

**Works:**

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

Uttarakhand - 263 153, INDIA.

Tel.: 05944 250032/33.

E-mail: reception.viola@tulipgroup.com

## MATERIAL SAFETY DATA SHEET

Product: Virucheck® HBsAg Device

Page 1 of 9

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

#### 1.1 Product identifier

Product name: Virucheck® HBsAg Device  
One Step Test for HBsAg

Product code: 302010001, 302010010, 302010025, 302010050 & 302010100

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

Use of substance/mixture: Virucheck® -One Step Test for HBsAg is a rapid, qualitative, two site sandwich Immunoassay for the detection Hepatitis B surface antigen, a marker of Hepatitis B infections, in serum/plasma specimen.

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)



**Viola Diagnostic Systems**  
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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Product: Virucheck® HBsAg Device

Page 2 of 9

### 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:** Virucheck® HBsAg Device (One Step Test for HBsAg)

**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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## MATERIAL SAFETY DATA SHEET

Product: Viruclick® HBsAg Device

Page 3 of 9

**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.

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## MATERIAL SAFETY DATA SHEET

Product: Virucheck® HBsAg Device

Page 4 of 9

### 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 Virucheck® HBsAg Device (One Step Test for HBsAg)

### 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: No data available.

### DNEL/PNEC Values

DNEL / PNEC No data available.

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## MATERIAL SAFETY DATA SHEET

Product: Virucheck® HBsAg Device

Page 5 of 9

### 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

	Cassette
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:	No data available
Melting point/range°C:	No data available
Auto flammability°C:	No data available
Relative density:	No data available

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## MATERIAL SAFETY DATA SHEET

Product: Virucheck® HBsAg Device

Page 6 of 9

### 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 and direct sunlight.

#### 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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Product: Virucheck® HBsAg Device

Page 7 of 9

### 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: Virucheck® HBsAg 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 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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## MATERIAL SAFETY DATA SHEET

Product: Virucheck® HBsAg Device

Page 9 of 9

### 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

Revision number: 02



**Manish Asgola**  
Quality Assurance  
Date: 04.11.2023

