

## SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

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### Uni-Gold™ C. difficile GDH Device and Buffer, 1206640D-B, 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™ C. difficile GDH Device and Buffer, 1206640D-B, Rev. 2
Product code	1206640

##### 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
<b>Local Supplier</b>	
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

	In accordance with EC directives, this product does not need to be labelled.
Risk phrases	No Significant Hazard

#### SECTION 3: Composition/Information on Ingredients

##### 3.1. Substances

## Uni-Gold™ C. difficile GDH Device and Buffer, 1206640D-B, Rev. 2

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**3.1. Substances****67/548/EEC / 1999/45/EC**

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
TEMPLATE No significant hazard Liquid							

**EC 1272/2008**

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
TEMPLATE No significant hazard Liquid							

**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	DO NOT INDUCE VOMITTING. Rinse mouth thoroughly. Seek medical attention. Never give anything by mouth to an unconscious person.

**SECTION 5: Firefighting measures****5.1. Extinguishing media**

	Use extinguishing media appropriate to the surrounding fire conditions. Alcohol resistant foam. Carbon dioxide (CO <sub>2</sub> ). Dry chemical. Water spray.
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**5.2. Special hazards arising from the substance or mixture**

	Carbon dioxide (CO <sub>2</sub> ). Nitrogen oxides.
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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**

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

	Prevent further spillage if safe. Do not allow product to enter drains. 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 in compliance with all local and federal regulations.
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**SECTION 7: Handling and storage****7.1. Precautions for safe handling**

	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.
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**SECTION 8: Exposure controls/personal protection****8.2. Exposure controls**

Skin protection - Handprotection	Wear suitable gloves.
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**SECTION 9: Physical and chemical properties**

## Uni-Gold™ C. difficile GDH Device and Buffer, 1206640D-B, Rev. 2

Revision 2

Revision date 2015-05-28

## 9.1. Information on basic physical and chemical properties

Appearance	Solid/Liquid
Colour	White/Colourless
pH	7.4
Melting point	-40 °C

## SECTION 10: Stability and reactivity

## 10.1. Reactivity

Avoid contact with: Amines and Mercaptans. Oxidising agents. Reducing agents.

## 10.2. Chemical stability

Will not decompose if stored and used as recommended.

## 10.4. Conditions to avoid

No data available.

## 10.5. Incompatible materials

No data available.

## 10.6. Hazardous decomposition products

Will not decompose if stored and used as recommended.

## SECTION 11: Toxicological information

## 11.1. Information on toxicological effects

Acute toxicity	Harmful if swallowed. May cause irritation to skin, eyes and mucous membranes. Seek medical attention.
Respiratory or skin sensitisation	May cause sensitisation by inhalation.

## SECTION 12: Ecological information

## 12.6. Other adverse effects

Very toxic to aquatic organisms.

## SECTION 13: Disposal considerations

## Disposal methods

Dispose of this material and its container to hazardous or special waste collection point.

## Disposal of packaging

Disposal of packaging. Empty containers can be sent for disposal or recycling.

## 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

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.

# Uni-Gold™ C. difficile GDH Device and Buffer, 1206640D-B, Rev. 2

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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.

## 15.2. Chemical safety assessment

No Significant Hazard.

## 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.



# SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

## Uni-Gold™ C. difficile GDH Controls, 1206641 P/N, Rev. 2

<b>SECTION 1: Identification of the substance/mixture and of the company/undertaking</b>
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<b>1.1. Product Identifier</b>	
Product name	Uni-Gold™ C. difficile GDH Controls, 1206641 P/N, Rev. 2
Product code	1206641
<b>1.3. Details of the supplier of the safety data sheet</b>	
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
<b>Local Supplier</b>	
Company	Trinity Biotech USA
Address	2823 Girls Rd Jamestown NY 14701 USA
Telephone	+1 800-325-3424
Fax	+1 716-487-1419
<b>1.4. Emergency telephone number</b>	
	Contact your local Emergency Health Provider. Ireland-Technical Support Group 00353 -1- 276- 9800 USA-Technical Support Group 1-800-325-3424

