

MATERIAL SAFETY DATA SHEET

Product Name: *para*-JEM® AS
MSDS #: L-MSDS7133-5

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Section 1: Product and Company Information

Product Name: *para*-JEM® AS
Product Code: 7133-42
Manufacturer: TREK Diagnostic Systems
982 Keynote Circle, Suite 6
Cleveland, OH 44131
(800) 871-8909

Section 2: Hazardous Ingredients of Mixture

<u>Common Name</u>	<u>Chemical Name</u>	<u>CAS No.</u>
Vancomycin Hydrochloride	Vancocine hydrochloride	1404-93-9
Amphotericin B	Amphotericin B	1397-89-3
Nalidixic Acid	1-ethyl-7-methyl-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid	389-08-2
Cyclodextrin	Beta-cycloamylose	7585-39-9

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

Section 3: Hazards Identification

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

Odor:

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 Aggravated by Exposure: None.

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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, hydrogen chloride gas.

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
- General:** Keep container tightly closed and store in a cool, dry place.
- Handling:** Do not breathe dust. Do not get in eyes, on skin, or on clothing

Section 8: Exposure Controls and Personal Protection

<u>Ingredient</u>	<u>ACGIH TLV (8-hr. TWA) (mg/m³)</u>	<u>U.S. OSHA PEL (8-hr. TWA) (mg/m³)</u>	<u>UK OEL (8-hr. TWA) (mg/m³)</u>
Vancomycin Hydrochloride	Not established	Not established	Not established
Amphotericin B	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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Section 8: Exposure Controls and Personal Protection (continued)

Personal Protection:

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

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

Eye Protection: Safety goggles.

Work Practices:

Wash thoroughly after handling. Do not take internally.
Follow safe laboratory practices.
Eye wash and safety equipment should be readily available.

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.	Odor Type:	Odorless.
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.

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

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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

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 clothing.

Other: None.

Section 16: Other Information

Preparation Date: July 19, 2006.

Disclaimer: Product is intended for use by qualified professionals experienced in handling potentially hazardous chemicals and trained in good laboratory practices. The above information is believed to be correct but does not purport to be all inclusive. All materials may present unknown hazards and should be used with caution. TREK Diagnostic Systems shall not be held liable for any damage resulting from handling or contact with above product.