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

Spiramycin Formulation

Version 1.3
Revision Date: 27.08.2021
SDS Number: 7979081-00004
Date of last issue: 18.06.2021
Date of first issue: 19.03.2021

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

1.1 Product identifier
Trade name: Spiramycin Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Veterinary product

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

<table>
<thead>
<tr>
<th>Classification (REGULATION (EC) No 1272/2008)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye irritation, Category 2</td>
<td>H319: Causes serious eye irritation.</td>
</tr>
<tr>
<td>Reproductive toxicity, Category 1B</td>
<td>H360FD: May damage fertility. May damage the unborn child.</td>
</tr>
</tbody>
</table>

2.2 Label elements

<table>
<thead>
<tr>
<th>Labelling (REGULATION (EC) No 1272/2008)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard pictograms:</td>
</tr>
<tr>
<td>Signal word:</td>
</tr>
<tr>
<td>Hazard statements:</td>
</tr>
<tr>
<td>Precautionary statements:</td>
</tr>
<tr>
<td>P201: Obtain special instructions before use.</td>
</tr>
<tr>
<td>P264: Wash skin thoroughly after handling.</td>
</tr>
<tr>
<td>P280: Wear protective gloves/ protective clothing/ eye protec-</td>
</tr>
</tbody>
</table>

Hazardous components which must be listed on the label:
2-Pyrrolidone

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

<table>
<thead>
<tr>
<th>Components</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>2-Pyrrolidone</td>
<td>616-45-5</td>
<td>210-483-1</td>
<td></td>
<td></td>
<td>Eye Irrit. 2; H319</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Repr. 1B; H360FD</td>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
<td>specific concent-</td>
<td></td>
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<td></td>
<td></td>
<td>ration limit</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Repr. 1B; H360FD</td>
<td>&gt; 3 %</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>202-859-9</td>
<td>603-057-00-5</td>
<td></td>
<td>Acute Tox. 4; H302</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 4; H332</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Eye Irrit. 2; H319</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute toxicity esti-</td>
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<td>mate</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute oral toxicity:</td>
<td></td>
</tr>
</tbody>
</table>
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Spiramycin Formulation

<table>
<thead>
<tr>
<th>Spiramycin</th>
<th>1.620 mg/kg</th>
<th>&lt; 0,1</th>
</tr>
</thead>
<tbody>
<tr>
<td>8025-81-8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>232-429-6</td>
<td></td>
<td></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 advice 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: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.

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: Causes serious eye irritation. May damage fertility. May damage the unborn child.

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.  

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  : Nitrogen oxides (NOx)  
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
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 vapours or spray mist.
- Do not swallow.
- Do not get in 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.
- 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
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### 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>Spiramycin</td>
<td>8025-81-8</td>
<td>TWA</td>
<td>1000 µg/m³ (OEB 1)</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>2-Pyrrolidone</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>57.8 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>10 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>277 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td></td>
<td>Long-term systemic effects</td>
<td>17.1 mg/m³</td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td></td>
<td>Long-term systemic effects</td>
<td>6 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td></td>
<td>Acute systemic effects</td>
<td>167 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td></td>
<td>Long-term systemic effects</td>
<td>5.2 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td></td>
<td>Acute systemic effects</td>
<td>33.3 mg/kg bw/day</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>22 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>110 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>8 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>40 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td></td>
<td>Long-term systemic effects</td>
<td>5.4 mg/m³</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td></td>
<td>Acute systemic effects</td>
<td>27 mg/m³</td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td></td>
<td>Long-term systemic effects</td>
<td>4 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td></td>
<td>Acute systemic effects</td>
<td>20 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td></td>
<td>Long-term systemic effects</td>
<td>4 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td></td>
<td>Acute systemic effects</td>
<td>20 mg/kg bw/day</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>
</table>

---

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### 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.

Laboratory operations do not require special containment.

**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

- **Skin and body protection**: Work uniform or laboratory coat.

