



SAFETY DATA SHEET — 16 Sections

SECTION 1 — CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

<u>Product Identifier</u> TV and TVC liquid Culture Media; Product numbers 11-031-001, 11-031-002, 11-035-001, 11-035-002, 11-041-003 and 11-051-004		WHMIS Classification D2, Subdivision B	
<u>Product Use and Description</u> TV and TVC products are designed for <i>in vitro</i> diagnostic use to identify <i>T. vaginalis</i> in humans. The media formulation is a nutrient mixture of amino acids, vitamins, organic supplements, antibiotics and inorganic salts.			
<u>Manufacturer's Name</u> Biomed Diagnostics, Inc.		<u>Supplier's Name</u> N/A	
<u>Street Address</u> 1388 Antelope Road		<u>Street Address</u> N/A	
<u>City</u> White City	<u>State/Province</u> OR	<u>City</u> N/A	<u>State/Province</u> N/A
<u>Postal Code</u> 97503	<u>Emergency Telephone</u> (541) 830-3000	<u>Postal Code</u> N/A	<u>Emergency Telephone</u> N/A
<u>Date SDS Prepared</u> 05/2019	<u>SDS Prepared By</u> Olivia Lonctot, QC Technician	<u>Phone Number</u> (1-541) 830-3000	

SECTION 2 — COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous Ingredient(s)	%	CAS Number	LD50 of Ingredient (<i>species and route</i>)	LC50 of Ingredient (<i>species</i>)
Iron Dextran; aqueous solution	<0.1	9004-66-4	2.24 g Fe/kg; Rat, Intravenous	No data available
Polymyxin B sulfate salt	<0.1	1405-20-5	790mg/kg; Mouse (Oral)	No data available
Ketoconazole	< 1.0	65277-42-1	166 mg/kg; Rat (Oral)	No data available
Chloramphenicol	< 1.0	56-75-7	2,500 mg/kg; Rat (Oral)	No data available

SECTION 3 — HAZARDS IDENTIFICATION

Route of Entry	<input checked="" type="checkbox"/> Skin Contact	<input type="checkbox"/> Skin Absorption	<input checked="" type="checkbox"/> Eye Contact	<input type="checkbox"/> Inhalation	<input checked="" type="checkbox"/> Ingestion
<u>Emergency Overview</u> Except for distilled water, hazardous ingredient(s) are in concentrations of less than 1%. All carcinogenic/teratogenic components are in concentrations of less than 0.1%.					
Pictogram 					
Signal Word(s): HEALTH HAZARD, WARNING					
<u>Potential Health Effects</u> This product contains a chemical known to the state of California to cause cancer. See Section 11: Toxicological Information for details.					

SECTION 4 — FIRST AID MEASURES

<u>Skin Contact</u> Immediately and thoroughly wash area of exposure with soap and water.
<u>Eye Contact</u> Flush thoroughly with water for 15 minutes, call a physician
<u>Inhalation</u> N/A
<u>Ingestion</u> Call a physician immediately

SECTION 5 — FIRE FIGHTING MEASURES

Flammable <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	If yes, under which conditions? N/A	
<u>Means of Extinction</u> N/A		
<u>Flashpoint (° C) and Method</u> NA	<u>Upper Flammable Limit (% by volume)</u> N/A	<u>Lower Flammable Limit (% by volume)</u> N/A
<u>Auto-ignition Temperature (°C)</u> N/A	<u>Explosion Data — Sensitivity to Impact</u> N/A	<u>Explosion Data — Sensitivity to Static Discharge</u> N/A
<u>Hazardous Combustion Products</u> N/A		
<u>NFPA</u> N/A		

SECTION 6 — ACCIDENTAL RELEASE MEASURES

<u>Leak and Spill Procedures</u> Wear appropriate medical gloves (nitrile, latex, etc.). Absorb liquid material with paper towels and dispose of with normal laboratory trash.

SECTION 7 — HANDLING AND STORAGE

<u>Handling Procedures and Equipment</u> Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.
Eyes: Eye protection (safety glasses or goggles) are recommended while using this product.
<u>Storage Requirements</u> Store in the dark between 15°C to 22°C. Do not allow product to be subjected to prolonged sunlight exposure.

