

Material Safety Data Sheet



According to REACH Regulation (EC) No. 1907/2006, Annex II

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Malaria Test Device

Version No. 2

Date of issue: 10 February 2009

*1. Identification of the substance/preparation and of the company/undertaking

Product details

Trade name: **Malaria Test Device**

Application of the substance / the preparation: In vitro diagnostic reagent. For professional use only.

Manufacturer/Supplier:

Manufacturer

Inverness Medical,
10 Southgate Road,
Scarborough,
Maine 04074, USA.

Tel: +1 207-730-5750

Fax: + 1 207-730-5717

Email: TS.Binax@invmed.com

Further information obtainable from: www.invernessmedicalpd.com

Information in case of emergency:

Tel: +1 207-730-5750

*2. Hazards identification

Hazard description:

The preparation is not classified as dangerous according to Directive 99/45/EC.

Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

*3. Composition/information on ingredients

Chemical characterisation

Description:

In vitro diagnostic reagent test device. Preparation. Laminated test strip consisting of solid support materials impregnated with dried chemical / biochemical reagents.

Dangerous components:

Component	CAS No.	EINECS No.	Classification	Concentration
Triton X100	9002-93-1	-	Xn (Xi); R22-41	1 – 5 %

Additional information:

For the wording of the listed risk phrases refer to section 16.

The test strip is housed in a hinged cardboard device.

*4. First-aid measures

General Information:

The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the test strip.

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact:

Wash with soap and water and rinse thoroughly.

After eye contact:

Rinse opened eye for several minutes under running water. Consult a doctor in case of complaint.

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After ingestion:

Wash out mouth with water. Consult a doctor in case of complaint.

5. Fire-fighting measures

Suitable extinguishing agents:

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Use fire-extinguishing methods suitable to surrounding conditions.

Special hazards caused by the substance, its products of combustion or resulting gases:

In case of fire, the following can be released: Hazardous fumes, carbon oxides (CO_x).

Protective equipment:

Wear full protective suit and self-contained respiratory protective device when extinguishing fires.

Additional information:

The device contains combustible materials.

6. Accidental release measures

Person-related safety precautions:

Refer to Section 8 for protective measures when handling the spillage.

Measures for environmental protection:

Avoid release to the environment.

Measures for cleaning/collecting:

Collect material and dispose of as waste according to Section 13.

*7. Handling and storage

Information for safe handling:

Observe the general safety regulations when handling chemicals.

Avoid contact with the eyes, skin and mucous membranes.

Storage:

Store in the original container at 2 to 37°C.

Requirements to be met by storerooms and receptacles:

No special requirements.

*8. Exposure controls/personal protection

Ingredients with limit values that require monitoring in the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

Additional information:

The lists valid during the creation of this MSDS were used as a basis for this assessment.

General protective and hygienic measures:

Specimens should be handled as potentially infectious materials. Refer to Directive 2000/54/EC for information on handling biohazardous materials.

Adhere to good laboratory practices (GLP).

Wash hands before breaks and at the end of work. Clean work areas with hypochlorite or other disinfecting agent.

Personal protective equipment

Respiratory protection: Not required.

Protection of hands: Disposable gloves (sample handling).

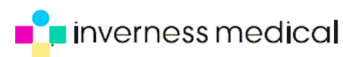
Material of gloves: Latex/natural rubber.

Penetration time of glove material: Gloves resistance is not critical when the product is handled according to the instructions for use.

Eye protection: Safety glasses recommended.

Body protection: Lab coat.

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9. Physical and chemical properties

General Information

Form: Solid test strip housed in a hinged book shape cardboard holder

Colour: White

Odour: Odourless

Flash point: Not applicable.

Self-igniting: Product is not self-igniting.

Danger of explosion: Product does not present an explosion hazard.

10. Stability and reactivity

Stability: The product is stable in accordance with the recommended storage conditions.

Materials to be avoided: strong acids, strong bases, strong oxidizers.

Hazardous reactions: Contact with acids may liberate trace amounts of toxic gas (hydrazoic acid).

Hazardous decomposition products: No dangerous decomposition products known.

11. Toxicological information

Acute toxicity:

Quantitative data on the toxic effects of this product is not available.

Primary effects

After skin contact: No irritating effects anticipated.

After eye contact: No irritating effects anticipated.

After ingestion: No significant harmful effects anticipated.

Sensitization: No sensitisation effects known.

12. Ecological information

Ecotoxic Effects:

Quantitative data on the toxic effects of this product are not available.

No ecological problems are to be expected when the product is handled and used with due care and attention.

13. Disposal considerations

Product:

Chemical residues and remains should be routinely handled as special waste. Used devices should be disposed of as potentially biohazardous material in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

European waste catalogue:

18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection

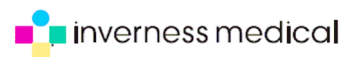
Packaging:

Disposal must be made in accordance with local waste management regulations.

Contaminated packaging must be disposed of in the same manner as the product.

Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

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14. Transport information

Land transport ADR/RID (cross-border):

Not regulated for transport.

Maritime transport IMDG:

Not regulated for transport.

Marine pollutant: No

Air transport ICAO-TI and IATA-DGR:

Not regulated for transport.

15. Regulatory information

Labelling according to EU guidelines:

Safety data sheet available for professional user on request.

Note:

The preparation is exempt from the above labelling requirements in accordance to Article 12.2 of Directive 99/45/EC as the form in which it is placed on the market does not present any significant risk to man or the environment when used according to the instructions for use.

16. Other information

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Relevant R-phrases:

22 Harmful if swallowed.

41 Risk of serious damage to eyes.

Reason for Update:

Change in contact information Section 1

General update in accordance with the REACH regulation.

* Indicates altered section.

Supersedes: Version 1

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