<b>SECTION 2: Hazards identification</b>
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<b>2.1. Classification of the substance or mixture</b>	
Main hazards	No Significant Hazard
<b>2.2. Label elements</b>	
Risk phrases	In accordance with EC directives, this product does not need to be labelled. No Significant Hazard

<b>SECTION 3: Composition/information on ingredients</b>
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<b>3.1. Substances</b>	
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## Uni-Gold™ C. difficile GDH Controls, 1206641 P/N, Rev. 2

Revision 2

Revision date 2015-05-28

## 3.1. Substances

## 67/548/EEC / 1999/45/EC

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
TEMPLATE No significant hazard Liquid							

## EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
TEMPLATE No significant hazard Liquid							
5-Chloro-2-methyl-2H-isothiazol-3-one		26172-55-4	247-500-7				
2-Methyl-2H-isothiazol-3-one		2682-20-4	220-239-6			Acute Tox. 4: H302; Skin Corr. 1A: H314; Skin Sens. 1: H317; Acute Tox. 3: H331; STOT SE 3: H335; Aquatic Acute 1: H400;	

## 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	DO NOT INDUCE VOMITING. Rinse mouth thoroughly. Seek medical attention. Never give anything by mouth to an unconscious person.

## SECTION 5: Firefighting measures

## 5.1. Extinguishing media

Use extinguishing media appropriate to the surrounding fire conditions. Alcohol resistant foam. Carbon dioxide (CO <sub>2</sub> ). Dry chemical. Water spray.
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## 5.2. Special hazards arising from the substance or mixture

Carbon dioxide (CO <sub>2</sub> ). Nitrogen oxides.
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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

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

Prevent further spillage if safe. Do not allow product to enter drains. 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 in compliance with all local and federal regulations.
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## SECTION 7: Handling and storage

## 7.1. Precautions for safe handling

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.
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## SECTION 8: Exposure controls/personal protection

## Uni-Gold™ C. difficile GDH Controls, 1206641 P/N, Rev. 2

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## 8.2. Exposure controls

Skin protection - Handprotection	Wear suitable gloves.
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## SECTION 9: Physical and chemical properties

## 9.1. Information on basic physical and chemical properties

Appearance	Liquid
Colour	Colourless
pH	7.4
Melting point	-40 °C

## SECTION 10: Stability and reactivity

## 10.1. Reactivity

	Avoid contact with: Mercaptans, Amines. Oxidising agents. Reducing agents.
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## 10.2. Chemical stability

	Will not decompose if stored and used as recommended.
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## 10.6. Hazardous decomposition products

	Will not decompose if stored and used as recommended.
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## SECTION 11: Toxicological information

## 11.1. Information on toxicological effects

Acute toxicity	Harmful if swallowed. May cause irritation to skin, eyes and mucous membranes. Seek medical attention.
Respiratory or skin sensitisation	May cause irritation to respiratory system.

## SECTION 12: Ecological information

## 12.6. Other adverse effects

	Very toxic to aquatic organisms.
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## SECTION 13: Disposal considerations

## Disposal methods

	Dispose of this material and its container to hazardous or special waste collection point.
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## Disposal of packaging

	Disposal of packaging. Empty containers can be sent for disposal or recycling.
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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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## Uni-Gold™ C. difficile GDH Controls, 1206641 P/N, Rev. 2

Revision 2

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

	<p>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>
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**15.2. Chemical safety assessment**

	No Significant Hazard.
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**SECTION 16: Other information****Other 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>
<b>Text of Hazard Statements in Section 3</b>	<p>Acute Tox. 4: H302 - Harmful if swallowed.</p> <p>Skin Corr. 1A: H314 - Causes severe skin burns and eye damage.</p> <p>Skin Sens. 1: H317 - May cause an allergic skin reaction.</p> <p>Acute Tox. 3: H331 - Toxic if inhaled.</p> <p>STOT SE 3: H335 - May cause respiratory irritation.</p> <p>Aquatic Acute 1: H400 - Very toxic to aquatic life.</p>