



## SAFETY DATA SHEET

1. PRODUCT AND COMPANY IDENTIFICATION		
(a)	Product Name:	Avioq HTLV-I/II Microelisa System
(b)	Product Number:	500192, 500576, 509600
(c)	Product Description:	The Avioq HTLV-I/II Microelisa System is a qualitative enzyme-linked immunosorbent assay (ELISA) for the detection of antibodies to Human T-Lymphotropic Virus Type I (HTLV-I) and/or Human T-Lymphotropic Virus Type II (HTLV-II) in human serum, plasma, and cadaveric blood specimens.
(d)	Supplier Information:	Avioq 104 T.W. Alexander Drive Research Triangle Park, North Carolina 27709 Telephone: 919-314-5535 Fax: 919-314-5536
(e)	Emergency Phone Number:	Telephone: 919-314-5535
2. HAZARDS IDENTIFICATION		
(a)	Classification of the substance or mixture:	
	<b>Kit Component</b>	<b>Description</b>
		<b><sup>1</sup>Hazardous Components of Mixture Present Above Threshold Levels</b>
	<b>HTLV-I/II Microelisa Strips</b>	Twelve strips per holder, each containing 8 wells coated with inactivated HTLV-I viral lysate, a recombinant HTLV-I antigen (rp21E), and inactivated HTLV-II viral lysate; contained in a foil pouch with silica gel desiccant.
	<b>EnzAbody<sup>®</sup> for HTLV-I/II (EnzAbody Concentrate) (50 mg ea vial)</b>	Horseradish Peroxidase Conjugated Goat Anti-human Immunoglobulin, ~0.06% w/w or 30µg; lyophilized with goat serum, sucrose, and non-fat dry milk.
	<b>EnzAbody<sup>®</sup> Diluent (55 ml ea bottle)</b>	Phosphate buffered saline containing 10% goat serum and non-ionic surfactants. Preservatives: 0.2% gentamicin sulfate and 0.02% cinnamaldehyde.
		<b>None</b>




## SAFETY DATA SHEET

<b>Sample Diluent</b> (100 ml ea bottle)	Phosphate buffered saline containing 10% goat serum, non-ionic surfactants, sodium chloride, 0.14% bovine serum albumin, non-fat dry milk and amaranth dye. Preservative: 0.03% (w/v) bromonitrodioxane.	<b>None</b>
<b>TMB Solution</b> (22 ml ea bottle)	Citric acid containing 0.03% tetramethylbenzidine•2HCl.	<b>None</b>
<b>Peroxide Solution</b> (22 ml ea bottle)	Citric acid/sodium citrate buffer containing 0.04% urea peroxide, 0.1% 2-Chloroacetamide.	<b>2-Chloroacetamide</b> , CAS 79-07-2: 0.1% Reproductive Toxicity (Category 2), H361
<b>Negative Control Serum</b> (1.5 ml ea vial)	Human serum with protein stabilizers; nonreactive by FDA licensed tests for antibodies to HTLV-I, HTLV-II, HIV-1, HIV-2, HCV, and nonreactive for HBsAg and HIV-Ag. Preservative: 0.05% (w/v) bromonitrodioxane.	<b>None</b>
<b>HTLV-I Positive Control Serum</b> (1.0 ml ea vial)	Inactivated human serum with protein stabilizers and Amaranth red dye; reactive for antibodies to HTLV-I; nonreactive by FDA licensed tests for antibodies to HIV-1, HIV-2, HCV, and nonreactive for HBsAg and HIV-Ag. May cross-react with HTLV-II antigen. Preservative: 0.05% (w/v) bromonitrodioxane.	<b>None</b>
<b>HTLV-II Positive Control Serum</b> (1.0 ml ea vial)	Inactivated human serum with protein stabilizers and Patent blue dye; reactive for antibodies to HTLV-II; nonreactive by FDA licensed tests for antibodies to HIV-1, HIV-2, HCV, and nonreactive for HBsAg and HIV-Ag. May cross-react with HTLV-I antigen. Preservative: 0.05% (w/v) bromonitrodioxane.	<b>None</b>



