according to the Globally Harmonized System



# **Spiramycin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 2.1
 30.09.2023
 7947477-00010
 Date of first issue: 19.03.2021

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Spiramycin Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

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 Restrictions on use : Not applicable

### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

#### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

**GHS Classification** 

Serious eye damage/eye irri-

tation

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:

P203 Obtain, read and follow all safety instructions before use. P264+P265 Wash hands thoroughly after handling. Do not

according to the Globally Harmonized System



# **Spiramycin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 2.1
 30.09.2023
 7947477-00010
 Date of first issue: 19.03.2021

touch eyes.

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.

P318 IF exposed or concerned, get medical advice. P337 + P317 If eye irritation persists: Get medical help.

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.

#### 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 - < 5
Spiramycin	8025-81-8	< 0.1

### 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice 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.

according to the Globally Harmonized System



# Spiramycin Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 2.1 30.09.2023 7947477-00010 Date of first issue: 19.03.2021

Most important symptoms and effects, both acute and

delayed

Protection of first-aiders

Causes serious eye irritation.

May damage fertility. May damage the unborn child.

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.

#### 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical None known.

Unsuitable extinguishing

media

Specific hazards during fire-

fighting

Hazardous combustion prod-

ucts

Exposure to combustion products may be a hazard to health.

Nitrogen oxides (NOx) Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

#### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 absor-

bent.

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

according to the Globally Harmonized System



# Spiramycin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 2.1
 30.09.2023
 7947477-00010
 Date of first issue: 19.03.2021

certain local or national requirements.

#### 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 as-

sessment

Keep container tightly closed.

Take care to prevent spills, waste and minimize release to the

environment.

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

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type : Organic vapour type

Hand protection

Material : Chemical-resistant gloves

according to the Globally Harmonized System



# Spiramycin Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 2.1 30.09.2023 7947477-00010 Date of first issue: 19.03.2021

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.

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.

#### 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

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

according to the Globally Harmonized System



# Spiramycin Formulation

Version **Revision Date:** Date of last issue: 04.04.2023 SDS Number: 2.1 30.09.2023 7947477-00010 Date of first issue: 19.03.2021

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 size Not applicable

#### 10. STABILITY AND REACTIVITY

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions.

Possibility of hazardous reac- :

tions

Can react with strong oxidizing agents.

Conditions to avoid None known. Incompatible materials Oxidizing agents

Hazardous decomposition No hazardous decomposition products are known.

products

### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of: Inhalation exposure

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

according to the Globally Harmonized System



# **Spiramycin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 2.1
 30.09.2023
 7947477-00010
 Date of first issue: 19.03.2021

**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 tox-

icity

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

according to the Globally Harmonized System



# **Spiramycin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 2.1
 30.09.2023
 7947477-00010
 Date of first issue: 19.03.2021

Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

**Components:** 

2-Pyrrolidone:

Species : Rabbit

Result : Irritation to eyes, reversing within 7 days

Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

**Components:** 

2-Pyrrolidone:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact

Species : Mouse

Method : OECD Test Guideline 429

Result : negative

Remarks : Based on data from similar materials

Benzyl alcohol:

Test Type : Maximisation Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Spiramycin:

Test Type : Magnusson-Kligman-Test

Exposure routes : Skin contact Species : Guinea pig

Result : Not a skin sensitizer.

according to the Globally Harmonized System



# Spiramycin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 2.1
 30.09.2023
 7947477-00010
 Date of first issue: 19.03.2021

### Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

2-Pyrrolidone:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

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.

according to the Globally Harmonized System



# Spiramycin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 2.1
 30.09.2023
 7947477-00010
 Date of first issue: 19.03.2021

#### **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 foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: positive

Reproductive toxicity - As-

sessment

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 develop- : Test Type: Embryo-foetal development

according to the Globally Harmonized System



# Spiramycin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 2.1
 30.09.2023
 7947477-00010
 Date of first issue: 19.03.2021

ment 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 re-

productive organs

Effects on foetal develop-

ment

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

LOAEL : 5.6 mg/kg
Application Route : Intravenous

according to the Globally Harmonized System



# **Spiramycin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 2.1
 30.09.2023
 7947477-00010
 Date of first issue: 19.03.2021

Exposure time : 32 d

Target Organs : Central nervous system

Species : Dog, male and female

NOAEL : 75 mg/kg
Application Route : Oral
Exposure time : 2 yr

Target Organs : Kidney, male reproductive organs, optic nerve

Species : Dog, male and female

LOAEL : 169 mg/kg
Application Route : Intravenous
Exposure time : 4 Weeks

Number of exposures : 2 injections per day Target Organs : spleen, Kidney

Species : Dog, male and female

LOAEL : 50 mg/kg
Application Route : Intravenous
Exposure time : 4 Weeks

Target Organs : Central nervous system

**Aspiration toxicity** 

Not classified based on available information.

**Experience with human exposure** 

**Components:** 

Spiramycin:

General Information : May cause

Symptoms: Nausea, Vomiting, Diarrhoea

**Further information** 

**Components:** 

Spiramycin:

Remarks : No data available

#### 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

according to the Globally Harmonized System



# Spiramycin Formulation

Version **Revision Date:** SDS Number: Date of last issue: 04.04.2023 2.1 30.09.2023 7947477-00010 Date of first issue: 19.03.2021

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

EC50: > 1,000 mg/lToxicity to microorganisms

Exposure time: 30 min

Method: OECD Test Guideline 209

Benzyl alcohol:

Toxicity to fish LC50 (Pimephales promelas (fathead minnow)): 460 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 230 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 770

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chron-

NOEC: 51 mg/l Exposure time: 21 d

ic toxicity)

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

### Persistence and degradability

**Components:** 

2-Pyrrolidone:

Biodegradability Result: Readily biodegradable.

Remarks: Based on data from similar materials

Benzyl alcohol:

Result: Readily biodegradable. Biodegradability

Biodegradation: 92 - 96 %

Exposure time: 14 d

according to the Globally Harmonized System



# **Spiramycin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 2.1
 30.09.2023
 7947477-00010
 Date of first issue: 19.03.2021

### **Bioaccumulative potential**

**Components:** 

2-Pyrrolidone:

Partition coefficient: n- : log Pow: -0.71

octanol/water Method: OECD Test Guideline 107

Benzyl alcohol:

Partition coefficient: n-

octanol/water

: log Pow: 1.05

Mobility in soil

No data available

Other adverse effects

No data available

#### 13. DISPOSAL CONSIDERATIONS

**Disposal methods** 

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

### 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 IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

### 15. REGULATORY INFORMATION

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

The components of this product are reported in the following inventories:

according to the Globally Harmonized System



# Spiramycin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 2.1
 30.09.2023
 7947477-00010
 Date of first issue: 19.03.2021

AICS : not determined

DSL : not determined

IECSC : not determined

#### 16. OTHER INFORMATION

Revision Date : 30.09.2023

**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 Agen-

cy, http://echa.europa.eu/

Date format : dd.mm.yyyy

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

according to the Globally Harmonized System



# **Spiramycin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 2.1
 30.09.2023
 7947477-00010
 Date of first issue: 19.03.2021

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.

IN / EN