

# **Spiramycin Formulation**

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

 1.10
 30.09.2023
 7947466-00011
 Date of first issue: 19.03.2021

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Spiramycin Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub- : Veterinary product

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

20 Spartan Road

1619 Spartan, South Africa

Telephone : +27119239300

E-mail address of person

responsible for the SDS

EHSDATASTEWARD@msd.com

# 1.4 Emergency telephone number

+1-908-423-6000

# **SECTION 2: Hazards identification**

# 2.1 Classification of the substance or mixture

#### Classification (REGULATION (EC) No 1272/2008)

Eye irritation, Category 2 H319: Causes serious eye irritation.

Reproductive toxicity, Category 1B H360FD: May damage fertility. May damage the

unborn child.

# 2.2 Label elements

# Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

**!** 

Signal word : Danger

Hazard statements : H319 Causes serious eye irritation.

H360FD May damage fertility. May damage the unborn

child.



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Precautionary statements : Prevention:

P201 Obtain special instructions before use. P264 Wash skin thoroughly after handling.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

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

attention.

Storage:

P405 Store locked up.

Hazardous components which must be listed on the label:

2-Pyrrolidone

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

# **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

# Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
2-Pyrrolidone	616-45-5 210-483-1	Eye Irrit. 2; H319 Repr. 1B; H360FD	>= 30 - < 50
Benzyl alcohol	100-51-6 202-859-9 603-057-00-5	Acute Tox. 4; H302 Acute Tox. 4; H332 Eye Irrit. 2; H319	>= 1 - < 10
Spiramycin	8025-81-8 232-429-6		< 0,1

For explanation of abbreviations see section 16.

#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

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

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.



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First Aid responders should pay attention to self-protection. Protection of first-aiders

> and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of contact, immediately flush eyes with plenty of water In case of eye contact

for at least 15 minutes.

If easy to do, remove contact lens, if worn.

Get medical attention.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Causes serious eye irritation. Risks

May damage fertility. May damage the unborn child.

4.3 Indication of any immediate medical attention and special treatment needed

**Treatment** : Treat symptomatically and supportively.

#### **SECTION 5: Firefighting measures**

5.1 Extinguishing media

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Nitrogen oxides (NOx)

Carbon oxides

# MSD Public

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5.3 Advice for firefighters

Special protective equipment:

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

Specific extinguishing 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.

#### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

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

tective equipment recommendations (see section 8).

#### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g. by containment or oil

barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

#### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable 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

certain local or national requirements.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

# **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust

ventilation.



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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.

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 contami-

nated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

## 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage

areas and containers

Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national

regulations.

Advice on common storage Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

**Explosives** Gases

7.3 Specific end use(s)

Specific use(s) No data available

# **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

#### **Occupational Exposure Limits**

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

#### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

		-	• •	
Substance name	End Use	Exposure routes	Potential health effects	Value
2-Pyrrolidone	Workers	Inhalation	Long-term systemic effects	57,8 mg/m3
	Workers	Skin contact	Long-term systemic effects	10 mg/kg bw/day



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	Workers	Skin contact	Acute systemic ef-	277 mg/kg
			fects	bw/day
	Consumers	Inhalation	Long-term systemic effects	17,1 mg/m3
	Consumers	Skin contact	Long-term systemic effects	6 mg/kg bw/day
	Consumers	Skin contact	Acute systemic ef- fects	167 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	5,2 mg/kg bw/day
	Consumers	Ingestion	Acute systemic ef- fects	33,3 mg/kg bw/day
Benzyl alcohol	Workers	Inhalation	Long-term systemic effects	22 mg/m3
	Workers	Inhalation	Acute systemic effects	110 mg/m3
	Workers	Skin contact	Long-term systemic effects	8 mg/kg bw/day
	Workers	Skin contact	Acute systemic ef- fects	40 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	5,4 mg/m3
	Consumers	Inhalation	Acute systemic ef- fects	27 mg/m3
	Consumers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Skin contact	Acute systemic ef- fects	20 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Ingestion	Acute systemic ef- fects	20 mg/kg bw/day

# Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value		
2-Pyrrolidone	Fresh water	0,5 mg/l		
	Freshwater - intermittent	0,5 mg/l		
	Marine water	0,05 mg/l		
	Sewage treatment plant	10 mg/l		
	Fresh water sediment	0,4205 mg/kg dry		
		weight (d.w.)		
	Soil	0,0612 mg/kg dry		
		weight (d.w.)		
Benzyl alcohol	Fresh water	1 mg/l		
	Marine water	0,1 mg/l		
	Intermittent use/release	2,3 mg/l		
	Sewage treatment plant	39 mg/l		
	Fresh water sediment	5,27 mg/kg		
	Marine sediment	0,527 mg/kg		
	Soil	0,456 mg/kg		



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#### 8.2 Exposure controls

#### **Engineering measures**

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Laboratory operations do not require special containment.

