



Date : 15/02/2017

Version : 5

SAFETY DATA SHEET

AmnioTest™

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name : AmnioTest™

Code
PL.901

Trade name : AmnioTest™

1.2 Relevant identified uses of the substance or mixture and uses advised against

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.

1.3 Details of the supplier of the safety data sheet

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

e-mail address of person responsible for this SDS : support@pro-lab.com

1.4 Emergency telephone number

Emergency telephone number (with hours of operation) : +44 (0)151 353 1613 -Monday to Friday 9:00 am to 5:00 pm.
+44 (0)7714 429 646 -Outside the above hours.

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition : Mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Not classified.

The product is not classified as hazardous according to Regulation (EC) 1272/2008 as amended.
See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Signal word : No signal word.

Hazard statements : No known significant effects or critical hazards.

Precautionary statements



SECTION 2: Hazards identification

Prevention : Not applicable.

Response : Not applicable.

Storage : Not applicable.

Disposal : Not applicable.

Hazardous ingredients : Not applicable.

Supplemental label elements : Not applicable.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles : Not applicable.

Special packaging requirements

Containers to be fitted with child-resistant fastenings : Not applicable.

Tactile warning of danger : Not applicable.

2.3 Other hazards

Other hazards which do not result in classification : None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures : Mixture

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, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

SECTION 4: First aid measures

4.1 Description of 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 : Not applicable.

Ingestion : Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

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

4.2 Most important symptoms and effects, both 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.

SECTION 4: First aid measures

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.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician : No specific treatment. Medical staff must contact Poison Control Center.

Specific treatments : No specific treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture : Non-flammable.

Hazardous combustion products : No specific data.

5.3 Advice for firefighters

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. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : Put on appropriate personal protective equipment.

For emergency responders : If specialised 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".

6.2 Environmental precautions : Avoid dispersal of spilt 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).

6.3 Methods and material for containment and cleaning up

SECTION 6: Accidental release measures

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, labelled waste container. Dispose of via a licensed waste disposal contractor.

6.4 Reference to other sections : See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

7.1 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.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed. Keep container in a cool, well-ventilated area. Store at room temperature (15°C to 30°C).

7.3 Specific end use(s)

Recommendations : Not available.
Industrial sector specific solutions : Not available.

SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance. Information is provided based on typical anticipated uses of the product. Additional measures might be required for bulk handling or other uses that could significantly increase worker exposure or environmental releases.

8.1 Control parameters

Occupational exposure limits

No exposure limit value known.

Recommended monitoring procedures : 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.

DNELs/DMELs

No DNELs/DMELs available.

PNECs

No PNECs available.

8.2 Exposure controls

Appropriate engineering controls : No special ventilation requirements. Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Individual protection measures

SECTION 8: Exposure controls/personal protection

- | | |
|--|---|
| 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. |
| 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 being 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. |
| Environmental exposure controls | : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. |

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

- | | |
|---|---|
| Physical state | : Solid. [Cotton tipped swab with reagent present.] |
| Colour | : Yellow. / Orange. |
| Odour | : Not available. |
| Odour threshold | : Not available. |
| pH | : Neutral. |
| Melting point/freezing point | : Not available. |
| Initial boiling point and boiling range | : Not available. |
| Flash point | : Not applicable. |
| Evaporation rate | : Not available. |
| Flammability (solid, gas) | : Not applicable. |
| Upper/lower flammability or explosive limits | : Not available. |
| Vapour pressure | : Not available. |
| Vapour density | : Not available. |
| Relative density | : Not available. |
| Solubility(ies) | : Miscible in water. |
| Partition coefficient: n-octanol/ water | : Not available. |
| Auto-ignition temperature | : Not available. |
| Decomposition temperature | : Not available. |
| Viscosity | : Not available. |
| Explosive properties | : Not available. |
| Oxidising properties | : Not available. |

9.2 Other information

SECTION 9: Physical and chemical properties

No additional information.

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

There is no data available.

Irritation/Corrosion

There is no data available.

Sensitisation

There is no data available.

Mutagenicity

There is no data available.

Carcinogenicity

There is no data available.

Reproductive toxicity

There is no data available.

Teratogenicity

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 likely routes of exposure : Dermal contact. Eye contact. Inhalation. Ingestion.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

SECTION 11: Toxicological information

- 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 as well as 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.

- Other information** : Not available.

SECTION 12: Ecological information

12.1 Toxicity

There is no data available.

12.2 Persistence and degradability

There is no data available.

12.3 Bioaccumulative potential

There is no data available.

12.4 Mobility in soil

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

12.5 Results of PBT and vPvB assessment

SECTION 12: Ecological information

PBT : Not applicable.
vPvB : Not applicable.

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

SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

13.1 Waste treatment methods

Product

Methods of disposal : The generation of waste should be avoided or minimised 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.

Hazardous waste : Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC.

Packaging

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions : 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 spilt material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
14.2 UN proper shipping name	-	-	-	-
14.3 Transport hazard class(es)	-	-	-	-
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.
Additional information	-	-	-	-

14.6 Special precautions for user : Not applicable.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

Annex XVII - Restrictions : Not applicable.
on the manufacture,
placing on the market and
use of certain dangerous
substances, mixtures and
articles

Other EU regulations

Europe inventory : All components are listed or exempted.

Ozone depleting substances (1005/2009/EU)

Not listed.

Prior Informed Consent (PIC) (649/2012/EU)

Not listed.

Seveso Directive

This product is not controlled under the Seveso Directive.

15.2 Chemical safety assessment : This product contains substances for which Chemical Safety Assessments are still required.

SECTION 16: Other information

Abbreviations and acronyms : ATE = Acute Toxicity Estimate
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level
EUH statement = CLP-specific Hazard statement
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
RRN = REACH Registration Number
vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Not classified.	

Full text of abbreviated H statements

Not applicable.

Full text of classifications [CLP/GHS]

SECTION 16: Other information

Not applicable.

History

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