



MATERIAL SAFETY DATA SHEET

Revision date: 20-Dec-2010

Version: 2.1

Page 1 of 7

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Animal Health
Pfizer Inc
235 East 42nd Street
New York, NY 10017
Poison Control Center Phone: 1-866-531-8896
Technical Services Phone: 1-800-366-5288
Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Neomycin Sulfate Soluble Powder

Trade Name:	NEOMIX
Chemical Family:	Aminoglycoside
Intended Use:	Veterinary product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance: White to off-white powder
Signal Word: WARNING

Statement of Hazard: May cause allergic skin and respiratory reaction
May cause skin irritation
Suspected of damaging the unborn child.
May cause damage to kidneys and ototoxicity (harmful effects on the ear)

Additional Hazard Information:

Short Term: May cause minimal eye irritation (based on animal data). Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

Long Term: Animal studies indicate that this material may cause adverse effects on the kidneys, ototoxicity (harmful effects on the ear), and blood forming organs.

Known Clinical Effects: The most common adverse effects reported with clinical use were diarrhea, nausea, rash, and vomiting. This compound can cross the placenta in pregnant women.

EU Indication of danger: Toxic to Reproduction: Category 3
Harmful
Irritant

EU Hazard Symbols:



EU Risk Phrases:

R63 - Possible risk of harm to the unborn child.
R42/43 - May cause sensitization by inhalation and skin contact.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

MATERIAL SAFETY DATA SHEET

Material Name: Neomycin Sulfate Soluble Powder
Revision date: 20-Dec-2010

Page 2 of 7
Version: 2.1

2. HAZARDS IDENTIFICATION

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Neomycin Sulfate	1405-10-3	215-773-1	Xn;R42/43 Repr.Cat.3;R63	70-75
Sucrose	57-50-1	200-334-9	Not Listed	30-35

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire. May include oxides of carbon nitrogen and sulfur

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

MATERIAL SAFETY DATA SHEET

Material Name: Neomycin Sulfate Soluble Powder
Revision date: 20-Dec-2010

Page 3 of 7
Version: 2.1

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: Minimize dust generation and accumulation. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Neomycin Sulfate

Pfizer OEL TWA-8 Hr: 100 µg/m³, Sensitizer

Sucrose

ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA
Australia TWA	10 mg/m ³
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Estonia OEL - TWA	Listed
France OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
OSHA - Final PELs - TWAs:	15 mg/m ³ total 5 mg/m ³
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

Analytical Method:

Analytical method available. Contact Pfizer Inc for further information.

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes:

Wear safety glasses or goggles if eye contact is possible.

MATERIAL SAFETY DATA SHEET

Material Name: Neomycin Sulfate Soluble Powder
Revision date: 20-Dec-2010

Page 4 of 7
Version: 2.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Free-flowing, granular powder	Color:	White to off-white
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: Heat. Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

Acute Toxicity: (Species, Route, End Point, Dose)

Neomycin Sulfate

Rat	Oral	LD 50	2750 mg/kg
Mouse	Oral	LD 50	2880 mg/kg
Mouse	Intraperitoneal	LD 50	116 mg/kg
Rat	Subcutaneous	LD 50	633 mg/kg
Mouse	Subcutaneous	LD 50	275 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Neomycin Sulfate

Skin Irritation	Rabbit	Moderate
Eye Irritation	Rabbit	Minimal

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Neomycin Sulfate

6 Week(s)	Dog	Oral	100 mg/kg/day	NOAEL	No effects at maximum dose
3 Month(s)	Guinea Pig	Oral	10 mg/kg/day	NOAEL	No effects at maximum dose
3 Month(s)	Dog	Subcutaneous	20 mg/kg/day	LOAEL	Kidney
12 Month(s)	Cat	Oral	12 mg/kg/day	NOAEL	Blood forming organs
3 Month(s)	Guinea Pig	Subcutaneous	10 mg/kg/day	LOAEL	Kidney

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Neomycin Sulfate

Reproductive & Fertility	Mouse	Oral	4000 mg/L	NOAEL	No effects at maximum dose
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MATERIAL SAFETY DATA SHEET

Material Name: Neomycin Sulfate Soluble Powder
Revision date: 20-Dec-2010

Page 5 of 7
Version: 2.1

11. TOXICOLOGICAL INFORMATION

2 Generation Reproductive Toxicity	Rat	Oral	25 mg/kg/day	NOAEL	Fetotoxicity
Reproductive & Fertility	Rat	Oral	25 mg/kg/day	NOAEL	No effects at maximum dose
Prenatal & Postnatal Development	Rat	Subcutaneous	6 mg/kg/day	LOAEL	Developmental toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Neomycin Sulfate

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
Mammalian Cell Mutagenicity	Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vivo</i> Cytogenetics	Mouse	Negative
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Positive

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Neomycin Sulfate

2 Year(s)	Rat	Oral	25 mg/kg/day	NOAEL	Not carcinogenic
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Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Bioaccumulation and Toxicity: This substance is not expected to bioaccumulate in the environment.

Persistence and Degradability: Inherently biodegradable

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Neomycin Sulfate

<i>Daphnia magna</i> (Water Flea)	OECD	EC50	48 Hours	68 mg/L
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<i>Salmo gairdneri</i> (Trout)	OECD	NOEC	96 Hours	>1000 mg/L
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Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Neomycin Sulfate

Activated sludge	OECD	EC50	3 Hours	399 mg/L
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13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

MATERIAL SAFETY DATA SHEET

Material Name: Neomycin Sulfate Soluble Powder
Revision date: 20-Dec-2010

Page 6 of 7
Version: 2.1

14. TRANSPORT INFORMATION

15. REGULATORY INFORMATION

EU Symbol: Xn
EU Indication of danger: Toxic to Reproduction: Category 3
Harmful
Irritant

EU Risk Phrases:
R63 - Possible risk of harm to the unborn child.
R42/43 - May cause sensitization by inhalation and skin contact.

EU Safety Phrases:
S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING
May cause allergic skin and respiratory reaction
May cause skin irritation
Suspected of damaging the unborn child.
May cause damage to kidneys and ototoxicity (harmful effects on the ear)

Canada - WHMIS: Classifications

WHMIS hazard class:
D2b toxic materials



Neomycin Sulfate

California Proposition 65	developmental toxicity, initial date 10/1/92 (internal use)
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	215-773-1

Sucrose

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-334-9

MATERIAL SAFETY DATA SHEET

Material Name: Neomycin Sulfate Soluble Powder
Revision date: 20-Dec-2010

Page 7 of 7
Version: 2.1

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

R63 - Possible risk of harm to the unborn child.
R42/43 - May cause sensitization by inhalation and skin contact.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.

Prepared by: Product Stewardship Hazard Communications
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet