



Vancomycin Hydrochloride for Oral Solution

Eli Lilly and Company
Material Safety Data Sheet

Effective Date: 21-May-2004

Section 1 - Chemical Product and Company

Manufacturer:
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

Manufacturer's Emergency Phone:
1-317-276-2000
CHEMTREC:
1-800-424-9300 (North America)
1-703-527-3887 (International)

Common Name: Vancomycin Hydrochloride for Oral Solution

Chemical Name: Vancomycin, hydrochloride

Synonym(s): 028811 Hydrochloride formulation; Vancomycin; 020460 Formulation

Trademarks(s): Diatracin; Enterocaps; Fibrantil; Vancocina; Vancocine; Voncon; Vancocina CP; Vancocin CP; Vancocin

Lilly Item Code(s): MS0206; MS5052; MS5105; QA266W; VF0181; VF0201; VF0353

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	95
Ethyl Alcohol	64-17-5	2 - 4

Exposure Guidelines:

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

Ethyl alcohol - PEL and TLV 1000 ppm (1900 mg/m³) TWA.

UK - Exposure Standard 1000 ppm (1920 mg/m³) TWA.

Ireland - Occupational Exposure Limit 1000 ppm (1900 mg/m³) TWA.

Italy - Occupational Exposure Limit 1000 ppm TWA.

France - Occupational Exposure Limit 1000 ppm (1900 mg/m³) (VME) TWA, 5000 ppm (9500 mg/m³) (VLE) STEL.

Spain - Occupational Exposure Limit 1000 ppm (1910 mg/m³) (VLA-ED) TWA.


Germany - TRGS 900 Limit Value 500 ppm (960 mg/m³), 15-minute limit not to exceed 4 times MAK.

Section 3 - Hazards Identification

Appearance: Off-white powder

Physical State: Solid

Odor: Odorless



Emergency Overview

Special
A = Allergen

Emergency Overview Effective Date: 13-Aug-1999

Lilly Laboratory Labeling Codes:
Health 2 **Fire 1** **Reactivity 0** **Special A**

Primary Physical and Health Hazards: Irritant (eyes). Allergen. Nervous System Effects.

Caution Statement: Vancomycin Hydrochloride for Oral Solution contains ethyl alcohol, may be irritating to the eyes and causes allergic reactions. Effects of exposure may include dizziness, nausea, and drowsiness.

Routes of Entry: Inhalation and skin contact.

Effects of Overexposure: None reported; however, the components may produce signs and symptoms as indicated.

Vancomycin hydrochloride - Allergic reactions to vancomycin have been reported including nasal congestion, itching and runny nose, watery eyes, and mild breathing difficulties or skin irritation with a rash and itching with or without hives. May be irritating to 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.

Ethyl alcohol - May include irritation of the eyes, skin, and respiratory tract, drowsiness, nausea, muscle incoordination, visual impairment, slowed reaction time, sensory loss, slurring of speech, stupor, and possible coma and death.

Medical Conditions Aggravated by Exposure: None known; however, the components may aggravate preexisting conditions as indicated.

Vancomycin hydrochloride - Hypersensitivity to vancomycin.

Ethyl alcohol - Ingestion of large volumes may aggravate liver disorders, hypersensitivity to alcohol, and gastrointestinal abnormalities (peptic ulcers, gastritis).

Carcinogenicity:

Vancomycin hydrochloride - Not listed by IARC, NTP, ACGIH, or OSHA.

Ethyl alcohol - ACGIH A4 - (not classifiable as a human carcinogen). Not listed by NTP or OSHA. Alcohol drinking is listed as IARC Group 1.

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: As a finely divided material, may form dust mixtures in air which could explode if subjected to an ignition source.

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

Section 6 - Accidental Release Measures

Spills: Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions). Vacuum material with appropriate dust collection filter in place. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist material and remove by sweeping or wet wiping.

Section 7 - Handling and Storage

Storage Conditions: Refrigerator: 2 to 8 C (36 to 46 F).

Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information.

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: Off-white powder

Odor: Odorless

Boiling Point: Not applicable

Melting Point: Decomposes when heated

Specific Gravity: Not applicable

pH: 2.4 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

No data available for mixture or formulation. Data for ingredient(s) or related material(s) are presented.

Oral:

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

Ethyl alcohol - Rat, median lethal dose 7060 mg/kg.

Skin:

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

Ethyl alcohol - Rabbit, median lethal dose greater than 20 g/kg.

Inhalation:

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

Ethyl alcohol - Rat, median lethal concentration 20,000 ppm for 10 hours (approximately 200,000 ppm for 1 hour).

