

SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

Page 1/4

ENA Profile Conjugate 385425

Revision 2

Revision date 2015-05-30

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

1.1. Product identifier

Product name	ENA Profile Conjugate 385425
Product code	2338170

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 Girts 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

ENA Profile Conjugate 385425

Revision 2

Revision date 2015-05-30

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
ProClin 300					0 - 0.5%		
Bromonitrodioxane					0 - 0.5%		
Gentamicin Sulfate		1405-41-0			0 - 0.5%		

Further information

No substance is present at a concentration level, specified by EC Directive, which presents a health or environmental hazard.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	May cause irritation to mucous membranes. Move the exposed person to fresh air.
Eye contact	May cause irritation to eyes. Rinse immediately with plenty of water for 15 minutes holding the eyelids open. Seek medical attention if irritation or symptoms persist.
Skin contact	May cause irritation to skin. Wash off immediately with plenty of soap and water. Remove contaminated clothing. Seek medical attention if irritation or symptoms persist.
Ingestion	May cause irritation to mucous membranes. DO NOT INDUCE VOMITING. Seek medical attention if irritation or symptoms persist.

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

Ensure adequate ventilation of the working area.

6.3. Methods and material for containment and cleaning up

Absorb with inert, absorbent material. Transfer to suitable, labelled containers for disposal. Clean spillage area thoroughly with plenty of water.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with eyes and skin. Ensure adequate ventilation of the working area. Adopt best Manual Handling considerations when handling, carrying and dispensing.

7.2. Conditions for safe storage, including any incompatibilities

2-8 °C.
Keep container tightly closed. Keep in a cool, dry, well ventilated area. Store in correctly labelled containers.

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Ensure adequate ventilation of the working area.

ENA Profile Conjugate 385425

Revision 2

Revision date 2015-05-30

8.2. Exposure controls

8.2.2. Individual protection measures

Wear protective clothing.

Eye / face protection

In case of splashing, wear: Approved safety goggles.

Skin protection - Handprotection

Wear suitable gloves.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid
Colour	Off white

SECTION 10: Stability and reactivity

10.2. Chemical stability

Stable under normal conditions.

SECTION 11: Toxicological information

11.1.13. Other information

No known adverse health effects.

SECTION 12: Ecological information

Further information

No known adverse environmental effects.

SECTION 13: Disposal considerations

Further information

Dispose of in compliance with all 'local and national regulations'.

SECTION 14: Transport information

Further information

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

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.

Further information

This SDS is prepared according to 29 CFR 1910.1200.

SECTION 16: Other information

Other information

Revision

This document differs from the previous version in the following areas:.

ENA Profile Conjugate 385425

Revision 2

Revision date 2015-05-30

Other information

	3 - Further information. 8 - Skin protection - Handprotection. 15 - 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.
--	---

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.
--	--

SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

Page 1/4

ENA Profile Calibrator 3817-2

Revision 2

Revision date 2015-05-30

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

1.1. Product identifier

Product name	ENA Profile Calibrator 3817-2
Product code	2338170

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 Girts 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	HCV by FDA approved tests, no test method can offer complete assurance that the above mentioned or any other infectious agents are absent, this reagent should be handled as recommended for any potentially infectious human serum or blood specimen.
--------------	--

2.2. Label elements

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

SECTION 3: Composition/information on ingredients

3.2. Mixtures

ENA Profile Calibrator 3817-2

Revision 2

Revision date 2015-05-30

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
Human Serum					70 - 80%		
Sodium azide (Sodium azide (as NaN ₃))	011-004-00-7	26628-22-8	247-852-1		0 - 0.5%	Acute Tox. 2: H300; Aquatic Acute 1: H400; Aquatic Chronic 1: H410;	

Hazardous ingredients

Biohazardous Material.

Further information

No substance is present at a concentration level, specified by EC Directive, which presents a health or environmental hazard.

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact	May cause irritation to eyes. Rinse immediately with plenty of water for 15 minutes holding the eyelids open.
Skin contact	May cause irritation to skin. Wash with soap and water.
Ingestion	Flush mouth with water, without swallowing.

General information

If you feel unwell, seek medical advice (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

Wear suitable protective equipment.

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 disinfectant. Flush down the drain with plenty of water.

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

2-8 °C.

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

8.2.2. Individual protection measures	Wear suitable protective equipment. Handle as if potentially infectious.
Eye / face protection	Face shield. Safety glasses.

