SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Ribavirin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
4.0	2024/09/28	402740-00020	Date of first issue: 2015/12/10

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ribavirin Liquid Formulation

Manufacturer or supplier's details

Company : MSD

Address : 199 Wenhai North Road
HEDA, Hangzhou - Zhejiang Province - CHINA 310018

Telephone : 908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance : liquid
Colour : clear
Odour : No data available

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

GHS Classification

Germ cell mutagenicity : Category 2

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure : Category 2

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : 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.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapours.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

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.

Physical and chemical hazards

Not classified based on available information.

Health hazards

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

Environmental hazards

Not classified based on available information.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Sucrose	57-50-1	>= 30 -< 50
Ribavirin	36791-04-5	>= 1 -< 10

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. 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.
Most important symptoms and effects, both acute and delayed	:	Suspected of causing genetic defects. May damage the unborn child. Suspected of damaging fertility. May cause damage to organs through prolonged or repeated exposure.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during firefighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. 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.
Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

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.
Avoidance of contact	:	Oxidizing agents

Storage

Conditions for safe storage : Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

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

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sucrose	57-50-1	TWA	10 mg/m3	ACGIH
Ribavirin	36791-04-5	Wipe limit	400 µg/100 cm²	Internal
		TWA	40 µg/m3 (OEB 3)	Internal

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Combined particulates and organic vapour type

Eye/face protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

Hand protection

Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	clear
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	4.8 - 5.5
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
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	:	No data available
Relative vapour density	:	No data available
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	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Particle characteristics		
Particle size	:	Not applicable

10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

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: > 5,000 mg/kg
Method: Calculation method

Components:

Sucrose:

Acute oral toxicity : LD50 (Rat): 29,700 mg/kg

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

Skin corrosion/irritation

Not classified based on available information.

Components:

Ribavirin:

Remarks	:	No data available May irritate skin.

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Ribavirin:

Remarks	:	No data available May irritate eyes.

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

Germ cell mutagenicity

Suspected of causing genetic defects.

Components:

Sucrose:

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

Ribavirin:

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

Carcinogenicity

Not classified based on available information.

Components:

Ribavirin:

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

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

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

Reproductive toxicity

May damage the unborn child. Suspected of damaging fertility.

Components:

Ribavirin:

Effects on fertility	:	Test Type: Fertility Species: Rat, male Application Route: Intraperitoneal injection Fertility: LOAEL: < 20 mg/kg body weight Symptoms: Reduced fertility Result: positive Test Type: Fertility Species: Mouse, male Application Route: Oral Fertility: LOAEL: 35 mg/kg body weight Symptoms: Reduced fertility Result: positive Test Type: Fertility Species: Rat, females Application Route: Oral Fertility: NOAEL: 10 mg/kg body weight Result: Animal testing did not show any effects on fertility. Test Type: Fertility Species: Rat, male Application Route: Oral Fertility: NOAEL: 160 mg/kg body weight Result: Animal testing did not show any effects on fertility.
Effects on foetal development	:	Test Type: Development Species: Rat, female Application Route: Oral

Developmental Toxicity: LOAEL: <= 1 mg/kg body weight
Symptoms: Reduced body weight, Reduced number of viable fetuses, Skeletal malformations
Result: Embryotoxic effects and adverse effects on the off-spring were detected.

Test Type: Development
Species: Rabbit, female
Application Route: Oral
General Toxicity Maternal: LOAEL: 1 mg/kg body weight
Developmental Toxicity: LOAEL: 1 mg/kg body weight
Symptoms: Reduced body weight, Skeletal malformations
Result: Embryotoxic effects and adverse effects on the off-spring were detected.

Test Type: Development
Species: Hamster
Application Route: Oral
Developmental Toxicity: LOAEL: 2.5 mg/kg body weight
Symptoms: Skeletal and visceral variations, Total Resorptions / resorption rate
Result: Embryotoxic effects and adverse effects on the off-spring were detected.

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

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments.

STOT - single exposure

Not classified based on available information.

Components:

Ribavirin:

Assessment : May cause respiratory irritation.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Ribavirin:

Exposure routes : Ingestion

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

Repeated dose toxicity

Components:

Ribavirin:

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

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

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

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

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Ribavirin:

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Ribavirin:

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

Persistence and degradability

No data available

Bioaccumulative potential

Components:

Sucrose:

Partition coefficient: n-octanol/water	:	Pow: < 1

Ribavirin:

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

Mobility in soil

No data available

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Environmentally hazardous	:	no

IATA-DGR

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

IMDG-Code

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
EmS Code	:	Not applicable
Marine pollutant	:	no

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

Not applicable for product as supplied.

National Regulations

GB 6944/12268

UN number	:	Not applicable
Proper shipping name	:	Not applicable

Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Marine pollutant	:	no

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

National regulatory information

Law on the Prevention and Control of Occupational Diseases

Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals	:	This product is not listed in the catalogue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of determination.
Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218)	:	Not listed
Hazardous Chemicals for Priority Management under SAWS	:	Not listed

Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals	:	Not listed

Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import and Export	:	Not listed

Regulation on the Administration of Precursor Chemicals

Catalogue and Classification of Precursor Chemicals	:	Not listed

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

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

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

16. OTHER INFORMATION

Revision Date	:	2024/09/28

Further information

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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format	:	yyyy/mm/dd

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA	:	8-hour, 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 concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Disclaimer

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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