

# SAFETY DATA SHEET



Revision date: 31-Mar-2014

Version: 3.0

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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name: Neomycin Sulfate Soluble Powder**

**Trade Name:** NEOMIX  
**Chemical Family:** Aminoglycoside

**Relevant Identified Uses of the Substance or Mixture and Uses Advised Against Intended Use:** Veterinary product used as antibiotic agent

### Details of the Supplier of the Safety Data Sheet

Zoetis Inc.  
100 Campus Drive, P.O. Box 651  
Florham Park, New Jersey 07932 (USA)  
Rocky Mountain Poison Control Center Phone: 1-866-531-8896  
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.  
Mercuriusstraat 20  
1930 Zaventem  
Belgium

**Emergency telephone number:**  
CHEMTREC (24 hours): 1-800-424-9300  
Contact E-Mail: VMIPSrecords@zoetis.com

**Emergency telephone number:**  
International CHEMTREC (24 hours): +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

**Appearance:** White to off-white powder

### Classification of the Substance or Mixture

#### GHS - Classification

Acute Oral Toxicity: Category 5  
Respiratory Sensitization: Category 1  
Skin Sensitization: Category 1  
Reproductive Toxicity: Category 2  
Acute aquatic toxicity: Category 3  
Chronic aquatic toxicity: Category 3

#### US OSHA Specific - Classification

**Physical Hazard:** Combustible Dust

#### EU Classification:

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

EU Symbol: Xn

EU Risk Phrases:

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

### Label Elements

**Signal Word:** Danger

(AG) 325

Rx  
NEOMIX 325

#020253

3/31/14

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### 2. HAZARDS IDENTIFICATION

- Hazard Statements:**
- H303 - May be harmful if swallowed
  - H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
  - H317 - May cause an allergic skin reaction
  - H361 - Suspected of damaging fertility or the unborn child
  - H412 - Harmful to aquatic life with long lasting effects
  - May form combustible dust concentrations in air
- Precautionary Statements:**
- P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
  - P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
  - P284 - Wear respiratory protection
  - P272 - Contaminated work clothing should not be allowed out of the workplace
  - P280 - Wear protective gloves/protective clothing/eye protection/face protection
  - P201 - Obtain special instructions before use
  - P202 - Do not handle until all safety precautions have been read and understood
  - P273 - Avoid release to the environment
  - P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
  - P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician
  - P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
  - P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
  - P362 - Take off contaminated clothing and wash before reuse
  - P308 + P313 - IF exposed or concerned: Get medical attention/advice
  - P312 - Call a POISON CENTRE/doctor/physician if you feel unwell
  - P405 - Store locked up
  - P501 - Dispose of contents/container in accordance with all local and national regulations



#### Other Hazards

**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. May cause skin irritation. Dust may cause irritation

**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.

**Australian Hazard Classification (NOHSC):**

Hazardous Substance. Non-Dangerous Goods.

**Note:**

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

| Ingredient       | CAS Number | EU EINECS/ELINCS List | EU Classification           | GHS Classification   | %     |
|------------------|------------|-----------------------|-----------------------------|--|-------|
| Neomycin Sulfate | 1405-10-3  | 215-773-1             | Xn;R42/43<br>Repr.Cat.3;R63 | Resp. Sens. 1 (H334)<br>Skin Sens.1(H317)<br>Repro. 2 (H361)<br>Aq. Acute 3 (H402)<br>Aq. Chronic 3 (H412) | 70-75 |
| Sucrose          | 57-50-1    | 200-334-9             | Not Listed                  | 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

**Description of 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.

**Most Important Symptoms and Effects, Both Acute and Delayed**

- 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.
- Medical Conditions Aggravated by Exposure:** Breathing dust may worsen asthma symptoms.

**Indication of the Immediate Medical Attention and Special Treatment Needed**

- Notes to Physician:** None

### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture**

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions. Dust can form an explosive mixture in air.

**Advice for Fire-Fighters**

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

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### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Avoid dust formation.

#### Environmental Precautions

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

#### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Contain the source of the spill if it is safe to do so. Collect spilled material by a method that controls dust generation. Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal. Clean contaminated surface thoroughly.

**Additional Consideration for Large Spills:** Avoid generating airborne dust. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. 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

#### Precautions for Safe Handling

Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Minimize dust generation and accumulation. Use with adequate ventilation. Wash thoroughly after handling. Prevent environmental releases. 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. Use appropriate personal protective equipment.

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

**Specific end use(s):** No data available

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Neomycin Sulfate

Zoetis OEL TWA 8-hr 100 µg/m<sup>3</sup>, Sensitizer

#### Sucrose

|                                   |                        |
|-----------------------------------|------------------------|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m <sup>3</sup>   |
| Australia TWA                     | 10 mg/m <sup>3</sup>   |
| Belgium OEL - TWA                 | 10 mg/m <sup>3</sup>   |
| Bulgaria OEL - TWA                | 10.0 mg/m <sup>3</sup> |
| Estonia OEL - TWA                 | 10 mg/m <sup>3</sup>   |
| France OEL - TWA                  | 10 mg/m <sup>3</sup>   |
| Ireland OEL - TWAs                | 10 mg/m <sup>3</sup>   |
| Latvia OEL - TWA                  | 5 mg/m <sup>3</sup>    |
| Lithuania OEL - TWA               | 10 mg/m <sup>3</sup>   |

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

|                           |                      |
|---------------------------|----------------------|
| OSHA - Final PELs - TWAs: | 15 mg/m <sup>3</sup> |
| Portugal OEL - TWA        | 10 mg/m <sup>3</sup> |
| Slovakia OEL - TWA        | 6 mg/m <sup>3</sup>  |
| Spain OEL - TWA           | 10 mg/m <sup>3</sup> |

