

## Spiramycin Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue:             |
| 8.0     | 20.06.2025     | 7947470-00014 | 14.04.2025                      |
|         |                |               | Date of first issue: 19.03.2021 |

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### 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 : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800  
CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

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### Section 2: Hazard identification

#### GHS Classification

Serious eye damage/eye irritation : Category 2

Skin sensitisation : Category 1

Reproductive toxicity : Category 1

#### GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H360FD May damage fertility. May damage the unborn child.

Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P261 Avoid breathing mist or vapours.

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P264 Wash skin thoroughly after handling.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P302 + P352 IF ON SKIN: Wash with plenty of water.  
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/ attention.  
P333 + P313 If skin irritation or rash occurs: Get medical advice/ 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**

| Chemical name  | CAS-No.   | Concentration (% w/w) |
|----------------|-----------|-----------------------|
| 2-Pyrrolidone  | 616-45-5  | >= 30 -< 50           |
| Benzyl alcohol | 100-51-6  | >= 1 -< 10            |
| Spiramycin     | 8025-81-8 | < 0.1                 |

**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.

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|                                                             |   |                                                                                                                                                                             |
|-------------------------------------------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| In case of eye contact                                      | : | In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention.          |
| If swallowed                                                | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.                                                                       |
| Most important symptoms and effects, both acute and delayed | : | May cause an allergic skin reaction.<br>Causes serious eye irritation.<br>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.                                                                                                                                     |

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**Section 5: Fire-fighting measures**

|                                               |   |                                                                                                                                                                                                                                                 |
|-----------------------------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Suitable extinguishing media                  | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>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 (NO <sub>x</sub> )<br>Carbon oxides                                                                                                                                                                                             |
| Specific extinguishing methods                | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.                                                                                                                                            |

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**Section 6: Accidental release measures**

|                                                                     |   |                                                                                                                                                                                                                           |
|---------------------------------------------------------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).                                                                      |
| Environmental precautions                                           | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g. by containment or oil barriers).<br>Retain and dispose of contaminated wash water. |

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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.

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**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.  
Avoid breathing mist or vapours.  
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.  
Contaminated work clothing should not be allowed out of the workplace.  
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

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## Section 8: Exposure controls/personal protection

## Components with workplace control parameters

| Components | CAS-No.   | Value type<br>(Form of exposure) | Control parameters / Permissible concentration | Basis    |
|------------|-----------|----------------------------------|------------------------------------------------|----------|
| Spiramycin | 8025-81-8 | TWA                              | 1000 ug/m3 (OEB 1)                             | Internal |

**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

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

Appearance : Aqueous solution

Colour : light yellow

Odour : No data available

Odour 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

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|                                                  |   |                                                          |
|--------------------------------------------------|---|----------------------------------------------------------|
| 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                                        |
| Vapour pressure                                  | : | No data available                                        |
| Relative vapour density                          | : | No data available                                        |
| Relative density                                 | : | No data available                                        |
| Density                                          | : | 0.950 - 1.150 g/cm <sup>3</sup>                          |
| Solubility(ies)                                  |   |                                                          |
| Water solubility                                 | : | No data available                                        |
| Partition coefficient: n-octanol/water           | : | Not applicable                                           |
| Auto-ignition 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 characteristics                         |   |                                                          |
| Particle size                                    | : | Not applicable                                           |

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**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. |

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|                                  |   |                                                |
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| Conditions to avoid              | : | None known.                                    |
| Incompatible materials           | : | Oxidizing agents                               |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

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**Section 11: Toxicological information**

|                 |   |                                                        |
|-----------------|---|--------------------------------------------------------|
| Exposure routes | : | Inhalation<br>Skin contact<br>Ingestion<br>Eye contact |
|-----------------|---|--------------------------------------------------------|

**Acute toxicity**

Not classified based on available information.

**Product:**

|                     |   |                                                                      |
|---------------------|---|----------------------------------------------------------------------|
| Acute oral toxicity | : | Acute toxicity estimate: > 2,000 mg/kg<br>Method: Calculation method |
|---------------------|---|----------------------------------------------------------------------|

|                       |   |                                                                      |
|-----------------------|---|----------------------------------------------------------------------|
| Acute dermal toxicity | : | Acute toxicity estimate: > 2,000 mg/kg<br>Method: Calculation method |
|-----------------------|---|----------------------------------------------------------------------|

**Components:****2-Pyrrolidone:**

|                     |   |                                                                                                                                 |
|---------------------|---|---------------------------------------------------------------------------------------------------------------------------------|
| Acute oral toxicity | : | LD50 (Rat): > 2,000 mg/kg<br>Method: OECD Test Guideline 401<br>Assessment: The substance or mixture has no acute oral toxicity |
|---------------------|---|---------------------------------------------------------------------------------------------------------------------------------|

|                       |   |                                                                                                                                      |
|-----------------------|---|--------------------------------------------------------------------------------------------------------------------------------------|
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg<br>Method: OECD Test Guideline 402<br>Assessment: The substance or mixture has no acute dermal toxicity |
|-----------------------|---|--------------------------------------------------------------------------------------------------------------------------------------|

