SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Spiramycin Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil  CEP 12730-340
Telephone: 908-740-4000
Emergency telephone: 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. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Eye irritation: Category 2A
Reproductive toxicity: Category 1B

GHS label elements in accordance with ABNT NBR 14725 Standard
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 protection/ face protection.

Response: P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

Storage: 

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P405 Store locked up.

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>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Pyrrolidone</td>
<td>616-45-5</td>
<td>Eye irritation, Category 2B Reproductive toxicity, Category 1B</td>
<td>&gt;= 30 &lt; 50</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>Acute toxicity (Oral), Category 4 Acute toxicity (Inhalation), Category 4 Eye irritation, Category 2A</td>
<td>&gt;= 1 &lt; 5</td>
</tr>
<tr>
<td>Spiramycin</td>
<td>8025-81-8</td>
<td>Acute toxicity (Oral), Category 5</td>
<td>&lt; 0.1</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 fire-fighters:
- 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 diking or other appropriate containment to keep material from spreading. If diked 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.
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 vapors 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 labeled 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
  - Organic peroxides
  - Explosives
  - Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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 ug/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.
**SAFETY DATA SHEET**

*Spiramycin Formulation*

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2</td>
<td>18.06.2021</td>
<td>7947471-00003</td>
<td>24.03.2021</td>
<td>19.03.2021</td>
</tr>
</tbody>
</table>

**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 vapor 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**

- **Appearance**: Aqueous solution
- **Color**: light yellow
- **Odor**: No data available
- **Odor Threshold**: No data available
- **pH**: 8,0 - 10,0
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: No data available
- **Evaporation rate**: No data available
- **Flammability (solid, gas)**: Not applicable
- **Flammability (liquids)**: No data available
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapor pressure**: No data available
- **Relative vapor density**: No data available
- **Relative density**: No data available
- **Density**: 0,950 - 1,150 g/cm³
Solubility(ies)
  Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Autoignition temperature : No data available
 Decomposition temperature : No data available
Viscosity
  Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
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
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: > 5,000 mg/kg
                     Method: Calculation method
  Acute inhalation toxicity : Acute toxicity estimate: > 10 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
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
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**Spiramycin Formulation**

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**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
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405

**Respiratory or skin sensitization**

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

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

**Components:**

**2-Pyrrolidone:**

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

**Benzyl alcohol:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximization Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Spiramycin:**

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

**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:** Cytogenetic assay
  - **Test system:** Chinese hamster ovary cells
  - **Result:** negative

- **Test Type:** In vitro mammalian cell gene mutation test
  - **Test system:** Mouse
  - **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

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 fetal development: Test Type: Embryo-fetal 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 fetal development: Test Type: Embryo-fetal 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 fetal development: Test Type: Embryo-fetal development
   Species: Rabbit
   Application Route: Oral
   General Toxicity Maternal: 100 mg/kg body weight
   Developmental Toxicity: LOAEL: 200 mg/kg body weight
   Embryo-fetal 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 y
Target Organs: Kidney, male reproductive organs, optic nerve

Species: Dog, male and female
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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.

Experience with human exposure

Components:

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

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: 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: \( \text{LC50 (Pimephales promelas (fathead minnow))}: 460 \text{ mg/l} \)  
Exposure time: 96 h

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

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

No toxic effects (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): \( \text{NOEC (Daphnia magna (Water flea))}: 51 \text{ mg/l} \)  
Exposure time: 21 d  
Method: OECD Test Guideline 211

**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

**Bioaccumulative potential**

**Components:**

**2-Pyrrolidone:**

Partition coefficient: \( \text{n-octanol/water} \)  
\( \text{log Pow} = -0.71 \)  
Method: OECD Test Guideline 107

**Benzyl alcohol:**

Partition coefficient: \( \text{n-octanol/water} \)  
\( \text{log Pow} = 1.05 \)

**Mobility in soil**

No data available

**Other adverse effects**

No data available
SECTION 13. DISPOSAL CONSIDERATIONS

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

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

Domestic regulation

ANTT
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH)
: Not applicable

Brazil. List of chemicals controlled by the Federal Police
: Not applicable

International Regulations

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

SECTION 16. OTHER INFORMATION

Further information
Sources of key data used to
: Internal technical data, data from raw material SDSs, OECD
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.