ENA Profile Calibrator 3817-2

Revision 2

Revision date 2015-05-30

8.2. Exposure controls

Skin protection - Handprotection	Wear suitable gloves.
----------------------------------	-----------------------

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid
Colour	Off white

SECTION 10: Stability and reactivity

10.2. Chemical stability

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

SECTION 11: Toxicological information

11.1.4. Toxicological Information

	No data is available on this product.
--	---------------------------------------

SECTION 12: Ecological information

12.1. Toxicity

	No data is available on this product.
--	---------------------------------------

SECTION 13: Disposal considerations

General information

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

Disposal methods

	Disposal should be made in accordance with existing procedures / protocols currently in place at facility for infectious waste.
--	---

Disposal of packaging

	Do NOT reuse empty containers.
--	--------------------------------

SECTION 14: Transport information

Further information

	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>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>
--	--

Further information

	This SDS is prepared according to 29 CFR 1910.1200.
--	---

SECTION 16: Other information

ENA Profile Calibrator 3817-2

Revision 2

Revision date 2015-05-30

Other information

Revision	This document differs from the previous version in the following areas: 3 - Further information. 8 - Skin protection - Handprotection. 12 - 12.1. Toxicity. 15 - 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.
Text of Hazard Statements in Section 3	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.

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.
--	--

SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

Page 1/4

ENA Profile Negative Control 3817-3

Revision 2

Revision date 2015-05-30

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

1.1. Product identifier

Product name	ENA Profile Negative Control 3817-3
Product code	2338170

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 Girts 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	HCV by FDA approved tests, no test method can offer complete assurance that the above mentioned or any other infectious agents are absent, this reagent should be handled as recommended for any potentially infectious human serum or blood specimen.
--------------	--

2.2. Label elements

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

SECTION 3: Composition/information on ingredients

3.2. Mixtures

ENA Profile Negative Control 3817-3

Revision 2

Revision date 2015-05-30

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
Human Serum					70 - 80%		
Sodium azide (Sodium azide (as NaN ₃))	011-004-00-7	26628-22-8	247-852-1		0 - 0.5%	Acute Tox. 2: H300; Aquatic Acute 1: H400; Aquatic Chronic 1: H410;	

Hazardous ingredients

Biohazardous Material.

Further information

No substance is present at a concentration level, specified by EC Directive, which presents a health or environmental hazard.

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact	May cause irritation to eyes. Rinse immediately with plenty of water for 15 minutes holding the eyelids open.
Skin contact	May cause irritation to skin. Wash with soap and water.
Ingestion	Flush mouth with water, without swallowing.

General information

If you feel unwell, seek medical advice (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

Wear suitable protective equipment.

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 disinfectant. Flush down the drain with plenty of water.

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

2-8 °C.

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

8.2.2. Individual protection measures	Wear suitable protective equipment. Handle as if potentially infectious.
Eye / face protection	Face shield. Safety glasses.

ENA Profile Negative Control 3817-3

Revision 2

Revision date 2015-05-30

8.2. Exposure controls

Skin protection - Handprotection	Wear suitable gloves.
-------------------------------------	-----------------------

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid
Colour	Off white

SECTION 10: Stability and reactivity

10.2. Chemical stability

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

SECTION 11: Toxicological information

11.1.4. Toxicological Information

	No data is available on this product.
--	---------------------------------------

SECTION 12: Ecological information

12.1. Toxicity

	No data is available on this product.
--	---------------------------------------

SECTION 13: Disposal considerations

General information

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

Disposal methods

	Disposal should be made in accordance with existing procedures / protocols currently in place at facility for infectious waste.
--	---

Disposal of packaging

	Do NOT reuse empty containers.
--	--------------------------------

SECTION 14: Transport information

Further information

	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>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>
--	--

Further information

	This SDS is prepared according to 29 CFR 1910.1200.
--	---

SECTION 16: Other information

ENA Profile Negative Control 3817-3

Revision 2

Revision date 2015-05-30

Other information

Revision	This document differs from the previous version in the following areas: 3 - Further information. 8 - Skin protection - Handprotection. 12 - 12.1. Toxicity. 15 - 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.
Text of Hazard Statements in Section 3	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.

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.
--	--

SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

Page 1/4

ENA Profile Serum Diluent Type III 616434

Revision 2

Revision date 2015-05-30

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

1.1. Product identifier

Product name	ENA Profile Serum Diluent Type III 616434
Product code	2338170

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 Girts 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

ENA Profile Serum Diluent Type III 616434

Revision 2

Revision date 2015-05-30

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
N-Z-Amine CH001A					1 - 10%		
Bovine Serum Albumin		9048-46-8			1 - 10%		
ProClin 300					0 - 0.5%		
Tween 20 CH016		9005-64-5	500-018-3		0 - 0.5%		
Potassium Chloride CH037		7447-40-7	231-211-8		0 - 0.5%		
Sodium Phosphate, Monobasic CH012A		7558-80-7	231-449-2		0 - 0.5%		

Description

Non Hazardous.

