



Vancomycin Hydrochloride Capsules

Effective Date: 12 Jan 2005

Material Safety Data Sheet

Section 1 - Chemical Product and Company

Manufacturer:

ViroPharma Incorporated
397 Eagleview Blvd.
Exton, PA 19465

Manufacturer's Emergency Phone:

610-832-0846, extension 343

CHEMTREC:

1-800-424-9300 (North America)

Common Name: Vancomycin Hydrochloride Capsules

Chemical Name: Vancomycin, hydrochloride

Cas Number: 1404-93-9

Trademarks(s): Vancocin

Item Code(s): 3125; 3126

See attached glossary for abbreviations.

Section 2 - Composition / Information on Ingredients

<u>Ingredient</u>	<u>CAS</u>	<u>Concentration %</u>
Vancomycin Hydrochloride	1404-93-9	30 - 42
Polyethylene Glycols	25322-68-3	50 - 68
Excipients	NA	2 - 5

Exposure Guidelines:

Vancomycin hydrochloride - LEG <100 micrograms/m³ TWA for 12 hours.

Polyethylene glycols - WEEL 10 mg/m³ TWA

Section 3 - Hazards Identification

Appearance: Capsules containing congealed liquid mixture

Physical State: Solid

Odor: Odorless

Hazard Codes: (see description last page)

I: 2 D: 0 F: 1 C: 3U

Hazard Summary:

Health:

Not hazardous if intact

Irritant (eyes). Allergen

Chemical/Physical:

Not determined

Routes of Entry: Inhalation and skin contact.

Effects of Overexposure: Capsules are intended for human consumption under guidance of a physician. Capsules are not considered hazardous under normal handling procedures. Allergic reactions including nasal congestion, itchy and runny nose, watery eyes, mild breathing difficulties, skin irritation, and rash with or without hives have been reported with occupational exposure to vancomycin hydrochloride. Contents of capsules may be irritating the eyes. The following events have been reported with therapeutic use of vancomycin: flushing (redness of the face), low blood pressure, nausea, dermatitis, rash, hearing loss, kidney effects, blood effects (IV only), and anaphylactic reactions.

Medical Conditions Aggravated by Exposure: Hypersensitivity to vancomycin.

Carcinogenicity: All ingredients - Not listed by IARC, NTP, ACGIH, or OSHA.

Section 4 - First Aid Measures

Eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. See an ophthalmologist (eye doctor) or other physician immediately.

Skin: Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation develops.

Inhalation: Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

Ingestion: Do not induce vomiting. Call a physician or poison control center. If available, administer activated charcoal (6-8 heaping teaspoons) with two to three glasses of water. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

Section 5 - Fire Fighting Measures

Flash Point: No applicable information found

UEL: No applicable information found

LEL: No applicable information found

Extinguishing Media: Use water, carbon dioxide, dry chemical, foam, or Halon.

Unusual Fire and Explosion Hazards: None known.

Hazardous Combustion Products: May emit toxic fumes when exposed to heat or fire.

Section 6 - Accidental Release Measures

The following are recommended for manufacturing or other situations where exposure to the capsule contents.

Spills: Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions). Scoop or scrape up for disposal.

Section 7 - Handling and Storage

Storage Conditions: Store in a cool, dry, well-ventilated area.

Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information. Filled capsules are not considered hazardous under normal handling procedures and protective equipment is not required. The following are recommended for manufacturing or other situations where exposure to contents may occur.

Respiratory Protection: Use an approved respirator.

Eye Protection: Chemical goggles and/or face shield.

Ventilation: Laboratory fume hood or local exhaust ventilation.

Other Protective Equipment: Chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.

Additional Exposure Precautions: In production settings, airline-supplied, hood-type respirators are preferred. Shower and change clothing if skin contact occurs.

Section 9 - Physical and Chemical Properties

Appearance: Capsules containing congealed liquid mixture

Odor: Odorless

Boiling Point: No applicable information found

Melting Point: Not applicable

Specific Gravity: No applicable information found

pH: 2.5 to 4.5 (5% Aqueous)

Evaporation Rate: No applicable information found

Water Solubility: Soluble

Vapor Density: No applicable information found

Vapor Pressure: No applicable information found

Section 10 - Stability and Reactivity

Stability: Stable at normal temperatures and pressures.

Incompatibility: May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.).

Hazardous Decomposition: May emit toxic fumes when heated to decomposition.

