1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name:	AMNISTRIP
Catalog #:	RAPB0513
Kit Components:	Strips Sterile Dacron vaginal swab Diluent Workstation

1.2 Intended Use

AMNISTRIP is an in vitro diagnosis medical device for the detection of amniotic fluid in vaginal swabs. This product is for use by healthcare professional only.

1.3 Company

DIAsource ImmunoAssays S.A.
Rue du Bosquet, 2
B-1348 Louvain-la-Neuve
Belgium
Tel. Nr. +32 (0)10/84.99.11
E-mail: products.support@diasource.be

1.4 Emergency telephone

DIAsource (only office hours): +32 (0)10/84.99.11
Centre Anti-Poisons (BE) 070 245 245
Please refer to your local Anti-Poison Center!

2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

The product contains Sodium azide in the buffer, at a concentration ≤ 0.1 %. So according to the classification rules related in the regulation 1272/2008, this product is non-hazardous.
Information about the sodium azide being present in the product is related on parts 2.3 and 3.
The product also contains some substances from animal origin. It is therefore recommended to handle it according to the convenient procedures relative to infectious material.

2.2 Label elements

Regarding Regulation 1721/2008, no particular statement is required since the product is not considered as hazardous.

2.3 Other hazards

Even in small amount, Sodium azide may react with lead and cooper plumbing to form highly explosive metal azides. Sodium azide is also rapidly absorbed through skin.

3 COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Product information

Cf. description of hazardous and non-hazardous components.

3.2 Hazardous components

Description	CAS Number	Einecs number	Origin	Concentration in the final product	Hazard classification and risk phrase*
Sodium azide	26628-22-8	247-852-1	Chemical	≤ 0,1 % of buffer	Acute toxicity 2, Acute aquatic tox. 1, Chronic aquatic tox. 1 H300, H410

*For the full text of H-statements and R-Phrases mentioned in this section, see Section 16

3.3 Non-hazardous compounds

Strip: Sample and conjugate pad: Glass fiber
Absorbent pad: Cellulose fiber
Nitrocellulose
Anti-IGFBP1 Ac
Anti-IGFBP1 Ac coupled with gold colloidal gold
PGD

Diluent: saline solution + BSA +Tween 20
Packaging: Aluminium foil pouches
Silica gel in paper bags

3.4 Confidential compounds

N/A

4 FIRST AID MEASURES

General information Consult a physician. Show this safety data sheet to the doctor in attendance.

After inhalation Expose to fresh air.
If breathing difficult, give oxygen. Consult a physician.

After skin contact: Rinse with water for at least 15 minutes. Consult a physician if irritation extended.

After eye contact: Flush with water for at least 15 minutes. If possible remove contact lenses. Consult doctor in case of prolonged irritation.

After swallowing: Rinse mouth. Contact the Poison Control Center.

5 FIRE FIGHTING MEASURES

Suitable extinguishing measures: No special measures. Adapt the measure to the environment

Extinguishing measures to avoid: No special measures

Special risk: Sodium oxides, no more special risk

Special protective equipment for the fire fighting : Wear self-contained breathing if necessary.

6 ACCIDENTAL RELEASE MEASURES

If any doubt, contact the person in charge of hygiene and safety.

6.1 Measure for individual protection

Use lab coat and gloves.

6.2 Measure for environmental protection

Do not throw the diluent into the sink.

6.3 Measures for cleaning and waste collection

Collect the test in containers according to official regulation.

7 HANDLING AND STORAGE

7.1 Precautions for safe handling

Use individual protective equipment (lab coat and gloves) for biological compound handling

7.2 Conditions for safe storage, including any incompatibilities

Information about storage in one common storage facility: The equipment must be stored between 2 and 30 ° C

Further information about storage condition: Do not freeze

7.3 Particular use

Professional in-vitro use only, See instruction for use.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposition cut off

Sodium azide: VLE= 0,3 mg/m^3
Sodium azide: VME= 0,1 mg/m^3

8.2 Individual exposure control

Respiratory exposure	N/A
Hand exposure	Gloves recommended
Eyes exposure	N/A
Skin exposure	Port of the coat

8.3 Environmental exposure control

Collect dipstick and buffer in containers according to the official local regulation.

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 General information

	Strip	Diluent
Aspect	Solid	Liquid
Colour	White	Colourless
Odour	N/A	N/A

9.2 Important information relatives to health, safety and environment

pH	neutral
Boiling point/range	N/A
Melting point/range	N/A
Flammability	None
Explosion limit	None
Ignition temperature	N/A
Self-ignition	N/A
Flash point	N/A
Danger of explosion	N/A
Explosion limit	N/A
Relative vapour density 20 °C	N/A
Density at 20 °C	N/A
Solubility in water at 20 °C	N/A

9.3 Other information

N/A

10 STABILITY AND REACTIVITY

10.1 Chemical stability:

No decomposition if used according to specifications

10.2 Reactivity:

Avoid contact with acidic solutions and metal compounds

10.3 Conditions to avoid:

Do not freeze

10.4 Incompatible materials:

Halogenated hydrocarbon, Metals, Acid, Acid chlorides

10.5 Hazardous decomposition products:

Vapours of chlorine, hydrochloric acid, hydrazoic acid can be formed in negligible quantities.

11 TOXICOLOGICAL INFORMATION

Immediate effects on health: Possibility of irritation in contact buffer extraction with skin and eyes: Rinse thoroughly. Possibility of irritation if swallowed buffer extraction: Contact a poison control center.

Differed and chronic effects on health:

Sensitization	no data available
Carcinogenicity	no data available
Mutagenicity	no data available
Toxicity for reproduction	no data available

Specific effects from particular compounds: No more known effects than described in phrase risk.

12 ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to daphnia and other aquatic invertebrates:
EC50 - Daphnia pulex (Water flea) - 4,2 mg/l - 48 h
No more data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

Very toxic to aquatic life with lasting effects

13 DISPOSAL CONSIDERATIONS

Products - recommendation:
Disposal must be made according to official regulation of medical samples elimination.

Unclean packaging - recommendation:
Must be composed together with household garbage.

14 TRANSPORT INFORMATION

Due to its composition, the product is not concerned by the transport regulation for dangerous products.

Maritime Transport IMDG:	No constraints
Transport by road ADR:	No constraints
Transport by train OACI/IATA:	No constraints
Air transport RID:	No constraints

15 REGULATORY INFORMATION

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

Product labelling complies with the 98/79/EC directive. No specific warning labelling is required.
This MSDS complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical Safety Assessment

No symbol is necessary based on our current knowledge.

16 OTHER INFORMATION

Text of H-phrases mentioned in section 3:

Hazard statement	Description
H300	Fatal if swallowed
H410	Very toxic to aquatic life with long lasting effects

The product is intended for in vitro diagnostic and destined to be used by health professionals. AMNISTRIP does not contain any hazardous substances beyond the limits set by the INRS (<0.3 mg/m^3). The toxic risk is then considerably reduced and acceptable.
The information in this document is based on the state of our current knowledge of the product. This document is composed in accordance with the Rules and Regulations REACH 1907/2006/EC and Article 31 from Directive 2001/58/EC.

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