

SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

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Uni-Gold HSV-2 Rapid Test Device 1206730

Revision 1

| | Revision date 2012-11-26 | |
|---------------------------------|---|--|
| SECTION 1: Identifica | ation of the substance/mixture and of the company/undertaking | |
| 1.1. Product identifier | | |
| Product name | Uni-Gold HSV-2 Rapid Test Device 1206730 | |
| Product code | 1206730 | |
| 1.3. Details of the suppl | ier of the safety data sheet | |
| Company | Trinity Biotech | |
| Address | IDA Business Park | |
| | Bray | |
| | Co. Wicklow | |
| | Ireland | |
| Web | www.trinitybiotech.com | |
| Telephone | +353 1 276 9800 | |
| Fax | +353 1 276 9883 | |
| Email | info@trinitybiotech.com | |
| Local Supplier | | |
| Company | Trinity Biotech USA | |
| Address | 2823 Girts Rd | |
| | Jamestown, NY | |
| | 14701 | |
| | USA | |
| Telephone | 800-325-3424 | |
| Fax | 716-487-1419 | |
| 1.4. Emergency telephone number | | |
| | Contact national poison unit: | |
| | Ireland 01-837-9964 | |
| | USA 1-800-603-8076 | |
| | France (+331) 40.37.04.04 | |
| SECTION 2: Hazarda | identification | |

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

| 2.1.1. Classification - | Xn; R22 R52/53 |
|-------------------------|--|
| 1999/45/EC | Symbols: Xn: Harmful. |
| Main hazards | Harmful if swallowed. Harmful to aquatic organisms, may cause long-term adverse effects in the |
| | aquatic environment. |

2.2. Label elements

Symbols Xn: Harmful.



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2.2. Label elements

Risk phrases R22 - Harmful if swallowed.

R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic

environment.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

67/548/EEC / 1999/45/EC

| Chemical Name | Index No. | CAS No. | EC No. | REACH Registration Number | Conc. (%w/w) | Classification |
|--------------------------------|--------------|------------|-----------|---------------------------|-----------------|-----------------------|
| Sodium azide (Sodium azide (as | 011-004-00-7 | 26628-22-8 | 247-852-1 | | 0 - 0.5% | T+; R28 R32 N; R50/53 |
| NaN3)) | | | | | | |

Description

For in vitro diagnostic use only. Test strip impregnated with dried chemical / biochemical reagents.

SECTION 4: First aid measures

4.1. Description of first aid measures

| Eye contact | Rinse immediately with plenty of water for 15 minutes holding the eyelids open. | |
|---------------------|---|--|
| Skin contact | Wash with soap and water. | |
| Ingestion | Seek medical attention. | |
| Our and lafe months | | |

General information

The above 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.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Carbon dioxide (CO2). Water spray. For large fires:. Alcohol resistant foam. Water spray.

5.2. Special hazards arising from the substance or mixture

Carbon oxides, Nitrogen oxides may be formed in fire conditions.

5.3. Advice for firefighters

Wear:. Protective equipment. Self-contained breathing apparatus.

Further information

Combustible materials.

SECTION 6: Accidental release measures

6.2. Environmental precautions

Avoid release to the environment. Refer to special instructions/Safety data sheets.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handle as if capable of transmitting a disease.

7.2. Conditions for safe storage, including any incompatibilities

Store at temperatures between 2 °C and 30 °C. Store in original container. Do NOT allow to freeze.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. Exposure Limit Values



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| 8.1.1. Exposure Li | imit Values |
|--------------------|-------------|
|--------------------|-------------|

| Sodium azide (Sodium azide (as | WEL 8-hr limit ppm: - | WEL 8-hr limit mg/m3: 0.1 |
|--------------------------------|-------------------------|-----------------------------|
| NaN3)) | WEL 15 min limit ppm: - | WEL 15 min limit mg/m3: 0.3 |

8.2. Exposure controls

| Skin protection - | Latex rubber gloves. |
|------------------------|-----------------------|
| Handprotection | |
| Respiratory protection | Not normally required |

SECTION 9: Physical and chemical properties

Further information

Laminated test strip housed in a plastic holder.

SECTION 10: Stability and reactivity

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Contact with acids liberates toxic gas.

