Conforms to EU Directive 91/155/EEC, as amended by 2001/58/EC - United Kingdom (UK)

SAFETY DATA SHEET



AmnioTest™

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

Identification of the substance or preparation

Product name : AmnioTest™
Code : PL.901

Use of the : AmnioTest™ is a convenient swab screening system intended as an aid in detecting

substance/preparation rupture of the amniotic membrane in pregnant women.

Company/undertaking identification

Supplier/Manufacturer: Pro-Lab Diagnostics

20 Mural Street, Unit 4 Richmond Hill, ON Canada L4B 1K3 Tel: +1-905-731-0300 Fax: +1-905-731-0206 www.pro-lab.com

Emergency telephone number: +44 (0)151 353 1613 -Monday to Friday 9:00 am to 5:00 pm.

+44 (0)7714 429 646 -Outside the above hours.

2. Composition/information on ingredients

Substance/preparation: Preparation

Within the present knowledge of the supplier, this product does not contain any hazardous ingredients in quantities requiring reporting in this section, in accordance with EU or national regulations.

3. Hazards identification

The preparation is not classified as dangerous according to Directive 1999/45/EC and its amendments.

Classification : Not classified.

See section 11 for more detailed information on health effects and symptoms.

4. First-aid measures

First-aid measures

Eye contact: Check for and remove any contact lenses. In case of contact with eyes, rinse

immediately with plenty of water. Obtain medical attention if symptoms occur.

Skin contact : Not applicable.

Inhalation : If inhaled, remove to fresh air. If not breathing, give artificial respiration. Get medical

attention if symptoms appear.

Ingestion: Do not induce vomiting. Never give anything by mouth to an unconscious person.

Get medical attention if symptoms appear.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training.

See section 11 for more detailed information on health effects and symptoms.

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5. Fire-fighting measures

Extinguishing media

Suitable

: Use an extinguishing agent suitable for the surrounding fire.

Not suitable

: None known.

Special exposure hazards

Special protective equipment for fire-fighters : No specific hazard.

: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

6. Accidental release measures

Personal precautions

: Immediately contact emergency personnel. Keep unnecessary personnel away. Use suitable protective equipment.

Environmental precautions

: Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Methods for cleaning up

: If emergency personnel are unavailable, vacuum or carefully scoop up spilt material and place in an appropriate container for disposal by incineration. Avoid creating dusty conditions and prevent wind dispersal.

7. Handling and storage

Handling

: Wash thoroughly after handling.

Storage

: Keep container tightly closed. Keep container in a cool, well-ventilated area.

Packaging materials

Recommended

: Use original container.

Exposure controls/personal protection

Exposure limit values

: Not available.

procedures

Recommended monitoring: If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to European Standard EN 689 for methods for the assessment of exposure by inhalation to chemical agents and national guidance documents for methods for the determination of hazardous substances.

Exposure controls

Occupational exposure controls

: No special ventilation requirements. Good general ventilation should be sufficient to control airborne levels. If this product contains ingredients with exposure limits, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.

Eye protection Skin protection : Safety glasses.

Lab coat.

Respiratory protection

: Not applicable.

Hand protection

Disposable vinyl gloves.



Hygiene measures

: Wash hands, forearms and face thoroughly after handling compounds and before eating, smoking and using the lavatory and at the end of the day. During formulation, follow good industrial hygiene practice.

Environmental exposure controls

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

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AmnioTest™

9. Physical and chemical properties

General information

Appearance

Physical state : Solid. (Disposable swabs impregnated with nitrazine yellow dye.)

Colour : Yellow. / Orange.

Important health, safety and environmental information

pH : Neutral.

Relative density : The only known value is 1

Solubility: Easily soluble in cold water, hot water, methanol, acetone.

10. Stability and reactivity

Stability: The product is stable.

Materials to avoid : Reactive with oxidizing materials.

11. Toxicological information

Potential acute health effects

Inhalation : No known significant effects or critical hazards.
 Ingestion : No known significant effects or critical hazards.
 Skin contact : No known significant effects or critical hazards.
 Eye contact : No known significant effects or critical hazards.

Potential chronic health effects

Carcinogenicity
 Mutagenicity
 No known significant effects or critical hazards.
 Reproductive toxicity
 No known significant effects or critical hazards.
 No known significant effects or critical hazards.

Over-exposure signs/symptoms

Inhalation
 Ingestion
 No known significant effects or critical hazards.
 Skin
 No known significant effects or critical hazards.
 No known significant effects or critical hazards.

12. Ecological information

Mobility : Not available.

13. Disposal considerations

Methods of disposal : The generation of waste should be avoided or minimized wherever possible. Avoid

dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal

legislation and any regional local authority requirements.

Hazardous waste : Within the present knowledge of the supplier, this product is not regarded as

hazardous waste, as defined by EU Directive 91/689/EEC.

14. Transport information

Regulatory information

UN/ IMDG/IATA / ADNR/ADR : Not regulated.

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15. Regulatory information

EU regulations

Risk phrases: This product is not classified according to EU legislation.

Contains : Not applicable.

Product use : Classification and labelling have been performed according to EU Directives

67/548/EEC and 1999/45/EC (including amendments) and the intended use.

- Industrial applications.

Other EU regulations

EU statistical classification: 32089091

(Tariff Code)

16. Other information

History

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Notice to reader

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.

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