

SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

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Uni-Gold™ Cryptosporidium Dilution Buffer, 1206620-B, Rev. 1

Revision 1
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™ Cryptosporidium Dilution Buffer, 1206620-B, Rev. 1
Product code	1206620-B

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;
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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 Glrfs 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

SECTION 4: First aid measures

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4.1. Description of first aid measures

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

General information

	IF exposed or concerned: Get medical advice/attention.
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SECTION 5: Firefighting measures

5.1. Extinguishing media

	Use extinguishing media appropriate to the surrounding fire conditions.
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5.3. Advice for firefighters

	Wear suitable protective clothing, gloves and eye/face protection.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

	Wear suitable protective clothing, gloves and eye/face protection.
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6.2. Environmental precautions

	Prevent further spillage if safe.
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6.3. Methods and material for containment and cleaning up

	Collect spilled liquid with absorbent material and place in a container for suitable disposal. Clean area thoroughly with detergent.
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SECTION 7: Handling and storage

7.1. Precautions for safe handling

	Handle and open container with care. Avoid contact with eyes and skin.
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SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

Eye / face protection	Wear eye/face protection.
Skin protection - Handprotection	Wear suitable gloves. Wash hands after handling the product.
8.2.3. Environmental exposure controls	Avoid release to the environment.

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.
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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Skin corrosion/irritation	May cause irritation to skin.
Serious eye damage/irritation	May cause irritation to eyes.
Respiratory or skin sensitisation	May cause sensitisation by inhalation.

Uni-Gold™ Cryptosporidium Dilution Buffer, 1206620-B, Rev. 1

Revision 1
Revision date 2015-05-28**SECTION 12: Ecological information****SECTION 13: Disposal considerations****Disposal 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.

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, 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**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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Uni-Gold™ Cryptosporidium Test Device, 1206620-D, Rev. 1

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

1.1. Product Identifier	
Product name	Uni-Gold™ Cryptosporidium Test Device, 1206620-D, Rev. 1
Product code	1206620-D
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

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

Uni-Gold™ Cryptosporidium Test Device, 1206620-D, Rev. 1

Revision 1

Revision date 2015-05-28

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).
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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.
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General information

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

	Avoid formation of dust. Do not breathe dust.
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6.2. Environmental precautions

	Avoid release to the environment.
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SECTION 7: Handling and storage**7.1. Precautions for safe handling**

	Avoid contact with skin and eyes.
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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 - 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

Uni-Gold™ Cryptosporidium Test Device, 1206620-D, Rev. 1

Revision 1
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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.
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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Skin corrosion/irritation	May cause irritation to skin.
Serious eye damage/irritation	May cause eye irritation.

11.1.4. Toxicological information

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

SECTION 13: Disposal considerations

Disposal methods

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

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

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, 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,

Uni-Gold™ Cryptosporidium Test Device, 1206620-D, Rev. 1

Revision 1

Revision date 2015-05-28

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

93/105/EC and 2000/21/EC.

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™ Cryptosporidium Control Kit, 1206621 P/N, Rev. 1

SECTION 1: Identification of the substance/mixture and of the company/undertaking
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1.1. Product Identifier

Product name	Uni-Gold™ Cryptosporidium Control Kit, 1206621 P/N, Rev. 1
Product code	1206621

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);
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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
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2.1. Classification of the substance or mixture

2.1.1. Classification - 1999/45/EC	Xn; R20/21/22-40 Xi; R43 Symbols: Xn: Harmful.
Main hazards	Harmful by inhalation, in contact with skin and if swallowed. Limited evidence of a carcinogenic effect. May cause sensitisation by skin contact.
2.1.2. Classification - EC 1272/2008	Skin Corr. 1B: H314; Skin Sens. 1: H317; Carc. 2: H351; STOT SE 2: H371;


