

	MATERIAL SAFETY DATA SHEET	Rev. 02 05/01/10
	IMUNO-CON CHAGAS	

1. COMPANY AND PRODUCT IDENTIFICATION	
Company	<p>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.wamadiagnostica.com.br atendimento@wamadiagnostica.com.br</p>
Product Name	<p>Trade name: IMUNO-CON CHAGAS Code: 1460-I – 60 determinations Code: 14100-I – 100 determinations Code: 14200-I – 200 determinations</p>
Intended Use	<i>An indirect immunofluorescence kit for the detection of anti-Trypanosoma cruzi antibody in human serum.</i>

2. PRODUCT INFORMATION	
Description	<p>Kit contains:</p> <ul style="list-style-type: none"> - Trypanosoma cruzi well slide - IgG: Fluorescein-labelled, anti-human IgG conjugate - phosphate buffered saline, contains sodium azide 0.095%. - mounting medium: Disodium phosphate, monosodium phosphate, glycerin - Evans Blue - positive serum control – positive serum diluted in saline solution 0.8%. It contains sodium azide 0.095% as preservative. - negative serum control – negative serum diluted in saline solution 0.8%. It contains sodium azide 0.095% as preservative. - coverslips
Product Use	In Vitro Diagnostic only
Hazard Components	<p>IgG, mounting medium, positive and negative controls It contains Sodium azide (0.095%) as preservative. Positive Control – Reagents for chagas</p>

3. HAZARD IDENTIFICATION	
<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>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>	

4. FIRST AID MEASURES	
Contact with eyes	Wash with plenty of water. Seek medical advice.
Contact with skin	Wash with plenty of water.
Inhalation	Exposure to fresh air immediately. Seek medical advice.

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Ingestion	Seek medical advice.
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5. FIRE FIGHTING MEASURES	
Non-inflamable	

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

7. HANDLING AND STORAGE	
Handling	Avoid contact with eyes, skin and mouth. Wash hands after handling. Handle the slides and coverslips with care.
Storage	Keep at 2 to 8°C

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

9. PHYSICAL AND CHEMICAL PROPERTIES	
<i>Appearance</i>	<i>Reagents in liquid</i> <i>Coverslips and glass slides –solid state</i>
<i>Color:</i>	<i>Slides – Colorless with parts in blue epoxy</i> <i>Coverslips – Colorless</i> <i>Positive serum control: Yellow</i> <i>Negative serum control: Colorless</i> <i>PBS: Colorless</i> <i>Glycerin: Colorless</i> <i>Anti-gammaglobulin: Yellow - fluorescent</i> <i>Evans blue –blue</i>
<i>Odor:</i>	<i>None</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 relevant</i>
Others	None relevant data for safety

10. STABILITY AND REACTIVITY	
Stability	The product is stable when used appropriately.

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

12. ECOLOGICAL INFORMATION
<i>No ecological data is available for this product.</i> Obs: Sodium azide may react with lead and copper plumbing to form highly explosive salts. On disposal, flush with large quantities of water.

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

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

15. REGULATORY INFORMATION
<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>

16. OTHER INFORMATION
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.