

Clearview IM Kit MSDS

Reference No. Kits:

501623

This document contains MSDS for the following kit components:

Test Device

Reagent 1

 2/10/07

Clearview IM, Test Device

SDS 022 Version 1

Date of issue: 02.October 2007

1. Identification of the substance/preparation and of the company/undertaking**Identification of the substance or preparation**Trade name: **Clearview IM, Test Device**

Reference No.: 501623

Use of the substance/preparation: In vitro diagnostic medical device. For professional use only.

Company/undertaking identification:

Unipath Ltd.,
Priory Business Park,
MK44 3UP,
United Kingdom.
Tel: +44 (0)1234 835000
Fax: +44 (0)1234 835009
Email: product.support@invmed.com

Further information obtainable from: www.clearview.com

Emergency telephone: +44 (0)1234 835000

2. Hazards identification**Hazard description:**

The test strip is not classified as dangerous according to directive 99/45/EC.

Information concerning particular hazards for human and environment:

Under the recommended conditions of use, there is no risk of exposure to any of the materials contained in the device.

Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

3. Composition/information on ingredients**Chemical characterisation****Description:**

In vitro diagnostics medical device. Test strip impregnated with dried chemical / biochemical reagents.

Dangerous components:

The device does not contain reportable quantities of hazardous components.

Additional information:

Each device is packaged in a foil pouch.



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4. 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 test strip.

After skin contact:

Wash with soap and water and rinse thoroughly.

After eye contact:

Rinse opened eye for several minutes under running water.

After ingestion:

If desiccant or other components are swallowed seek medical attention.

5. Fire-fighting measures

Suitable extinguishing agents:

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

Use fire-extinguishing methods suitable to surrounding conditions.

Special hazards caused by the substance, its products of combustion or resulting gases:

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

Protective equipment:

Wear full protective suit and self-contained respiratory protective device when extinguishing fires.

Additional information:

The device contains combustible materials.

6. Accidental release measures

Person-related safety precautions:

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

Measures for environmental protection:

Avoid release to the environment.

Measures for cleaning/collecting:

Collect material and dispose of as waste according to Section 13.

7. Handling and storage

Information for safe handling:

Keep out of reach of children.

Storage:

Store in the original container at 2...30°C.

Requirements to be met by storerooms and receptacles:

No special requirements.

8. Exposure controls/personal protection

Ingredients with limit values that require monitoring in the workplace:

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

Additional information:

The lists valid during the creation of this MSDS were used as a basis for this assessment.



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Personal protective equipment:**General protective and hygienic measures:**

- Adhere to good laboratory practices.
- Wash hands before breaks and at the end of work.

Respiratory protection:

Not required

Protection of hands:

Disposable gloves (for sample handling)

Material of gloves: Latex/natural rubber.**Penetration time of glove material:** Glove resistance is not critical as the gloves are intended to provide protection against the sample material.**Eye protection:**

Not required

Body protection:

Lab coat

9. Physical and chemical properties**General Information**

- Form:** The device is an article containing solid components
- Appearance:** Laminated test strip housed in a plastic holder.
- Odour:** Odourless
- Flash point:** Not applicable.
- Self-igniting:** Product is not self-igniting.
- Danger of explosion:** Product does not present an explosion hazard.

10. Stability and reactivity

- Stability:** The product is stable in accordance with the recommended storage conditions.
- Materials to be avoided:** None
- Hazardous reactions:** No dangerous reactions known.
- Hazardous decomposition products:** No dangerous decomposition products known.

11. Toxicological information**Acute toxicity:**

Quantitative data on the toxic effects of this product is not available.

Primary effects:

- After skin contact:** No irritating effects known.
- After eye contact:** No irritating effects known
- Sensitization:** No sensitizing effects known.

12. Ecological information**Environmental Toxicity:**

Quantitative data on the toxic effects of this product is not available.

Persistence and Degradability:

The device contains plastic and other components that are not readily degradable.



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13. Disposal considerations**Product:**

Used devices and other contaminated materials should be disposed of as potentially biohazardous waste. To ensure compliance with anti-pollution and other laws of the country concerned, we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

European waste catalogue:

18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection.

Packaging:

Disposal must be made in accordance with local waste management regulations. Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

14. Transport information**Land transport ADR/RID (cross-border)**

Not regulated for transport.

Maritime transport IMDG:

Not regulated for transport.

Marine pollutant: No

Air transport ICAO-TI and IATA-DGR:

Not regulated for transport.

15. Regulatory information**Labelling according to EU guidelines:**

No marking required.

16. Other information


To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Reason for Update:

General Update in accordance with REACH regulation.
All sections changed.

Supersedes: Unipath MSDS SDS/IM/002.1

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



Clearview IM, R1

SDS 022 Version 1

Date of issue: 02.October 2007

1. Identification of the substance/preparation and of the company/undertaking

Identification of the substance or preparation

Trade name: **Clearview IM, R1**

Reference No.: 501623

Use of the substance/preparation: In vitro diagnostic medical device. For professional use only.

Company/undertaking identification:

Unipath Ltd.,
 Priory Business Park,
 MK44 3UP,
 United Kingdom.
 Tel: +44 (0)1234 835000
 Fax: +44 (0)1234 835009
 Email: product.support@invmed.com

Further information obtainable from: www.clearview.com

Emergency telephone: +44 (0)1234 835000

2. Hazards identification

Hazard description:

Xn, Harmful

Information concerning particular hazards for human and environment:

R 22 Harmful if swallowed.

Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

3. Composition/information on ingredients

Chemical characterisation

Description:

Aqueous preparation containing the hazardous components listed below.