- **Respiratory protection**
  - **Filter type**: Organic vapour type (A)

### SECTION 9: Physical and chemical properties

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

- **Physical state**: Aqueous solution
- **Colour**: Light yellow
- **Odour**: No data available
- **Odour Threshold**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available

<table>
<thead>
<tr>
<th>Substance</th>
<th>Fresh water</th>
<th>Marine water</th>
<th>Sewage treatment plant</th>
<th>Fresh water sediment</th>
<th>Soil</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Pyrrolidone</td>
<td>0.5 mg/l</td>
<td>0.05 mg/l</td>
<td>10 mg/l</td>
<td>0.4205 mg/kg dry weight (d.w.)</td>
<td>0.0612 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>1 mg/l</td>
<td>0.1 mg/l</td>
<td>2.3 mg/l</td>
<td>39 mg/l</td>
<td>0.527 mg/kg</td>
</tr>
</tbody>
</table>
### 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

### Flash point
- No data available

### Auto-ignition temperature
- No data available

### Decomposition temperature
- No data available

### pH
- 8.0 - 10.0

### Viscosity
- Viscosity, kinematic: No data available

### Solubility(ies)
- Water solubility: No data available

### Partition coefficient: n-octanol/water
- Not applicable

### Vapour pressure
- No data available

### Relative density
- No data available

### Density
- 0.950 - 1.150 g/cm³

### Relative vapour density
- No data available

### Particle characteristics
- Particle size: Not applicable

9.2 Other information

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

- Acute inhalation toxicity: Acute toxicity estimate: > 5 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: Calculation method

Components:
2-Pyrrolidone:
- Acute oral toxicity: LD50 (Rat): > 2.000 mg/kg
  Method: OECD Test Guideline 401
  Assessment: The substance or mixture has no acute oral toxicity

- Acute dermal toxicity: LD50 (Rabbit): > 2.000 mg/kg
  Method: OECD Test Guideline 402
  Assessment: The substance or mixture has no acute dermal toxicity

Benzyl alcohol:
- Acute oral toxicity: LD50 (Rat): 1.620 mg/kg
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Acute toxicity estimate: 1.620 mg/kg
Method: Calculation method

Acute inhalation toxicity:
LC50 (Rat): > 4,178 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Spiramycin:

Acute oral toxicity:
LD50 (Mouse, adult): 2.900 mg/kg
LD50 (Rat, adult): 3.550 mg/kg
LD50 (Dog, adult): 5.200 mg/kg
LD50 (Rabbit, adult): 4.300 mg/kg

Acute inhalation toxicity:
Remarks: No data available

Acute toxicity (other routes of administration):
LD50 (Mouse): 130 mg/kg
Application Route: Intravenous
LD50 (Rat): 170 mg/kg
Application Route: Intravenous
LD50 (Rabbit): 182 mg/kg
Application Route: Intravenous

Skin corrosion/irritation
Not classified based on available information.

Components:

2-Pyrrolidone:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Benzyl alcohol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

2-Pyrrolidone:
Species: Rabbit
Result: Irritation to eyes, reversing within 7 days
**Benzyl alcohol:**
- **Species:** Rabbit
- **Method:** OECD Test Guideline 405
- **Result:** Irritation to eyes, reversing within 21 days

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

**2-Pyrrolidone:**
- **Test Type:** Local lymph node assay (LLNA)
- **Exposure routes:** Skin contact
- **Species:** Mouse
- **Method:** OECD Test Guideline 429
- **Result:** negative
- **Remarks:** Based on data from similar materials

**Benzyl alcohol:**
- **Test Type:** Maximisation Test
- **Exposure routes:** Skin contact
- **Species:** Guinea pig
- **Method:** OECD Test Guideline 406
- **Result:** negative

**Spiramycin:**
- **Test Type:** Magnusson-Kligman-Test
- **Exposure routes:** Skin contact
- **Species:** Guinea pig
- **Result:** Not a skin sensitiser.

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**2-Pyrrolidone:**
- **Genotoxicity in vitro**
  - **Test Type:** Bacterial reverse mutation assay (AMES)
    - **Result:** negative
  - **Test Type:** In vitro mammalian cell gene mutation test
    - **Method:** OECD Test Guideline 476
    - **Result:** negative
    - **Remarks:** Based on data from similar materials
  - **Test Type:** Chromosome aberration test in vitro
Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) 
Species: Mouse 
Application Route: Intraperitoneal injection 
Method: OECD Test Guideline 474 
Result: negative

Benzyl alcohol: 
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES) 
Result: negative 
Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) 
Species: Mouse 
Application Route: Intraperitoneal injection 
Result: negative 

Spiramycin: 
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test 
Test system: Chinese hamster ovary cells 
Result: negative 

Test Type: Cytogenetic assay 
Test system: Chinese hamster ovary cells 
Result: negative 

Test Type: In vitro mammalian cell gene mutation test 
Test system: Mouse 
Result: negative

Carcinogenicity 
Not classified based on available information.

