



SAFETY DATA SHEET

Revision date: February 2016

Version: 1

Page 1 of 10

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

Product Identifier

Material Name: NEO-SOL

Trade Name: NEO-SOL 50
Synonyms: Neomycin Sulfate Soluble Powder
Chemical Family: Aminoglycoside

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary product used as antibiotic agent
Restrictions on Use: Not for human use

Manufacturer/ Supplier:

Huvepharma Inc.
1301 Iowa Ave.
Longmont, CO 80501

Huvepharma Inc.
525 Westpark Drive, Suite 230
Peachtree City, GA 30269

Emergency telephone number: 1-877-994-4883

Contact E-Mail: customerservice@huvepharma.us

2. HAZARDS IDENTIFICATION

Appearance: White to tan powder

Classification of the Substance or Mixture

GHS - Classification

Skin Corrosion/Irritation: Category 2
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

EU Symbol: Xn

EU Risk Phrases:

R63 - Possible risk of harm to the unborn child.
R38 - Irritating to skin.
R42/43 - May cause sensitization by inhalation and skin contact.
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

SAFETY DATA SHEET

Material Name: NEO-SOL
Revision date: February 2016

Page 2 of 10
Version: 1

2. HAZARDS IDENTIFICATION

Label Elements

Signal Word: Danger
Hazard Statements: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H317 - May cause an allergic skin reaction
H315 - Causes skin irritation
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: P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
P240 - Ground/Bond container and receiving equipment
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P285 - In case of inadequate ventilation wear respiratory protection
P264 - Wash hands thoroughly after handling
P272 - Contaminated work clothing should not be allowed out of the workplace
P273 - Avoid release to the environment
P308 + P313 - IF exposed or concerned: Get medical attention/advice
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
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations



Other Hazards

Short Term: Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted. May produce slight eye irritation. Signs and symptoms might include redness, swelling, blurred vision or pain. Dust may cause irritation. May be harmful if swallowed.

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

SAFETY DATA SHEET

Material Name: NEO-SOL
Revision date: February 2016

Page 3 of 10
Version: 1

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

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Neomycin Sulfate	1405-10-3	215-773-1	Xn;R42/43 Repr.Cat.3;R63	Resp. Sens. 1 (H334) Skin Sens.1(H317) Repro. 2 (H361d) Aq. Acute 3 (H402) Aq. Chronic 3 (H412)	80
Sucrose	57-50-1	200-334-9	Not Listed	Not Listed	20

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:** Individuals with a history of hypersensitivity to this material or other materials in its chemical class, individuals with other allergic conditions or diseases (asthma, eczema, etc.). 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 CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

SAFETY DATA SHEET

Material Name: NEO-SOL
Revision date: February 2016

Page 4 of 10
Version: 1

Hazardous Combustion Products:

Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards:

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

Advice for Fire-Fighters

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

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. Collect spilled material by a method that controls dust generation. Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area 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. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal. 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. When handling, use appropriate personal protective equipment (see Section 8). 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions:

Store at room temperature in properly labeled containers. Keep away from heat, sparks, flame, and other sources of ignition. Keep away from direct sunlight.

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

Huvepharma OEL TWA 8-hr

100 µg/m³, Sensitizer

Sucrose

SAFETY DATA SHEET

Material Name: NEO-SOL
Revision date: February 2016

Page 5 of 10
Version: 1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Estonia OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	10 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	6 mg/m ³
Spain OEL - TWA	10 mg/m ³

Exposure Controls

Engineering Controls:	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.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Wear impervious gloves if skin contact is possible.
Eyes:	Safety glasses or goggles
Skin:	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
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. Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Free-flowing, granular powder	Color:	White to tan
Odor:	Mild, earthy odor	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water solubility:	162 g/100 ml		
Water Solubility:	No data available		
pH:	No data available.		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available.		
Partition Coefficient: (Method, pH, Endpoint, Value)			
No data available			
Neomycin Sulfate			
Predicted 7.4 Log D 1.20			
Decomposition Temperature (°C):	No data available.		
Evaporation Rate (Gram/s):	No data available		
Vapor Pressure (kPa):	No data available		
Vapor Density (g/ml):	No data available		
Relative Density:	No data available		
Viscosity:	No data available		

SAFETY DATA SHEET

Material Name: NEO-SOL
Revision date: February 2016

Page 6 of 10
Version: 1

Flammability:

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

Polymerization:

Will not occur

10. STABILITY AND REACTIVITY

Reactivity:

No data available

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:

Thermal decomposition products may include carbon monoxide, carbon dioxide and oxides of nitrogen.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:

Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation.
Routes of exposure: eye contact , skin contact , inhalation

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
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Inhalation Acute Toxicity

Inhalation of dust may cause irritation of the respiratory tract and mucous membranes and allergic reactions in susceptible individuals.

Ingestion Acute Toxicity

May be harmful if swallowed

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

Neomycin Sulfate

Skin Irritation	Rabbit	Moderate
Eye Irritation	Rabbit	Minimal
Skin Sensitization		Positive

Irritation / Sensitization Comments:

May cause eye irritation.

Skin Irritation / Sensitization

May cause skin irritation. May cause allergic reactions in susceptible individuals.

SAFETY DATA SHEET

Material Name: NEO-SOL
Revision date: February 2016

Page 7 of 10
Version: 1

11. TOXICOLOGICAL INFORMATION

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
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,

Reproductive & Developmental Toxicity Comments: may have the potential to produce effects on the developing fetus.

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.

Product Level Toxicity Data

Acute Toxicity Estimate (ATE), oral	3448 mg/kg
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SAFETY DATA SHEET

Material Name: NEO-SOL
Revision date: February 2016

Page 8 of 10
Version: 1

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been investigated. The following information is available for the individual ingredients. may be harmful to aquatic organisms. Releases to the environment should be avoided.

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

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Should not be released into the environment. 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.

SAFETY DATA SHEET

Material Name: NEO-SOL
Revision date: February 2016

Page 9 of 10
Version: 1

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 SDS 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

16. OTHER INFORMATION

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

Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction

Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Reproductive toxicity-Cat.2; H361 - Suspected of damaging fertility or the unborn child

Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life

Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects

Xn - Harmful

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 SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

SAFETY DATA SHEET

Material Name: NEO-SOL
Revision date: February 2016

Page 10 of 10
Version: 1

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
Huvepharma Global Risk Management

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End of Safety Data Sheet