

SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

Uni-Gold™ Giardia Test Device, 1206610-D, Rev. 2

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|--|
| SECTION 1: Identification of the substance/mixture and of the company/undertaking |
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| | |
|--------------------------------|--|
| 1.1. Product Identifier | |
| Product name | Uni-Gold™ Giardia Test Device, 1206610-D, Rev. 2 |
| Product code | 1206610 |

| | |
|---|---|
| 1.2. Relevant identified uses of the substance or mixture and uses advised against | |
| Product Use | [SU21] Consumer uses: Private households (= general public = consumers); [PC0] Other: |

| | |
|--|---|
| 1.3. Details of the supplier 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 Girls Rd Jamestown NY 14701 USA |
| Telephone | +1 800-325-3424 |
| Fax | +1 716-487-1419 |

| | |
|--|--|
| 1.4. Emergency telephone number | |
| | Contact your local Emergency Health Provider. Ireland-Technical Support Group 00353 -1- 276- 9800 USA-Technical Support Group 1-800-325-3424 |

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|--|
| SECTION 2: Hazards identification |
|--|

| | |
|--|-----------------------|
| 2.1. Classification of the substance or mixture | |
| Main hazards | No Significant Hazard |
| 2.2. Label elements | |
| Risk phrases | No Significant Hazard |

| |
|--|
| SECTION 3: Composition/information on ingredients |
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|----------------------|
| 3.2. Mixtures |
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Uni-Gold™ Giardia Test Device, 1206610-D, Rev. 2

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3.2. Mixtures

67/548/EEC / 1999/45/EC

| Chemical Name | Index No. | CAS No. | EC No. | REACH Registration Number | Conc. (%w/w) | Classification | M-factor. |
|---------------------------|-----------|---------|-----------|---------------------------|--------------|----------------|-----------|
| SUCROSE 005-265 (Sucrose) | | 57-50-1 | 200-334-9 | | | | |

EC 1272/2008

| Chemical Name | Index No. | CAS No. | EC No. | REACH Registration Number | Conc. (%w/w) | Classification | M-factor. |
|---------------------------|-----------|---------|-----------|---------------------------|--------------|----------------|-----------|
| SUCROSE 005-265 (Sucrose) | | 57-50-1 | 200-334-9 | | | | |

SECTION 4: First aid measures

4.1. Description of first aid measures

| | |
|-----------|---|
| Ingestion | If swallowed, rinse mouth with water (only if the person is conscious). |
|-----------|---|

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

| | |
|-----------|--|
| Ingestion | May be harmful by ingestion, inhalation or if absorbed through the skin. |
|-----------|--|

General Information

| | |
|--|---|
| | In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). |
|--|---|

SECTION 5: Firefighting measures

5.1. Extinguishing media

| | |
|--|---|
| | Use extinguishing media appropriate to the surrounding fire conditions. |
|--|---|

5.2. Special hazards arising from the substance or mixture

| | |
|--|---|
| | Burning produces irritating, toxic and obnoxious fumes. |
|--|---|

5.3. Advice for firefighters

| | |
|--|---|
| | Wear suitable respiratory equipment when necessary. |
|--|---|

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

| | |
|--|---|
| | Avoid formation of dust. Do not breathe dust. |
|--|---|

6.2. Environmental precautions

| | |
|--|--------------------------------|
| | No environmental requirements. |
|--|--------------------------------|

SECTION 7: Handling and storage

7.1. Precautions for safe handling

| | |
|--|-----------------------------------|
| | Avoid contact with skin and eyes. |
|--|-----------------------------------|

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. Exposure Limit Values

| | | |
|---------------------------|------------------------------|--------------------------------|
| SUCROSE 005-265 (Sucrose) | WEL 8-hr limit ppm: - | WEL 8-hr limit mg/m3: 10 |
| | WEL 15 min limit ppm: - | WEL 15 min limit mg/m3: 20 |
| | WEL 8-hr limit mg/m3 total - | WEL 15 min limit mg/m3 total - |
| | inhalable dust: | inhalable dust: |
| | WEL 8-hr limit mg/m3 total - | WEL 15 min limit mg/m3 total - |
| | respirable dust: | respirable dust: |

