



SAFETY DATA SHEET

AmnioTest™

Section 1. Identification

GHS product identifier : AmnioTest™

Other means of identification : Not available.

Trade name : AmnioTest™

Code
PL.901

Identified uses

AmnioTest™ is a qualitative, pH based, swab screening system intended as an aid in detecting rupture of the amniotic membrane in pregnant women.

Supplier's details : 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 (with hours of operation) : 905-731-0300 –Monday to Friday 8:30 am to 5:00 pm Eastern Standard Time.
416-230-0692 –Outside the above hours.

Section 2. Hazards identification

OSHA/HCS status : While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

Classification of the substance or mixture : Not classified.

GHS label elements

Signal word : No signal word.

Hazard statements : No known significant effects or critical hazards.

Precautionary statements

Prevention : Not applicable.

Response : Not applicable.

Storage : Not applicable.

Disposal : Not applicable.

Hazards not otherwise classified (HNOC)

Physical hazards not otherwise classified (PHNOC) : None known.

Health hazards not otherwise classified (HHNOC) : None known.



Section 3. Composition/information on ingredients

Substance/mixture : Mixture
Other means of identification : Not available.

CAS number/other identifiers

CAS number : Not applicable.

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section. Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.

Skin contact : Flush contaminated skin with plenty of water. Get medical attention if symptoms occur.

Ingestion : Wash out mouth with water. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

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

Over-exposure signs/symptoms

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

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : Treat symptomatically.
Specific treatments : No specific treatment.
Protection of first-aiders : No special protection is required.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.
Unsuitable extinguishing media : None known.

Section 5. Fire-fighting measures

- Specific hazards arising from the chemical** : No specific fire or explosion hazard.
- Hazardous thermal decomposition products** : No specific data.
- Special protective actions for fire-fighters** : No special measures are required.
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : Put on appropriate personal protective equipment.
- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".
- Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

- Spill** : Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8).
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.
- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. Store at room temperature (15°C to 30°C).

Section 8. Exposure controls/personal protection

Control parameters

United States

Occupational exposure limits

None.

Canada

Occupational exposure limits

None.

- Appropriate engineering controls** : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts.

Skin protection

Hand protection : Use gloves appropriate for work or task performed. Recommended: Disposable vinyl gloves.

Body protection : No special protective clothing is required.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Not required under normal conditions of use.

Section 9. Physical and chemical properties

Appearance

- Physical state** : Solid. [Cotton tipped swab with reagent present.]
- Color** : Yellow. / Orange.
- Odor** : Not available.
- Odor threshold** : Not available.
- pH** : Neutral.
- Melting point** : Not available.
- Boiling point** : Not available.
- Flash point** : Not applicable.
- Evaporation rate** : Not available.
- Flammability (solid, gas)** : Not applicable.
- Lower and upper explosive (flammable) limits** : Not available.
- Vapor pressure** : Not available.
- Vapor density** : Not available.
- Relative density** : Not available.

Section 9. Physical and chemical properties

| | |
|---|----------------------|
| Solubility | : Miscible in water. |
| Partition coefficient: n-octanol/water | : Not available. |
| Auto-ignition temperature | : Not available. |
| Decomposition temperature | : Not available. |
| Viscosity | : Not available. |
| Volatility | : Not available. |
| VOC (w/w) | : 0.03 % (w/w) |

Section 10. Stability and reactivity

| | |
|---|--|
| Reactivity | : No specific test data related to reactivity available for this product or its ingredients. |
| Chemical stability | : The product is stable. |
| Possibility of hazardous reactions | : Under normal conditions of storage and use, hazardous reactions will not occur. |
| Conditions to avoid | : No specific data. |
| Incompatible materials | : Reactive or incompatible with the following materials: oxidizing materials. |
| Hazardous decomposition products | : Under normal conditions of storage and use, hazardous decomposition products should not be produced. |

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

There is no data available.

Irritation/Corrosion

There is no data available.

Sensitization

There is no data available.

Carcinogenicity

There is no data available.

Specific target organ toxicity (single exposure)

There is no data available.

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Information on the likely routes of exposure : Dermal contact. Eye contact. Inhalation. Ingestion.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Section 11. Toxicological information

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

Symptoms related to the physical, chemical and toxicological characteristics

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

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

- Potential immediate effects** : No known significant effects or critical hazards.
Potential delayed effects : No known significant effects or critical hazards.

Long term exposure

- Potential immediate effects** : No known significant effects or critical hazards.
Potential delayed effects : No known significant effects or critical hazards.

Potential chronic health effects

- General** : No known significant effects or critical hazards.
Carcinogenicity : No known significant effects or critical hazards.
Mutagenicity : No known significant effects or critical hazards.
Teratogenicity : No known significant effects or critical hazards.
Developmental effects : No known significant effects or critical hazards.
Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

There is no data available.

Section 12. Ecological information

Toxicity

There is no data available.

Persistence and degradability

There is no data available.

Bioaccumulative potential

There is no data available.

Mobility in soil

- Soil/water partition coefficient (K_{oc})** : There is no data available.
Mobility : There is no data available.

Section 12. Ecological information

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

| | DOT | TDG | IMDG | IATA |
|-----------------------------------|----------------|----------------|----------------|----------------|
| UN number | Not regulated. | Not regulated. | Not regulated. | Not regulated. |
| UN proper shipping name | - | - | - | - |
| Transport hazard class(es) | - | - | - | - |
| Packing group | - | - | - | - |
| Environmental hazards | No. | No. | No. | No. |
| Additional information | - | - | - | - |

AERG : Not applicable.

Special precautions for user : Not applicable.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code : Not available.

Section 15. Regulatory information

U.S. Federal regulations : **United States inventory (TSCA 8b)**: All components are listed or exempted.
Clean Water Act (CWA) 311: Hydrogen Chloride

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

Section 15. Regulatory information

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

| Name | % | EHS | SARA 302 TPQ | | SARA 304 RQ | |
|-------------------|-------------|------|--------------|-----------|-------------|-----------|
| | | | (lbs) | (gallons) | (lbs) | (gallons) |
| Hydrogen Chloride | 0.025 - 0.1 | Yes. | - | - | - | - |

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : Not applicable.

SARA 313

No products were found.

State regulations

Massachusetts : None of the components are listed.

New York : None of the components are listed.

New Jersey : None of the components are listed.

Pennsylvania : None of the components are listed.

California Prop. 65

No products were found.

Canada

Canadian lists

Canadian NPRI : None of the components are listed.

CEPA Toxic substances : None of the components are listed.

Canada inventory : At least one component is not listed in DSL but all such components are listed in NDSL.

International lists

National inventory

Australia : Not determined.

China : All components are listed or exempted.

Europe : All components are listed or exempted.

Japan : All components are listed or exempted.

Malaysia : Not determined.

New Zealand : Not determined.

Philippines : All components are listed or exempted.

Republic of Korea : Not determined.

Taiwan : Not determined.

Section 16. Other information

History

Date of issue mm/dd/yyyy : 08/15/2015
Date of previous issue : 08/15/2012
Version : 4
Prepared by : KMK Regulatory Services Inc.

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.