SAFETY DATA SHEET

Prednisolone / Neomycin / Tetracycline Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/26/2022
7.2	04/09/2022	407520-00017	Date of first issue: 01/07/2016

SECTION 1. IDENTIFICATION

Product name : Prednisolone / Neomycin / Tetracycline Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.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 the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

Skin sensitization : Category 1

Reproductive toxicity : Category 1A

Effects on or via lactation

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

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Gastrointestinal tract, Nervous system, Skin, Teeth)

GHS label elements

Hazard pictograms :

Signal Word : Danger

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
H317 May cause an allergic skin reaction.
H360D May damage the unborn child.
H362 May cause harm to breast-fed children.
H373 May cause damage to organs (Kidney, inner ear) through prolonged or repeated exposure.

H373 May cause damage to organs (Gastrointestinal tract, Nervous system, Skin, Teeth) through prolonged or repeated exposure if swallowed.

Precautionary Statements :

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P263 Avoid contact during pregnancy and while nursing.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P308 + P313 IF exposed or concerned: Get medical attention.
P333 + P313 If skin irritation or rash occurs: Get medical attention.
P363 Wash contaminated clothing before reuse.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards

Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Paraffin waxes and Hydrocarbon waxes	8002-74-2	87.7
Neomycin, sulfate (salt)	1405-10-3	4.6
Magnesium stearate	557-04-0	4.6
Tetracycline hydrochloride	64-75-5	2.43
prednisolone	50-24-8	0.13

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 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. May damage the unborn child. May cause harm to breast-fed children. May cause damage to organs through prolonged or repeated exposure. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.
Protection of first-aiders	:	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.

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 Nitrogen oxides (NOx) Chlorine compounds Metal oxides Sulfur 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.

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. 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	:	If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	:	Avoid contact during pregnancy and while nursing. Do not get on skin or clothing. Do not breathe dust. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. 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. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the

environment.

Conditions for safe storage : Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Paraffin waxes and Hydrocarbon waxes	8002-74-2	TWA (Fumes)	2 mg/m³	ACGIH
		TWA (Fumes)	2 mg/m³	NIOSH REL
Neomycin, sulfate (salt)	1405-10-3	TWA	1 mg/m3 (OEB 1)	Internal
	Further information: DSEN, OTO			
		Wipe limit	0.1 mg/100 cm²	Internal
Magnesium stearate	557-04-0	TWA (Inhalable particulate matter)	10 mg/m³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m³	ACGIH
Tetracycline hydrochloride	64-75-5	TWA	0.9 mg/m3 (OEB 2)	Internal
prednisolone	50-24-8	TWA	10 µg/m3 (OEB 3)	Internal
		Wipe limit	100 µg/100 cm²	Internal

Engineering measures : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn.

Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	No data available
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
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture 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 explosive dust-air mixture 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
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:

Paraffin waxes and Hydrocarbon waxes:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg Method: OECD Test Guideline 420
Acute dermal toxicity	:	LD50 (Rabbit): > 3,600 mg/kg Method: OECD Test Guideline 402 Assessment: The substance or mixture has no acute dermal toxicity

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

Magnesium stearate:

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 423
Assessment: The substance or mixture has no acute oral toxicity
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Remarks: Based on data from similar materials

Tetracycline hydrochloride:

Acute oral toxicity : LD50 (Rat): 6,443 mg/kg

LD50 (Mouse): 2,759 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 128 mg/kg
Application Route: Intravenous

LD50 (Mouse): 157 mg/kg
Application Route: Intravenous

prednisolone:

Acute oral toxicity : LD50 (Mouse): 1,680 mg/kg

LD50 (Rat): > 3,857 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : LD50 (Rat): 147 mg/kg
Application Route: Subcutaneous

LD50 (Mouse): 767 mg/kg
Application Route: Intraperitoneal

Skin corrosion/irritation

Not classified based on available information.

