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
   Classification (REGULATION (EC) No 1272/2008)
   Eye irritation, Category 2
   Reproductive toxicity, Category 1B

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms:
   Signal word: Danger
   Hazard statements:
      H319: Causes serious eye irritation.
      H360FD: May damage fertility. May damage the unborn child.
   Precautionary statements:
      Prevention:
      P201 Obtain special instructions before use.
      P264 Wash skin thoroughly after handling.
      P280 Wear protective gloves/ protective clothing/ eye protec-
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>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>2-Pyrrolidone</td>
<td>616-45-5</td>
<td>210-483-1</td>
<td></td>
<td></td>
<td>Eye Irrit. 2; H319 Repr. 1B; H360FD</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>2-Pyrrolidone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>specific concentration limit Repr. 1B; H360FD &gt; 3 %</td>
<td></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 Acute Tox. 4; H332 Eye Irrit. 2; H319</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute toxicity estimate</td>
<td></td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute oral toxicity: 1,620 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>
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 employed in the cleanup of releases. You will need to determine which regulations are applicable.
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
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 ug/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>Long-term systemic effects</td>
<td>17.1 mg/m3</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>6 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>167 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>5.2 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
<td>33.3 mg/kg bw/day</td>
<td></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>Long-term systemic effects</td>
<td>5.4 mg/m3</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>27 mg/m3</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>4 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>20 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>4 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
<td>20 mg/kg bw/day</td>
<td></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></td>
<td></td>
<td></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. 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**: Chemical-resistant gloves

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

- **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 I.S. EN 14387

- **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
Spiramycin Formulation

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

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
Ingestion
Skin contact
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-Pyrolidone:
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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Spiramycin Formulation

Version 1.3
Revision Date: 27.08.2021
SDS Number: 7979094-00004
Date of last issue: 18.06.2021
Date of first issue: 19.03.2021

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
Spiramycin Formulation

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 sensitizer.

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
Method: OECD Test Guideline 474
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

Benzy 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
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
NOAEL: 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
NOAEL: 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

SECTION 12: Ecological information

12.1 Toxicity

Components:

2-Pyrrolidone:
Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 4,600 - 10,000 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

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
**Spiramycin Formulation**

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

Spiramycin Formulation

Version 1.3 Revision Date: 27.08.2021 SDS Number: 7979094-00004 Date of last issue: 18.06.2021 Date of first issue: 19.03.2021

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

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

Spiramycin Formulation

Version 1.3
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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; AILC - 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; EC50 - Half maximal inhibitory concentration; IC50 - Half maximal inhibitory concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population; 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; TECL - 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 compile the Safety Data Sheet:

Classification of the mixture:
Eye Irrit. 2 H319 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.

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