

Material Safety Data Sheet

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

Product details

Trade name: Alere PBP2a Test Strip

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

Manufacturer/Supplier:

Manufacturer

Alere Scarborough, Inc. 10 Southgate Road, Scarborough, Maine 04074, USA.

Tel: + 1 207-730-5750 Fax: + 1 207-730-5717 Email: ts.scr@alere.com

Further information obtainable from: www.alere.com

Information in case of emergency:

Tel: +1 207-730-5750

2. Hazards identification

Classification according to OSHA Hazard Communication Standard 29 CFR 1910.1200:

As an article, the device is exempt from OSHA's Hazard Communication Standard 29 CFR 1910.1200

3. Composition/information on ingredients

Chemical characterization

Description:

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

Dangerous components:

The preparation does not contain reportable quantities of dangerous components.

Additional information:

Dipstick and assay tube contained within a foil pouch.

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.

After ingestion: Wash mouth out with water. Consult a doctor in case of complaints.

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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) , nitrogen oxides (NO_x) , sulphur oxides (SO_x) , phosphorous oxides (P_xO_y) .

Protective equipment:

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

Additional information:

Non-combustible. Not considered a significant fire risk.

6. Accidental release measures

Personal 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 eyes, skin and mucous membranes.

Storage:

Store in original container at 2-30°C.

Requirements to be met by storerooms and receptacles:

No special requirements.

8. Exposure controls/personal protection

Ingredients with limit values the require monitoring in the workplace:

This 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 of 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: Glove 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: Laminated test strip and plastic assay tube housed within a workstation/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 date 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 sensitization 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:

Used devices should be disposed of as potentially biohazardous material in compliance with applicable federal, state, and local waste management regulations. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Packaging:

Disposal must be made in accordance with federal, state, and local waste management regulations.

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

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

14. Transport Information

US DOT Transport Regulations:

Not regulated for transport.

Maritime transport IMDG:

Not regulated for transport. **Marine pollutant:** No

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Air transport ICAO-TI and IATA-DGR:

Not regulated for transport.

15. Regulatory information

US Hazard warnings according to 16 CFR 1600 and ANSI Standard Z129.1:

Not required.

Chemical inventory listings relevant to US regulations:

Carcinogen listings:

IARC: None of the ingredients is listed.

NTP: None of the ingredients is listed.
ACGIH: None of the ingredients is listed.
OSHA: None of the ingredients is listed.
EPA: None of the ingredients is listed.

Californian Proposition 65:

Chemicals known to cause cancer: None of the ingredients is listed.

Chemicals known to cause reproductive toxicity:

None of the ingredients is listed.

SARA

Section 355 (extremely hazardous substances): None of the ingredients is listed.

Section 313 (specific toxic chemical listings): None of the ingredients is listed.

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 and 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.

Prepared by:

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