

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

### 1.1. Product identifier

Product form	: Substance
Substance name	: Spiramycin
Chemical name	: Spiramycin
EC-No.	: 232-429-6
CAS-No.	: 8025-81-8
Product code	: 201600836

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

#### Relevant identified uses

Use of the substance/mixture	: Scientific research and development Technical testing and analysis For professional use only
Function or use category	: Laboratory chemicals

#### Uses advised against

Restrictions on use	: Not for food, drug or home use
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### 1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare  
EDQM, Council of Europe  
7, Allée Kastner, CS30026  
F 67081 Strasbourg  
France  
T +33(0)388412035, F +33(0)388412771  
[sds@edqm.eu](mailto:sds@edqm.eu), [www.edqm.eu](http://www.edqm.eu)

### 1.4. Emergency telephone number

Emergency number	: +33(0)390215608
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## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

#### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin corrosion/irritation, Category 2	H315	
Serious eye damage/eye irritation, Category 2	H319	
Respiratory sensitisation, Category 1	H334	
Skin sensitisation, Category 1	H317	
Specific target organ toxicity – Repeated exposure, Category 1	H372	
Hazardous to the aquatic environment – Acute Hazard, Category 1	H400	(M=100)
Hazardous to the aquatic environment – Chronic Hazard, Category 1	H410	(M=100)

Full text of H- and EUH-statements: see section 16

#### Adverse physicochemical, human health and environmental effects

Very toxic to aquatic life with long lasting effects. Causes serious eye irritation. May cause an allergic skin reaction. Causes skin irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Causes damage to organs through prolonged or repeated exposure.

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according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### 2.2. Label elements

#### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



GHS08

GHS09

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H315 - Causes skin irritation.  
H317 - May cause an allergic skin reaction.  
H319 - Causes serious eye irritation.  
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H372 - Causes damage to organs (cardiovascular system) through prolonged or repeated exposure.

Precautionary statements (CLP)

: H410 - Very toxic to aquatic life with long lasting effects.  
P260 - Do not breathe dust/fume/gas/mist/vapours/spray.  
P264 - Wash hands, forearms and face thoroughly after handling.  
P270 - Do not eat, drink or smoke when using this product.  
P272 - Contaminated work clothing should not be allowed out of the workplace.  
P273 - Avoid release to the environment.  
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.  
P284 - Wear respiratory protection.  
P302+P352 - IF ON SKIN: Wash with plenty of water.  
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P314 - Get medical advice/attention if you feel unwell.  
P321 - Specific treatment (see supplemental first aid instruction on this label).  
P332+P313 - If skin irritation occurs: 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.  
P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor.  
P362+P364 - Take off contaminated clothing and wash it before reuse.  
P391 - Collect spillage.  
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: Exemption for inner packaging where the contents do not exceed 10ml.

Hazard pictograms (CLP)



GHS08

### 2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

Other information

: Active substance (in pharmaceutical products).  
Warning - substance not yet tested completely.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Substance type

: Mono-constituent

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Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Spiramycin	CAS-No.: 8025-81-8 EC-No.: 232-429-6	≤ 100	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Resp. Sens. 1, H334 Skin Sens. 1, H317 STOT RE 1, H372 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100)

Full text of H- and EUH-statements: see section 16

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If experiencing respiratory symptoms: Call a poison center or a doctor.
First-aid measures after skin contact	: Take off contaminated clothing. Gently wash with plenty of soap and water. If symptoms persist, call a physician. Get medical advice if skin irritation persists.
First-aid measures after eye contact	: Rinse immediately and thoroughly, pulling the eyelids well away from the eye (15 minutes minimum). Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion	: Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.

#### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Symptoms/effects after skin contact	: May cause an allergic skin reaction. Causes skin irritation.
Symptoms/effects after eye contact	: Causes serious eye irritation. Redness, pain.

#### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket.
Unsuitable extinguishing media	: Do not use a heavy water stream.

#### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released.
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#### 5.3. Advice for firefighters

Firefighting instructions	: Prevent fire fighting water from entering the environment.
Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

### SECTION 6: Accidental release measures

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

General measures	: Avoid contact with skin, eyes and clothing.
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### For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

### For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

## 6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

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

For containment : Absorb with an inert material and place in an appropriate waste disposal container.  
Methods for cleaning up : Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

## 6.4. Reference to other sections

See Section 13 for disposal information.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Avoid all unnecessary exposure. Ensure good ventilation of the work station.  
Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.  
Packaging materials : Keep in original containers.

### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

#### Appropriate engineering controls

##### Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

#### Personal protection equipment

##### Eye and face protection

###### Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

##### Skin protection

###### Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

###### Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

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### Respiratory protection

#### Respiratory protection:

In case of dust formation use respirator with filter: P3

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: White, yellowish.
Appearance	: Powder.
Molecular mass	: 843 – 900 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: 125 – 140 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: 8,5 – 10,5 (5 g/L)
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: 1 – 10 g/l
Partition coefficient n-octanol/water (Log Kow)	: < 4
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

No additional information available

### 10.3. Possibility of hazardous reactions

No additional information available

### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

No additional information available

### 10.6. Hazardous decomposition products

No additional information available

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### SECTION 11: Toxicological information

#### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Lack of data)
Acute toxicity (inhalation)	: Not classified (Lack of data)

Spiramycin (8025-81-8)	
LD50 oral rat	3550 mg/kg (RTECS No WG9400000)
Skin corrosion/irritation	: Causes skin irritation. pH: 8,5 – 10,5 (5 g/L)
Serious eye damage/irritation	: Causes serious eye irritation. pH: 8,5 – 10,5 (5 g/L)
Respiratory or skin sensitisation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Lack of data)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Lack of data)
STOT-repeated exposure	: Causes damage to organs (cardiovascular system) through prolonged or repeated exposure.
Aspiration hazard	: Not classified (Lack of data)

#### 11.2. Information on other hazards

No additional information available

### SECTION 12: Ecological information

#### 12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute)	: Very toxic to aquatic life.
Hazardous to the aquatic environment, long-term (chronic)	: Very toxic to aquatic life with long lasting effects.

Spiramycin (8025-81-8)	
EC50 - Crustacea [1]	> 100 mg/l (48 Hours, Daphnia magna (Water flea)) (Directive 92/69/EEC)
ErC50 algae	0,005 mg/l (7 days, Microcystis aeruginosa) (ISO 8692)

#### 12.2. Persistence and degradability

Spiramycin (8025-81-8)	
Persistence and degradability	Not rapidly degradable

#### 12.3. Bioaccumulative potential

Spiramycin (8025-81-8)	
Partition coefficient n-octanol/water (Log Kow)	< 4

#### 12.4. Mobility in soil

No additional information available

#### 12.5. Results of PBT and vPvB assessment

Spiramycin (8025-81-8)	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	

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### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

No additional information available




## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

No additional information available

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
<b>14.1. UN number or ID number</b>		
UN 3077	UN 3077	UN 3077
<b>14.2. UN proper shipping name</b>		
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	Environmentally hazardous substance, solid, n.o.s.
<b>Transport document description</b>		
UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, (-)	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, MARINE POLLUTANT	UN 3077 Environmentally hazardous substance, solid, n.o.s., 9, III
<b>14.3. Transport hazard class(es)</b>		
9	9	9
		
<b>14.4. Packing group</b>		
III	III	III
<b>14.5. Environmental hazards</b>		
Dangerous for the environment: Yes	Dangerous for the environment: Yes Marine pollutant: Yes EmS-No. (Fire): F-A EmS-No. (Spillage): S-F	Dangerous for the environment: Yes
No supplementary information available		

### 14.6. Special precautions for user

#### Overland transport

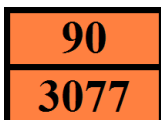
Classification code (ADR)	: M7
Special provisions (ADR)	: 274, 335, 375, 601
Limited quantities (ADR)	: 5kg
Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P002, IBC08, LP02, R001
Special packing provisions (ADR)	: PP12, B3
Mixed packing provisions (ADR)	: MP10
Portable tank and bulk container instructions (ADR)	: T1, BK1, BK2, BK3

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Portable tank and bulk container special provisions (ADR) : TP33  
Tank code (ADR) : SGAV, LGBV  
Vehicle for tank carriage : AT  
Transport category (ADR) : 3  
Special provisions for carriage - Packages (ADR) : V13  
Special provisions for carriage - Bulk (ADR) : VC1, VC2  
Special provisions for carriage - Loading, unloading and handling (ADR) : CV13  
Hazard identification number (Kemler No.) : 90  
Orange plates :



Tunnel restriction code (ADR) : -

### Transport by sea

Special provisions (IMDG) : 274, 335, 375, 966, 967, 969  
Limited quantities (IMDG) : 5 kg  
Excepted quantities (IMDG) : E1  
Packing instructions (IMDG) : LP02, P002  
Special packing provisions (IMDG) : PP12  
IBC packing instructions (IMDG) : IBC08  
IBC special provisions (IMDG) : B3  
Tank instructions (IMDG) : BK1, BK2, BK3, T1  
Tank special provisions (IMDG) : TP33  
Stowage category (IMDG) : A  
Stowage and handling (IMDG) : SW23

### Air transport

PCA Excepted quantities (IATA) : E1  
PCA Limited quantities (IATA) : Y956  
PCA limited quantity max net quantity (IATA) : 30kgG  
PCA packing instructions (IATA) : 956  
PCA max net quantity (IATA) : 400kg  
CAO packing instructions (IATA) : 956  
CAO max net quantity (IATA) : 400kg  
Special provisions (IATA) : A97, A158, A179, A197, A215  
ERG code (IATA) : 9L

## 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

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

#### EU-Regulations

##### REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

##### REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

##### REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

##### Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

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### Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

### Explosives Precursors Regulation (EU 2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

### Drug Precursors Regulation (EC 273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

## 15.2. Chemical safety assessment

No additional information available

## SECTION 16: Other information

### Full text of H- and EUH-statements:

Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H372	Causes damage to organs (cardiovascular system) through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Resp. Sens. 1	Respiratory sensitisation, Category 1
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1

Safety Data Sheet (SDS), EU

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