SECTION 8 — EXPOSURE CONTROL / PERSONAL PROTECTION

Exposure Limits <input type="checkbox"/> ACGIH TLV <input type="checkbox"/> OSHA PEL <input checked="" type="checkbox"/> Other (specify)
Other: No data available
<u>Specific Engineering Controls (such as ventilation, enclosed process, etc.)</u> Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.
Personal Protective Equipment (PPE) <input checked="" type="checkbox"/> Gloves <input type="checkbox"/> Respirator <input checked="" type="checkbox"/> Eye <input checked="" type="checkbox"/> Footwear <input checked="" type="checkbox"/> Clothing (specify) <input type="checkbox"/> Other (specify)
Gloves: Handle with medical gloves (i.e., nitrile rubber) while inoculating this product. Gloves must be inspected prior to use. Dispose of used gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
Respirator: N/A
Eye: Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

Footwear: Closed-toe shoes are recommended
Clothing: Wearing a long sleeve lab coat is recommended while inoculating this product.
Other: N/A

SECTION 9 — PHYSICAL AND CHEMICAL PROPERTIES

<u>Physical State</u> Liquid	<u>Odor and Appearance</u> Clear particulate-free fluid, Light Amber	<u>Odor Threshold (ppm)</u> No data available
<u>Specific Gravity</u> No data available	<u>Vapor Density (air = 1)</u> No data available	<u>Vapor Pressure (mmHg)</u> No data available
<u>Evaporation Rate</u> No data available	<u>Boiling Point (° C)</u> 90	<u>Freezing Point (° C)</u> 0
<u>pH Value</u> 6.1 ± 0.5	<u>Coefficient of Water/Oil Distribution</u> No data available	<u>Solubility in Water</u> No data available

SECTION 10 — STABILITY AND REACTIVITY

Chemical Stability <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<u>If no, under which conditions?</u> N/A
Incompatibility with Other Substances <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<u>If yes, which ones?</u> N/A
<u>Reactivity and under what conditions</u> <i>Trichomonas vaginalis</i> medium is stable	
<u>Hazardous Decomposition Products</u> Hazardous polymerization of liquid media will not occur.	

SECTION 11 — TOXICOLOGICAL INFORMATION

<u>Effects of Acute Exposure</u> No data available	
<u>Effects of chronic exposure</u> Persons known to be allergic to antibiotics must avoid exposure. May cause allergic skin reaction on susceptible individuals. This product contains a chemical known to cause cancer, birth defects or other reproductive harm. NOTE: There is no evidence that the ingredients could be released from the mixture in concentrations that could present a health hazard.	
<i>Irritancy of Product</i>	
<u>Skin sensitization</u> No data available	<u>Respiratory sensitization</u> No data available
<u>Carcinogenicity-IARC</u> No data available	<u>Carcinogenicity – ACGIH</u> No data available
<u>Reproductive toxicity</u> No data available	<u>Teratogenicity</u> No data available
<u>Embryotoxicity</u> No data available	<u>Mutagenicity</u> No data available
<u>Name of synergistic products/effects</u> No data available	

SECTION 12 — ECOLOGICAL INFORMATION

<u>Aquatic / Environmental Toxicity</u> No data available, though large amounts may be harmful to water and wildlife. Appropriately dispose of and store product in accordance with regulatory, federal and state requirements.
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SECTION 13 — DISPOSAL CONSIDERATIONS

<p><u>Waste Disposal</u> Dispose of with normal lab trash. Obey all Federal, State and local regulations.</p>

SECTION 14 — TRANSPORT INFORMATION

<p><u>Special Shipping Information</u> N/A</p>	
<p><i>This space intentionally left blank</i></p>	
<p><u>PIN</u> No data available</p>	
<p><u>TDG</u> No data available</p>	<p><u>DOT</u> No data available</p>
<p><u>MO</u> No data available</p>	<p><u>CAO</u> No data available</p>

SECTION 15 — REGULATORY INFORMATION

<p><u>WHMIS Classification</u> D2, Subdivision B</p>	<p><u>OSHA</u> No data available</p>
<p><u>SERA</u> No data available</p>	<p><u>TSCA</u> No data available</p>
<p><i>This product is an FDA registered Class I medical device. It conforms to the Regulatory requirements as depicted in 21CFR820 and 29CFR1910.1200</i></p>	

SECTION 16 — OTHER INFORMATION

<p>The information, data and recommendations contained herein are believed to be accurate. Biomed Diagnostics, Inc. makes no warranty of any kind whatsoever with respect thereto and disclaims all liability from reliance thereon. We reserve the right to revise this SDS periodically as new information becomes available.</p>