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

Ethyl alcohol - Rabbit, irritant

Eye Contact:

Vancomycin hydrochloride - Rabbit, irritant

Ethyl alcohol - Rabbit, irritant

Chronic Exposure

No data available for mixture or formulation. Data for ingredient(s) or related material(s) are presented.

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).

Ethyl alcohol - Nervous system effects (depression), liver and kidney effects (tissue changes).

Other Effects:

Vancomycin hydrochloride - Decreased body weight, excessive salivation.

Reproduction:

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

Ethyl alcohol - Decreased fertility, fetal growth retardation, increased behavioral abnormalities in offspring, and decreased offspring survival at doses toxic to the mother.

Sensitization: No applicable information found.

Mutagenicity:

Vancomycin hydrochloride - Not mutagenic in bacterial or mammalian cells.

Ethyl alcohol - Not mutagenic in bacterial or mammalian cells.

Section 12 - Ecological Information

No environmental data for the mixture or formulation. The environmental information for ingredient(s) or related material(s) are presented.

Ecotoxicity Data:

Ethyl alcohol

Rainbow trout 96-hour median lethal concentration: 13 g/L

Fathead minnow 96-hour median lethal concentration: 13.5 g/L

Daphnia magna 48-hour median lethal concentration: 9.3 g/L

Blue-green algae (*A. aeruginosa*) 8-day median effective concentration: 1450 mg/L

Microorganisms:

Green algae (*C. pyrenoidosa*): MIC 1.18%

Environmental Fate:

Ethyl alcohol

Log Kow: -0.31

Atmospheric half-life (days): 4 to 5.9

5-Day biological oxygen demand: 37 to 86%

Environmental Summary:

Ethyl alcohol - Practically non-toxic to aquatic organisms. Material can be considered not to bioaccumulate and will have little adsorption to the soil. Ethanol will photodegrade and biodegrade when released to the environment and can not be considered to be persistent in the environment.

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

Ethyl alcohol
TSCA - Yes
CERCLA - Not on this list
SARA 302 - Not on this list
SARA 313 - Not on this list
OSHA Substance Specific - No

EU Regulations

EC Classification

Contains vancomycin hydrochloride (C = 95%).
Xn (Harmful)
Xi (Irritant)

Risk Phrases

R 36 - Irritating to eyes.
R 42/43 - May cause sensitization by inhalation and skin contact.

Safety Phrases

S 25 - Avoid contact with eyes.
S 26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S 36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

Section 16 - Other Information

MSDS Sections Revised: Sections 3 and 4.

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. 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 (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 which may accompany the finished product.

For additional information contact:
Eli Lilly and Company
Hazard Communication
317-277-6029

GLOSSARY:

ACGIH = American Conference of Governmental Industrial Hygienists
AIHA = American Industrial Hygiene Association
BEI = Biological Exposure Index
CAS Number = Chemical Abstract Service Registry Number
CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN = Chemical Hazard Alert Notice
CHEMTREC = Chemical Transportation Emergency Center
DOT = Department of Transportation
EC = European Community
EINECS = European Inventory of Existing Chemical Substances
ELINCS = European List of New Chemical Substances
EPA = Environmental Protection Agency
HEPA = High Efficiency Particulate Air (Filter)
IARC = International Agency for Research on Cancer
ICAO/IATA = International Civil Aviation Organization/International Air Transport Association
IEG = Lilly Interim Exposure Guideline
IMO = International Maritime Organization
Kow = Octanol/Water Partition Coefficient
LEG = Lilly Exposure Guideline
LEL = Lower Explosive Limit
MSDS = Material Safety Data Sheet
MSHA = Mine Safety and Health Administration
NA = Not Applicable, except in Section 14 where NA = North America
NADA = New Animal Drug Application
NAIF = No Applicable Information Found
NCI = National Cancer Institute
NIOSH = National Institute for Occupational Safety and Health
NOS = Not Otherwise Specified
NTP = National Toxicology Program
OSHA = Occupational Safety and Health Administration
PEL = Permissible Exposure Limit (OSHA)
RCRA = Resource Conservation and Recovery Act
RQ = Reportable Quantity
RTECS = Registry of Toxic Effects of Chemical Substances
SARA = Superfund Amendments and Reauthorization Act
STEG = Lilly Short Term Exposure Guideline
STEL = Short Term Exposure Limit
TLV = Threshold Limit Value (ACGIH)
TPQ = Threshold Planning Quantity
TSCA = Toxic Substances Control Act
TWA = Time Weighted Average/8 Hours Unless Otherwise Noted
UEL = Upper Explosive Limit
UN = United Nations
WEEL = Workplace Environmental Exposure Level (AIHA)