

SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

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Uni-Gold™ H. pylori Antigen Test Device 1206650-D, Rev. 2

Revision 2
Revision date 2015-05-28

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

1.1. Product identifier

Product name	Uni-Gold™ H. pylori Antigen Test Device 1206650-D, Rev. 2
Product code	1206650

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
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2.2. Label elements

Risk phrases	No Significant Hazard
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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	M-factor.
SUCROSE 005-265 (Sucrose)		57-50-1	200-334-9				

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3.2. Mixtures

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				
5-Chloro-2-methyl-2H-isothiazol-3-one		26172-55-4	247-500-7			Acute Tox. 4: H302; Skin Corr. 1A: H314; Skin Sens. 1: H317; Acute Tox. 3: H331; STOT SE 3: H335; Aquatic Acute 1: H400;	
2-Methyl-2H-isothiazol-3-one		2682-20-4	220-239-6				
CASEIN 005-297		9000-71-9	232-555-1				
TRIS		77-86-1	201-064-4			Skin Irrit. 2: H315; Eye Irrit. 2: H319; STOT SE 3: H335;	

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	If breathing is difficult give oxygen. Move the exposed person to fresh air. Seek medical attention.
Eye contact	Contact lenses should be removed. Rinse immediately with plenty of water for 15 minutes. Seek medical attention if irritation or symptoms persist.
Skin contact	Rinse immediately with plenty of water. Seek medical attention if irritation or symptoms persist.
Ingestion	Never give anything by mouth to an unconscious person. Rinse mouth thoroughly. Seek medical attention.

SECTION 5: Firefighting measures

5.1. Extinguishing media

	Use extinguishing media appropriate to the surrounding fire conditions.
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5.2. Special hazards arising from the substance or mixture

	Burning produces irritating, toxic and obnoxious fumes. Carbon dioxide (CO ₂).
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5.3. Advice for firefighters

	Wear suitable respiratory equipment when necessary.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

	Do not breathe gas/fumes/vapour/spray. Ensure adequate ventilation of the working area. Evacuate personnel to a safe area. Wear suitable protective clothing and gloves.
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6.2. Environmental precautions

	Do not allow runoff water to enter sewers or drains. Prevent further spillage if safe. Avoid release to the environment. Refer to special instructions/Safety data sheets.
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6.3. Methods and material for containment and cleaning up

	Dispose of as special waste in compliance with local and national regulations.
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SECTION 7: Handling and storage

7.1. Precautions for safe handling

	Avoid contact with eyes and skin. Wear suitable protective clothing and gloves.
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7.2. Conditions for safe storage, including any incompatibilities

	Store at temperatures between 2 °C and 30 °C. Keep container tightly closed. Store in correctly labelled containers.
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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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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 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

8.2.2. Individual protection measures	Wash hands after handling the product. Wear eye/face protection. Wear suitable gloves.
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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Solid
Colour	White

SECTION 10: Stability and reactivity

10.2. Chemical stability

	Stable under normal conditions.
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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Skin corrosion/irritation	May cause irritation to skin, eyes and mucous membranes.
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11.1.4. Toxicological information

SUCROSE 005-265	Oral Rat LD50: 29700mg/Kg
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SECTION 12: Ecological information

Further information

	No data is available on this product.
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SECTION 13: Disposal considerations

Disposal methods

	Dispose of as special waste in compliance with local and national regulations.
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Disposal of packaging

	This material and its container must be disposed of as hazardous waste.
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SECTION 14: Transport information

ADR/RID

	The product is not classified as dangerous for carriage.
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IMDG

	The product is not classified as dangerous for carriage.
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IATA

	The product is not classified as dangerous for carriage.
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SECTION 15: Regulatory information

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

	Complies with CFR 1910.1200. 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.
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15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

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.

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.

SECTION 16: Other information**Other Information****Text of Hazard Statements in Section 3**

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.

