TULIP DIAGNOSTICS (P) LTD.
a revvity company
CIN: U85195GA1988PTC005717

Works:
Plot Nos. M 46 - 47, Phase III B, Verna Industrial Estate,
Verna, Goa - 403 722, INDIA.
Tel.: (0832) 6624502 / 6682000, Fax: (0832) 6680156.
E-mail: zephyr@tulipgroup.com

SAFETY DATA SHEET
AMICHECK-TROP I™ WB Device

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

1.1 Product identifier

Product name: AMICHECK-TROP I™ WB Device

Product code/(s): 506010010 , 506010003

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

Use of substance/mixture: Rapid, two-site sandwich immunoassay for the detection of human cardiac Troponin I (cTnI) levels in human whole blood, serum and plasma. This product is intended for IN VITRO diagnostic use only. NOT FOR USE IN HUMANS.

1.3 Details of the supplier of the safety data sheet

Company name: Zephyr Biomedicals,
A Division of Tulip Diagnostics (P) Ltd.
Plot nos. M 46-47, Phase III B,
Verna Industrial Estate,
Verna, Goa - 403 722,
INDIA.

www.tulipgroup.com

Tel: +91 (0832) 6682000 / 6624502

Fax: (0832) 6680156

Email: zephyr@tulipgroup.com

1.4 Emergency telephone number

Emergency tel: +91 (0832) 6682000 / +91 (0832) 6624502

(office hours only)

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Section 2 : Hazards identification

2.1 Classification of the substance or mixture

Classification under CLP: This product has no classification under CLP.
The product is regulated as an in vitro diagnostic medical device and is not considered hazardous in accordance with regulation (EC) No.1272/2008.

2.2 Label elements

Label elements: None are present.

Precautionary statements: P102: Keep out of reach of children.
P234: Keep only in original container.

2.3 Other hazards

PBT: This product is not identified as a PBT/vPvB substance.

Section 3 : Composition /information on ingredients

3.1 Substances

Chemical identity: In-Vitro Diagnostic test for Troponin I.

Contains: Contains no hazardous substances in reportable quantities under the CLP.

Section 4 : First aid measures

4.1 Description of first aid measures

Skin contact: Wash immediately with plenty of soap and water.

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. If eye irritation persists, seek medical advice/attention.

Ingestion: Do not induce vomiting. Wash mouth with water and give plenty of water to drink immediately. Obtain medical attention if necessary and show label on container.

Inhalation: Irritation is unlikely to occur but in the event of discomfort, provide plenty of fresh air and if necessary seek medical assistance.

4.2 Most important symptoms and effects, both acute and delayed

Skin contact: There may be mild irritation at the site of contact.
Eye contact: There may be irritation and redness.
Ingestion : There may be irritation of the throat.
Inhalation: No symptoms.

4.3 Indication of any immediate medical attention and special treatment needed

Immediate / special treatment: Not applicable.

Section 5: Fire -fighting measures

5.1 Extinguishing media

Extinguishing media: Suitable extinguishing media such as carbon dioxide, dry chemical powder or polymer foam for the surrounding fire should be used. Use water spray to cool containers.

5.2 Special hazards arising from the substance or mixture

Exposure hazards: No known specific hazards

5.3 Advice for fire fighters

Advice for fire-fighters: Do not enter fire without proper protective equipment, including respiratory protection.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

1. Follow Standard Biosafety guidelines during handling of potentially infectious human specimens.
2. Refer to section 8 of SDS for personal protection details.
3. Turn leaking containers leak-side up prevent the escape of liquid.

6.2 Environmental precautions

Environmental precautions: Do not discharge into drains or rivers.

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6.3 Methods and material for containment and cleaning up

Clean-up procedures: For small spills, clean up with paper/cloth, or mop up, and dispose off safely. Clean area of spillage down with plenty of water.

6.4 Reference to other sections

Reference to other sections: Refer to section 8 of SDS.

Section 7: Handling and storage

7.1 Precautions for safe handling

Handling requirements: Refer IFU for AMICHECK-TROP I™ WB Device.

7.2 Conditions for safe storage , including any incompatibilities

Storage conditions: Store in original container between 4°C to 30°C. Keep buffer container tightly closed and once opened must be carefully closed back and kept in upright position to prevent leakage.

Suitable packaging: Must only be kept in original packaging.