Further information

No substance is present at a concentration level, specified by EC Directive, which presents a health or environmental hazard.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Inhalation may cause coughing, tightness of the chest and irritation of the respiratory system. Move the exposed person to fresh air. Seek medical attention.
Eye contact	May cause irritation to eyes. Rinse immediately with plenty of water for 15 minutes holding the eyelids open. Seek medical attention if irritation or symptoms persist.
Skin contact	May cause irritation to skin. Remove contaminated clothing. Seek medical attention if irritation or symptoms persist. Wash off immediately with plenty of soap and water.
Ingestion	Ingestion may cause nausea and vomiting. Seek medical attention if irritation or symptoms persist.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Use extinguishing media appropriate to the surrounding fire conditions.

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

Ensure adequate ventilation of the working area. Wear suitable protective equipment.

6.2. Environmental precautions

Do not allow product to enter drains.

6.3. Methods and material for containment and cleaning up

Wash area with a 5% chlorine bleach solution or equivalent, rinse with water.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with eyes and skin. Ensure adequate ventilation of the working area. Adopt best Manual Handling considerations when handling, carrying and dispensing.

7.2. Conditions for safe storage, including any incompatibilities

Store in correctly labelled containers.

Further information

ENA Profile Serum Diluent Type III 616434

Revision 2

Revision date 2015-05-30

Further information

2-8 °C.

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

8.2.1. Appropriate engineering controls	Ensure adequate ventilation of the working area.
8.2.2. Individual protection measures	Wear suitable protective clothing.
Eye / face protection	Approved safety goggles.
Skin protection - Handprotection	Wear suitable gloves.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Aqueous solution
Colour	Yellow

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions.

SECTION 11: Toxicological information

Further information

To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

SECTION 12: Ecological information

Further information

No known adverse environmental effects.

SECTION 13: Disposal considerations

Disposal methods

Dispose of in compliance with all local and national regulations.

SECTION 14: Transport information

Further information

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

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,

ENA Profile Serum Diluent Type III 616434

Revision 2

Revision date 2015-05-30

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

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

Further information

This SDS is prepared according to 29 CFR 1910.1200.

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.

SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

Page 1/4

ENA Profile Wash Buffer Type II 827402

Revision 2

Revision date 2015-05-30

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

1.1. Product identifier

Product name	ENA Profile Wash Buffer Type II 827402
Product code	2338170

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 Girts 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

ENA Profile Wash Buffer Type II 827402

Revision 2

Revision date 2015-05-30

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
Hydrochloric acid...%	017-002-01-X		231-595-7		0 - 0.5%	Skin Corr. 1B: H314; STOT SE 3: H335;	
Tween 80 CH016A		9005-65-6			1 - 10%		
Tris Base		77-86-1	201-064-4		1 - 10%		
EDTA		6381-92-6	205-358-3		0 - 0.5%		
ProClin 300					0 - 0.5%		

Further information

Aqueous solution. No substance is present at a concentration level, specified by EC Directive, which presents a health or environmental hazard.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	May cause irritation to mucous membranes. Move the exposed person to fresh air.
Eye contact	May cause irritation to eyes. Rinse immediately with plenty of water for 15 minutes holding the eyelids open. Seek medical attention if irritation or symptoms persist.
Skin contact	May cause irritation to skin. Wash off immediately with plenty of soap and water. Remove contaminated clothing. Seek medical attention if irritation or symptoms persist.
Ingestion	May cause irritation to mucous membranes. DO NOT INDUCE VOMITING. Seek medical attention if irritation or symptoms persist.

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

Ensure adequate ventilation of the working area.

6.2. Environmental precautions

Do not allow product to enter drains.

6.3. Methods and material for containment and cleaning up

Absorb with inert, absorbent material. Transfer to suitable, labelled containers for disposal. Clean spillage area thoroughly with plenty of water.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with eyes and skin. Ensure adequate ventilation of the working area. Adopt best Manual Handling considerations when handling, carrying and dispensing.

7.2. Conditions for safe storage, including any incompatibilities

Keep in a cool, dry, well ventilated area. Keep container tightly closed. Store in correctly labelled containers.

