

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Troponin I
Catalog #: RAPU04A097
Kit Components: Test Device
Transfer pipette (if applicable)

1.2 Intended Use

Rapid Test device for professional In vitro Diagnostic use. The Test is a rapid immunoassay test for the qualitative determination of Cardiac Troponin I in human whole blood, serum and plasma specimen.

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: tech.support@diasource.be

1.4 Emergency telephone

DIAsource (only office hours): +32 (0)10/84.99.23
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

Classification according to regulation (EC) No. 1272/2008 appendix VII: Not applicable

Classification according to regulation 67/548/EEC or regulation 1999/45/EC: Not applicable

2.2 Label elements

2.2.1 Labelling according to regulation (EC) No. 1272/2008

Hazard pictograms and Signal word: Not applicable

2.2.2 Hazardous components for labeling

Hazard statements: Not applicable

Precautionary statements: Not applicable

2.3 Other hazards

This substance/mixture contains no components that are assessed to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB).

3 COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Description of the mixture:

In vitro diagnostic medical device. Test strip impregnated with dried chemical / biochemical reagent, is cased in plastic cassette

Hazardous ingredients:

The product contains no substances which at their given concentration, are considered to be hazardous to health.

Additional information:

Not applicable

4 FIRST AID MEASURES

4.1 Description of first aid measures

General advice: Do not leave the victim unattended.

After Inhalation	Not expected to be an inhalation hazard with any component in this kit.
After skin contact	Contact with the test strip contained within the test cassette is unlikely.
After eye contact	Contact with the test strip contained within the test cassette is unlikely.
After Ingestion	If a component of this kit is ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No data available

4.3 Indication of any immediate medical attention and special treatment needed

No data available

5 FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	Use fire-extinguishing methods suitable to surrounding conditions.

5.2 Special hazards arising from the substance or mixture

No data available

5.3 Advice for fire fighters

No data available

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precaution, protective equipment and emergency procedures

Test strip of this kit contains materials of biological origin. Avoid personal contact. Use Universal Precautions during clean-up procedures involving patient samples.

6.2 Environmental Precautions

No environmental hazard is anticipated provided that this material is handled and disposed of with due care.

6.3 Methods and material for containment and cleaning-up

Pick up and arrange disposal. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

Collect material and dispose of waste according to section 13.

7 HANDLING AND STORAGE

7.1 Precautions for safe handling

Adhere to good laboratory practices (GLP) Wash hands before breaks and at the end of work. In areas where work, do not eat, drink or smoke.

7.2 Conditions for safe storage, including any incompatibilities

To maintain efficacy, store according to instruction in package insert.

7.3 Specific Use(s)

Rapid immunoassay for the qualitative detection of Cardiac Troponin I (cTnI) in human whole blood, serum and plasma specimen.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

This kit contains no substances with occupational exposure limit values.

8.2.2 Personal protective equipment:

General protective and hygienic measures	Adhere to good laboratory practices (GLP) Wash hands before breaks and at the end of work.
Respiratory protection	Not required
Protective gloves	Disposable gloves
Material of gloves	Latex/natural rubber
Penetration time of glove material	Gloves resistance is not critical when the product is handled according to the instruction for use.
Eye Protection	Safety glasses recommended while handling specimen

Body protection	Wearing a Lab coat recommended while handling specimen
------------------------	--

8.2.3 Enviromental exposure controls

There are no special precautions and measures. See section 6 and 7!

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical State	Solid
Appearance	Laminated test strip, housed in a plastic holder
Odour	Odourless
Odour threshold	not established
Flash point	not established
Self-igniting	The product is not self –igniting
Danger of explosion	There is no substances in the kit could lead to the danger of explosion
Melting point	not established
Boiling point	not established
Vapour pressure	not established
Density (20°C)	not established
pH-value at 20°C	not established
Solubility in water	Not soluble

9.2 Other safety information

Other physical-chemical data were not determined.

10 STABILITY AND REACTIVITY

10.1 Reactivity

No dangerous reaction known under condition of normal use.

10.2 Chemical Stability

The product is stable in accordance with the recommended storage conditions.

10.3 Possibility of hazardous reactions

Stable under recommended storage conditions. No hazards to be specially mentioned.

10.4 Conditions to Avoid

No information available.

10.5 Incompatible materials

No dangerous reaction known under condition of normal use.

10.6 Hazardous Decomposition Products

No data available.

11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity	No data available
Irritation	No data available
Corrosivity	No data available
Sensitisation	No data available
Repeated dose toxicity	No data available
Carcinogenicity	No data available
Mutagenicity	No data available
Toxicity for reproduction	No data available

12 ECOLOGICAL INFORMATION

12.1 Toxicity

Quantitative data on the toxic effects of this product is not available.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulation

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

This kit does not contain any substances that are assessed to be a PBT or vPvB.

12.6 Other adverse effects

No data available.

13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product	Used devices and other contaminated materials should be disposed of as extremely biohazardous waste. To ensure compliance with anti-pollution and other laws of the country concerned, we recommend that you contact the relevant (local) authorities and/or an approved waste disposal company for information.
European waste catalogue	18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection.
Packaging	Disposal must be made in accordance with local waste management regulations. Contaminated packaging must be disposed of in the same manner as the product. Non-Contaminated packaging materials may be recycled. Contact your local service providers for further informations.

14 TRANSPORT INFORMATION

14.1 UN-Number

Not applicable

14.2 UN proper shipping name

ADR/RID: Not applicable

IMDG-Code / ICAO-TI / IATA-DGR: Not applicable

14.3 Transport hazard class

No hazardous good.

14.4 Packing group

Not applicable

14.5 Environmental hazards

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: No

Marine Pollutant: No

14.6 Special precautions for user

See sections 6-8.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Delivery will only be taken in suitable and regulatory approved packaging.

15 REGULATORY INFORMATION

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

EU regulations: Not applicable

Germany: Not applicable

15.2 Chemical Safety Assessment

The mixture was not subjected to security assessment.

16 OTHER INFORMATION

General information

To the best of our knowledge, the information contained herein is accurate, but does not purport to be all inclusive and shall be used only as a guide. Therefore, the above named supplier 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 and mixtures 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.

Legend:

ADR: Accord européen relatif au transport international des marchandises Dangereuses par Route.
RID: Règlement internationale concernent le transport des marchandises dangereuses par chemin de fer.
IMDG: International Maritime Code for Dangerous goods
IATA: International Air Transport Association
ICAO: International Civil Aviation Organisation
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (devison of the American Chemical Society)

MSDS established : 2015-04-15
Revision number : 1