8.2. Exposure controls

| | |
|--|--|
| | |
|--|--|

Uni-Gold™ Giardia Test Device, 1206610-D, Rev. 2

Revision 2
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8.2. Exposure controls

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|------------|-----------|
| Appearance | Solid |
| Odour | Odourless |

SECTION 10: Stability and reactivity

Further Information

| | |
|--|---------------------------------|
| | Stable under normal conditions. |
|--|---------------------------------|

SECTION 11: Toxicological information

11.1. Information on toxicological effects

| | |
|---------------------------|--|
| Skin corrosion/irritation | May cause irritation to skin, eyes and mucous membranes. |
|---------------------------|--|

11.1.4. Toxicological Information

| | |
|-----------------|---------------------------|
| SUCROSE 005-265 | Oral Rat LD50: 29700mg/Kg |
|-----------------|---------------------------|

SECTION 12: Ecological information

SECTION 13: Disposal considerations

Disposal methods

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

Disposal of packaging

| | |
|--|--|
| | Containers must be recycled in compliance with national legislation and environmental regulations. |
|--|--|

SECTION 14: Transport information

ADR/RID

| | |
|--|--|
| | The product is not classified as dangerous for carriage. |
|--|--|

IMDG

| | |
|--|--|
| | The product is not classified as dangerous for carriage. |
|--|--|

IATA

| | |
|--|--|
| | The product is not classified as dangerous for carriage. |
|--|--|

SECTION 15: Regulatory information

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

| | |
|--|--|
| | <p>Complies with CFR 1910.1200.</p> <p>COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.</p> <p>REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.</p> |
|--|--|

Uni-Gold™ Giardia Test Device, 1206610-D, Rev. 2

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Revision date 2015-05-27

SECTION 16: Other information**Other 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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Uni-Gold™ Giardia Dilution Buffer, 1206610-B, Rev. 2

Revision 2
Revision date 2015-05-27

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

1.1. Product Identifier

| | |
|--------------|--|
| Product name | Uni-Gold™ Giardia Dilution Buffer, 1206610-B, Rev. 2 |
| Product code | 1206610 |

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

| | |
|-------------|---|
| Product Use | [SU21] Consumer uses: Private households (= general public = consumers); [PC0] Other; [PROC4] Use in batch and other process (synthesis) where opportunity for exposure arises; |
|-------------|---|

1.3. Details of the supplier 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 Girls Rd Jamestown NY 14701 USA |
| Telephone | +1 800-325-3424 |
| Fax | +1 716-487-1419 |

1.4. Emergency telephone number

| | |
|--|--|
| | Contact your local Emergency Health Provider. Ireland-Technical Support Group 00353 -1- 276- 9800 USA-Technical Support Group 1-800-325-3424 |
|--|--|

SECTION 2: Hazards Identification

2.1. Classification of the substance or mixture

| | |
|--------------|-----------------------|
| Main hazards | No Significant Hazard |
|--------------|-----------------------|

2.2. Label elements

| | |
|--------------|-----------------------|
| Risk phrases | No Significant Hazard |
|--------------|-----------------------|

SECTION 3: Composition/information on ingredients

SECTION 4: First aid measures

Uni-Gold™ Giardia Dilution Buffer, 1206610-B, Rev. 2

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Revision date 2015-05-27

4.1. Description of first aid measures

| | |
|--------------|---|
| Skin contact | Wash off immediately with plenty of soap and water. |
| Ingestion | Rinse mouth thoroughly. |

SECTION 5: Firefighting measures

5.1. Extinguishing media

| | |
|--|---|
| | Use extinguishing media appropriate to the surrounding fire conditions. |
|--|---|

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

| | |
|--|--|
| | Wear suitable protective clothing, gloves and eye/face protection. |
|--|--|

6.2. Environmental precautions

| | |
|--|-----------------------------------|
| | Prevent further spillage if safe. |
|--|-----------------------------------|

6.3. Methods and material for containment and cleaning up

| | |
|--|--|
| | Collect spilled liquid with absorbent material and place in a container for suitable disposal. |
|--|--|