## SAFETY DATA SHEET

	<p><sup>1</sup>According to the OSHA Hazard Communication Standard (29 CFR 1910.1200), if a mixture contains less than 1% of a hazardous chemical or 0.1% of a carcinogen, the mixture shall not be considered hazardous. Under GHS, the cutoff level for reproductive toxicity, carcinogenicity and category 1 mutagenicity is <math>\geq 0.1\%</math>. The cutoff level for all other hazard classes is <math>\geq 1\%</math></p>	
(b)	GHS label elements, precautionary statements:	
	Kit Component	GHS Label Elements, Precautionary Statements:
	Peroxide Solution (22 ml ea bottle)  Contains 0.1% 2-Chloroacetamide	 <p>Signal Word: Warning            Hazard Statements            H361: Suspected of damaging fertility or the unborn child.            Precautionary Statements            P262: Do not get in eyes, on skin, on clothing.            P270: Do not eat, drink or smoke when using this product.            P280: Wear protective gloves and eye protection.            Response Precautionary Statements            P301 + P310 + P330 IF SWALLOWED: Immediately call a Poison Control Center or doctor/physician. Rinse mouth.            P302 + P352 IF ON SKIN: Wash with plenty of soap and water.            P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.            P363 Wash contaminated clothing before reuse.</p>
(c)	Hazards not otherwise covered:	<p><sup>2</sup>According to the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1450), all human blood components and certain body fluids must be treated as if known to be infectious for HIV, HBV and other bloodborne pathogens.</p> <p>Handle all Avioq HTLV-I/II biological materials as though capable of transmitting infectious agents. The antigens used to coat the microelisa wells have been inactivated for viruses by detergent disruption and the HTLV-I and HTLV-II Positive Control Sera have been inactivated by addition of detergent. The positive and negative controls are derived from human serum or plasma and have been tested for HIV-1 antigen, HBsAg, anti-HIV-1, anti-HIV-2, and anti-HCV, and have been found to be nonreactive by FDA licensed tests. As no test method can offer complete assurance that infectious agents are absent, all materials of human origin should be handled as though capable of transmitting infectious agents.</p>



## SAFETY DATA SHEET

<b>3.</b>	<b>COMPOSITION</b>	
(a)	Mixtures:	Refer to table of Kit Components in Section 2(a).
<b>4.</b>	<b>FIRST AID MEASURES</b>	
(a)	Route of Exposure	
	In case of skin contact:	See 2(b).
	In case of eye contact	See 2(b).
	If inhaled:	Not an expected route of exposure.
	If swallowed:	See 2(b).
(b)	Symptoms of exposure:	None known.
(c)	Indication of immediate medical attention	See 4(a).
<b>5.</b>	<b>FIRE-FIGHTING MEASURES</b>	
(a)	Extinguishing media:	The components in this kit do not burn. Use extinguishing media that is appropriate for surrounding fire.
(b)	Specific hazards arising from the product:	Not considered to be a fire or explosion hazard
(c)	Special equipment and precautions for fire-fighters:	None.
<b>6.</b>	<b>ACCIDENTAL RELEASE MEASURES</b>	
(a)	Personal precautions, protective equipment, and emergency procedures:	Use suitable personal protective equipment such as gloves, protective clothing or laboratory coat and eye or face protection to avoid skin and eye contact.
(b)	Methods and materials for containment and cleaning up:	Immediately clean up any spillage of material potentially containing antigen or antibody with a 1:10 dilution of 5% sodium hypochlorite. Dispose of the cleaning material by an acceptable method.
<b>7.</b>	<b>HANDLING AND STORAGE</b>	
(a)	Precautions for safe handling:	Avoid contact with skin and eyes. Avoid ingestion and inhalation.
(b)	Precautions for safe storage:	Store between 2-8°C as indicated in the package insert.
<b>8.</b>	<b>EXPOSURE CONTROLS/PERSONAL PROTECTION</b>	
(a)	Permissible exposure limits:	No data available.
(b)	Appropriate engineering controls:	General laboratory ventilation is adequate.
(c)	Personal protective equipment:	Appropriate personal protective equipment should be worn to avoid contact with skin and eyes.
<b>9.</b>	<b>PHYSICAL AND CHEMICAL PROPERTIES:</b>	
(a)	Appearance:	Multiple kit components.
(b)	Odor:	None reported.
(c)	Odor threshold:	No data available.



