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|  | MATERIAL SAFETY DATA SHEET | Rev. 02 05/11/09 |
| | IMUNO-RÁPIDO HBsAg | |


| 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.wamadiagnóstica.com.br atendimento@wamadiagnostica.com.br</p> |
| Product Name | <p>Trade name: IMUNO-RÁPIDO HBsAg Code: 617010 – 10 determinations Code: 617020 – 20 determinations Code: 617040 – 40 determinations</p> |
| Intended Use | <p><i>A rapid chromatographic immunoassay kit for the qualitative detection of Hepatitis B surface antigen (HBsAg), using monoclonal and polyclonal antibodies immobilized on the membrane for the selective identification of HBsAg in serum specimens.</i></p> |

| 2. PRODUCT INFORMATION | |
|------------------------|--|
| Description | <p><i>Kit comprises: It is made of a plastic base where there is a specimen filter (fiberglass), a conjugate region (fiberglass) coated with a combination of polyclonal and monoclonal antibodies of solid phase in a sandwich format and two regions for detecting selectively the high levels of Hepatitis B surface antigens - plus one absorbent base. All material is mounted and fitted inside a plastic device.</i></p> |
| Product Use | In Vitro Diagnostic only |
| Hazard Components | N/A |

| 3. HAZARD IDENTIFICATION | |
|---|--|
| This kit does not contain ingredients listed as dangerous substances. | |

| 4. FIRST AID MEASURES | |
|-----------------------|-----|
| Contact with eyes | N/A |
| Contact with skin | N/A |
| Inhalation | N/A |
| Ingestion | N/A |

| 5. FIRE FIGHTING MEASURES | |
|---------------------------|--|
| Non-inflamable | |

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| 6. MEASURES OF CONTROL – LEAKING/SPILLAGE | |
|---|--|
| N/A | |

| 7. HANDLING AND STORAGE | |
|-------------------------|----------------------------|
| Handling | Wash hands after handling. |
| Storage | Keep at 2 to 30°C |

| 8. EXPOSURE CONTROL AND PERSONAL PROTECTION | |
|---|---|
| Preventive Measure | Protection for hands: wear gloves; wash hands after handling. |


| 9. PHYSICAL AND CHEMICAL PROPERTIES | |
|-------------------------------------|--------------------------------------|
| <i>Appearance</i> | <i>Test device: Plastic cassette</i> |
| <i>Color:</i> | <i>Cassette – White</i> |
| <i>Odor:</i> | <i>None</i> |
| <i>pH:</i> | <i>No applicable</i> |
| <i>Solubility:</i> | <i>Test Device: Insoluble</i> |
| <i>Explosive properties:</i> | <i>No applicable</i> |
| 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. |

| 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> | |

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

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14. TRANSPORT INFORMATION

This product is not hazardous when transported by sea, land or air.

15. REGULATORY INFORMATION

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.

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.