7.3 Specific end use(s)

Specific end use(s): Refer Section 1.2

Section 8: Exposure controls/personal protection

8.1 Control parameters

Workplace exposure limits: Contains no substance with occupational exposure limit values.

DNEL/PNEC Values

DNEL / PNEC No data available.

8.2 Exposure controls

Engineering measures: Ensure all engineering measures mentioned in section 7 of SDS are in place.

Respiratory protection: Respiratory protection not required. Ensure adequate ventilation.

Hand protection: Protective gloves.

Eye protection: No specific measures are required when using good safe practice.

Skin protection: Protective clothing not required in normal use. Use proper glove removal technique to avoid skin contact.

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Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

	Device	Sample Running Buffer
State :	Solid	Liquid
Colour :	White	Colourless
Odour :	Odourless	Odourless
Solubility in water :	Insoluble	Not Applicable
Viscosity :	Not Applicable	No data available
Boiling point/range°C:	No data available	No data available
Flash point°C:	No data available	No data available
Vapour pressure:	No data available	No data available
pH:	No data available	7.5
Melting point/range°C:	No data available	No data available
Auto flammability°C:	No data available	No data available
Relative density:	No data available	1.0

9.2 Other Information

Other information: No data available.

Section 10: Stability and reactivity

10.1 Reactivity

Reactivity: Stable under recommended transport or storage conditions.

10.2 Chemical stability

Chemical stability: Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions: Hazardous reactions will not occur under normal transport or storage conditions.

Zephyr Biomedicals
A Division of Tulip Diagnostics (P) Ltd.

Corporate Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Bambolim Complex
Post Office, Goa - 403 202, INDIA. Tel : (0832) 2458546-51, Fax: (0832) 2458544.
E-mail: sales@tulipgroup.com, Website: www.tulipgroup.com

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10.4 Conditions to avoid

Conditions to avoid: Heat and moisture

10.5 Incompatible materials

Materials to avoid: Strong acids /alkalines, oxidising / reducing agents.

10.6 Hazardous decomposition products

Hazardous decomposition products: No known hazardous decomposition products are formed in high quantities.

Section 11: Toxocological information

Section 11.1 Information on Toxocological effects

Toxicity values: No data available.

Symptoms/routes of exposure

Skin contact: There may be mild irritation at the site of contact

Eye contact: There may be irritation and redness.

Ingestion: There may be irritation of the throat.

Inhalation: No symptoms.

Section 12: Ecological information

12.1 Toxicity

Ecotoxicity values: No data available.

12.2 Persistence and degradability

Persistence and degradability :No data available

12.3 Bioaccumulative potential

Bioaccumulative potential: No data available.

12.4 Mobility in soil

Mobility: No data available.

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12.5 Results of PBT and vPvB assessment

PBT identification: This product is not identified as a PBT/vPvB substance.

12.6 Other adverse effects

Other adverse effects: Negligible ecotoxicity.

Section 13: Disposal considerations

13.1 Waste treatment methods

Disposal operations: Dispose off in accordance with current legislation and local authority regulations as per established safety procedures.

NB: The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

Section 14: Transport information

14.1 UN number

UN number: N/A

14.2 UN proper shipping name

Shipping name: This product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.3 Transport hazard class(es)

Non -hazardous for transport.

14.4 Packing group

N/A

14.5 Environmental hazards

Environmentally hazardous : Reagents in this kit & the sample running buffer contain Sodium Azide.

Marine pollutant: No

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14.6 Special precautions for user

Special precautions: 1. Shipper boxes should be arranged / stacked in the direction as indicated the shipper label / Carton.

2. Avoid over-stacking. Do not stack more than 5 boxes.

3. The reagent in this sample running buffer, contains Sodium Azide as a preservative. Sodium Azide has been reported to form Lead or Copper Azide in laboratory plumbing, which may explode on percussion. Flush drains with large volumes of water thoroughly after disposing of fluids containing Sodium Azide.

Section 15: Regulatory information

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

Specific regulations: Applicable national / regional or local regulations.
Safe for all kinds of modes of transportation.

15.2 Chemical Safety assessment

The Sample running buffer contain 0.1% of Sodium Azide (NaN_3) as preservative.
CAS:No.: 26628-228 EINECS-No.: 247-852-1

Xn

R22 - S23-46-61
NaN_3

Section 16: Other information

Legal disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.

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