>Oral</li> <li>6 Months</li> <li>75 mg/kg body</li> <li>negative</li> <li>Blood, Testes</li> <li>The mechanis mans.</li> <li>Rat</li> <li>Oral</li> <li>2 Years</li> <li>10 mg/kg body</li> <li>negative</li> <li>The mechanis mans.</li> </ol>	m or mode of action may not be relevant in hu
Not cl Comp Ribav Speci Applic Expos LOAE Resul Targe Rema Speci Applic Expos NOAE Resul Resul Resul Speci Applic Expos NOAE Resul Resul Resul Speci Applic Expos	assified based on availa <u>ponents:</u> <u>virin:</u> es cation Route sure time EL t Organs urks es cation Route sure time EL t urks es cation Route sure time EL t urks	<ul> <li>Mouse</li> <li>Oral</li> <li>6 Months</li> <li>75 mg/kg body</li> <li>negative</li> <li>Blood, Testes</li> <li>The mechanis mans.</li> <li>Rat</li> <li>Oral</li> <li>2 Years</li> <li>10 mg/kg body</li> <li>negative</li> <li>The mechanis mans.</li> </ul>	m or mode of action may not be relevant in hu

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	roductive toxicity		
May	damage the unborn chil	d. Suspected of dam	aging fertility.
<u>Com</u>	ponents:		
Riba	virin:		
Effects on fertility			male ute: Intraperitoneal injection L: < 20 mg/kg body weight educed fertility e tility
		Application Ro Fertility: LOAE Symptoms: Re Result: positive	L: 35 mg/kg body weight educed fertility
			emales
			male
Effeo men	cts on foetal develop- t	Symptoms: Re fetuses, Skele	emale ute: Oral I Toxicity: LOAEL: <= 1 mg/kg body weight educed body weight, Reduced number of viable tal malformations otoxic effects and adverse effects on the off-
		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 off-
		Test Type: De Species: Hams Application Ro	ster

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			Symptoms: Ske / resorption rate	toxic effects and adverse effects on the off-
			Species: Rat Application Rou General Toxicity Embryo-foetal to	y Maternal: NOAEL: 0.3 mg/kg body weight oxicity: LOAEL: 1 mg/kg body weight eletal malformations
Repro sessr	oductive toxicity - As- nent	:	fertility, based c	of adverse effects on sexual function and on animal experiments., Clear evidence of ad- n development, based on animal experiments
	<b>- single exposure</b> lassified based on avai	ilable	information.	
<u>Com</u>	oonents:			
<b>Riba</b> v Asses	<b>virin:</b> ssment	:	May cause resp	piratory irritation.
STO	- repeated exposure	2		
	cause damage to organ		ough prolonged o	or repeated exposure.
<u>Com</u>	ponents:			
Riba	/irin:			
	sure routes	:	Ingestion	
-	et Organs ssment	:	Blood Causes damage exposure.	e to organs through prolonged or repeated
Repe	ated dose toxicity			
<u>Com</u>	oonents:			
Riba	/irin:			
Speci		:	Monkey	
LOAE		:	30 mg/kg	
	sure time et Organs	:	10 d Blood, Gastroin	testinal tract
Speci	es		Rat	
NOA		:	7.6 mg/kg	
	 cation Route		Inhalation	

Application Route

Exposure time

Target Organs

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Expos		: Dog : 5 mg/kg : Oral : 1 yr : Blood, Gastroi	ntestinal tract

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

#### Aspiration toxicity

Not classified based on available information.

