

SAFETY DATA SHEET

CCPOINT® TEST DEVICE

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Compilation date: 14/02/2017

Revision No: 1

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

1.1. Product identifier

Product name: CCPOINT® TEST DEVICE

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

Use of substance / mixture: Test device for in vitro diagnostic

1.3. Details of the supplier of the safety data sheet

Company name: BBI Solutions OEM Ltd

Cardiff Facility

73 Ty Glas Avenue

Cardiff

CF14 5DX

United Kingdom

Tel: +44 (0) 29 2074 7232

Email: info@bbisolutions.com

1.4. Emergency telephone number

Emergency tel: +44 (0) 29 2074 7232

(office hours only)

Section 2: Hazards identification

2.1. Classification of the substance or mixture

Classification under CLP: This product has no classification under CLP.

2.2. Label elements

Label elements: This product has no label elements.

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: CCPOINT® TEST DEVICE

Contains: Individually sealed pouch which contains 1 test strip in a plastic cassette with 1 desiccant pack. Each strip is composed of nitrocellulose membrane, backing card, sample pad, fibre pad, conjugate pad and absorbent pad.

The membrane, conjugate pad and sample pad, contain dried chemicals and biological material preserved by sodium azide.

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Section 4: First aid measures

4.1. Description of first aid measures

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

Eye contact: Bathe the eye with running water for 15 minutes. Consult a doctor if necessary

Ingestion: Ingestion of this material is unlikely Never give anything by mouth to an unconscious person Wash out mouth with water. Consult a doctor.

Inhalation: Move to fresh air Consult a doctor in case of complaint

4.2. Most important symptoms and effects, both acute and delayed

Skin contact: No data available.

Eye contact: No data available.

Ingestion: No data available.

Inhalation: No data available.

4.3. Indication of any immediate medical attention and special treatment needed

Immediate / special treatment: First aid measures are only relevant in event of exposure to chemicals on the test strips or as stated. This should not occur under normal conditions of use.

Section 5: Fire-fighting measures

5.1. Extinguishing media

Extinguishing media: Suitable extinguishing media for the surrounding fire should be used.

5.2. Special hazards arising from the substance or mixture

Exposure hazards: May evolve toxic fumes in fire

5.3. Advice for fire-fighters

Advice for fire-fighters: Wear self-contained breathing apparatus.

Section 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Refer to section 8 of SDS for personal protection details.

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: Wash the spillage site with water

6.4. Reference to other sections

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

Section 7: Handling and storage

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7.1. Precautions for safe handling

Handling requirements: Handle according to instructions for use

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Store at 2-25°C

Suitable packaging: Must only be kept in original packaging.

7.3. Specific end use(s)

Specific end use(s): Test device for in vitro diagnostic

Section 8: Exposure controls/personal protection

8.1. Control parameters

Workplace exposure limits: No data available.

DNEL/PNEC Values

DNEL / PNEC No data available.

8.2. Exposure controls

Engineering measures: Not required under normal working conditions

Respiratory protection: Respiratory protection not required.

Hand protection: Select gloves to meet the specifications of standard EN374

Eye protection: Safety glasses with side-shields.

Skin protection: Laboratory coat

Environmental: Do not let product enter the drains

Section 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

State: Solid

Evaporation rate: Not applicable.

Oxidising: No data available.

Solubility in water: No data available.

Viscosity: No data available.

Boiling point/range°C: Not applicable.

Flammability limits %: lower: No data available.

Flash point°C: No data available.

Autoflammability°C: No data available.

Relative density: No data available.

VOC g/l: No data available.

Melting point/range°C: Not applicable.

upper: No data available.

Part.coeff. n-octanol/water: Not applicable.

Vapour pressure: Not applicable.

pH: Not applicable.

9.2. Other information

Other information: No data available.

[cont...]

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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: The product contains sodium azide, which may react with lead to form explosive compounds. Contact with acids may liberate trace amounts of toxic gas (hydrazoic acid)

10.4. Conditions to avoid

Conditions to avoid: The product contains a low concentration of sodium azide, which may react with lead to form explosive compounds. Contact with acids may liberate trace amounts of toxic gas (hydrazoic acid). Hazardous polymerisation will not occur.

10.5. Incompatible materials

Materials to avoid: Acids.

10.6. Hazardous decomposition products

Haz. decomp. products: Contact with acids may liberate toxic gas

Section 11: Toxicological information

11.1. Information on toxicological effects

Toxicity values: No data available.

Symptoms / routes of exposure

Skin contact: No data available.

Eye contact: No data available.

Ingestion: No data available.

Inhalation: No data available.

Section 12: Ecological information

12.1. Toxicity

Ecotoxicity values: No data available.

12.2. Persistence and degradability

Persistence and degradability: Not biodegradable.

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: No data available.

Section 13: Disposal considerations

13.1. Waste treatment methods

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

Section 14: Transport information

Transport class: This product does not require a classification for transport.

Section 15: Regulatory information

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

Specific regulations: Not applicable.

15.2. Chemical Safety Assessment

Chemical safety assessment: A chemical safety assessment has not been carried out for the substance or the mixture by the supplier.

Section 16: Other information

Other information

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

* indicates text in the SDS which has changed since the last revision.

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.