2.2. Label elements

Uni-Gold™ Cryptosporidium Control Kit, 1206621 P/N, Rev. 1

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2.2. Label elements

Hazard pictograms	
Signal Word	Danger
Hazard Statement	Skin Corr. 1B: H314 - Causes severe skin burns and eye damage. Skin Sens. 1: H317 - May cause an allergic skin reaction. Carc. 2: H351 - Suspected of causing cancer . STOT SE 2: H371 - May cause damage to organs .
Precautionary Statement: Prevention	P201 - Obtain special instructions before use. P202 - Do not handle until all safety precautions have been read and understood. P260 - Do not breathe dust/fume/gas/mist/vapours/spray. P261 - Avoid breathing dust/fume/gas/mist/vapours/spray. P264 - Wash thoroughly after handling. P270 - Do no eat, drink or smoke when using this product. P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear protective gloves/protective clothing/eye protection/face protection.
Precautionary Statement: Response	P301+P330+P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting. P302+P352 - IF ON SKIN: Wash with plenty of water/ . P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308+P313 - IF exposed or concerned: Get medical advice/attention. P310 -Immediately call a POISON CENTER/doctor/ . P321 - Specific treatment (see on this label). P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P363 - Wash contaminated clothing before reuse.
Precautionary Statement: Storage	P405 - Store locked up.
Precautionary Statement: Disposal	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.
Formaldehyde...% (Formaldehyde)	605-001-00-5	50-00-0	200-001-8			Carc. Cat. 3; R40 T; R23/24/25 C; R34 R43	
Methanol	603-001-00-X	67-56-1	200-659-6			F; R11 T; R23/24/25-39/23/24/25	

Uni-Gold™ Cryptosporidium Control Kit, 1206621 P/N, Rev. 1

Revision 1
Revision date 2015-05-28

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
Formaldehyde...% (Formaldehyde)	605-001-00-5	50-00-0	200-001-8			Carc. 2: H351; Acute Tox. 3: H331; Acute Tox. 3: H311; Acute Tox. 3: H301; Skin Corr. 1B: H314; Skin Sens. 1: H317;	
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. Seek medical attention.
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. Seek medical attention if irritation or symptoms persist.
Ingestion	IF SWALLOWED: rinse mouth. Do NOT induce vomiting. Seek medical attention.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Use as appropriate: Water spray, Alcohol resistant foam, Dry chemical, Carbon dioxide (CO ₂).

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.
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SECTION 7: Handling and storage

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

Formaldehyde...% (Formaldehyde)	WEL 8-hr limit ppm: 2	WEL 8-hr limit mg/m ³ : 2.5
	WEL 15 min limit ppm: 2	WEL 15 min limit mg/m ³ : 2.5
	WEL 8-hr limit mg/m ³ total - inhalable dust:	WEL 15 min limit mg/m ³ total - inhalable dust:
	WEL 8-hr limit mg/m ³ total - respirable dust:	WEL 15 min limit mg/m ³ total - respirable dust:
	Methanol	WEL 8-hr limit ppm: 200
	WEL 15 min limit ppm: 250	WEL 15 min limit mg/m ³ : 333
	WEL 8-hr limit mg/m ³ total - inhalable dust:	WEL 15 min limit mg/m ³ total - inhalable dust:
	WEL 8-hr limit mg/m ³ total - respirable dust:	WEL 15 min limit mg/m ³ total - respirable dust:

8.2. Exposure controls

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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	May cause irritation to skin, eyes and mucous membranes.
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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.

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, 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

Uni-Gold™ Cryptosporidium Control Kit, 1206621 P/N, Rev. 1

Revision 1

Revision date 2015-05-28

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

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

	<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>
<p>Text of risk phrases in Section 3</p>	<p>R11 - Highly flammable. R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed. R34 - Causes burns. R39/23/24/25 - Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed. R40 - Limited evidence of a carcinogenic effect. R43 - May cause sensitisation by skin contact.</p>
<p>Text of Hazard Statements in Section 3</p>	<p>Acute Tox. 3: H301 - Toxic if swallowed. Acute Tox. 3: H311 - Toxic in contact with skin. Skin Corr. 1B: 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. Carc. 2: H351 - Suspected of causing cancer . Flam. Liq. 2: H225 - Highly flammable liquid and vapour. STOT SE 1: H370 - Causes damage to organs .</p>