10.5. Incompatible materials

No Significant Hazard.

10.6. Hazardous decomposition products

None.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

| Acute toxicity | No data is available on this product. | |
|-------------------------------|---------------------------------------|--|
| Skin corrosion/irritation | No irritation expected. | |
| Serious eye damage/irritation | No irritation expected. | |

11.1.4. Toxicological Information

| Uni-Gold HSV-2 Rapid Test | Oral Rat LD50: 27 mg/kg | Dermal Rabbit LD50: 20 mg/kg |
|---------------------------|-------------------------|------------------------------|
| Device 1206730 | | |

Further information

LD50 listed is specific to Sodium Azide, CAS No. 26628-22-8.

SECTION 12: Ecological information

12.1. Toxicity

| Uni-Gold HSV-2 Rapid Test Device 1206730 | Fish LC50/96h: 0.70000 mg/l |
|---|-----------------------------|
| | |

12.2. Persistence and degradability

Contains:. Plastic containers. Not readily biodegradable.

Further information

LC50 listed is specific to Sodium Azide, CAS No. 26628-22-8.

SECTION 13: Disposal considerations

General information

Disposal should be made in accordance with local and national disposal practices employed for blood products and is typically disposed as potentially infectious waste.

SECTION 14: Transport information

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| Further | information |
|----------|----------------|
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| | The product is not classified as dangerous for carriage. | | |
|--|--|--|--|
| SECTION 15: Regulatory inf | ormation | | |
| Further information | | | |
| | This SDS is prepared according to 29 CFR 1910.1200. | | |
| SECTION 16: Other information | tion | | |
| Other information | | | |
| Text of risk phrases in Section 3 R28 - Very toxic if swallowed. R32 - Contact with acids liberates very toxic gas. R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. | | | |
| Further information | Further information | | |
| | The information supplied in this Safety Data Sheet is designed only as guidance for the safe use, storage and handling of the product. This information is correct to the best of our knowledge and belief at the date of publication however no guarantee is made to its accuracy. This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process. | | |





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Revision date 2012-11-26

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|-------------------------------|--|
| SECTION 1: Identification | on of the substance/mixture and of the company/undertaking |
| 1.1. Product identifier | |
| Product name | Uni-Gold HSV-2 Rapid Test Buffer 6730 |
| Product code | 1206730 |
| 1.3. Details of the supplier | r of the safety data sheet |
| Company | Trinity Biotech |
| Address | IDA Business Park |
| | Bray |
| | Co. Wicklow |
| | Ireland |
| Web | www.trinitybiotech.com |
| Telephone | +353 1 276 9800 |
| Fax | +353 1 276 9883 |
| Email | info@trinitybiotech.com |
| Local Supplier | |
| Company | Trinity Biotech USA |
| Address | 2823 Girts Rd |
| | Jamestown, NY |
| | 14701 |
| | USA |
| Telephone | 800-325-3424 |
| Fax | 716-487-1419 |
| 1.4. Emergency telephone | e number |
| | Contact national poison unit: |
| | Ireland 01-837-9964 |
| | USA 1-800-603-8076 |
| | France (+331) 40.37.04.04 |
| SECTION 2: Hazards id | dentification |
| 2.1. Classification of the se | ubstance or mixture |
| | |

| 2.1.1. Classification - 1999/45/EC | Xn; R22 Symbols: Xn: Harmful. | |
|------------------------------------|----------------------------------|--|
| Main hazards | Harmful if swallowed. | |

2.2. Label elements

Symbols Xn: Harmful.

Risk phrases R22 - Harmful if swallowed

Uni-Gold HSV-2 Rapid Test Buffer 6730

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SECTION 3: Composition/information on ingredients

3.2. Mixtures

67/548/EEC / 1999/45/EC

| Chemical Name | Index No. | CAS No. | EC No. | REACH Registration Number | Conc. (%w/w) | Classification |
|---------------------------------------|--------------|------------|-----------|---------------------------|-----------------|-----------------------|
| Sodium azide (Sodium azide (as NaN3)) | 011-004-00-7 | 26628-22-8 | 247-852-1 | | 0 - 0.5% | T+; R28 R32 N; R50/53 |

Description

For in vitro diagnostic use only.

