

MATERIAL SAFETY DATA SHEET

Product Name: VersaTREK[®] Myco PVNA

MSDS #: L-MSDS7113-5

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Section 1: Product and Company Information

Product Name: VersaTREK[®] Myco PVNA
Product Code: 7113-42
Manufacturer: TREK Diagnostic Systems
982 Keynote Circle, Suite 6
Cleveland, OH 44131
USA
Phone Number: (800) 871-8909
Fax: (216) 351-5456
24-hour Emergency: (800) 642-7029

European: TREK Diagnostic Systems
Unit 17-19,
Birches Industrial Estate
East Grinstead
West Sussex, RH19 1XZ
UK
Telephone No. 44-1342-318777

Section 2: Composition and Ingredient Information

<u>Common Name</u>	<u>Chemical Name</u>	<u>CAS No.</u>	<u>EINECS / ELINCS</u>	<u>Wt.%</u>	<u>Symbol</u>	<u>*R-phrases</u>
Vancomycin Hydrochloride	Vancocine hydrochloride	1404-93-9	Not listed	0.2	Xi	R43
Amphotericin B	Amphotericin B	1397-89-3	215-742-2	0.3	T	R25 R36/37/38
Polymyxin B sulfate	Polymyxin B sulfate	1405-20-5	215-744-7	0.4	Xn	R22
Nalidixic Acid	1-ethyl-7-methyl-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid	389-08-2	206-864-7	1.3	Xn	R22 R40
Cyclodextrin	Beta-cycloamylose	7585-39-9	231-493-2	97.8	Xn	R22

* See Section 16 for the full text of the R-phrases declared above

Note: See Section 8 of this MSDS for exposure limit data for these ingredients.

Section 3: Hazards Identification

Appearance, Color and Odor: Solid, yellow, crystalline, caked powder (freeze-dried)

Primary Route(s) of Exposure: Inhalation, ingestion, skin, eyes.

Potential Health Effects:

ACUTE (short term): see Section 8 for exposure controls

Inhalation: May cause allergic reaction.

Ingestion: May cause allergic reaction.

Skin: Frequent or prolonged contact may cause allergic reaction.

Eyes: May cause allergic reaction.

CHRONIC (long term): see Section 11 for additional toxicological data

Target organs: Blood, eyes and central nervous system have been affected by Nalidixic acid. Kidneys have been affected by Amphotericin B. Blood and kidneys have been affected by Vancomycin hydrochloride.

May cause harm to the unborn child based on Nalidixic acid content.

The NTP has found clear evidence of carcinogenicity in rats for Nalidixic acid.

Amphotericin B is a possible mutagen.

Medical Conditions

None.

Aggravated by Exposure:

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Section 4: First Aid Measures

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical advice.

Eye Contact: Rinse immediately with plenty of water and seek medical advice.

Skin Contact: Wash immediately with plenty of water, and seek medical advice if symptoms arise.

Ingestion: Seek medical advice immediately and show this container.

Section 5: Fire Fighting Measures

Flash Point and Method (°F): Not considered to be a fire hazard.

Flammability Limits (%): Not applicable.

Auto Ignition Temperature (°F): Not applicable.

Extinguishing Media: Use appropriate extinguishing media for surrounding material.

Unusual Fire and Explosion Hazards: Emits toxic fumes under fire conditions.

Fire Fighting Instructions: Wear self-contained breathing apparatus, and protective clothing to prevent contact with eyes and skin.

Hazardous Combustion Products: Carbon monoxide, carbon dioxide, nitrogen oxides.

Section 6: Accidental Release Measures

Air Release: Avoid creating dust clouds.

Land Spill: While wearing protective equipment, sweep up and place in a container for proper disposal.

Water Spill: Completely soluble in water.

Section 7: Handling and Storage

Storage Temperature: 2 – 8 °C

Storage Pressure: Not applicable.

General: Keep container tightly closed and store in a cool, dry place. Use a chemical fume hood to rehydrate.

Section 8: Exposure Controls and Personal Protection

<u>Ingredient</u>	<u>ACGIH TLV</u> <u>(8-hr. TWA)</u> <u>(mg/m³)</u>	<u>U.S. OSHA PEL</u> <u>(8-hr. TWA)</u> <u>(mg/m³)</u>	<u>UK OEL</u> <u>(8-hr. TWA)</u> <u>(mg/m³)</u>
Vancomycin Hydrochloride	Not established	Not established	Not established
Amphotericin B	Not established	Not established	Not established
Polymyxin B sulfate	Not established	Not established	Not established
Nalidixic Acid	Not established	Not established	Not established
Cyclodextrin	Not established	Not established	Not established

Engineering Controls: Provide general and/or local exhaust ventilation to control airborne concentrations below the recommended exposure guideline.

