

## Neomycin Formulation

Version 2.1      Revision Date: 30.09.2023      SDS Number: 9404848-00007      Date of last issue: 04.04.2023  
Date of first issue: 02.09.2021

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**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Neomycin Formulation

**Manufacturer or supplier's details**

Company name of supplier : MSD  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 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

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**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Skin sensitization : Category 1  
Reproductive toxicity : Category 2  
Specific target organ toxicity : Category 2 (Kidney, inner ear)  
- repeated exposure

**GHS label elements**

Hazard pictograms : 

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 (Kidney, inner ear) through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe dust.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P302 + P352 IF ON SKIN: Wash with plenty of water.  
P308 + P313 IF exposed or concerned: Get medical advice/

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attention.  
 P333 + P313 If skin irritation or rash occurs: Get medical advice/  
 attention.  
 P362 + P364 Take off contaminated clothing and wash it before  
 reuse.

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents/ container to an approved waste dis-  
 posal plant.

**Other hazards**

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**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Neomycin, sulfate (salt)	1405-10-3	>= 50 -< 70

**SECTION 4. FIRST AID MEASURES**

General advice : In the case of accident or if you feel unwell, seek medical  
 advice immediately.  
 When symptoms persist or in all cases of doubt seek medical  
 advice.

If inhaled : If inhaled, remove to fresh air.  
 Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty  
 of water.  
 Remove contaminated clothing and shoes.  
 Get medical attention.  
 Wash clothing before reuse.  
 Thoroughly clean shoes before reuse.

In case of eye contact : If in eyes, rinse well with water.  
 Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.  
 Get medical attention.  
 Rinse mouth thoroughly with water.

Most important symptoms  
 and effects, both acute and  
 delayed : May cause an allergic skin reaction.  
 Suspected of damaging the unborn child.  
 May cause damage to organs through prolonged or repeated  
 exposure.  
 Contact with dust can cause mechanical irritation or drying of  
 the skin.

Protection of first-aiders : Dust contact with the eyes can lead to mechanical irritation.  
 First Aid responders should pay attention to self-protection,

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Notes to physician : and use the recommended personal protective equipment when the potential for exposure exists (see section 8).  
: Treat symptomatically and supportively.

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**SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

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 products : Carbon oxides

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances 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 fire-fighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

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**SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
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 : Sweep up or vacuum up spillage and collect in suitable container 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 determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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**SECTION 7. HANDLING AND STORAGE**

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : Use only with adequate 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 assessment  
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, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- Conditions for safe storage : Keep in properly labeled containers.  
Store locked up.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Ingredients with workplace control parameters**

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

- 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

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protect products, workers, and the environment.

**Personal protective equipment**

Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	:	Particulates type
Hand protection	:	
Material	:	Chemical-resistant gloves
Eye protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	:	Work uniform or laboratory coat.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	:	powder
Color	:	White to light yellow
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form combustible dust concentrations in air during processing, 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
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available

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Density : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle size : No data available

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : May form combustible dust concentrations in air during processing, handling or other means.  
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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**SECTION 11. TOXICOLOGICAL INFORMATION****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: > 5,000 mg/kg  
Method: Calculation method

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### 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

#### **Respiratory or skin sensitization**

##### **Skin sensitization**

May cause an allergic skin reaction.

##### **Respiratory sensitization**

Not classified based on available information.

### Components:

#### **Neomycin, sulfate (salt):**

Routes of exposure : Dermal  
Species : Humans  
Result : positive

#### **Germ cell mutagenicity**

Not classified based on available information.

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### 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

#### **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 development were detected.

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Embryo-fetal toxicity.: NOAEL: 275 mg/kg body weight  
Result: No adverse effects., No teratogenic effects.

Test Type: Development  
Species: Rat



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Application Route: Subcutaneous  
 Developmental Toxicity: LOAEL: 6 mg/kg body weight  
 Result: positive

Reproductive toxicity - Assessment : 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 (Kidney, inner ear) 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

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

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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.

**Experience with human exposure****Components:****Neomycin, sulfate (salt):**

Skin contact : Symptoms: Sensitization  
Remarks: May irritate skin.  
Eye contact : Remarks: May cause eye irritation.  
Ingestion : Symptoms: Nausea, Vomiting, Diarrhea, tinnitus, hearing loss,  
Loss of balance

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Neomycin, sulfate (salt):**

Toxicity to daphnia and other aquatic invertebrates : 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 mg/l  
Exposure time: 72 h

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Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)):  
0.0022 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

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

Exposure time: 3 h

Test Type: Respiration inhibition

Method: OECD Test Guideline 209

**Persistence and degradability****Components:****Neomycin, sulfate (salt):**

Biodegradability : Result: rapidly degradable  
Biodegradation: 50 %  
Exposure time: 1.2 d  
Method: OECD Test Guideline 314

**Bioaccumulative potential****Components:****Neomycin, sulfate (salt):**

Partition coefficient: n-octanol/water : log Pow: < -2

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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**SECTION 14. TRANSPORT INFORMATION****International Regulations**

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**UNRTDG**

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Neomycin, sulfate (salt))  
Class : 9  
Packing group : III  
Labels : 9  
Environmentally hazardous : yes

**IATA-DGR**

UN/ID No. : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(Neomycin, sulfate (salt))  
Class : 9  
Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 956  
Packing instruction (passenger aircraft) : 956  
Environmentally hazardous : yes

**IMDG-Code**

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Neomycin, sulfate (salt))  
Class : 9  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F  
Marine pollutant : yes

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**Domestic regulation****NOM-002-SCT**

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Neomycin, sulfate (salt))  
Class : 9  
Packing group : III  
Labels : 9

**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.

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**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

**The ingredients of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

**SECTION 16. OTHER INFORMATION**

Revision Date : 30.09.2023  
Date format : dd.mm.yyyy

**Full text of other abbreviations**

AIIIC - 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 Recom-

# SAFETY DATA SHEET



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recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8