

**Works:**Plot Nos. M 46 - 47, Phase III B, Verna Industrial Estate,  
Verna, Goa - 403 722, INDIA.

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## SAFETY DATA SHEET

### Dengucheck™ NS 1 Device

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**Section 1: Identification of the substance /mixture and of the company undertaking****1.1 Product identifier**

Product name: Dengucheck™ NS 1 Device

Product code: 502030010

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

**Use of substance/mixture:** Rapid, qualitative immunochromatographic test for the detection of Dengue NS 1 (Dengue Non-Structural Protein-1) antigen in human serum or plasma. The test can be used as a screening test in early phase of Dengue viral infection in conjunction with other criteria. 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](http://www.tulipgroup.com)

Tel: +91 (0832) 6682000 / 6624502

Fax: (0832) 6680156

Email: [zephyr@tulipgroup.com](mailto:zephyr@tulipgroup.com)**1.4 Emergency telephone number**

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

(office hours only)

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**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.  
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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 detection of Dengue NS 1 antigen.

**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.

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**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 Dengucheck™ NS 1 Device

**7.2 Conditions for safe storage , including any incompatibilities**

**Storage conditions:** Store in original container between 4°C to 30°C.

**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**

State: Solid

Colour: White

Odour: Odourless

Solubility in water: Insoluble

Viscosity: Not Applicable

Boiling point/range°C: No data available

Flash point°C: No data available

Vapour pressure: No data available.

pH: Not Applicable

Melting point/range°C: No data available.

Autoflammability°C: No data available.

Relative density: No data available.

**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.

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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: Toxicological information****Section 11.1 Information on Toxicological 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 Bio accumulative potential**

Bio accumulative 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 : No

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 on the shipper label / Carton.
  2. Avoid over-stacking. Do not stack more than 5 boxes.

**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**

Not carried out for this product.

**Section 16: Other information**

**Other information:** This safety data sheet is prepared in accordance with Commission Regulation (EU) No 453/2010.

**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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