#### Exposure Controls

|                                       |  |
|---------------------------------------|--|
| <b>Engineering Controls:</b>          | Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section.  |
| <b>Personal Protective Equipment:</b> | Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).  |
| <b>Hands:</b>                         | Wear impervious gloves if skin contact is possible.  |
| <b>Eyes:</b>                          | Safety glasses or goggles  |
| <b>Skin:</b>                          | Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.   |
| <b>Respiratory protection:</b>        | 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

|                           |                               |                          |                    |
|---------------------------|-------------------------------|--------------------------|--------------------|
| <b>Physical State:</b>    | Free-flowing, granular powder | <b>Color:</b>            | White to off-white |
| <b>Odor:</b>              | No data available.            | <b>Odor Threshold:</b>   | No data available. |
| <b>Molecular Formula:</b> | Mixture                       | <b>Molecular Weight:</b> | Mixture            |

|   |                    |
|---|--------------------|
| <b>Solvent Solubility:</b>                                  | No data available  |
| <b>Water Solubility:</b>                                    | No data available  |
| <b>pH:</b>  | No data available. |
| <b>Melting/Freezing Point (°C):</b>                         | No data available. |
| <b>Boiling Point (°C):</b>                                  | No data available. |
| <b>Partition Coefficient: (Method, pH, Endpoint, Value)</b> | No data available  |
| <b>Neomycin Sulfate</b>                                     |                    |
| Predicted 7.4 Log D 1.20                                    |                    |
| <b>Decomposition Temperature (°C):</b>                      | No data available. |

|                                   |                   |
|-----------------------------------|-------------------|
| <b>Evaporation Rate (Gram/s):</b> | No data available |
| <b>Vapor Pressure (kPa):</b>      | No data available |
| <b>Vapor Density (g/ml):</b>      | No data available |
| <b>Relative Density:</b>          | No data available |
| <b>Viscosity:</b>                 | No data available |

#### Flammability:

|   |                   |
|---|-------------------|
| <b>Autoignition Temperature (Solid) (°C):</b>       | No data available |
| <b>Flammability (Solids):</b>                       | No data available |
| <b>Flash Point (Liquid) (°C):</b>                   | No data available |
| <b>Upper Explosive Limits (Liquid) (% by Vol.):</b> | No data available |
| <b>Lower Explosive Limits (Liquid) (% by Vol.):</b> | No data available |

**Polymerization:** Will not occur

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available

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### 10. STABILITY AND REACTIVITY

**Chemical Stability:** Stable under normal conditions of use.  
**Possibility of Hazardous Reactions**  
**Oxidizing Properties:** No data available  
**Conditions to Avoid:** Keep away from heat, spark, flames and all other sources of ignition. Avoid dispersion as a dust cloud. Dust may form explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions.  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers  
**Hazardous Decomposition Products:** No data available

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

**General Information:** Toxicological properties of the formulation have not been fully investigated. The information included in this section describes the potential hazards of the individual ingredients.

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

##### Neomycin Sulfate

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

##### Sucrose

Rat Oral LD 50 29,700 mg/kg

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

##### Neomycin Sulfate

Skin Irritation Rabbit Moderate  
Eye Irritation Rabbit Minimal  
Skin Sensitization Positive

#### 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  
2 Generation Reproductive Toxicity Rat Oral 25 mg/kg/day NOAEL Fetotoxicity

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### 11. TOXICOLOGICAL INFORMATION

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) *Salmonella*, *E. coli* Negative  
Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Negative  
*In Vivo* Cytogenetics Mouse Negative  
*In Vitro* 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

#### 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. See aquatic toxicity data for individual components below:

#### Toxicity:

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

##### Neomycin Sulfate

*Daphnia magna* (Water Flea) OECD EC50 48 Hours 68 mg/L  
*Salmo gairdneri* (Trout) OECD NOEC 96 Hours >1000 mg/L

#### 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 399 mg/L

#### Persistence and Degradability:

No data available

#### Bio-accumulative Potential:

##### Neomycin Sulfate

Predicted 7.4 Log D 1.20

#### Mobility in Soil:

No data available

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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

The following refers to all modes of transportation unless specified below.

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

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**

Class D, Division 2, Subdivision A

Class D, Division 2, Subdivision B

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.



**Neomycin Sulfate**

|   |  |
|---|--|
| CERCLA/SARA 313 Emission reporting          | Not Listed   |
| California Proposition 65                   | developmental toxicity initial date 10/1/92 internal use |
| Inventory - United States TSCA - Sect. 8(b) | Present  |
| Australia (AICS):                           | Present  |
| EU EINECS/ELINCS List                       | 215-773-1  |

**Sucrose**

|   |            |
|---|------------|
| CERCLA/SARA 313 Emission reporting                              | Not Listed |
| California Proposition 65                                       | Not Listed |
| Inventory - United States TSCA - Sect. 8(b)                     | Present    |
| Australia (AICS):   | Present    |
| REACH - Annex IV - Exemptions from the obligations of Register: | Present    |
| EU EINECS/ELINCS List   | 200-334-9  |



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### 15. REGULATORY INFORMATION

### 16. OTHER INFORMATION

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

H303 - May be harmful if swallowed  
H317 - May cause an allergic skin reaction  
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled  
H361 - Suspected of damaging fertility or the unborn child  
H402 - Harmful to aquatic life  
H412 - Harmful to aquatic life with long lasting effects

Xn - Harmful  
Xi - Irritant  
Toxic to Reproduction: Category 3

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

**Data Sources:** The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**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 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

**Prepared by:** Toxicology and Hazard Communication  
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this 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**