

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

COMMON NAME: TRITOP® Topical Ointment

SYNONYMS: 425000 - EDP Number

MOLECULAR FORMULA: Mixture

USE: Veterinary product for the treatment or adjunctive therapy of certain ear and skin conditions in dogs, cats and horses caused by or associated with neomycin susceptible organisms and/or allergy. In addition, it is indicated as superficial dressing applied to minor cuts, wounds, lacerations, abrasions, and for post-surgical application where reduction of pain and inflammatory response is deemed desirable. Not for human use.

MANUFACTURER/SUPPLIER:

PHARMACIA & UPJOHN CO., A SUBSIDIARY OF PHARMACIA CORP.

7171 PORTAGE RD

KALAMAZOO, MI 49001-0199

TELEPHONE NUMBERS:

(616) 833-5122 - (24 Hours)

(616) 833-7555 - (8:00 AM - 4:30 PM, EST)

2. COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT 1

COMMON NAME: Non-hazardous Ingredient(s)

% BY WEIGHT: > 98 % (includes Mineral Oil USP, Lanolin USP, and White Petrolatum USP)

EXPOSURE LIMIT(S): Not established.

INGREDIENT 2

COMMON NAME: Tetracaine hydrochloride

CHEMICAL NAME: 4-Butylaminobenzoic acid 2-(dimethylamino)ethyl ester monohydrochloride

% BY WEIGHT: 0.5 %

CAS NUMBER: 136-47-0

EXPOSURE LIMIT(S): Not established.

INGREDIENT 3

COMMON NAME: Neomycin Sulfate

% BY WEIGHT: 0.5 % (5 mg; equivalent to 3.5 mg neomycin)

CAS NUMBER: 1405-10-3

EXPOSURE LIMIT(S): PHARMACIA & UPJOHN

EXPOSURE LIMIT-TWA: 2 mg/m³

INGREDIENT 4

COMMON NAME: Isoflupredone acetate

% BY WEIGHT: 0.1 %

CAS NUMBER: 338-98-7

EXPOSURE LIMIT(S): Not established.

EXPOSURE LIMIT(S) FOR THE MATERIAL: Not established.

3. HAZARDS IDENTIFICATION

PRIMARY ROUTE(S) OF EXPOSURE: Skin contact, eye contact, ingestion and inhalation.

EFFECTS OF OVEREXPOSURE: Inhalation or skin exposure to neomycin sulfate may cause very mild to severe allergic reaction in susceptible individuals. Allergic response may include skin rash, fever, bronchospasm, angioderma (swelling of lips, tongue, and face accompanied by asthmatic breathing and hives) and anaphylaxis. Overexposure to isoflupredone acetate may cause suppression of adrenal gland secretion; Cushing's Syndrome; water retention; electrolyte imbalance; hyperglycemia. Contact of mucous membrane to tetracaine hydrochloride may cause an anesthetic effect. Tetracaine hydrochloride has the potential to sensitize.

MEDICAL CONDITIONS AGGRAVATED BY

EXPOSURE: Hypersensitivity to neomycin sulfate or the aminoglycoside group of antibiotics. Systemic fungal infections (from exposure to isoflupredone acetate).

4. FIRST AID MEASURES

EYES: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

SKIN: Wash off with soap and water. Take off all contaminated clothing immediately.

INHALATION: Move to fresh air.

INGESTION: Contact a physician or poison control center.

5. FIRE FIGHTING MEASURES

FLASH POINT: Nonflammable.

LOWER EXPLOSION LIMIT (LEL): Not applicable.

UPPER EXPLOSION LIMIT (UEL): Not applicable.

EXTINGUISHING MEDIA: Water, carbon dioxide, or dry chemical.

FIRE-FIGHTING PROCEDURES: Wear self-contained breathing apparatus and full-body protective equipment.

UNUSUAL FIRE OR EXPLOSION HAZARDS: None known.

HAZARDOUS COMBUSTION PRODUCTS: Carbon monoxide. Carbon dioxide. Nitrogen oxides. Sulfur oxides.

6. ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN CASE MATERIAL IS

RELEASED OR SPILLED: Provide ventilation and respiratory, skin and eye protection to prevent overexposure. Keep out of drains; prevent entry to surface water, groundwater and soil. Vacuum or scoop spilled material and place in container.

7. HANDLING AND STORAGE

PRECAUTIONS FOR HANDLING AND STORING:

Avoid contact with skin, eyes and clothing. Wash thoroughly after handling. Launder contaminated clothes before reuse. Store in a cool, dry place and protect from light. Keep out of the reach of children.

8. EXPOSURE CONTROLS/ PERSONAL PROTECTION

RESPIRATORY PROTECTION: Not required.

VENTILATION: Local exhaust.

PROTECTIVE GLOVES: Not required.

EYE PROTECTION: Not required.

OTHER PROTECTIVE EQUIPMENT: Not required.

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/PHYSICAL STATE: Ointment.

MOLECULAR WEIGHT: Mixture.

10. STABILITY AND REACTIVITY

STABILITY: Stable at normal conditions.

PHYSICAL CONDITIONS TO AVOID: None.

INCOMPATIBILITY WITH OTHER MATERIALS:
None.

HAZARDOUS DECOMPOSITION PRODUCTS: None.

HAZARDOUS POLYMERIZATION: Does not occur.

11. TOXICOLOGICAL INFORMATION

ACUTE STUDIES:

SENSITIZATION: Hypersensitivity reactions (primarily skin rashes) have occurred in persons treated with neomycin sulfate.

ORAL LD50 (RAT): > 4,325 mg/kg (neomycin sulfate; 1,025 mg/kg tetracaine hydrochloride)

INTRAPERITONEAL LD50 (MOUSE): 70 mg/kg (tetracaine hydrochloride)

SUBCUTANEOUS LD50 (MOUSE): 35 mg/kg (tetracaine hydrochloride)

SUBCHRONIC/CHRONIC STUDIES:

ORAL (NOEL) (RAT): 25 mg/kg/day (lifetime feeding study) (for neomycin sulfate).

OTHER STUDIES:

CARCINOGENICITY: Ingredient(s) are not listed as carcinogenic by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

ECOTOXICITY: Muscular injection (fish - Chinook Salmon): 11 mg/kg, 10% mortality - 10 days (for neomycin sulfate).

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Dispose of by incineration in accordance with applicable international, national, state and/or local waste disposal regulations.

14. SHIPPING REGULATIONS

Not regulated for transportation by the United States Department of Transportation (DOT), International Maritime Organization (IMO), or International Air Transport Association (IATA). May be subject to state and/or local transportation requirements.

15. OTHER INFORMATION

REVIEWED BY: Environment & Safety

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16. LABELING

This drug is subject to FDA labeling requirements; therefore, it is exempt from the labeling requirements of the OSHA Hazard Communication Standard.

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