SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ribavirin Liquid Formulation

Version 2.6
Revision Date: 27.08.2021
SDS Number: 406978-00016
Date of last issue: 09.04.2021
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 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company : MSD
   Kilsheelan
   Clonmel Tipperary, IE
   Telephone : 353-51-601000
   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 : H341: Suspected of causing genetic defects.
   Reproductive toxicity, Category 1B : H360Df: May damage the unborn child. Suspected of damaging fertility.
   Specific target organ toxicity - repeated exposure, Category 2 : H373: May cause damage to organs through prolonged or repeated exposure.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   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.
- 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.

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**

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

For explanation of abbreviations see section 16.

### 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 effects, both acute and delayed

Risks: Suspected of causing genetic defects. May damage the unborn child. Suspected of damaging fertility. 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


Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.
Hazardous combustion products: Carbon oxides

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 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.

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 protective 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

Methods for 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.

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
Ribavirin Liquid Formulation

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

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 Organic peroxides Explosives Gases

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA</td>
<td>25 ppm</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>79 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Ribavirin</td>
<td>36791-04-5</td>
<td>TWA</td>
<td>25 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>250 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>
### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>168 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>50 mg/m³</td>
</tr>
<tr>
<td>Glycerine</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>56 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>229 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>33 mg/m³</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>Fresh water</td>
<td>260 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>183 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>26 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>20000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>572 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>57.2 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>50 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Glycerine</td>
<td>Fresh water</td>
<td>0.885 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.0885 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>8.85 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>3.3 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.33 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.141 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>

### 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 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.

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

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.

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS EN 14387

Filter type: Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>clear</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>4.8 - 5.5</td>
</tr>
</tbody>
</table>
Ribavirin Liquid Formulation

9.2 Other information

Explosives : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Evaporation rate : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : None known.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
Ribavirin Liquid Formulation

Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.

**Product:**

**Acute oral toxicity**

Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

**Components:**

**Ribavirin:**

Acute oral toxicity
LD50 (Rat): 4.116 - 5.584 mg/kg
LD50 (Mouse): > 10.000 mg/kg
LD50 (Dog): >= 1.500 mg/kg

Acute inhalation toxicity
Remarks: No data available

Acute dermal toxicity
Remarks: No data available

Acute toxicity (other routes of administration)
LD50 (Rat): 1.554 - 1.758 mg/kg
Application Route: Intraperitoneal
LD50 (Mouse): 1.268 mg/kg
Application Route: Intraperitoneal

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.
Ribavirin Liquid Formulation

Respiratory sensitisation
Not classified based on available information.

Components:
Ribavirin:
Remarks : No data available

Germ cell mutagenicity
Suspected of causing genetic defects.

Components:
Ribavirin:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Test Type: In vitro mammalian cell gene mutation test
Test system: Rodent cell line
Result: positive

Test Type: Chromosomal aberration
Test system: Human lymphocytes
Result: negative

Genotoxicity in vivo : Test Type: dominant lethal test
Species: Rat
Result: negative

Test Type: Mouse Lymphoma
Species: Mouse
Result: positive

Test Type: Micronucleus test
Species: Mouse
Result: positive

Germ cell mutagenicity Assessment : Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

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

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Exposure time</th>
<th>NOAEL</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>2 Years</td>
<td>10 mg/kg body weight</td>
<td>negative</td>
<td>The mechanism or mode of action may not be relevant in humans.</td>
</tr>
</tbody>
</table>

**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.

**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.

**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

### Reproductive toxicity

May damage the unborn child. Suspected of damaging fertility.

### Components:

**Ribavirin:**

**Effects on fertility**

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Species</th>
<th>Fertility Type</th>
<th>LOAEL</th>
<th>Symptoms</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>Rat, male</td>
<td>Test Type: Fertility</td>
<td>&lt;= 20 mg/kg body weight</td>
<td>Reduced fertility</td>
<td>positive</td>
</tr>
</tbody>
</table>

**Test Type**: Fertility

**Species**: Rat, male

**Application Route**: Oral

**Fertility**: LOAEL: <= 20 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.
Result: Embryotoxic effects and adverse effects on the offspring 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 offspring 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 offspring 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.

11.2 Information on other hazards

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.

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,
Ribavirin Liquid Formulation

Dizziness, insomnia, Fatigue, Headache, Itching, Rash, liver function change, Gastrointestinal disturbance

SECTION 12: Ecological information

12.1 Toxicity

**Components:**

**Ribavirin:**

Toxicity to fish

\[ \text{LC50 (Oncorhynchus mykiss (rainbow trout)):} > 119 \text{ mg/l} \]

Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates

\[ \text{EC50 (Daphnia magna (Water flea)):} > 117 \text{ mg/l} \]

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants

\[ \text{EC50 (Pseudokirchneriella subcapitata (green algae)):} > 119 \text{ mg/l} \]

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

\[ \text{EC50 :} > 1.000 \text{ mg/l} \]

Exposure time: 3 h

Test Type: Respiration inhibition

Method: OECD Test Guideline 209

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

**Components:**

**Ribavirin:**

Partition coefficient: n-octanol/water

\[ \text{log Pow: 0.971} \]

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

SECTION 13: Disposal considerations

**13.1 Waste treatment methods**

**Product:** Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

**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

**14.1 UN number or ID number**

Not regulated as a dangerous good

**14.2 UN proper shipping name**

Not regulated as a dangerous good

**14.3 Transport hazard class(es)**

Not regulated as a dangerous good

**14.4 Packing group**

Not regulated as a dangerous good

**14.5 Environmental hazards**

Not regulated as a dangerous good

**14.6 Special precautions for user**

Not applicable

**14.7 Maritime transport in bulk according to IMO instruments**

**Remarks:** Not applicable for product as supplied.

SECTION 15: Regulatory information

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ribavirin Liquid Formulation

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REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).
REACH - List of substances subject to authorisation (Annex XIV)
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals

Not applicable

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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 fertility.
H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Muta. : Germ cell mutagenicity
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Repr. : Reproductive toxicity
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / TWA : Long term exposure limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for 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 associated 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; TSCA - Toxic Substances Control Act (United States); vPvB - Very Persistent and Very Bioaccumulative

Further information:

Classification of the mixture:

| 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.