SECTION 8: Exposure controls/personal protection

ENA Profile Wash Buffer Type II 827402

Revision 2

Revision date 2015-05-30

8.2. Exposure controls

8.2.1. Appropriate engineering controls	Ensure adequate ventilation of the working area.
8.2.2. Individual protection measures	Wear protective clothing.
Eye / face protection	In case of splashing, wear: Eye protection.
Skin protection - Handprotection	Wear suitable gloves.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Aqueous solution
Colour	Blue

SECTION 10: Stability and reactivity

10.2. Chemical stability

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

SECTION 11: Toxicological information

11.1.13. Other information

	To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.
--	--

SECTION 12: Ecological information

Further information

	No known adverse environmental effects.
--	---

SECTION 13: Disposal considerations

General information

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

SECTION 14: Transport information

Further information

	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>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>
--	--

Further information

	This SDS is prepared according to 29 CFR 1910.1200.
--	---

ENA Profile Wash Buffer Type II 827402

Revision 2

Revision date 2015-05-30

SECTION 16: Other information**Other information**

Revision	This document differs from the previous version in the following areas: 3 - Further information. 8 - Skin protection - Handprotection. 15 - 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.
Text of Hazard Statements in Section 3	Skin Corr. 1B: H314 - Causes severe skin burns and eye damage. STOT SE 3: H335 - May cause respiratory irritation.

General 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

Page 1/4

ENA Profile Substrate Solution 525700

Revision 2

Revision date 2015-05-30

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

1.1. Product identifier

Product name	ENA Profile Substrate Solution 525700
Product code	2338170

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 Girts 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

ENA Profile Substrate Solution 525700

Revision 2

Revision date 2015-05-30

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
Hydrogen Peroxide		7722-84-1			0 - 0.5%		

Further information

No substance is present at a concentration level, specified by EC Directive, which presents a health or environmental hazard.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Move the exposed person to fresh air.
Eye contact	May cause irritation to eyes. Rinse immediately with plenty of water for 15 minutes holding the eyelids open. Seek medical attention.
Skin contact	Remove contaminated clothing. Wash off immediately with plenty of soap and water. Seek medical attention if irritation or symptoms persist.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Use extinguishing media appropriate to the surrounding fire conditions. Carbon dioxide (CO₂). Foam. Water spray.

5.3. Advice for firefighters

Self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear suitable protective equipment.

6.3. Methods and material for containment and cleaning up

Transfer to suitable, labelled containers for disposal.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Wear protective clothing.

7.2. Conditions for safe storage, including any incompatibilities

2-8 °C.

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

8.2.1. Appropriate engineering controls	Ensure adequate ventilation of the working area.
8.2.2. Individual protection measures	Wear protective clothing.
Eye / face protection	Safety glasses.
Skin protection - Handprotection	Protective clothing. Wear suitable gloves.
Respiratory protection	Use in a well ventilated area.
8.2.3. Environmental exposure controls	Do not eat, drink or smoke in areas where this product is used or stored.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

ENA Profile Substrate Solution 525700

Revision 2

Revision date 2015-05-30

9.1. Information on basic physical and chemical properties

Appearance	Aqueous solution
Colour	Clear
Initial boiling point	100

SECTION 10: Stability and reactivity

10.2. Chemical stability

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

10.4. Conditions to avoid

	Heat, sparks and open flames.
--	-------------------------------

SECTION 11: Toxicological information

11.1.4. Toxicological Information

	When used and handled according to the specifications, the solution does not have a toxicological effect.
--	---

SECTION 12: Ecological information

Further information

	No data is available on this product.
--	---------------------------------------

SECTION 13: Disposal considerations

General information

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

SECTION 14: Transport information

Further information

	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>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>
--	--

Further information

	This SDS is prepared according to 29 CFR 1910.1200.
--	---

SECTION 16: Other information

Other information

Revision	<p>This document differs from the previous version in the following areas:</p> <p>3 - Further information.</p> <p>8 - Skin protection - Handprotection.</p> <p>15 - 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.</p>
----------	---

ENA Profile Substrate Solution 525700

Revision 2

Revision date 2015-05-30

General 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>
--	---

SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

Page 1/5

ENA Profile Stop Solution 915401

Revision 2

Revision date 2015-05-30

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

1.1. Product identifier

Product name	ENA Profile Stop Solution 915401
Product code	2338170

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 Girts 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	Skin Irrit. 2: H315; Eye Irrit. 2: H319;
--------------------------------------	--

2.2. Label elements

Hazard pictograms	
Signal Word	Warning
Hazard Statement	Skin Irrit. 2: H315 - Causes skin irritation. Eye Irrit. 2: H319 - Causes serious eye irritation.