## SAFETY DATA SHEET

(d)	pH:	No data available.
(e)	Melting point/freezing point:	No data available.
(f)	Initial boiling point and boiling range:	No data available.
(g)	Flash point:	No data available.
(h)	Evaporation rate:	No data available.
(i)	Flammability (solid/gas):	No data available.
(j)	Upper/lower flammability or explosive limits:	No data available.
(k)	Vapor pressure:	No data available.
(l)	Vapor density:	No data available.
(m)	Relative density:	No data available.
(n)	Solubility:	No data available.
(o)	Partition coefficient: n-octanol/water:	No data available.
(p)	Auto-ignition temperature:	No data available.
(q)	Decomposition temperature:	No data available.
(r)	Viscosity:	No data available.
<b>10.</b>	<b>STABILITY AND REACTIVITY</b>	
(a)	Reactivity:	No data available.
(b)	Chemical stability:	No data available.
(c)	Possibility of hazardous reactions:	No data available.
(d)	Conditions to avoid:	No data available.
(e)	Incompatible materials:	No data available.
(f)	Hazardous decomposition products:	No data available.
<b>11.</b>	<b>TOXICOLOGICAL INFORMATION</b>	
(a)	Information of likely routes of exposure:	No data available.
(b)	Symptoms related to the physical, chemical and toxicological characteristics:	No data available.
(c)	Delayed and immediate	No data available.



## SAFETY DATA SHEET

	effects and also chronic effects form short- and long-term exposure:		
(d)	Numerical measures of toxicity:	No data available.	
(e)	Carcinogenicity:	No component of this product present at levels greater than 0.1% are listed by OSHA, IARC, NTP, or CA Prop 65	
<b>12.</b>	<b>ECOLOGICAL INFORMATION</b>		
(a)	Eco-toxicity (aquatic and terrestrial, where available):	No data available.	
(b)	Persistence and degradability:	No data available.	
(c)	Bioaccumulation:	No data available.	
(d)	Mobility in soil:	No data available.	
(e)	Other adverse effects:	This product released into the environment is not expected to have a significant impact.	
<b>13.</b>	<b>DISPOSAL CONSIDERATIONS</b>		
	In accordance with 40 CFR Parts 261.3t this product is not considered to be an EPA Hazardous Waste. Waste generators should always consult with state and local regulations to ensure complete and accurate classification.		
<b>14.</b>	<b>TRANSPORT INFORMATION</b>		
	Not regulated as a hazardous material.		
<b>15.</b>	<b>REGULATORY INFORMATION</b>		
	SARA 302 Components	No ingredients in this product are subject to the reporting requirements of SARA Title III, Section 302.	
	SARA 313 Components	This product does not contain any ingredients with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.	
	SARA 311/312 Hazards	No SARA Hazards	
	California Prop 65 Components	This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.	
<b>16.</b>	<b>OTHER INFORMATION</b>		
	Kit Component	NFPA Rating	HMIS Rating
	Peroxide Solution (1 x 22 ml bottle)	Health Hazard: 2 Fire Hazard: 0 Reactivity Hazard: 0	Health Hazard: 2 Fire Hazard: 0 Physical Hazard: 0