Acute Tox. 4: H302 - Harmful if swallowed.
 Skin Corr. 1A: H314 - Causes severe skin burns and eye damage.
 Skin Sens. 1: H317 - May cause an allergic skin reaction.
 Acute Tox. 3: H331 - Toxic if inhaled.
 STOT SE 3: H335 - May cause respiratory irritation.
 Aquatic Acute 1: H400 - Very toxic to aquatic life.
 Skin Irrit. 2: H315 - Causes skin irritation.
 Eye Irrit. 2: H319 - Causes serious eye irritation.

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Uni-Gold™ H. pylori Antigen Sample Dilution Buffer, 1206650-B, Rev. 2

Revision 2
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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product Identifier

Product name	Uni-Gold™ H. pylori Antigen Sample Dilution Buffer, 1206650-B, Rev. 2
Product code	1206650

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
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2.2. Label elements

Risk phrases	No Significant Hazard
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SECTION 3: Composition/information on ingredients

3.2. Mixtures

Uni-Gold™ H. pylori Antigen Sample Dilution Buffer, 1206650-B, Rev. 2

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3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
TRIS		77-86-1	201-064-4			Skin Irrit. 2: H315; Eye Irrit. 2: H319; STOT SE 3: H335;	
Bovine Serum Albumin		9048-46-8					
Sodium azide (Sodium azide (as NaN ₃))	011-004-00-7	26628-22-8	247-852-1			Acute Tox. 2: H300; Aquatic Acute 1: H400; Aquatic Chronic 1: H410;	

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	If breathing is difficult give oxygen. Move the exposed person to fresh air. Seek medical attention.
Eye contact	Contact lenses should be removed. Rinse immediately with plenty of water for 15 minutes. Seek medical attention if irritation or symptoms persist.
Skin contact	Rinse immediately with plenty of water. Seek medical attention if irritation or symptoms persist.
Ingestion	Never give anything by mouth to an unconscious person. Rinse mouth thoroughly. Seek medical attention.

SECTION 5: Firefighting measures

5.1. Extinguishing media

	Use extinguishing media appropriate to the surrounding fire conditions.
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5.2. Special hazards arising from the substance or mixture

	Burning produces irritating, toxic and obnoxious fumes. Carbon dioxide (CO ₂).
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5.3. Advice for firefighters

	Wear suitable respiratory equipment when necessary.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

	Do not breathe gas/fumes/vapour/spray. Ensure adequate ventilation of the working area. Evacuate personnel to a safe area. Wear suitable protective clothing and gloves. Caution ! All components containing biological material must be treated as potentially biohazardous.
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6.2. Environmental precautions

	Do not allow runoff water to enter sewers or drains. Prevent further spillage if safe. Avoid release to the environment. Refer to special instructions/Safety data sheets.
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6.3. Methods and material for containment and cleaning up

	Dispose of as special waste in compliance with local and national regulations.
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SECTION 7: Handling and storage

7.1. Precautions for safe handling

	Avoid contact with eyes and skin. Wear suitable protective clothing and gloves. Caution ! All components containing biological material must be treated as potentially biohazardous.
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7.2. Conditions for safe storage, including any incompatibilities

	Store at temperatures between 2 °C and 30 °C. Keep container tightly closed. Store in correctly labelled containers.
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SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

8.2.2. Individual protection measures	Wash hands after handling the product. Wear eye/face protection. Wear suitable gloves.
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SECTION 9: Physical and chemical properties

Uni-Gold™ H. pylori Antigen Sample Dilution Buffer, 1206650-B, Rev. 2

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9.1. Information on basic physical and chemical properties

Appearance	Liquid
Colour	Colourless
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

Dispose of as special waste in compliance 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.

SECTION 15: Regulatory information

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

This SDS is prepared according to 29 CFR 1910.1200.

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.

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SECTION 16: Other information

Other information

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Other Information

Text of Hazard Statements In Section 3

Skin Irrit. 2: H315 - Causes skin irritation.
Eye Irrit. 2: H319 - Causes serious eye irritation.
STOT SE 3: H335 - May cause respiratory irritation.
EUH032 - Contact with acids liberates very toxic gas.
Acute Tox. 2: H300 - Fatal if swallowed.
Aquatic Acute 1: H400 - Very toxic to aquatic life.
Aquatic Chronic 1: H410 - Very toxic to aquatic life with long lasting effects.

SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

Uni-Gold™ H. pylori Antigen Controls, 1206651 P/N, Rev. 2

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

1.1. Product identifier	
Product name	Uni-Gold™ H. pylori Antigen Controls, 1206651 P/N, Rev. 2
Product code	1206651

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

3.2. Mixtures	
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Uni-Gold™ H. pylori Antigen Controls, 1206651 P/N, Rev. 2

Revision 2

Revision date 2015-05-29

3.2. Mixtures**EC 1272/2008**

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
TRIS		77-86-1	201-064-4			Skin Irrit. 2: H315; Eye Irrit. 2: H319; STOT SE 3: H335;	
Bovine Serum Albumin		9048-46-8					
Sodium azide (Sodium azide (as NaN ₃))	011-004-00-7	28828-22-8	247-852-1			Acute Tox. 2: H300; Aquatic Acute 1: H400; Aquatic Chronic 1: H410;	

SECTION 4: First aid measures**4.1. Description of first aid measures**

Inhalation	If breathing is difficult give oxygen. Move the exposed person to fresh air. Seek medical attention.
Eye contact	Contact lenses should be removed. Rinse immediately with plenty of water for 15 minutes. Seek medical attention if irritation or symptoms persist.
Skin contact	Rinse immediately with plenty of water. Seek medical attention if irritation or symptoms persist.
Ingestion	Never give anything by mouth to an unconscious person. Rinse mouth thoroughly. Seek medical attention.

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. Carbon dioxide (CO ₂).
--	--------------------------------------------------------------------------------------------

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**

	Do not breathe gas/fumes/vapour/spray. Ensure adequate ventilation of the working area. Evacuate personnel to a safe area. Wear suitable protective clothing and gloves. Caution ! All components containing biological material must be treated as potentially biohazardous.
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6.2. Environmental precautions

	Do not allow runoff water to enter sewers or drains. Prevent further spillage if safe. Avoid release to the environment. Refer to special instructions/Safety data sheets.
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6.3. Methods and material for containment and cleaning up

	Dispose of as special waste in compliance with local and national regulations.
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SECTION 7: Handling and storage**7.1. Precautions for safe handling**

	Avoid contact with eyes and skin. Wear suitable protective clothing and gloves. Caution ! All components containing biological material must be treated as potentially biohazardous.
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7.2. Conditions for safe storage, including any incompatibilities

	Store at temperatures between 2 °C and 8 °C. Keep container tightly closed. Store in correctly labelled containers.
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SECTION 8: Exposure controls/personal protection**8.2. Exposure controls**

8.2.2. Individual protection measures	Wash hands after handling the product. Wear eye/face protection. Wear suitable gloves.
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SECTION 9: Physical and chemical properties

Uni-Gold™ H. pylori Antigen Controls, 1206651 P/N, Rev. 2

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9.1. Information on basic physical and chemical properties

Appearance	Liquid
Colour	Colourless
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.
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SECTION 12: Ecological information

SECTION 13: Disposal considerations

Disposal methods

Dispose of as special waste in compliance 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.

SECTION 15: Regulatory information

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SECTION 16: Other information

Other Information

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Uni-Gold™ H. pylori Antigen Controls, 1206651 P/N, Rev. 2

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Other Information**Text of Hazard Statements In Section 3**

Skin Irrit. 2: H315 - Causes skin irritation.
Eye Irrit. 2: H319 - Causes serious eye irritation.
STOT SE 3: H335 - May cause respiratory irritation.
EUH032 - Contact with acids liberates very toxic gas.
Acute Tox. 2: H300 - Fatal if swallowed.
Aquatic Acute 1: H400 - Very toxic to aquatic life.
Aquatic Chronic 1: H410 - Very toxic to aquatic life with long lasting effects.