

Neomycin Formulation

Version 2.1 Revision Date: 30.09.2023 SDS Number: 9404867-00007 Date of last issue: 04.04.2023
Date of first issue: 02.09.2021

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Neomycin Formulation

Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Skin sensitization : Category 1

Reproductive toxicity : Category 2

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

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard

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.

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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 protection/ face protection.

Response:
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.
 P391 Collect spillage.

Other hazards which do not result in classification

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.	Classification	Concentration (% w/w)
Neomycin, sulfate (salt)	1405-10-3	Acute toxicity (Oral), Category 5 Skin sensitization, Sub-category 1B Reproductive toxicity, Category 2 Specific target organ toxicity - repeated exposure (Kidney, inner ear), Category 2 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1	>= 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

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- 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, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.
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SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
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.

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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.

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:

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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 ³ (OEB 1)	Internal
Further information: DSEN, OTO				
		Wipe limit	0.1 mg/100 cm ²	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 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.

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

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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
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

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

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Hazardous decomposition products : No hazardous decomposition products are known.

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

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

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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.

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.

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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
 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

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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.

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

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

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

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aquatic invertebrates		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 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 toxicity)	:	1.000
M-Factor (Chronic aquatic toxicity)	:	10
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
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Bioaccumulative potential**Components:****Neomycin, sulfate (salt):**

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

Mobility in soil

No data available

Other adverse effects

No data available

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.

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

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

Not applicable for product as supplied.

Domestic regulation**ANTT**

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Neomycin, sulfate (salt))
Class	:	9
Packing group	:	III
Labels	:	9
Hazard Identification Number	:	90

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.

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

National List of Carcinogenic Agents for Humans - (LINACH)	:	Not applicable
Brazil. List of chemicals controlled by the Federal Police	:	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

Further information

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/
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Full text of other abbreviations

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be 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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