#### 11.2 Information on other hazards

#### **Endocrine disrupting properties**

#### **Product:**

Assessment

The substance/mixture does not contain components consid-: ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

#### Experience with human exposure

Com	ponents:

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,
<u> </u>		Dizziness, insomnia, Fatigue, Headache, Itching, Rash, liver
		function change, Gastrointestinal disturbance

#### **SECTION 12: Ecological information**

#### 12.1 Toxicity

#### **Components:**

#### **Ribavirin:**

Toxicity to fish

LC50 (Oncorhynchus mykiss (rainbow trout)): > 119 mg/l : Exposure time: 96 h



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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 (Pseudokin mg/l Exposure time: 96 Method: OECD Te	
Toxicity to microorganisms		:	EC50 : > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209		
<ul> <li>12.2 Persistence and degradability</li> <li>No data available</li> <li>12.3 Bioaccumulative potential</li> </ul>		ity			
Components:					

#### **Ribavirin:**

Partition coefficient: n- : log Pow: 0.971 octanol/water

#### 12.4 Mobility in soil

No data available

#### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment

: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

#### **12.6 Endocrine disrupting properties**

#### Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

#### 12.7 Other adverse effects

No data available



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#### **SECTION 13: Disposal considerations**

13.1 Waste treatment methods	
Product	<ul> <li>Dispose of in accordance with local regulations.</li> <li>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.</li> <li>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.</li> <li>Do not dispose of waste into sewer.</li> </ul>
Contaminated packaging	<ul> <li>Empty containers should be taken to an approved waste han- dling site for recycling or disposal.</li> <li>If not otherwise specified: Dispose of as unused product.</li> </ul>

### **SECTION 14: Transport information**

14.1 UN number or ID number

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.2 UN proper shipping name		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.3 Transport hazard class(es)		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.4 Packing group		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Ribavirin Liquid Formulation**

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ΙΑΤΑ	(Cargo)	: Not regulated a	as a dangerous good				
ΙΑΤΑ	(Passenger)	: Not regulated a	: Not regulated as a dangerous good				
	ronmental hazards egulated as a dangero	us good					
•	<b>ial precautions for u</b>	ser					
14.7 Marit	time transport in bull	according to IMO in	struments				
Rema	arks	: Not applicable	for product as supplied.				
SECTION	N 15: Regulatory in	formation					

# 15.1 Safety, health and environmental regulations/legislation specific for the substance or mix-ture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	l	Conditions of restriction for the fol- lowing entries should be considered: Number on list 3
	I	Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.
		Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the condi- tions in corresponding Regulation to determine whether an entry is appli- cable to the placing on the market or not.
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
Regulation (EC) on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollu- tants (recast)	:	Not applicable
Regulation (EU) No 649/2012 of the European Parlia- ment and the Council concerning the export and import of dangerous chemicals	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Seveso III: Directive 2012/18/EU of the European Parliar major-accident hazards involving dangerous substances		and of the Council on the control of

Not applicable



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Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

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

#### 15.2 Chemical safety assessment

**SECTION 16: Other information** 

A Chemical Safety Assessment has not been carried out.

Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
Full text of H-Statements		
H302		Harmful if swallowed.
H335	÷	May cause respiratory irritation.
H341	÷	Suspected of causing genetic defects.
H360Df	÷	May damage the unborn child. Suspected of damaging fertili-
		ty.
H372	:	Causes damage to organs through prolonged or repeated exposure if swallowed.
Full text of other abbreviation	ons	
Acute Tox.	:	Acute toxicity
Muta.	:	Germ cell mutagenicity
Repr.	:	Reproductive toxicity
STOT RE	:	Specific target organ toxicity - repeated exposure
STOT SE	:	Specific target organ toxicity - single exposure
IE OEL	:	Ireland. List of Chemical Agents and Carcinogens with Occu-
IE OEL / OELV - 8 hrs (TWA) IE OEL / OELV - 15 min (STEL)	:	pational Exposure Limit Values - Code of Practice, Schedule 1 and 2 Occupational exposure limit value (8-hour reference period) Occupational exposure limit value (15-minute reference peri- od)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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 as-



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sociated with x% growth rate response; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

#### Further information

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

Classification of the mix	Classification procedure:	
Muta. 2	H341	Calculation method
Repr. 1B	H360Df	Calculation method
STOT RE 2	H373	Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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