SAFETY DATA SHEET

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

Product Identifier

Material Name: Neomycin Sulfate with Tetracaine Hydrochloride Topical Powder

Trade Name: NEO-PREDEF(R) with TETRACAINE POWDER
Chemical Family: Not determined

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

Intended Use: Veterinary product used as antibiotic agent , anti-inflammatory , anesthetic agent
Restrictions on Use: Not for human use

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:
1-866-531-8896 (24 hrs.)
Telephone: 1-800-366-5288
Contact E-Mail: VMIPSrecords@zoetis.com

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

2. HAZARDS IDENTIFICATION

Appearance: White powder

Classification of the Substance or Mixture

GHS - Classification

Respiratory Sensitization: Category 1
Skin Sensitization: Category 1
Reproductive Toxicity: Category 2

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

EU Classification:

EU Indication of danger: Not classified

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
H361d - Suspected of damaging the unborn child
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
P272 - Contaminated work clothing should not be allowed out of the workplace
P308 + P313 - IF exposed or concerned: Get medical attention/advice
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
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
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.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus.

Known Clinical Effects: The most common adverse effects reported with clinical use were diarrhea, nausea, rash, and vomiting. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Clinical use of this drug has caused kidney dysfunction effects on hearing decrease in blood pressure (hypotension) nervousness blurred vision anxiety drowsiness convulsion respiratory arrest Drugs of this class may cause Cushing's syndrome, manifested by moon face, obesity, headache, acne, thirst, increased urination, impotence, menstrual irregularities, facial hair growth, and mental changes.

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

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Tetracaine Hydrochloride	136-47-0	205-248-5	T; R25	Acute Tox. Cat 3 (H301)	0.5

3. COMPOSITION/INFORMATION ON INGREDIENTS

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 (H361) Aq. Acute 3 (H402) Aq. Chronic 3 (H412)	0.5
Isoflupredone Acetate	338-98-7	206-423-9	Repr.Cat.3;R63	Repr. 2 (H361d)	0.1
Myristyl-gamma-picolinium chloride	2748-88-1	220-387-1	Xn;R22	Acute Tox.3 (H301)	0.02

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Lactose hydrous	64044-51-5	Not Listed	Not Listed	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: If irritation occurs or persists, get medical attention. Remove clothing and wash affected skin with soap and water.

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: None known

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

Hazardous Combustion Products: May emit toxic fumes of oxides of carbon and nitrogen.

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

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

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.

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: Contain the source of the spill if it is safe to do so. Avoid generating airborne dust. Collect spilled material by a method that controls dust generation. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. 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: 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. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging. Keep away from heat, sparks, flame, and other sources of ignition.

Specific end use(s): Veterinary antibiotic agent , anti-inflammatory , anesthetic agent

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^3, Sensitizer

Isoflupredone Acetate

Zoetis OEL TWA 8-hr 1µg/m^3, Contact Hazards Unknown

Exposure Controls

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

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

Hands: Impervious, disposable gloves (double suggested) 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.

Skin: Impervious disposable 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: Powder
Color: White
Odor: No data available.
Odor Threshold: No data available.
Molecular Formula: Mixture
Molecular Weight: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
Solubility: Soluble: Water
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
Isoflupredone Acetate
Predicted 7.4 Log D 2.46
Myristyl-gamma-picolinium chloride
Predicted 7.4 Log D 1.30
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

Flammablity:
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

10. STABILITY AND REACTIVITY

Reactivity: No data available

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: None

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 other toxic vapors.

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: inhalation , eye contact , skin contact
Symptoms of exposure may include (but may not be limited to) the following: skin irritation (redness, itching, swelling), allergic skin reaction (redness/rash, itching, swelling), allergic respiratory reaction (difficulty breathing, wheezing); adverse effects on fertility and/or the unborn child after repeated overexposure.

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

Tetracaine Hydrochloride
Mouse Oral LD 50 160 mg/kg
Rat Sub-tenon injection (eye) LD 50 23.5mg/kg
Rat Subcutaneous LD 50 24mg/kg

Isoflupredone Acetate
Mouse IP LD50 > 1000 mg/kg

Myristyl-gamma-picolinium chloride
Rat Oral LD 50 250 mg/kg
Rat Para-periosteal LD50 30mg/kg
Rat Intraperitoneal LD50 7500ug/kg
Rat Subcutaneous LD50 200mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

Neomycin Sulfate
Skin Irritation Rabbit Moderate
Eye Irritation Rabbit Minimal

11. TOXICOLOGICAL INFORMATION

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

Isoflupredone Acetate
21 Day(s) Rat Oral10 mg/kg/day LOAEL Liver, Male reproductive system, Thymus
90 Day(s) Rat Oral 0.2 mg/kg/day NOAEL None identified

Myristyl-gamma-picolinium chloride
60 Day(s) Rat Oral 2400 mg/kg Death

Reproduction & Development Toxicity: (Duration, 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

Isoflupredone Acetate
Embryo / Fetal Development Rat Oral0.1 mg/kg/day NOAEL Maternal toxicity, Fetotoxicity, Not teratogenic
2 Generation Reproductive Toxicity Rat Oral 1 mg/kg/day NOAEL Fetotoxicity
Reproductive & Fertility Cow Intramuscular 20 mg/kg/day LOEL Fetotoxicity

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.

Product Level Toxicity Data
Acute Toxicity Estimate (ATE), oral >5000 mg/kg

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been investigated. The following information is available for the individual ingredients. 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
Isoflupredone Acetate
Predicted 7.4 Log D 2.46
Myristyl-gamma-picolinium chloride
Predicted 7.4 Log D 1.30

Mobility in Soil: No data available

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
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.

Lactose hydrous

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	Not Listed

Tetracaine Hydrochloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	205-248-5

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

Isoflupredone Acetate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	206-423-9

Myristyl-gamma-picolinium chloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present

15. REGULATORY INFORMATION

Australia (AICS):	Present
EU EINECS/ELINCS List	220-387-1

16. OTHER INFORMATION

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

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Acute toxicity, oral-Cat.5; H303 - May be harmful if swallowed
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; H361d - Suspected of damaging 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

Toxic to Reproduction: Category 3
Xn - Harmful

R22 - Harmful if swallowed.
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.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 3 - Composition / Information on Ingredients.

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