	MATERIAL SAFETY DATA SHEET	Rev. 02 17/08/09
IMUNO-HAI Toxoplasmose		

1. COMPANY AND PRODUCT IDENTIFICATION	
Company	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 atendimento@wamadiagnostica.com.br
Product Name	Trade name: IMUNO-HAI TOXOPLASMOSE Code: 36096-H - 96 determinations Code: 36192-H - 192 determinations Code: 36380-H - 380 determinations
Intended Use	An indirect hemagglutination kit for the qualitative and semi-quantitative detection of anti-Toxoplasma gondii antibodies in human serum.

2. PRODUCT INFORMATION	
Description	The kit comprises:: - Toxoplasma gondii sensitised formalised tanned fowl erythrocytes. It contains sodium azide 0.095% as preservative -Positive serum control - Positive human serum for T.gondii, diluted in PBS, liquid and ready for use. It contains sodium azide 0.095% as preservative - Negative Serum control - Negative human serum for T.gondii, diluted in PBS, liquid and ready for use. It contains sodium azide 0.095% as preservative - Diluent solution - It contains disodium phosphate, phosphate monopotassium, sodium chloride, orange G solution, distilled water and sodium azide 0.095% as preservative. - 2-mercaptoethanol
Product Use	In Vitro Diagnostic only.
Hazard Components	Suspension of red cells, positive serum control, negative serum control It contains Sodium azide (0.095%) as preservative. 2-mercaptoethanol Positive Serum – Reagents for toxoplasmose.

3. HAZARD IDENTIFICATION	
<p>Sodium azide 0.1% 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>	

4. FIRST AID MEASURES	
Contact with eyes	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.

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.
Storage	Keep at 2 to 8°C

8. EXPOSURE CONTROL AND PERSONAL PROTECTION


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.
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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Reagents in liquid Microtritation plate solid state
Color:	Microtritation plate – Colorless Erythrocytes -Red Positive serum control: Yellow Negative serum control: Colorless Diluent solution: Orange 2-mercaptoethanol – Colorless
Odor:	2-mercaptoethanol: characteristic (unpleasant)
pH:	Not relevant
Solubility:	Reagents in liquid –soluble in water
Explosive properties::	Not available
Others	None relevant data for safety.

10. STABILITY AND REACTIVITY

Stability	The product is stable when used appropriately.
Avoid	Exposure to heat can damage the product. Do not freeze.

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11. TOXICOLOGICAL INFORMATION
2-mercaptoethanol: If inhaled: mucous irritation – Skin contact: Burning – Eyes contact: Burning. Systemic effects :nervous system disturbances (nausea,vomit).

12. ECOLOGICAL INFORMATION
2-mercaptoetanol: It is biodegradable: it is hard to eliminate- eco-toxical effects: Toxic to aquatic organisms. It can cause negative effects to aquatic environment. Sodium azide 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.

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

14. TRANSPORT INFORMATION
This product is not hazardous when transported by sea, land or air. The product must be carried with the cares necessary not to become damaged the packings, with consequent loss of the product.

15. REGULATORY INFORMATION
The product is manufactured in accordance with Good Manufacturing Practice (GMP) for IVD – Ordinance nº 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.

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.