ENA Profile Stop Solution 915401

Revision 2

Revision date 2015-05-30

2.2. Label elements

Precautionary Statement: Prevention	P264 - Wash thoroughly after handling.
	P280 - Wear protective gloves/protective clothing/eye protection/face protection.
Precautionary Statement: Response	<p>P302+P352 - IF ON SKIN: Wash with plenty of water/ .</p> <p>P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P321 - Specific treatment (see on this label).</p> <p>P332+P313 - If skin irritation occurs: Get medical advice/attention.</p> <p>P337+P313 - If eye irritation persists: Get medical advice/attention.</p>

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.
Sulphuric acid...% (Sulphuric acid (mist))	016-020-00-8	7664-93-9	231-639-5		1 - 10%	C; R35	

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
Sulphuric acid...% (Sulphuric acid (mist))	016-020-00-8	7664-93-9	231-639-5		1 - 10%	Skin Corr. 1A: H314;	

Further information

No substance is present at a concentration level, specified by EC Directive, which presents a health or environmental hazard.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Inhalation may cause coughing, tightness of the chest and irritation of the respiratory system. Irritating to respiratory system. Move the exposed person to fresh air. Seek medical attention.
Eye contact	Irritating to eyes. Rinse immediately with plenty of water for 15 minutes holding the eyelids open. Seek medical attention if irritation or symptoms persist.
Skin contact	Irritating to skin. Wash off immediately with plenty of soap and water. Remove contaminated clothing. Seek medical attention if irritation or symptoms persist.
Ingestion	DO NOT INDUCE VOMITING. Ingestion may cause nausea and vomiting. Seek medical attention if irritation or symptoms persist.

General information

First aid measures given apply to concentrated solutions. Exposure to dilute solutions may not require these extensive first aid procedures.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Dry chemical. Foam. Water. Carbon dioxide (CO₂).

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

Ensure adequate ventilation of the working area. Wear suitable protective equipment.

6.2. Environmental precautions

ENA Profile Stop Solution 915401

Revision 2

Revision date 2015-05-30

6.2. Environmental precautions

Do not allow product to enter drains.

6.3. Methods and material for containment and cleaning up

Absorb with inert, absorbent material. Transfer to suitable, labelled containers for disposal. Clean spillage area thoroughly with plenty of water.

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. Ensure adequate ventilation of the working area.

7.2. Conditions for safe storage, including any incompatibilities

Keep in a cool, dry, well ventilated area. Keep containers tightly closed. Store in correctly labelled containers.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. Exposure Limit Values

Sulphuric acid...% (Sulphuric acid (mist))	WEL 8-hr limit ppm: -	WEL 8-hr limit mg/m3: 0.05
	WEL 15 min limit ppm: -	WEL 15 min limit mg/m3: -
	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	Ensure adequate ventilation of the working area.
8.2.2. Individual protection measures	Wear chemical protective clothing.
Eye / face protection	Approved safety goggles.
Skin protection - Handprotection	Wear suitable gloves.
Respiratory protection	Wear suitable respiratory equipment when necessary.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Aqueous solution
Colour	Colourless
Initial boiling point	100

SECTION 10: Stability and reactivity

10.2. Chemical stability

Stable under normal conditions.

SECTION 11: Toxicological information

11.1.4. Toxicological Information

Sulphuric acid...%	Inhalation Rat LC50/2 h: 510	Oral Rat LD50: 2140
	When used and handled according to the specifications, the solution does not have a toxicological effect.	

ENA Profile Stop Solution 915401

Revision 2

Revision date 2015-05-30

SECTION 12: Ecological information

12.1. Toxicity

Sulphuric acid...%	Fish LC50/96h: 42.00000 mg/l
--------------------	------------------------------

12.4. Mobility in soil

When released into soil, this material may leach into groundwater.

SECTION 13: Disposal considerations

General information

Dispose of in compliance with all local and national regulations.

SECTION 14: Transport information

Further information

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

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.

Further information

This SDS is prepared according to 29 CFR 1910.1200.

SECTION 16: Other information

Other information

Revision

This document differs from the previous version in the following areas:.

2 - 2.1.2. Classification - EC 1272/2008.

2 - Hazard pictograms.

2 - Signal Word.

2 - Precautionary Statement: Prevention.

2 - Precautionary Statement: Response.

3 - Further information.

8 - Skin protection - Handprotection.

15 - 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.

Text of risk phrases in Section 3

R35 - Causes severe burns.

Text of Hazard Statements in Section 3

Skin Corr. 1A: H314 - Causes severe skin burns and eye damage.

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

ENA Profile Stop Solution 915401

Revision 2

Revision date 2015-05-30

Further 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.
--	---
