

**Works:**

Plot No. 33, Sector-3, I.I.E., SIDCUL, Pantnagar (U.S. Nagar),

Uttarakhand - 263 153, INDIA.

Tel.: 9219474701 / 02 / 04 / 05.

E-mail: violadiagnostic@gmail.com

**MATERIAL SAFETY DATA SHEET****Product: Malascan Plus Device****Page 1 of 9****Section 1: Identification of the substance /mixture and of the company undertaking****1.1 Product identifier****Product name:** Malascan Plus Device  
Rapid Test for Malaria Pan/Pf Device**Product code:** 503140001, 503140010, 503140025, 503140050**1.2 Relevant identified uses of the substance or mixture and uses advised against****Use of substance/mixture:** Malascan Plus is a rapid, qualitative, two site sandwich Immunoassay utilizing whole blood for the detection of P. falciparum specific histidine rich protein-2 and Pan malaria specific pLDH.

This reagent 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:** Viola Diagnostic Systems – A Division of Tulip Diagnostics Pvt. Ltd.,  
Plot No. -33, Sector-3, IIE, SIDCUL, Pantnagar, U.S.Nagar, Uttarakhand-  
263153, India.**Tel. No. :** + 91 5944 - 250032, 250033**www.** tulipgroup.com**E-mail:** violadiagnostic@gmail.com , viola.rudrapur@tulipgroup.com**1.4 Emergency telephone number****Emergency tel:** + 91 5944 - 250032, 250033 (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:** Malascan Plus Device (Rapid Test for Malaria Pan/Pf Device)

**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.



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**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.





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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.

**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 Malascan Plus Device (Rapid Test for Malaria Pan/Pf Device)

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

**Storage conditions:** Store in original container between 1°C to 40°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:** No data available.

**DNEL/PNEC Values**





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**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.

**Section 9: Physical and chemical properties**

**9.1 Information on basic physical and chemical properties**

	<b>Cassette</b>	<b>Buffer</b>
<b>State :</b>	Solid	Liquid
<b>Colour :</b>	White	Colourless
<b>Odour :</b>	Odourless	Odourless
<b>Solubility in water :</b>	Insoluble	Not Applicable
<b>Viscosity :</b>	Not Applicable	No data available
<b>Boiling point/range°C:</b>	No data available	No data available
<b>Flash point°C:</b>	No data available	No data available
<b>Vapour pressure:</b>	No data available	No data available
<b>pH:</b>	No data available	8.5
<b>Melting point/range°C:</b>	No data available	No data available
<b>Auto flammability°C:</b>	No data available	No data available
<b>Relative density:</b>	No data available	No data available



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**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.

**10.4 Conditions to avoid**

**Conditions to avoid:** Heat and moisture

**10.5 Incompatible materials**

**Materials to avoid:** None known

**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.





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**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.

**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.



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**MATERIAL SAFETY DATA SHEET****Product: Malascan Plus Device****Page 8 of 9****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 & Clearing Buffer contain Sodium Azide.

**Marine pollutant:** No.

**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.





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### Section 15: Regulatory information

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

**Specific regulations:** Not applicable

Safe for all kinds of modes of transportation.

#### 15.2 Chemical Safety assessment

Not carried out for this product.

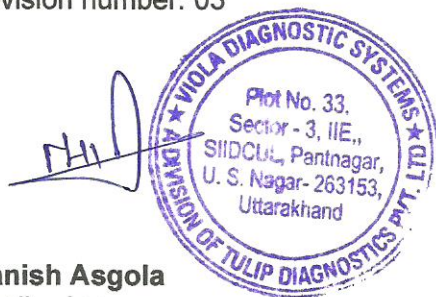
### Section 16: Other information

**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.

MSDS established: 2023

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**Manish Asgola**  
Quality Assurance  
Date: 02.11.2023