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Personal Protection: Use a NIOSH/MSHA approved respirator to protect from dust exposures.

Respiratory

Protection:

Skin Protection: Chemical resistant gloves and body-covering clothing to prevent contact.
Nitrile or neoprene gloves recommended.

Eye Protection: Safety goggles.

Other: None.

Section 9: Physical and Chemical Properties

Physical State:	Solid	Vapor Pressure: (mm Hg @ 20°C)	Not applicable.
Appearance:	Yellow, crystalline, caked powder (freeze-dried)	Vapor Density: (Air = 1)	Not applicable.
pH:	9.0-10.5 when rehydrated with 25 ml of water	Solubility in Water:	Complete
Specific Gravity: (water = 1)	Not applicable.	Water / Oil distribution coefficient:	Not available.
Boiling Point:	Not applicable.	Odour Type:	Odourless.
Freezing Point:	Not applicable.	Evaporation Rate: (n-Butyl Acetate = 1)	Not applicable.
Viscosity:	Not applicable.	Other:	None.

Section 10: Stability and Reactivity

Stability:	Stable.
Incompatible Materials and Conditions to Avoid:	Incompatible with strong oxidizing agents. Protect from light and moisture.
Hazardous Decomposition Products:	Carbon monoxide, carbon dioxide, nitrogen oxides.
Hazardous Polymerization:	Will not occur.
Other Reactivity Concerns:	None.

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Section 11: Toxicological Information

Carcinogenicity: The table below indicates whether or not each agency has listed each ingredient as a carcinogen.

<u>Ingredient</u>	<u>ACGIH</u>	<u>IARC</u>	<u>NTP</u>	<u>OSHA</u>
Vancomycin Hydrochloride	Not listed	Not listed	Not listed	Not listed
Amphotericin B	Not listed	Not listed	Not listed	Not listed
Polymyxin B sulfate	Not listed	Not listed	Not listed	Not listed
Nalidixic Acid	Not listed	Not listed	Clear evidence (rat)	Not listed
Cyclodextrin	Not listed	Not listed	Not listed	Not listed

<u>Ingredient</u>	<u>LD₅₀ Oral</u> <u>(mg/kg)</u>	<u>LD₅₀ Dermal</u> <u>(mg/kg)</u>	<u>LC₅₀ Inhalation</u> <u>(mg/m³, 4 hrs.)</u>
Vancomycin Hydrochloride	>10 000 (rat)	Not available	Not available
Amphotericin B	>5000 (rat)	Not available	Not available
Polymyxin B sulfate	790 (rat)	Not available	Not available
Nalidixic Acid	2040 (rat)	Not available	Not available
	572 (mouse)		
Cyclodextrin	18 800 (rat)	Not available	Not available

Section 12: Ecological Information

The ecological effects have not been thoroughly investigated, but currently none have been identified.

Section 13: Disposal Considerations

Waste Disposal Method: Dispose of in accordance with local, state and federal regulations.

Section 14: Transport Information

DOT Proper Shipping Name:		Not regulated
DOT Hazard Classification:	Primary:	Not regulated
	Secondary:	
DOT Special Provisions:		None
DOT Packaging Exceptions:		None
DOT Non-bulk Packaging:		None
DOT Bulk Packaging:		None
IMDG Proper Shipping Name:		Not regulated
IATA Proper Shipping Name:		Not regulated

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Section 15: Regulatory Information

TSCA Status: Exempt under TSCA
California Proposition 65: Nalidixic Acid CAS# 389-08-2
SARA Title III:
Sec. 302/304: None
Sec. 311/312: CAS# 389-08-2 Acute, Chronic
Sec. 313: None
Right to Know: None
EC Directive: The preparation is classified as dangerous according to Directive 1999/45/EC and its amendments.



Xn Harmful

R42/43 May cause sensitization by inhalation and skin contact

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36 Wear suitable protective equipment

Other: None.

Section 16: Other Information

HMIS and NFPA Hazard Rating:

Category	HMIS	NFPA
Acute Health	2	2
Flammability	0	0
Reactivity	0	0

Full Text of R-phrases appearing in Section 2:
R22 – Harmful if swallowed
R25 – Toxic if swallowed
R36/37/38 – Irritating to eyes, respiratory system and skin
R40 – Possible risks of irreversible effects
R43 - May cause sensitization by skin contact

Text of classifications appearing in Section 2:
Xi - Irritant
Xn - Harmful
T - Toxic

Preparation Information:

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Preparation date: September 23, 1999. Revised November 7, 2002 by TREK to update TREK USA address. Revised July 8, 2003 by TREK to update regulatory information. Revised August 14, 2010 by TREK to update TREK UK address.

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