Components:

Paraffin waxes and Hydrocarbon waxes:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Neomycin, sulfate (salt):

Species : Rabbit
Result : Mild skin irritation

Magnesium stearate:

Species : Rabbit

Result : No skin irritation
Remarks : Based on data from similar materials

Tetracycline hydrochloride:
Remarks : No data available

prednisolone:
Remarks : No data available

Serious eye damage/eye irritation
Not classified based on available information.

Components:

Paraffin waxes and Hydrocarbon waxes:
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

Neomycin, sulfate (salt):
Species : Rabbit
Result : No eye irritation

Magnesium stearate:
Species : Rabbit
Result : No eye irritation
Remarks : Based on data from similar materials

Tetracycline hydrochloride:
Remarks : No data available

prednisolone:
Remarks : No data available

Respiratory or skin sensitization

Skin sensitization
May cause an allergic skin reaction.

Respiratory sensitization
Not classified based on available information.

Components:

Paraffin waxes and Hydrocarbon waxes:
Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406

Result : negative

Neomycin, sulfate (salt):

Routes of exposure : Dermal
Species : Humans
Result : positive

Magnesium stearate:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative
Remarks : Based on data from similar materials

Tetracycline hydrochloride:

Remarks : No data available

prednisolone:

Remarks : No data available

Germ cell mutagenicity

Not classified based on available information.

Components:

Paraffin waxes and Hydrocarbon waxes:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative
Remarks: Based on data from similar materials

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

Magnesium stearate:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

Tetracycline hydrochloride:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Cytogenetic assay
Test system: Chinese hamster ovary cells
Result: negative

Test Type: sister chromatid exchange assay
Result: negative

Test Type: Mouse Lymphoma
Result: negative

prednisolone:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Mouse Lymphoma
Result: negative

Test Type: sister chromatid exchange assay
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Rat
Application Route: Oral
Result: negative

Test Type: sister chromatid exchange assay
Species: Humans
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Paraffin waxes and Hydrocarbon waxes:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	2 Years
Result	:	negative

Neomycin, sulfate (salt):

Species	:	Rat
Exposure time	:	2 Years
Result	:	negative

Tetracycline hydrochloride:

Species	:	Rat
Application Route	:	Oral
Exposure time	:	103 W
Result	:	negative
Species	:	Mouse
Application Route	:	Oral
Exposure time	:	103 W
Result	:	negative

prednisolone:

Species	:	Rat
Application Route	:	Oral
Exposure time	:	18 Months
Result	:	negative

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

May damage the unborn child.
May cause harm to breast-fed children.

Components:

Paraffin waxes and Hydrocarbon waxes:

Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Skin contact
Result: negative
Remarks: Based on data from similar materials

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.

Magnesium stearate:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

Remarks: Based on data from similar materials

Tetracycline hydrochloride:

Effects on fertility : Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: NOAEL: 400 mg/kg body weight
Result: No effects on fertility.

Effects on fetal development : Test Type: Development
Result: Embryo-fetal toxicity., Specific developmental abnormalities., Skeletal malformations.

Reproductive toxicity - Assessment : Studies indicating a hazard to babies during the lactation period, May damage the unborn child.

prednisolone:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Subcutaneous
Fertility: NOAEL: 1 mg/kg body weight
Result: No effects on fertility.

Effects on fetal development : Test Type: Embryo-fetal development
Species: Mouse
Application Route: Oral
Developmental Toxicity: LOAEL: 0.5 mg/kg body weight
Result: Malformations were observed., Cleft palate

Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 30 mg/kg body weight
Result: decreased blood formation

Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: NOAEL: 25 mg/kg body weight
Result: No effects on fetal development.

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.
May cause damage to organs (Gastrointestinal tract, Nervous system, Skin, Teeth) through prolonged or repeated exposure if swallowed.

Components:

Paraffin waxes and Hydrocarbon waxes:

Routes of exposure	:	Ingestion
Assessment	:	No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Neomycin, sulfate (salt):

Target Organs	:	Kidney, inner ear
Assessment	:	May cause damage to organs through prolonged or repeated exposure.
Remarks	:	Based on human experience.

Tetracycline hydrochloride:

Routes of exposure	:	Oral
Target Organs	:	Gastrointestinal tract, Nervous system, Skin, Teeth
Assessment	:	May cause damage to organs through prolonged or repeated exposure.

prednisolone:

Target Organs	:	Bone marrow, Adrenal gland, Liver
Assessment	:	Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Paraffin waxes and Hydrocarbon waxes:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	90 Days
Method	:	OECD Test Guideline 408

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
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

Magnesium stearate:

Species	:	Rat
NOAEL	:	> 100 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days
Remarks	:	Based on data from similar materials

Tetracycline hydrochloride:

Species	:	Rat
NOAEL	:	625 mg/kg
LOAEL	:	1,250 mg/kg
Application Route	:	oral (feed)
Exposure time	:	13 W
Target Organs	:	Liver
Symptoms	:	Reduced body weight

Species	:	Mouse
NOAEL	:	3,750 mg/kg
LOAEL	:	7,500 mg/kg
Application Route	:	oral (feed)
Exposure time	:	13 W
Symptoms	:	Reduced body weight

prednisolone:

Species	:	Rat
LOAEL	:	0.6 mg/kg
Application Route	:	Oral
Exposure time	:	63 Days
Target Organs	:	Bone marrow

Species	:	Dog
LOAEL	:	2.5 mg/kg
Application Route	:	Oral
Exposure time	:	6 Weeks
Target Organs	:	Adrenal gland

Species	:	Rabbit
LOAEL	:	1 mg/kg
Application Route	:	Oral
Exposure time	:	24 Weeks
Target Organs	:	Liver

Aspiration toxicity

Not classified based on available information.

Components:

Tetracycline hydrochloride:

Not applicable

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

Tetracycline hydrochloride:

Ingestion	:	Target Organs: Teeth Symptoms: Gastrointestinal disturbance, Nausea, Vomiting, Diarrhea, Liver effects, skin rash, central nervous system effects Remarks: May cause sensitization of susceptible persons. May cause photosensitization. Based on Human Evidence

prednisolone:

Ingestion	:	Symptoms: sodium retention, Headache, Vertigo, fluid retention, subcutaneous bleeding, striae, skin atrophy, menstrual irregularities

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Paraffin waxes and Hydrocarbon waxes:

Toxicity to fish	:	LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 1,000 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	:	NOEC (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 10 mg/l Exposure time: 21 d Remarks: Based on data from similar materials

Neomycin, sulfate (salt):

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

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

Magnesium stearate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l
Exposure time: 48 h
Method: DIN 38412
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 1 mg/l
Exposure time: 47 h
Test substance: Water Accommodated Fraction
Method: Directive 67/548/EEC, Annex V, C.2.
Remarks: Based on data from similar materials
No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants : EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
No toxicity at the limit of solubility.

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (Pseudomonas putida): > 100 mg/l
Exposure time: 16 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Tetracycline hydrochloride:

Toxicity to algae/aquatic plants : EC50 (Anabaena flos-aquae (cyanobacterium)): 6.2 mg/l
Exposure time: 72 h

NOEC (Anabaena flos-aquae (cyanobacterium)): 2.5 mg/l
Exposure time: 72 h

EC50 (Pseudokirchneriella subcapitata (green algae)): 3.31

mg/l
Exposure time: 72 h

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.032 mg/l
Exposure time: 72 h

EC50 (Microcystis aeruginosa (blue-green algae)): 0.09 mg/l
Exposure time: 7 d

Toxicity to microorganisms : EC50: 0.08 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

prednisolone:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 85 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): 160 mg/l
Exposure time: 72 h

EC50 (Pseudokirchneriella subcapitata (green algae)): > 160 mg/l
Exposure time: 72 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Ceriodaphnia dubia (water flea)): 0.23 mg/l
Exposure time: 7 d