SECTION 7: Handling and storage

7.1. Precautions for safe handling

| | |
|--|--|
| | Handle and open container with care. Avoid contact with eyes and skin. |
|--|--|

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

| | |
|-------------------------------------|--|
| Eye / face protection | Wear.. Eye protection. |
| Skin protection - Handprotection | Wear suitable gloves. Wash hands after handling the product. |

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|------------|-----------|
| Appearance | Liquid |
| Colour | Clear |
| Odour | Odourless |

SECTION 10: Stability and reactivity

10.2. Chemical stability

| | |
|--|---------------------------------|
| | Stable under normal conditions. |
|--|---------------------------------|

SECTION 11: Toxicological information

11.1. Information on toxicological effects

| | |
|---------------------------|--|
| Skin corrosion/irritation | May cause irritation to skin, eyes and mucous membranes. |
|---------------------------|--|

SECTION 12: Ecological information

SECTION 13: Disposal considerations

Disposal methods

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

Disposal of packaging

| | |
|--|---|
| | Empty containers can be sent for disposal or recycling. |
|--|---|

SECTION 14: Transport information

Uni-Gold™ Giardia Dilution Buffer, 1206610-B, Rev. 2

Revision 2
Revision date 2015-05-27**ADR/RID**

| | |
|--|--|
| | The product is not classified as dangerous for carriage. |
|--|--|

IMDG

| | |
|--|--|
| | The product is not classified as dangerous for carriage. |
|--|--|

IATA

| | |
|--|--|
| | The product is not classified as dangerous for carriage. |
|--|--|

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

| | |
|--|--|
| | <p>Complies with CFR 1910.1200.</p> <p>COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.</p> <p>REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.</p> |
|--|--|

SECTION 16: Other 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 2
Revision date 2015-05-27

| |
|--|
| SECTION 1: Identification of the substance/mixture and of the company/undertaking |
|--|

1.1. Product Identifier

| | |
|---------------------|--|
| Product name | Uni-Gold™ Giardia Positive and Negative Controls 1206611 P-N, Rev. 2 |
| Product code | 1206611 |

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

| | |
|--------------------|---|
| Product Use | [SU22] Professional uses: Public domain (administration, education, entertainment, services, craftsmen); [PC21] Laboratory chemicals; [PROC3] Use in closed batch process (synthesis or formulation); |
|--------------------|---|

1.3. Details of the supplier 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 Girls Rd Jamestown NY 14701 USA |
| Telephone | +1 800-325-3424 |
| Fax | +1 716-487-1419 |

1.4. Emergency telephone number

| | |
|--|--|
| | Contact your local Emergency Health Provider. Ireland-Technical Support Group 00353 -1- 276- 9800 USA-Technical Support Group 1-800-325-3424 |
|--|--|

| |
|--|
| SECTION 2: Hazards identification |
|--|


| | |
|--|------------------|
| 2.1. Classification of the substance or mixture | |
| 2.1.2. Classification - EC 1272/2008 | STOT SE 2: H371; |
| 2.2. Label elements | |

Uni-Gold™ Giardia Positive and Negative Controls 1206611 P-N, Rev. 2

Revision 2

Revision date 2015-05-27

2.2. Label elements

| | |
|-------------------------------------|---|
| Hazard pictograms |  |
| Signal Word | Warning |
| Hazard Statement | STOT SE 2: H371 - May cause damage to organs . |
| Precautionary Statement: Prevention | P260 - Do not breathe dust/fume/gas/mist/vapours/spray. P264 - Wash thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. |
| Precautionary Statement: Storage | P405 - Store locked up. |
| Precautionary Statement: Disposal | Disposal should be made in accordance with local and national regulations. P501 - Dispose of contents/container to |

2.3. Other hazards

| | |
|---------------|--|
| Other hazards | Caution ! All components containing biological material must be treated as potentially biohazardous. |
|---------------|--|

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 | M-factor. |
|---------------|--------------|---------|-----------|---------------------------|--------------|------------------------------------|-----------|
| Methanol | 603-001-00-X | 67-56-1 | 200-659-6 | | | F; R11 T; R23/24/25-39/23/24/25 | |