## Personal protective equipment

Eye/face protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Hand protection

Material : Chemical-resistant gloves

Skin and body protection : Work uniform or laboratory coat.

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 (A)

#### **SECTION 9: Physical and chemical properties**

# 9.1 Information on basic 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

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



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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- : Not applicable

octanol/water

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.

9.2 Other information

Flammability (liquids) : No data available

Molecular weight : No data available

Particle size : Not applicable

# **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

## 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

## 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

# **SECTION 11: Toxicological information**

## 11.1 Information on toxicological effects



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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: > 2.000 mg/kg

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

**Components:** 

2-Pyrrolidone:

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



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Application Route: Intravenous

LD50 (Rabbit): 182 mg/kg Application Route: Intravenous

#### Skin corrosion/irritation

Not classified based on available information.

#### **Components:**

2-Pyrrolidone:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

## Serious eye damage/eye irritation

Causes serious eye irritation.

# **Components:**

2-Pyrrolidone:

Species : Rabbit

Result : Irritation to eyes, reversing within 7 days

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



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Benzyl alcohol:

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

Method : OECD Test Guideline 406

Result : negative

Spiramycin:

Test Type : Magnusson-Kligman-Test

Exposure routes : Skin contact Species : Guinea pig

Result : Not a skin sensitizer.

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

2-Pyrrolidone:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

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



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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 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

12/19



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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-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Ingestion

Result: negative

Spiramycin:

Effects on fertility : Test Type: Fertility

Species: Rat, male

Target Organs: Reproductive organs

Result: alteration in sperm morphology, Effects on male 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



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Spiramycin:

Species : Rat, male and female

NOAEL: 140 mg/kgApplication Route: OralExposure time: 13 WeeksTarget 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

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



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# **SECTION 12: Ecological information**

#### 12.1 Toxicity

**Components:** 

2-Pyrrolidone:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 4.600 - 10.000 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 500 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

ErC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l

Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): 22,2 mg/l

Exposure time: 72 h

Toxicity to microorganisms : EC50 : > 1.000 mg/l

Exposure time: 30 min

Method: OECD Test Guideline 209

Benzyl alcohol:

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

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

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

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 770

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 51 mg/l Exposure time: 21 d

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

# 12.2 Persistence and degradability

**Components:** 

2-Pyrrolidone:

Biodegradability : Result: Readily biodegradable.



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Remarks: Based on data from similar materials

Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 92 - 96 % Exposure time: 14 d

12.3 Bioaccumulative potential

**Components:** 

2-Pyrrolidone:

Partition coefficient: n- : log Pow: -0,71

octanol/water Method: OECD Test Guideline 107

Benzyl alcohol:

Partition coefficient: n-

octanol/water

log Pow: 1,05

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

**Product:** 

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

12.6 Other adverse effects

**Product:** 

Endocrine disrupting poten-

tial

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

**SECTION 13: Disposal considerations** 

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

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.



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# **SECTION 14: Transport information**

#### 14.1 UN number

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.4 Packing group

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA (Cargo) : Not regulated as a dangerous good
IATA (Passenger) : Not regulated as a dangerous good

#### 14.5 Environmental hazards

Not regulated as a dangerous good

## 14.6 Special precautions for user

Not applicable

# 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.



# **Spiramycin Formulation**

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

 1.10
 30.09.2023
 7947466-00011
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## **SECTION 15: Regulatory information**

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

## 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

#### **SECTION 16: Other information**

Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

#### **Full text of H-Statements**

H302 : Harmful if swallowed.

H319 : Causes serious eye irritation.

H332 : Harmful if inhaled.

H360FD : May damage fertility. May damage the unborn child.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity Eye Irrit. : Eye irritation

Repr. : Reproductive toxicity

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road: AIIC - Australian Inventory of Industrial Chemicals: ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Ef-



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fect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

#### **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/

Classification of the mixture: Classification procedure:

Eye Irrit. 2 H319 Calculation method Repr. 1B H360FD Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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