Persistence and degradability

Components:

Paraffin waxes and Hydrocarbon waxes:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
Remarks: Based on data from similar materials

Neomycin, sulfate (salt):

Biodegradability : Result: rapidly degradable
Biodegradation: 50 %
Exposure time: 1.2 d
Method: OECD Test Guideline 314

Magnesium stearate:

Biodegradability : Result: Not biodegradable
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

Paraffin waxes and Hydrocarbon waxes:

Partition coefficient: n-octanol/water : log Pow: 5.3 - 6.7

Neomycin, sulfate (salt):

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

Magnesium stearate:

Partition coefficient: n-octanol/water : log Pow: > 4

Tetracycline hydrochloride:

Partition coefficient: n-octanol/water : log Pow: -1.37
pH: 7

prednisolone:

Partition coefficient: n-octanol/water : log Pow: 1.46

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : 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), tetracycline hydrochloride)

Class : 9

Packing group : III

Labels : 9

IATA-DGR

UN/ID No. : UN 3077

Proper shipping name : Environmentally hazardous substance, solid, n.o.s.

(Neomycin, sulfate (salt), Tetracycline hydrochloride)

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), Tetracycline hydrochloride)
Class	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

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

Not applicable for product as supplied.

Domestic regulation

49 CFR

UN/ID/NA number	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Neomycin, sulfate (salt), Tetracycline hydrochloride)
Class	:	9
Packing group	:	III
Labels	:	CLASS 9
ERG Code	:	171
Marine pollutant	:	yes(Neomycin, sulfate (salt), Tetracycline hydrochloride)
Remarks	:	Above applies only to containers over 119 gallons or 450 liters., Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

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

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Combustible dust
Respiratory or skin sensitization
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

SARA 313 : The following components are subject to reporting levels established by SARA Title III, Section 313:

Tetracycline hydrochloride	64-75-5	2.43 %

US State Regulations

Pennsylvania Right To Know

Paraffin waxes and Hydrocarbon waxes	8002-74-2
Magnesium stearate	557-04-0
Neomycin, sulfate (salt)	1405-10-3

California Prop. 65

WARNING: This product can expose you to chemicals including Neomycin, sulfate (salt), which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances

Paraffin waxes and Hydrocarbon waxes	8002-74-2

California Permissible Exposure Limits for Chemical Contaminants

Paraffin waxes and Hydrocarbon waxes	8002-74-2
Magnesium stearate	557-04-0

The ingredients of this product are reported in the following inventories:

AICS : not determined

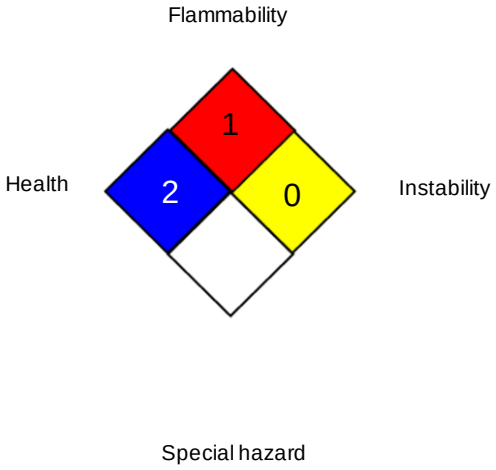
DSL : not determined

IECSC : not determined

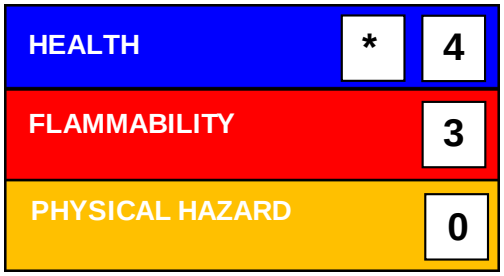
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concern-

ing the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

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/
Revision Date	:	04/09/2022

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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