SAFETY DATA SHEET

Spiramycin Formulation

Section 1: Identification

Product name : Spiramycin Formulation

Manufacturer or supplier's details

Company : MSD
Address : 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand
Telephone : +1-908-740-4000
Emergency telephone number : +1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product

Section 2: Hazard identification

GHS Classification

Serious eye damage/eye irritation : Category 2A
Reproductive toxicity : Category 1B

GHS label elements

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.
P202 Do not handle until all safety precautions have been read
and understood.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ protective clothing/ eye protec-
tion/ face protection.
Response:
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water
for several minutes. Remove contact lenses, if present and
easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/
SAFETY DATA SHEET

Spiramycin Formulation

Version 2.0  Revision Date: 27.08.2021  SDS Number: 7947470-00004  Date of last issue: 18.06.2021  Date of first issue: 19.03.2021

Attention.
P337 + P313 If eye irritation persists: Get medical advice/attention.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.

Other hazards which do not result in classification
None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Pyrrolidone</td>
<td>616-45-5</td>
<td>&gt;= 30 - &lt; 60</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Spiramycin</td>
<td>8025-81-8</td>
<td>&lt; 10</td>
</tr>
</tbody>
</table>

Section 4: 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.

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.

Most important symptoms and effects, both acute and delayed : Causes serious eye irritation.
May damage fertility. May damage the unborn child.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.
Section 5: Fire-fighting measures

Suitable extinguishing media
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

Unsuitable extinguishing media
- None known.

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

Hazardous combustion products
- Nitrogen oxides (NOx)
- Carbon oxides

Specific extinguishing methods
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

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

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Prevent spreading over a wide area (e.g. by containment or oil barriers).
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up
- Soak up with inert absorbent material.
- For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

Section 7: Handling and storage

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.

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

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

Section 8: Exposure controls/personal protection

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</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>

Engineering measures:
- Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections).
- All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
- Laboratory operations do not require special containment.

Personal protective equipment

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

Hand protection:
- Material: Chemical-resistant gloves
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.

Skin and body protection : Work uniform or laboratory coat.

Section 9: Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Aqueous solution</td>
</tr>
<tr>
<td>Colour</td>
<td>Light yellow</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>pH</td>
<td>8.0 - 10.0</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>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</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>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>0.950 - 1.150 g/cm³</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility : No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Decomposition temperature : No data available
Viscosity
  Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : Not applicable

Section 10: Stability and reactivity
Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

Section 11: Toxicological information
Exposure routes : Inhalation
  Skin contact
  Ingestion
  Eye contact

Acute toxicity
| Not classified based on available information.

Product:
Acute oral toxicity : Acute toxicity estimate: > 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:
| Not classified based on available information.

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
- **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:

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Irritation to eyes, reversing within 7 days</td>
</tr>
</tbody>
</table>

### Benzyl alcohol:

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Irritation to eyes, reversing within 21 days</td>
</tr>
</tbody>
</table>

**Respiratory or skin sensitisation**

### Skin sensitisation

Not classified based on available information.

### Respiratory sensitisation

Not classified based on available information.

### Components:

#### 2-Pyrrolidone:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local lymph node assay (LLNA)</td>
<td>Skin contact</td>
<td>Mouse</td>
<td>OECD Test Guideline 429</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

#### Benzyl alcohol:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximisation Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>OECD Test Guideline 406</td>
<td>negative</td>
</tr>
</tbody>
</table>

#### Spiramycin:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnusson-Kligman-Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>Not a skin sensitizer.</td>
</tr>
</tbody>
</table>

### Chronic toxicity

**Germ cell mutagenicity**

Not classified based on available information.

### Components:

#### 2-Pyrrolidone:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>
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  
Method: OECD Test Guideline 473  
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

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

**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. Clear evidence of adverse effects on development, 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.

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

Ecotoxicity

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: EC50 (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
## Toxicity to daphnia and other aquatic invertebrates

Exposure time: 96 h

<table>
<thead>
<tr>
<th>Toxity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): 230 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 48 h</td>
<td>Method: OECD Test Guideline 202</td>
</tr>
</tbody>
</table>

## Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Toxity to algae/aquatic plants</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 72 h</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

| 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)

<table>
<thead>
<tr>
<th>Toxity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>NOEC (Daphnia magna (Water flea)): 51 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 21 d</td>
<td>Method: OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

## Persistence and degradability

**Components:**

### 2-Pyrrolidone:

<table>
<thead>
<tr>
<th>Biodegradability</th>
<th>Result: Readily biodegradable.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Benzyl alcohol:

<table>
<thead>
<tr>
<th>Biodegradability</th>
<th>Result: Readily biodegradable.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradation</td>
<td>92 - 96 %</td>
</tr>
<tr>
<td>Exposure time</td>
<td>14 d</td>
</tr>
</tbody>
</table>

## Bioaccumulative potential

**Components:**

### 2-Pyrrolidone:

<table>
<thead>
<tr>
<th>Partition coefficient: n-octanol/water</th>
<th>log Pow: -0.71</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method: OECD Test Guideline 107</td>
<td></td>
</tr>
</tbody>
</table>

### Benzyl alcohol:

<table>
<thead>
<tr>
<th>Partition coefficient: n-octanol/water</th>
<th>log Pow: 1.05</th>
</tr>
</thead>
</table>

## Mobility in soil

No data available

## Other adverse effects

No data available
Section 13: Disposal considerations

Disposal methods

<table>
<thead>
<tr>
<th>Waste from residues</th>
<th>Dispose of in accordance with local regulations.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contaminated packaging</td>
<td>Empty containers should be taken to an approved waste handling site for recycling or disposal.</td>
</tr>
<tr>
<td></td>
<td>If not otherwise specified: Dispose of as unused product.</td>
</tr>
</tbody>
</table>

Section 14: Transport information

International Regulations

**UNRTDG**
- UN number: Not applicable
- Proper shipping name: Not applicable
- Class: Not applicable
- Subsidiary risk: Not applicable
- Packing group: Not applicable
- Labels: Not applicable

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

**IMDG-Code**
- UN number: Not applicable
- Proper shipping name: Not applicable
- Class: Not applicable
- Subsidiary risk: Not applicable
- Packing group: Not applicable
- Labels: Not applicable
- EmS Code: Not applicable
- Marine pollutant: Not applicable

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

**NZS 5433**
- UN number: Not applicable
- Proper shipping name: Not applicable
- Class: Not applicable
- Subsidiary risk: Not applicable
- Packing group: Not applicable
- Labels: Not applicable
- Hazchem Code: Not applicable
Special precautions for user
Not applicable

Section 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

HSNO Approval Number
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

Section 16: Other information

Further information

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

Date format : dd.mm.yyyy

Full text of other abbreviations

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International
SAFETY DATA SHEET

Spiramycin Formulation

Version 2.0  Revision Date: 27.08.2021  SDS Number: 7947470-00004  Date of last issue: 18.06.2021

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

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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