SECTION 4: First aid measures

4.1. Description of first aid measures

| Inhalation | Move the exposed person to fresh air. Seek medical attention if irritation or symptoms persist. |
|--------------|---|
| Eye contact | Rinse immediately with plenty of water for 15 minutes holding the eyelids open. Seek medical attention if irritation or symptoms persist. |
| | attention in initiation of symptoms persist. |
| Skin contact | Wash with soap and water. Remove contaminated clothing. |
| Ingestion | Flush mouth with water, without swallowing. Seek medical attention. |

SECTION 5: Firefighting measures

5.1. Extinguishing media

Carbon dioxide (CO2). Water spray. For large fires:. Alcohol resistant foam. Water spray.

5.2. Special hazards arising from the substance or mixture

Carbon oxides, Nitrogen oxides, Phosphorous oxides may be formed in fire conditions.

5.3. Advice for firefighters

Wear:. Protective equipment. Self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.2. Environmental precautions

Do not allow product to enter drains. Do not allow runoff water to enter sewers or drains. Do not flush into surface water.

6.3. Methods and material for containment and cleaning up

Absorb with inert, absorbent material. Sand. Binding agents. Dispose of as special waste in compliance with local and national regulations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Adopt best Manual Handling considerations when handling, carrying and dispensing. Avoid contact with eyes and skin. Do not breathe gas/fumes/vapour/spray.

7.2. Conditions for safe storage, including any incompatibilities

Store at temperatures between 2 °C and 30 °C. Store in original container. Do NOT allow to freeze.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. Exposure Limit Values

| Sodium azide (Sodium azide (as | WEL 8-hr limit ppm: - | WEL 8-hr limit mg/m3: 0.1 |
|--------------------------------|-------------------------|-----------------------------|
| NaN3)) | | |
| | WEL 15 min limit ppm: - | WEL 15 min limit mg/m3: 0.3 |



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8.2. Exposure controls

Respiratory protection

Skin protection -Handprotection

Latex rubber gloves.

Not normally required

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

State Liquid Colour

Colourless

Odour Odourless

> рΗ 7.4

Melting point ≈ 0

Boiling point ≈ 100

Flash point Not applicable.

Vapour pressure

≈ 23

Solubility

Explosive Not applicable.

Miscible in water

SECTION 10: Stability and reactivity

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Contact with acids liberates toxic gas.

10.5. Incompatible materials

Acids. Metal Salts. Heavy metals.

10.6. Hazardous decomposition products

None

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

No data is available on this product.

Skin corrosion/irritation

No irritation expected.

Serious eye damage/irritation

No irritation expected.

11.1.4. Toxicological Information

Uni-Gold HSV-2 Rapid Test Buffer 6730

Oral Rat LD50: 27 mg/kg

Dermal Rabbit LD50: 20 mg/kg

Further information

LD50 listed is specific to Sodium Azide, CAS No. 26628-22-8.

SECTION 12: Ecological information

12.1. Toxicity

Uni-Gold HSV-2 Rapid Test Buffer 6730

Fish LC50/96h: 0.70000 mg/l

Further information

LC50 listed is specific to Sodium Azide, CAS No. 26628-22-8

SECTION 13: Disposal considerations

General information

Disposal should be made in accordance with local and national regulations.

Uni-Gold HSV-2 Rapid Test Buffer 6730

Revision 1
Revision date 2012-11-26

| | Revision date 2012-11-26 |
|-----------------------------------|--|
| SECTION 14: Transport info | rmation |
| Further information | |
| | The product is not classified as dangerous for carriage. |
| SECTION 15: Regulatory inf | ormation |
| Further information | |
| | This SDS is prepared according to 29 CFR 1910.1200. |
| SECTION 16: Other information | tion |
| Other information | |
| Text of risk phrases in Section 3 | R28 - Very toxic if swallowed. R32 - Contact with acids liberates very toxic gas. R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. |
| Further information | |
| | The information supplied in this Safety Data Sheet is designed only as guidance for the safe use, storage and handling of the product. This information is correct to the best of our knowledge and belief at the date of publication however no guarantee is made to its accuracy. This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process. |