EC 1272/2008

| Chemical Name | Index No. | CAS No. | EC No. | REACH Registration Number | Conc. (%w/w) | Classification | M-factor. |
|---------------|--------------|---------|-----------|---------------------------|--------------|---|-----------|
| Methanol | 603-001-00-X | 67-56-1 | 200-659-6 | | | Flam. Liq. 2: H225; Acute Tox. 3: H331; Acute Tox. 3: H311; Acute Tox. 3: H301; STOT SE 1: H370; | |

SECTION 4: First aid measures

4.1. Description of first aid measures

| | |
|--------------|---|
| Inhalation | In case of accident by inhalation: remove casualty to fresh air and keep at rest. |
| Eye contact | In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. |
| Skin contact | After contact with skin, wash immediately with plenty of water. |
| Ingestion | IF SWALLOWED: rinse mouth. Do NOT induce vomiting. |

SECTION 5: Firefighting measures

5.1. Extinguishing media

| | |
|--|--|
| | Dispose of in compliance with all. local and national regulations. |
|--|--|

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

| | |
|--|---|
| | Use appropriate personal protective equipment. Avoid contact with eyes and skin. Do not breathe gas/fumes/vapour/spray. |
|--|---|

6.2. Environmental precautions

| | |
|--|--|
| | Collect spilled liquid with absorbent material and place in a container for suitable disposal. |
|--|--|

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Uni-Gold™ Giardia Positive and Negative Controls 1206611 P-N, Rev. 2

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7.1. Precautions for safe handling

Avoid contact with eyes and skin.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. Exposure Limit Values

| | | |
|----------|--|--|
| Methanol | WEL 8-hr limit ppm: 200 | WEL 8-hr limit mg/m3: 266 |
| | WEL 15 min limit ppm: 250 | WEL 15 min limit mg/m3: 333 |
| | WEL 8-hr limit mg/m3 total - Inhalable dust: | WEL 15 min limit mg/m3 total - Inhalable dust: |
| | WEL 8-hr limit mg/m3 total - respirable dust: | WEL 15 min limit mg/m3 total - respirable dust: |
| | | |
| | | |

8.2. Exposure controls

| | |
|---|---|
| 8.2.1. Appropriate engineering controls | Handle and open container with care. Wash hands after handling the product. |
| Eye / face protection | Wear eye/face protection. |
| Skin protection - Handprotection | Wear suitable gloves. |

SECTION 9: Physical and chemical properties

SECTION 10: Stability and reactivity

10.2. Chemical stability

Stable under normal conditions.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Skin corrosion/irritation Irritating to eyes, respiratory system and skin.

11.1.4. Toxicological information

| | | |
|----------|--------------------------------|--------------------------|
| Methanol | Inhalation Rat LC50/4 h: 128.2 | Oral Rat LD50: 1187-2769 |
| | Dermal Rabbit LD50: 17100 | |

SECTION 12: Ecological information

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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

SECTION 14: Transport information

ADR/RID

The product is not classified as dangerous for carriage.

IMDG

The product is not classified as dangerous for carriage.

IATA

The product is not classified as dangerous for carriage.

Uni-Gold™ Giardia Positive and Negative Controls 1206611 P-N, Rev. 2

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Revision date 2015-05-27

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

| | |
|--|--|
| | <p>Complies with CFR 1910.1200.</p> <p>COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.</p> <p>REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.</p> |
|--|--|

SECTION 16: Other information**Other information**

| | |
|---|--|
| Text of risk phrases in Section 3 | <p>R11 - Highly flammable.</p> <p>R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.</p> <p>R39/23/24/25 - Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.</p> |
| Text of Hazard Statements in Section 3 | <p>Flam. Liq. 2: H225 - Highly flammable liquid and vapour.</p> <p>Acute Tox. 3: H301 - Toxic if swallowed.</p> <p>Acute Tox. 3: H311 - Toxic in contact with skin.</p> <p>Acute Tox. 3: H331 - Toxic if inhaled.</p> <p>STOT SE 1: H370 - Causes damage to organs .</p> |

Further information

| | |
|--|---|
| | <p>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.</p> |
|--|---|