according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Neomycin Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 3.3 28.09.2024 9422656-00009 Date of first issue: 02.09.2021

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

1.1 Product identifier

Trade name **Neomycin 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

**MSD** Company

Kilsheelan

Clonmel Tipperary, IE

Telephone 353-51-601000

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)

Skin sensitisation, Category 1 H317: May cause an allergic skin reaction. Reproductive toxicity, Category 2 H361d: Suspected of damaging the unborn child. Specific target organ toxicity - repeated H373: May cause damage to organs through pro-

exposure, Category 2 longed or repeated exposure.

Short-term (acute) aquatic hazard, Cate-

gory 1

Long-term (chronic) aquatic hazard, Cat-

egory 1

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting

effects.

#### 2.2 Label elements

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

Hazard pictograms





according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Neomycin Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 3.3 28.09.2024 9422656-00009 Date of first issue: 02.09.2021

Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.

H361d Suspected of damaging the unborn child.

H373 May cause damage to organs through prolonged or

repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P260 Do not breathe dust.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

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

attention.

P391 Collect spillage.

Hazardous components which must be listed on the label:

Neomycin, sulfate (salt)

#### 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.

Ecological information: 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.

Toxicological information: 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.

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form combustible dust concentrations in air during processing, handling or other means.

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

#### 3.2 Mixtures

#### Components

•			
Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		, ,
	Registration number		
Neomycin, sulfate (salt)	1405-10-3	Skin Sens. 1B;	>= 50 - < 70
	215-773-1	H317	

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Neomycin Formulation**

Version 3.3	Revision Date: 28.09.2024	SDS Number: 9422656-00009	Date of last issue: 06.04.2024 Date of first issue: 02.09.2021	
			Repr. 2; H361d STOT RE 2; H373 (Kidney, inner ear) Aquatic Acute 1; H400 Aquatic Chronic 1; H410	
			M-Factor (Acute aquatic toxicity): 1.000 M-Factor (Chronic aquatic toxicity): 10	

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.

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).

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 : If in eyes, rinse well with water.

Get medical attention if irritation develops and persists.

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

Risks : May cause an allergic skin reaction.

Suspected of damaging the unborn child.

May cause damage to organs through prolonged or repeated

exposure.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Neomycin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 3.3
 28.09.2024
 9422656-00009
 Date of first issue: 02.09.2021

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation.

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

Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Neomycin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 3.3
 28.09.2024
 9422656-00009
 Date of first issue: 02.09.2021

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 : Sweep up or vacuum up spillage and collect in suitable con-

tainer for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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 : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres. Use only with adequate ventilation.

Local/Total ventilation
Advice on safe handling

Do not get on skin or clothing.

Do not breathe dust. Do not swallow.

Avoid contact with eyes.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges. 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,

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Neomycin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 3.3
 28.09.2024
 9422656-00009
 Date of first issue: 02.09.2021

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. Store in

accordance with the particular national regulations.

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

Strong oxidizing agents

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**

Dust 5 mg/m3

Value type (Form of exposure): TWA (respirable dust)

Basis: FOR-2011-12-06-1358

10 mg/m3

Value type (Form of exposure): TWA (total dust)

Basis: FOR-2011-12-06-1358

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Neomycin, sulfate (salt)	1405-10-3	TWA	1 mg/m3 (OEB 1)	Internal
	Further information: DSEN, OTO			
		Wipe limit	0.1 mg/100 cm <sup>2</sup>	Internal

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

Substance name	Environmental Compartment	Value
Neomycin, sulfate (salt)	Water	0,00004 mg/l

### 8.2 Exposure controls

#### **Engineering measures**

Use feasible engineering controls to minimize exposure to compound.

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

#### 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Neomycin Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 3.3 28.09.2024 9422656-00009 Date of first issue: 02.09.2021

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 Equipment should conform to NS EN 143

Farticulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : powder

Colour : White to light yellow

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flammability (solid, gas) : May form combustible dust concentrations in air during pro-

cessing, handling or other means.

Flammability (liquids) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Flash point : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, kinematic : Not applicable

Solubility(ies)

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Neomycin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 3.3
 28.09.2024
 9422656-00009
 Date of first issue: 02.09.2021

Water solubility : No data available

Partition coefficient: n-

octanol/water

: Not applicable

Vapour pressure : Not applicable

Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Particle characteristics

Particle size : No data available

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : Not applicable

Molecular weight : No data available

### **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 : May form combustible dust concentrations in air during pro-

cessing, handling or other means.

Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

#### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Neomycin Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 3.3 28.09.2024 9422656-00009 Date of first issue: 02.09.2021

### **SECTION 11: Toxicological information**

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

Information on likely routes of : Inhalation

exposure Skin contact Ingestion

Eye contact

**Acute toxicity** 

Not classified based on available information.

**Components:** 

Neomycin, sulfate (salt):

Acute oral toxicity : LD50 (Mouse): 2.880 mg/kg

LD50 (Rat): 2.750 mg/kg

Acute toxicity (other routes of:

administration)

LD50 (Rat): 633 mg/kg

Application Route: Subcutaneous

LD50 (Mouse): 116 mg/kg

Application Route: Intraperitoneal

LD50 (Mouse): 27,6 mg/kg Application Route: Intravenous

LD50 (Mouse): 275 mg/kg

Application Route: Subcutaneous

#### Skin corrosion/irritation

Not classified based on available information.

Components:

Neomycin, sulfate (salt):

Species : Rabbit

Result : Mild skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

Neomycin, sulfate (salt):

Species : Rabbit

Result : No eye irritation

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Neomycin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 3.3
 28.09.2024
 9422656-00009
 Date of first issue: 02.09.2021

#### Respiratory or skin sensitisation

#### Skin sensitisation

May cause an allergic skin reaction.

### Respiratory sensitisation

Not classified based on available information.

#### **Components:**

### Neomycin, sulfate (salt):

Exposure routes : Dermal Species : Humans Result : positive

#### Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

#### Neomycin, sulfate (salt):

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: Chinese hamster ovary cells

Result: negative

Test Type: Chromosomal aberration Test system: Human lymphocytes

Result: positive

Test Type: in vitro micronucleus test

Result: negative

Genotoxicity in vivo : Test Type: Cytogenetic assay

Species: Mouse

Cell type: Bone marrow

Application Route: Intravenous injection

Result: negative

#### Carcinogenicity

Not classified based on available information.

#### **Components:**

#### Neomycin, sulfate (salt):

Species : Rat
Exposure time : 2 Years
Result : negative

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Neomycin Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 3.3 28.09.2024 9422656-00009 Date of first issue: 02.09.2021

#### Reproductive toxicity

Suspected of damaging the unborn child.

#### **Components:**

Neomycin, sulfate (salt):

Effects on fertility : Test Type: Three-generation reproduction toxicity study

Species: Rat

Application Route: Oral

General Toxicity - Parent: NOAEL: 25 mg/kg body weight Result: No effects on fertility and early embryonic develop-

ment were detected.

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral

Embryo-foetal toxicity: NOAEL: 275 mg/kg body weight Result: No adverse effects, No teratogenic effects

Test Type: Development

Species: Rat

Application Route: Subcutaneous

Developmental Toxicity: LOAEL: 6 mg/kg body weight

Result: positive

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

#### STOT - single exposure

Not classified based on available information.

#### STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

#### **Components:**

### Neomycin, sulfate (salt):

Target Organs : Kidney, inner ear

Assessment : May cause damage to organs through prolonged or repeated

exposure.

Remarks : Based on human experience.

## Repeated dose toxicity

#### **Components:**

#### Neomycin, sulfate (salt):

Species : Mouse
LOAEL : 30 mg/kg
Application Route : Subcutaneous

Exposure time : 14 d
Target Organs : Kidney

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Neomycin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 3.3
 28.09.2024
 9422656-00009
 Date of first issue: 02.09.2021

Species : Guinea pig
NOAEL : 50 mg/kg
LOAEL : 100 mg/kg
Application Route : Intramuscular
Exposure time : 30 - 60 Weeks

Target Organs : ear

Species : Guinea pig
NOAEL : 10 mg/kg
Application Route : Oral
Exposure time : 90 d

Remarks : No significant adverse effects were reported

Species : Guinea pig LOAEL : 100 mg/kg Application Route : Subcutaneous

Exposure time : 34 d

Species : Dog LOAEL : 24 mg/kg Application Route : Intramuscular

Exposure time : 30 d
Target Organs : Kidney

Species : Rat
LOAEL : 25 mg/kg
Application Route : oral (feed)
Exposure time : 84 Weeks
Target Organs : ear

Symptoms : hearing loss Remarks : mortality observed

Species : Dog LOAEL : 20 mg/kg Application Route : Subcutaneous

Exposure time : 90 d
Target Organs : Kidney

## **Aspiration toxicity**

Not classified based on available information.

#### 11.2 Information on other hazards

### **Endocrine disrupting properties**

#### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered 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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Neomycin Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 28.09.2024 9422656-00009 Date of first issue: 02.09.2021 3.3

#### **Experience with human exposure**

### **Components:**

Neomycin, sulfate (salt):

Skin contact Symptoms: Sensitisation

Remarks: May irritate skin.

