

	<b>MATERIAL SAFETY DATA SHEET</b>	Rev. 01 10/08/10
<b>IMUNO-HAI Chagas</b>		

<b>1. COMPANY AND PRODUCT IDENTIFICATION</b>	
<b>Company</b>	WAMA PRODUTOS PARA LABORATÓRIO LTDA 100, Aldo Germano Klein – CEAT – São Carlos Zip Code: 13560-971 SP – Brasil Phone. 55 16 3377 9977 – Fax 55 16 3377 9970 www.wamadiagnóstica.com.br <a href="mailto:atendimento@wamadiagnostica.com.br">atendimento@wamadiagnostica.com.br</a>
<b>Product Name</b>	Trade name: IMUNO-HAI CHAGAS Code: 34096-H - 96 determinations Code: 34192-H - 192 determinations Code: 34380-H - 380 determinations
<b>Intended Use</b>	<i>An indirect hemagglutination kit for the qualitative and semi-quantitative detection of anti-Trypanosoma cruzi antibodies in human serum.</i>

<b>2. PRODUCT INFORMATION</b>	
<b>Description</b>	<b>Kit contains:</b> - <i>suspension of sensitized red cells with components of T.cruzi</i> - <i>positive serum control: Positive human serum for T.cruzi, diluted in PBS, liquid and ready for use. It contains sodium azide 0.095% as preservative.</i> - <i>negative serum control Negative human serum for T.cruzi, diluted in PBS, liquid and ready for use. It contains sodium azide 0.095% as preservative.</i> - <i>Diluent solution - It contains disodium phosphate, phosphate monopotassium, sodium chloride, orange G solution, distilled water and sodium azide 0.095% as preservative.</i> - <i>2-mercaptoethanol</i>
<b>Product Use</b>	In Vitro Diagnostic only.
<b>Hazard Components</b>	Suspension of red cells, 2-mercaptoethanol, positive serum control, negative serum control. It contains Sodium azide (0.095%) as preservative.

<b>3. HAZARD IDENTIFICATION</b>	
<p>Sodium azide 0.095% may react with lead and cooper plumbing to form highly explosive metal azides. Upon disposal of liquids, flush with large volumes of water to prevent azide buildup.</p> <p>2-mercaptoethanol is harmful to the environment and toxic if inhaled. It is toxic for aquatic organisms. Avoid the leaking/spillage into rivers, lakes and sewage.</p> <p>All human derived components used have been tested for HBsAg, HIV 1 and 2, HCV and found negative. All human serum specimens and human derived products should be treated as potentially hazardous. Follow the Good Manufacturing Practices (GMP).</p>	

<b>4. FIRST AID MEASURES</b>	
<b>Contact with eyes</b>	Wash with plenty of water. Seek medical advice.

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Contact with skin	Wash with plenty of water.
Inhalation	Exposure to fresh air immediately. Seek medical advice.
Ingestion	Seek medical advice.

<b>5. FIRE FIGHTING MEASURES</b>	
Non-inflamable.	

<b>6. MEASURES OF CONTROL - LEAKING/SPILLAGE</b>	
Isolate and ventilate the area. Remove with absorbent material. Clean up area and wash with plenty of water.	

<b>7. HANDLING AND STORAGE</b>	
Handling	Avoid contact with eyes, skin and mouth. Wash hands after handling.
Storage	Store at 2 to 8°C

<b>8. EXPOSURE CONTROL AND PERSONAL PROTECTION</b>	
Preventive Measure	Avoid ingestion, inhalation and contact with eyes and skin. Use mask. Protection for eyes: yes Protection for hands: wear gloves; wash hands after handling.

<b>9. PHYSICAL AND CHEMICAL PROPERTIES</b>	
<i>Appearance</i>	<i>Reagents in liquid</i> <i>Microtritation plate solid state</i>
<i>Color:</i>	<i>Microtritation plate – Colorless</i> <i>Erythrocytes -Red</i> <i>Positive serum control: Yellow</i> <i>Negative serum control: Colorless</i> <i>Diluent solution: Orange</i> <i>2-mercaptoethanol: Colorless</i>
<i>Odor:</i>	<i>Not relevant</i>
<i>pH:</i>	<i>Not relevant</i>
<i>Solubility:</i>	<i>Reagents in liquid –soluble in water</i>
<i>Explosive properties::</i>	<i>Not available</i>
Others	None relevant data for safety.

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<b>10. STABILITY AND REACTIVITY</b>	
Stability	The product is stable when used appropriately.
Avoid	Exposure to heat can damage the product. Do not freeze

<b>11. TOXICOLOGICAL INFORMATION</b>	
<i>No toxicological data is available for this product. The product can be harmful to health if performed inappropriately. Avoid inhalation and ingestion.</i>	

<b>12. ECOLOGICAL INFORMATION</b>	
<i>No ecological data is available for this product.</i> Sodium azide 0.095% may react with lead and cooper plumbing to form highly explosive metal azides. Upon disposal of liquids, flush with large volumes of water to prevent azide buildup.	

<b>13. DISPOSAL CONSIDERATIONS</b>	
Disposal in accordance with local regulations. Brazil: See RDC 306 of 07/12/04 - ANVISA	

<b>14. TRANSPORT INFORMATION</b>	
<i>This product is not hazardous when transported by sea, land or air.</i>	

<b>15. REGULATORY INFORMATION</b>	
<i>The product is manufactured in accordance with Good Manufacturing Practice (GMP) for IVD – Ordinance n° 686 of 27/08/98, Directive 98/79 – CE, Quality Management System NBR ISO 13485:2004 (EN ISO 13485:200) and labelling and symbols information in accordance with Ordinance 206 of 17/11/06, NBR ISO 15223:2004, EN 980:2008.</i>	

<b>16. OTHER INFORMATION</b>	
All products can contain unknown risks and they should be handled with care. It is the duty of the user to comply with all local regulations.	