

DMSDS-007 Clearview Simplify D-dimer Test Strip.doc**1. SECTION 1: IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING****1.1 Product identifier**

Trade name

Clearview® Simplify D-dimer, Test Device

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

Identified use(s)

In vitro diagnostic reagent.
For professional use only.**1.3 Details of the supplier of the safety data sheet**

Company Identification

BBInternational, Dundee Facility
8 Tom McDonald Avenue, Medipark
Dundee, DD1 2NH
UK.

Telephone

+44 (0)1382 561000

E-Mail (competent person)

simplify@britishbiocell.co.uk

1.4 Emergency telephone number

Emergency Phone No.

+44 (0)2920 747232 (8:00 – 5:00)

2. SECTION 2: HAZARDS IDENTIFICATION**2.1 Classification of the substance or mixture****2.1.1 Regulation (EC) No. 1272/2008 (CLP)**

Not classified as dangerous for supply/use

2.1.2 Directive 67/548/EEC & Directive 1999/45/EC

Not classified as dangerous for supply/use

2.2 Label elements**2.2.1 Label elements**

GHS Product Identifier

According to Regulation (EC) No. 1272/2008 (CLP)

Hazard pictogram(s)

Not applicable

Signal word(s)

Not applicable

Hazard statement(s)

Not applicable

Precautionary statement(s)

Not applicable

2.3 Other hazards

None

3. SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS**3.1 Substances**

Not applicable

3.2 Mixtures

Description

In vitro diagnostic reagent test device

Preparation

Laminated test strip consisting of solid support materials impregnated with dried chemical / biochemical reagents.

Dangerous components

The product does not contain reportable quantities of dangerous components.

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4. SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General information

The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the test strip.

Inhalation

Not relevant for this material

Skin Contact

Wash skin with soap and water

Eye Contact

Rinse cautiously with water for several minutes. Consult doctor in case of complaint.

Ingestion

Wash out mouth with water. Consult a doctor.

4.2 Most important symptoms and effects, both acute and delayed

None known

4.3 Indication of the immediate medical attention and special treatment needed

None

5. SECTION 5: FIRE-FIGHTING MEASURES
5.1 Extinguishing media

Suitable Extinguishing Media

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released: Hazardous fumes and vapours

5.3 Advice for fire-fighters

Use fire-extinguishing methods suitable to surrounding conditions.
Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires.

6. SECTION 6: ACCIDENTAL RELEASE MEASURES
6.1 Personal precautions, protective equipment and emergency procedures

Refer to Section 8 for protective measures when handling the spillage.

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Collect material and dispose of as waste according to Section 13

6.4 Reference to other sections

8, 13

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7. SECTION 7: HANDLING AND STORAGE
7.1 Precautions for safe handling

Keep out of reach of children.
Observe the general safety regulations when handling chemicals.
Wash hands before breaks and after work.
Clean work areas with hypochlorite or other disinfecting agent.
Specimens should be handled as potentially infectious materials. Refer to Directive 2000/54/EC for information on handling biohazardous materials.

7.2 Conditions for safe storage, including any incompatibilities

Storage Temperature

Store in original container at 2 to 25°C

7.3 Specific end use(s)

Use as per instructions for use

8. SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION
8.1 Control parameters
8.1.1 Occupational Exposure Limits

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

8.2 Exposure controls
8.2.1 Appropriate engineering controls

Not relevant for this material

8.2.2 Personal protection equipment

Eye/face protection

Not normally required

Skin protection (Hand protection/ Other)

Disposable gloves (sample handling)
(EN374)



Material of gloves:

Latex / natural rubber

Penetration time of glove material:

Gloves resistance is not critical when the product is handled according to the instructions for use

Body protection

Laboratory coat

Respiratory protection

Not normally required

8.2.3 Environmental Exposure Controls

No special measures are required.

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9. SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
9.1 Information on basic physical and chemical properties

Appearance	Solid test strip housed in a plastic holder.
Colour	White & Purple
Odour	No odour
Odour Threshold (ppm)	Not applicable
pH (Value)	Not determined
Melting Point (°C) / Freezing Point (°C)	Not determined
Boiling point/boiling range (°C)	Not determined
Flash Point (°C)	Not applicable
Evaporation rate (BA = 1)	Not applicable
Flammability (solid, gas)	Not determined
Explosive limit ranges	Not applicable
Vapour Pressure (mm Hg)	Not applicable
Vapour Density (Air=1)	Not applicable
Density (g/ml)	Not determined
Solubility (Water)	Not determined
Solubility (Other)	Not determined
Partition Coefficient (n-Octanol/water)	Not determined
Auto Ignition Temperature (°C)	Not determined
Decomposition Temperature (°C)	Not determined
Viscosity (mPa.s)	Not determined
Explosive properties	Not explosive
Oxidising properties	Not oxidising

9.2 Other information

Not available

10. SECTION 10: STABILITY AND REACTIVITY
10.1 Reactivity

None known

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

None known. Hazardous polymerisation will not occur.

10.4 Conditions to avoid

None

10.5 Incompatible materials

None known

10.6 Hazardous decomposition product(s)

None known

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11. SECTION 11: TOXICOLOGICAL INFORMATION
11.1 Information on toxicological effects

Acute toxicity	Based upon the available data, the classification criteria are not met.
Irritation	Based upon the available data, the classification criteria are not met.
Corrosivity	Based upon the available data, the classification criteria are not met.
Sensitisation	Based upon the available data, the classification criteria are not met.
Repeated dose toxicity	No data
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Mutagenicity	No data
Toxicity for reproduction	Based upon the available data, the classification criteria are not met.
STOT-single exposure	Based upon the available data, the classification criteria are not met.
STOT-repeated exposure	Based upon the available data, the classification criteria are not met.
Aspiration hazard	Based upon the available data, the classification criteria are not met.

11.2 Other information
Potential Health Effects and Symptoms

Skin Contact	No significant harmful effects anticipated
Eye Contact	No significant harmful effects anticipated
Ingestion	No significant harmful effects anticipated
Inhalation	No significant harmful effects anticipated

12. SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity	The product does not contain significant quantities of ingredients that are environmentally toxic.
12.2 Persistence and degradability	The product is likely to persist in the environment
12.3 Bioaccumulative potential	None anticipated
12.4 Mobility in soil	The product is predicted to have low mobility in soil
12.5 Results of PBT and vPvB assessment	Not applicable
12.6 Other adverse effects	Not applicable

DMSDS-007 Clearview Simplify D-dimer Test Strip.doc**13. SECTION 13: DISPOSAL CONSIDERATIONS****13.1 Waste treatment methods****Product:**

Chemical residues and remains should be routinely handled as special waste. Used devices should be disposed of as potentially biohazardous material in compliance with antipollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste disposal company for information.

European waste catalogue:

18 01 03.

13.2 Packaging:

Disposal should be in accordance with local, state or national legislation. Packaging materials may be recycled. Contact your local service providers for further information.

14. SECTION 14: TRANSPORT INFORMATION**14.1 UN number**

Not applicable

14.2 UN Proper Shipping Name

Not applicable

14.3 Transport hazard class(es)

Not classified as dangerous for transport.

14.4 Packing Group

Not applicable

14.5 Environmental hazards

Not applicable

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable

15. SECTION 15: REGULATORY INFORMATION**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

In Vitro diagnostics medical devices directive 98/79/EC

15.2 Chemical Safety Assessment

Not applicable

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STOT

Specific Target Organ Toxicity

Additional InformationPrepared by: Dr. J. J. Tobin, ChemHaz Solutions, Email: info@chemhazsolutions.com

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