Dangerous components:

Component	CAS No.	EINECS No.	Classification	Concentration
Sodium Azide	26628-22-8	247-852-1	T+, N, R 28-32-50/53	0.1 – 0.2 %

Additional information:

For the wording of the listed risk phrases refer to section 16.

4. First-aid measures

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact:

Wash with soap and water and rinse thoroughly. Remove soiled clothing.

After eye contact:

Rinse opened eye for several minutes under running water. Consult a doctor in case of complaints.

After ingestion:

Wash out mouth with water. Consult a doctor.



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5. Fire-fighting measures

Suitable extinguishing agents:

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

Use fire-extinguishing methods suitable to surrounding conditions.

Special hazards caused by the substance, its products of combustion or resulting gases:

In case of fire, the following can be released: Nitrogen oxides (NO_x), Phosphorous oxides (P_xO_y).

Protective equipment:

Wear full protective suit and self-contained respiratory protective device when extinguishing fires.

6. Accidental release measures

Person-related safety precautions:

Isolate spillage and clean up immediately.

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

Measures for environmental protection:

Do not allow the undiluted product to enter sewers/surface or ground water.

Measures for cleaning/collecting:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders)

Dispose of contaminated material as waste according to Section 13.

Rinse off area with water.

7. Handling and storage

Information for safe handling:

Observe the general safety regulations when handling chemicals.

Avoid contact with the eyes, skin and mucous membranes.

Keep out of reach of children.

Storage:

Store in the original container at 2...30°C.

Requirements to be met by storerooms and receptacles:

No special requirements.

8. Exposure controls/personal protection

Ingredients with limit values that require monitoring in the workplace:

Sodium azide CAS No. 26628-22-8

UK WEL / IRL OELV 8-hour TWA: 0.1 mg/m³ Short-term value: 0.3 mg/m³ as NaN₃

Additional information:

The lists valid during the creation of this MSDS were used as a basis for this assessment.

Personal protective equipment:

General protective and hygienic measures:

Adhere to good laboratory practices (GLP).

Wash hands before breaks and at the end of work.

Respiratory protection:

Not required

Protection of hands:

Disposable gloves.

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.

Eye protection:

Not required

Body protection:

Lab coat



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9. Physical and chemical properties**General Information****Form:** Liquid**Colour:** Colourless**Odour:** Odourless**Change in condition****Melting point/Melting range:** Similar to water, approximately 0°C.**Boiling point/Boiling range:** Similar to water, approximately 100°C.**Flash point:** Not applicable.**Self-igniting:** Product is not self-igniting.**Danger of explosion:** Product does not present an explosion hazard.**Vapour pressure:** Similar to water, approximately 23 hPa.**Density at 20°C:** 1.01 g/cm³**Solubility in/Miscibility with:****Water:** Fully miscible.**pH-value at 20°C:** 7.0**10. Stability and reactivity****Stability:** The product is stable in accordance with the recommended storage conditions.**Materials to be avoided:** concentrated acids, heavy metals, metallic salts**Hazardous reactions:** Preparation contains sodium azide, which may react with lead to form explosive compounds. Contact with acids may liberate trace amounts of toxic (azide) gas.**Hazardous decomposition products:** No dangerous decomposition products known.**11. Toxicological information****Acute toxicity:**

Quantitative data on the toxic effects of this product is not available.

LD₅₀/LC₅₀ values relevant for classification:

Sodium azide CAS No. 26628-22-8

LD₅₀ (Oral, rat): 27 mg/kgTDL₀(Human): 0.71 mg/kgLD₅₀ (Dermal, rabbit): 20 mg/kg**Primary effects:****After skin contact:** No irritating effects anticipated.**After eye contact:** No irritating effect anticipated**After ingestion:** Possible systemic effects following ingestion of substantial quantities: headache, dizziness, nausea, vomiting,

CNS disorders, drop in blood pressure, cardiovascular failure, collapse.

Sensitization: No sensitizing effects known.**12. Ecological information****Ecotoxic Effects:**

Quantitative data on the toxic effects of this product are not available.

No ecological problems are to be expected when the product is handled and used with due care and attention.

Aquatic toxicity:

Sodium azide CAS No. 26628-22-8

LC₅₀ (96 h, Fish): 0.7 mg/lEC₅₀ (96 h, Daphnia): 4.2 mg/l**Mobility and bioaccumulation potential:**

Does not accumulate in organisms.



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13. Disposal considerations

Product:

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution 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.

To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent.

European waste catalogue:

18 01 06 chemicals consisting of or containing dangerous substances

Packaging:

Disposal must be made in accordance with local waste management regulations.

Contaminated packaging must be disposed of in the same manner as the product.

Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

14. Transport information

Land transport ADR/RID (cross-border)

Not regulated for transport.

Maritime transport IMDG:

Not regulated for transport.

Marine pollutant: No

Air transport ICAO-TI and IATA-DGR:

Not regulated for transport.

15. Regulatory information

Labelling according to EU guidelines:**Code letter and hazard designation of product:**

Xn Harmful

Hazard-determining components of labelling:

Sodium Azide

Risk phrases:

22 Harmful if swallowed.

Safety phrases:

2 Keep out of the reach of children.

35 This material and its container must be disposed of in a safe way.

46 If swallowed, seek medical advice immediately and show this container or label.

Water Hazard Class (Germany): WGK -, not hazardous for water.

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16. Other information

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Relevant R-phrases:

28 Very toxic if swallowed.

32 Contact with acids liberates very toxic gas.

50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Reason for Update:

Data update.

* Indicates altered section.

Supersedes: Unipath MSDS SDS/IM/002.1**Prepared by:** Dr. J. J. Tobin, ChemHaz Solutions,
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