Eve contact Remarks: May cause eye irritation.

Ingestion Symptoms: Nausea, Vomiting, Diarrhoea, tinnitus, hearing

loss, Loss of balance

### **SECTION 12: Ecological information**

## 12.1 Toxicity

#### **Components:**

Neomycin, sulfate (salt):

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 72 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

LC50 (Americamysis): 39 mg/l

Exposure time: 96 h

Method: US-EPA OPPTS 850.1035

Toxicity to algae/aquatic

plants

EC50 (Anabaena flos-aquae (cyanobacterium)): 0,00075 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 0,0003 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 (Pseudokirchneriella subcapitata (green algae)): 0,0099

ma/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)):

0,0022 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icity)

1.000

Toxicity to microorganisms EC50 (Natural microorganism): 107,6 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

EC10 (Natural microorganism): 2,8 mg/l

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Neomycin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 3.3
 28.09.2024
 9422656-00009
 Date of first issue: 02.09.2021

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

M-Factor (Chronic aquatic

toxicity)

: 10

#### 12.2 Persistence and degradability

### **Components:**

Neomycin, sulfate (salt):

Biodegradability : Result: rapidly degradable

Biodegradation: 50 % Exposure time: 1,2 d

Method: OECD Test Guideline 314

#### 12.3 Bioaccumulative potential

### **Components:**

Neomycin, sulfate (salt):

Partition coefficient: n-

octanol/water

: log Pow: < -2

## 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 Endocrine disrupting properties

#### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered 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.

#### 12.7 Other adverse effects

No data available

#### **SECTION 13: Disposal considerations**

## 13.1 Waste treatment methods

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Neomycin Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 3.3 28.09.2024 9422656-00009 Date of first issue: 02.09.2021

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.

#### **SECTION 14: Transport information**

#### 14.1 UN number or ID number

ADN : UN 3077
ADR : UN 3077
RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

#### 14.2 UN proper shipping name

**ADN** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Neomycin, sulfate (salt))

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Neomycin, sulfate (salt))

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Neomycin, sulfate (salt))

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Neomycin, sulfate (salt))

**IATA** : Environmentally hazardous substance, solid, n.o.s.

(Neomycin, sulfate (salt))

#### 14.3 Transport hazard class(es)

Class Subsidiary risks

ADN : 9
ADR : 9
RID : 9
IMDG : 9
IATA : 9

#### 14.4 Packing group

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Neomycin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 3.3
 28.09.2024
 9422656-00009
 Date of first issue: 02.09.2021

**ADN** 

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

**ADR** 

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

**RID** 

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

**IMDG** 

Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo : 956

aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen- : 956

ger aircraft)

Packing instruction (LQ) : Y956 Packing group : III

Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

**IMDG** 

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Neomycin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 3.3
 28.09.2024
 9422656-00009
 Date of first issue: 02.09.2021

#### 14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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

Remarks : Not applicable for product as supplied.

#### **SECTION 15: Regulatory information**

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

REACH - Restrictions on the manufacture, placing on

the market and use of certain dangerous substances,

mixtures and articles (Annex XVII)

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation

(Annex XIV)

Regulation (EC) on substances that deplete the ozone

aver

E1

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import

of dangerous chemicals

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of

major-accident hazards involving dangerous substances.

ENVIRONMENTAL

**HAZARDS** 

Quantity 1

: Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

Quantity 2

100 t 200 t

#### Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

### 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**

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Neomycin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 3.3
 28.09.2024
 9422656-00009
 Date of first issue: 02.09.2021

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** 

H317 : May cause an allergic skin reaction.
H361d : Suspected of damaging the unborn child.

H373 : May cause damage to organs through prolonged or repeated

exposure.

H400 : Very toxic to aquatic life.

H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Acute : Short-term (acute) aquatic hazard Aquatic Chronic : Long-term (chronic) aquatic hazard

Repr. : Reproductive toxicity Skin Sens. : Skin sensitisation

STOT RE : Specific target organ toxicity - repeated exposure

FOR-2011-12-06-1358 : Norway. Occupational Exposure limits

FOR-2011-12-06-1358 / : Long term exposure limit

TWA

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) Effect 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Neomycin Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 3.3 28.09.2024 9422656-00009 Date of first issue: 02.09.2021

- United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

#### **Further information**

Sheet

Sources of key data used to compile the Safety Data

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:

Skin Sens. 1	H317	Calculation method
Repr. 2	H361d	Calculation method
STOT RE 2	H373	Calculation method
Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 1	H410	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.

NO / EN