**Benzyl alcohol:**

|                           |   |                                                                                                                                                                                        |
|---------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Acute oral toxicity       | : | LD50 (Rat): 1,200 mg/kg                                                                                                                                                                |
| Acute inhalation toxicity | : | LC50 (Rat): > 5.4 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Method: OECD Test Guideline 403<br>Assessment: The substance or mixture has no acute inhalation toxicity |
| Acute dermal toxicity     | : | Acute toxicity estimate: 1,100 mg/kg<br>Method: Expert judgement<br>Remarks: Based on national or regional regulation.                                                                 |

**Spiramycin:**

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| Acute oral toxicity | : | LD50 (Mouse, adult): 2,900 mg/kg |
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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: IntravenousLD50 (Rat): 170 mg/kg  
Application Route: IntravenousLD50 (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                                       |
| Result  | : Irritation to eyes, reversing within 21 days |
| Method  | : OECD Test Guideline 405                      |



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**Respiratory or skin sensitisation****Skin sensitisation**

May cause an allergic skin reaction.

**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       | : Human repeat insult patch test (HRIPT) |
| Exposure routes | : Skin contact                           |
| Species         | : Humans                                 |
| Result          | : positive                               |

|            |                                                                                |
|------------|--------------------------------------------------------------------------------|
| Assessment | : Probability or evidence of low to moderate skin sensitisation rate in humans |
|------------|--------------------------------------------------------------------------------|

**Spiramycin:**

|                 |                          |
|-----------------|--------------------------|
| Test Type       | : Magnusson-Kligman-Test |
| Exposure routes | : Skin contact           |
| Species         | : Guinea pig             |
| Result          | : Not a skin sensitizer. |

**Chronic toxicity****Germ cell mutagenicity**

Not classified based on available information.

**Components:****2-Pyrrolidone:**

|                       |                                                                          |
|-----------------------|--------------------------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>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 |
| Method: OECD Test Guideline 473                |

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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

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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<br>Species: Rat<br>Application Route: Ingestion<br>Result: positive<br>Remarks: Based on data from similar materials |
|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                               |                                                                                                            |
|-------------------------------|------------------------------------------------------------------------------------------------------------|
| Effects on foetal development | : Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Ingestion<br>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<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative<br>Remarks: Based on data from similar materials |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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

**Spiramycin:**

|                      |                                                                                                                                                                   |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility | : Test Type: Fertility<br>Species: Rat, male<br>Target Organs: Reproductive organs<br>Result: alteration in sperm morphology, Effects on male reproductive organs |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                               |                                                                                      |
|-------------------------------|--------------------------------------------------------------------------------------|
| Effects on foetal development | : Test Type: Embryo-foetal development<br>Species: Rabbit<br>Application Route: Oral |
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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   |
| 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              |

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|                     |                          |
|---------------------|--------------------------|
| 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<br>Symptoms: Nausea, Vomiting, Diarrhoea |
|---------------------|------------------------------------------------------|

**Further information****Components:****Spiramycin:**

|         |                     |
|---------|---------------------|
| Remarks | : No data available |
|---------|---------------------|

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**Section 12: Ecological information****Ecotoxicity****Components:****2-Pyrrolidone:**

|                                                     |                                                                                                                                                                          |
|-----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish                                    | : LC50 (Danio rerio (zebra fish)): > 4,600 - 10,000 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203                                                       |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (Daphnia magna (Water flea)): > 500 mg/l<br>Exposure time: 48 h                                                                                                   |
| Toxicity to algae/aquatic plants                    | : ErC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l<br>Exposure time: 72 h<br><br>EC10 (Desmodesmus subspicatus (green algae)): 22.2 mg/l<br>Exposure time: 72 h |
| Toxicity to microorganisms                          | : EC50: > 1,000 mg/l<br>Exposure time: 30 min<br>Method: OECD Test Guideline 209                                                                                         |

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**Benzyl alcohol:**

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

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

Toxicity to algae/aquatic : EC50 (Pseudokirchneriella subcapitata (green algae)): 770  
plants 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 : NOEC (Daphnia magna (Water flea)): 51 mg/l  
aquatic invertebrates (Chron- Exposure time: 21 d  
ic toxicity) 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: n- : log Pow: -0.71  
octanol/water Method: OECD Test Guideline 107

**Benzyl alcohol:**

Partition coefficient: n- : log Pow: 1.05  
octanol/water

**Mobility in soil**

No data available

**Spiramycin Formulation**

|         |                |               |                                 |
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**Other adverse effects**

No data available

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**Section 13: Disposal considerations****Disposal methods**

|                        |   |                                                                                                                                                             |
|------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Waste from residues    | : | Do not dispose of waste into sewer.<br>Dispose of in accordance with local regulations.                                                                     |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product. |

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**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 |
| Environmentally hazardous | : | no             |

**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**

**Spiramycin Formulation**

|         |                |               |                                 |
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|                      |   |                |
|----------------------|---|----------------|
| 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

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**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

**Tolerable Exposure Limits (TEL)**

Not applicable

**Environmental Exposure Limits (EEL)**

Not applicable

**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

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**Section 16: Other information**

Revision Date : 20.06.2025

**Further information**

|                                                           |   |                                                                                                                                                                                   |
|-----------------------------------------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Sources of key data used to compile the Safety Data Sheet | : | Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <a href="http://echa.europa.eu/">http://echa.europa.eu/</a> |
|-----------------------------------------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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

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**Spiramycin Formulation**

|         |                |               |                                 |
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**Full text of other abbreviations**

AIIC - 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 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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