Components:
2-Pyrrolidone: 
Species: Mouse 
Application Route: Ingestion 
Exposure time: 18 month(s) 
Result: negative 
Remarks: Based on data from similar materials

Benzyl alcohol: 
Species: Mouse 
Application Route: Ingestion 
Exposure time: 103 weeks 
Method: OECD Test Guideline 451 
Result: negative
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Spiramycin:
Species: Rat, male and female
Application Route: Oral
Exposure time: 2 Years
Result: negative

Reproductive toxicity
May damage fertility. May damage the unborn child.

Components:

2-Pyrrolidone:
Effects on fertility: Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: positive
Remarks: Based on data from similar materials

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: positive

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

Benzyl alcohol:
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development: Test Type: Embryo-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative

Spiramycin:
Effects on fertility: Test Type: Fertility
Species: Rat, male
Target Organs: Reproductive organs
Result: alteration in sperm morphology, Effects on male reproductive organs

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
General Toxicity Maternal: 100 mg/kg body weight
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Developmental Toxicity: LOAEL: 200 mg/kg body weight
Embryo-foetal toxicity: LOAEL: 200 mg/kg body weight

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

2-Pyrrolidone:
- Species: Rat
- NOAEL: 207 mg/kg
- Application Route: Ingestion
- Exposure time: 3 Months
- Method: OECD Test Guideline 408

Benzyl alcohol:
- Species: Rat
- NOAEL: 1,072 mg/l
- Application Route: Inhalation (dust/mist/fume)
- Exposure time: 28 Days
- Method: OECD Test Guideline 412

Spiramycin:
- Species: Rat, male and female
- NOAEL: 140 mg/kg
- Application Route: Oral
- Exposure time: 13 Weeks
- Target Organs: Immune system
- Species: Rat, male and female
- LOAEL: 5.6 mg/kg
- Application Route: Intravenous
- Exposure time: 32 d
- Target Organs: Central nervous system
- Species: Dog, male and female
- NOAEL: 75 mg/kg
- Application Route: Oral
- Exposure time: 2 yr
- Target Organs: Kidney, male reproductive organs, optic nerve
- Species: Dog, male and female
- LOAEL: 169 mg/kg
- Application Route: Intravenous
- Exposure time: 4 Weeks
- Number of exposures: 2 injections per day
- Target Organs: Spleen, Kidney
Species: Dog, male and female
LOAEL: 50 mg/kg
Application Route: Intravenous
Exposure time: 4 Weeks
Target Organs: Central nervous 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:

Spiramycin:
General Information: May cause Symptoms: Nausea, Vomiting, Diarrhoea

Further information

Components:

Spiramycin:
Remarks: No data available

SECTIONS 12: Ecological information

12.1 Toxicity

Components:

2-Pyrrolidone:
Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 4.600 - 10.000 mg/l
Method: OECD Test Guideline 203
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 500 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: ErC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l
Exposure time: 72 h
EC10 (Desmodesmus subspicatus (green algae)): 22.2 mg/l
Exposure time: 72 h

Toxicity to microorganisms: EC50: > 1.000 mg/l
  Exposure time: 30 min
  Method: OECD Test Guideline 209

**Benzyl alcohol:**

Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
  Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 230 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

  NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: 51 mg/l
  Exposure time: 21 d
  Species: Daphnia magna (Water flea)
  Method: OECD Test Guideline 211

**12.2 Persistence and degradability**

**Components:**

**2-Pyrrolidone:**

Biodegradability: Result: Readily biodegradable.
  Remarks: Based on data from similar materials

**Benzyl alcohol:**

Biodegradability: Result: Readily biodegradable.
  Biodegradation: 92 - 96 %
  Exposure time: 14 d

**12.3 Bioaccumulative potential**

**Components:**

**2-Pyrrolidone:**

Partition coefficient: n-octanol/water: log Pow: -0.71
  Method: OECD Test Guideline 107

**Benzyl alcohol:**
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Partition coefficient: n-octanol/water : log Pow: 1.05

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
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according to Regulation (EC) No. 1907/2006

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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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Conditions of restriction for the following entries should be considered:
Number on list 3

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). Not applicable

REACH - List of substances subject to authorisation (Annex XIV). Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable

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.
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Full text of H-Statements

H302 : Harmful if swallowed.
H319 : Causes serious eye irritation.
H332 : Harmful if inhaled.
H360FD : May damage fertility. May damage the unborn child.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Eye Irrit. : Eye irritation
Repr. : Reproductive toxicity

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 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 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; 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

Classification of the mixture:

Eye Irrit. 2 H319

Further information


Classification procedure:

Calculation method
Repr. 1B H360FD 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.

NO / EN