Hazardous Polymerization: Will not occur.

Section 11 - Toxicological Information

Acute Exposure

Data for the active ingredient, vancomycin hydrochloride, are reported.

Oral:

Vancomycin hydrochloride - Rat, 5000 mg/kg, no deaths, leg weakness, diarrhea.

Skin:

Vancomycin hydrochloride - Rabbit, 500 mg/kg, no deaths or toxicity.

Inhalation:

Vancomycin hydrochloride - Rat, 3080 mg/m³ for 1 hour, no deaths, increased activity.

Intravenous:

Vancomycin hydrochloride - Rat, median lethal dose between 251 and 312 mg/kg, convulsions, labored breathing, reduced activity.

Dog, median lethal dose 292 mg/kg, increased blood urea nitrogen, renal failure.

Skin Contact:

Vancomycin hydrochloride - Rabbit, nonirritant

Eye Contact:

Vancomycin hydrochloride - Rabbit, irritant

Chronic Exposure

Data for the active ingredient, vancomycin hydrochloride, are reported.

Target Organ Effects:

Vancomycin hydrochloride - Nervous system effects (weakness, incoordination, vomiting, shaking), heart effects (decreased blood pressure, change in heart rate/rhythm), blood effects (increased reticulocyte count, decreased lymphocyte count, changes in blood chemistry), kidney effects (kidney tissue changes), digestive effects (intestinal tissue changes).

Other Effects:

Vancomycin hydrochloride - Decreased body weight, excessive salivation.

Reproduction:

Vancomycin hydrochloride - Reduced fetal body weight at doses toxic to the mother.

Sensitization: No applicable information found.

Mutagenicity:

Vancomycin hydrochloride - Not mutagenic in bacterial or mammalian cells.

Section 12 - Ecological Information
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No applicable ecological information found.

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Eli Lilly and Company usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations

Vancomycin hydrochloride

TSCA - No

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

OSHA Substance Specific - No

Polyethylene glycol

TSCA - Yes

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

OSHA Substance Specific - No

Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace by a properly trained person having the necessary technical skills. All information contained herein is offered with the

good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND, EXPRESS OR IMPLIED (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature that may accompany the finished product. Users should consider these data only as a supplement to other information gathered by them and must make independent determinations of suitability and completeness of information from all sources to assure proper use, storage and disposal of these materials and the safety and health of employees and customers and the protection of the environment.

GLOSSARY:

ACGIH = American Conference of Governmental Industrial Hygienists

AIHA = American Industrial Hygiene Association

CAS Number = Chemical Abstract Service Registry Number

CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)

CHEMTREC = Chemical Transportation Emergency Center

DOT = Department of Transportation

IARC = International Agency for Research on Cancer

ICAO/IATA = International Civil Aviation Organization/International Air Transport Association

IMO = International Maritime Organization

LEG = Lilly Exposure Guideline

LEL = Lower Explosive Limit

MSDS = Material Safety Data Sheet

NA = Not Applicable, except in Section 14 where NA = North America

NTP = National Toxicology Program

OSHA = Occupational Safety and Health Administration

SARA = Superfund Amendments and Reauthorization Act

TSCA = Toxic Substances Control Act

TWA = Time Weighted Average/8 Hours Unless Otherwise Noted

UEL = Upper Explosive Limit

WEEL = Workplace Environmental Exposure Level (AIHA)

GUIDE FOR VIROPHARMA, INCORPORATED HAZARD CODES

HEALTH HAZARDS:

I = Inhalation Hazards

D = Dermal Hazards

0 = Basically inert

1 = Low hazard - minor, reversible effects

2 = Moderate hazard - may be harmful

3 = Severe hazard - effects may be dangerous

4 = Extreme hazard - effects dangerous at very low level of exposure

CHEMICAL/PHYSICAL HAZARDS:

F = Fire and explosion hazard

F0 = Basically inert

F1 = Low hazard

F2 = Moderate hazard - combustible

F3 = Severe hazard - flammable, readily ignites

F4 = Extreme hazard - very flammable

C = Reactivity hazard

C0 = Basically inert

C1 = Low hazard

C2 = Moderate hazard - heat sensitive, decomposes when heated

C3 = Severe hazard - decomposes violently when heated

C4 = Extreme hazard - decomposes very violently when heated

Additional comments: Indicate special hazard consideration

U = Unknown

E = Eye Hazard