

SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

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Macra Lp(a) Conjugate 333910

Revision 2

Revision date 2015-05-27

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

1.1. Product identifier

Product name	Macra Lp(a) Conjugate 333910
Product code	2339100

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
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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

Macra Lp(a) Conjugate 333910

Revision 2

Revision date 2015-05-27

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
Goat Serum, Heat Inactivated					1 - 10%		
Sodium Phosphate, Dibasic CH012		7558-79-4	231-448-7		0 - 0.5%		
ProClin 300					0 - 0.5%		
Disodium EDTA		6381-92-6	205-358-3		0 - 0.5%		
Bromophenol Blue		62625-28-9	263-653-2		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	No known adverse health effects.
Eye contact	Rinse immediately with plenty of water for 15 minutes holding the eyelids open. Seek medical attention.
Skin contact	Wash with soap and water. Seek medical attention.
Ingestion	Immediate medical attention is required.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Use extinguishing media appropriate to the surrounding fire conditions.

SECTION 6: Accidental release measures

6.3. Methods and material for containment and cleaning up

Absorb with inert, absorbent material. Clean spillage area thoroughly with plenty of water.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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

7.2. Conditions for safe storage, including any incompatibilities

2-8 °C.

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

Eye / face protection	Safety glasses.
Skin protection - Handprotection	Wear suitable gloves.
Skin protection - Other	Wear suitable protective clothing.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid
Colour	Blue

SECTION 10: Stability and reactivity

10.2. Chemical stability

Stable under normal conditions.

Macra Lp(a) Conjugate 333910

Revision 2

Revision date 2015-05-27

SECTION 11: Toxicological information**11.1.4. Toxicological Information**

	To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.
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SECTION 12: Ecological information**Further information**

	No known adverse environmental effects.
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SECTION 13: Disposal considerations**General information**

	Dispose of in compliance with all local and national regulations.
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SECTION 14: Transport information**Further information**

	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****Regulations**

	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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	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.
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Further information

	This SDS is prepared according to 29 CFR 1910.1200.
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SECTION 16: Other information**Other information****Revision**

	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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	This document differs from the previous version in the following areas:.
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	3 - Further information.
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	8 - Skin protection - Handprotection.
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	15 - 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.
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	15 - Regulations.
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Macra Lp(a) 0 Standard 9100-5

Revision 2

Revision date 2015-05-27

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

1.1. Product identifier

Product name	Macra Lp(a) 0 Standard 9100-5
Product code	2339100

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
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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

Macra Lp(a) 0 Standard 9100-5

Revision 2

Revision date 2015-05-27

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
Goat Serum, Heat Inactivated					1 - 10%		
Sodium phosphate monobasic monohydrate		10049-21-5	231-449-2		0 - 0.5%		
ProClin 300					0 - 0.5%		
Disodium EDTA		6381-92-6	205-358-3		0 - 0.5%		
Bromophenol Blue		62625-28-9	263-653-2		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	No known adverse health effects.
Eye contact	Rinse immediately with plenty of water for 15 minutes holding the eyelids open. Seek medical attention.
Skin contact	Wash with soap and water. Seek medical attention.
Ingestion	Immediate medical attention is required.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Use extinguishing media appropriate to the surrounding fire conditions.

SECTION 6: Accidental release measures

6.3. Methods and material for containment and cleaning up

Absorb with inert, absorbent material. Clean spillage area thoroughly with plenty of water.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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

7.2. Conditions for safe storage, including any incompatibilities

2-8 °C.

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

Eye / face protection	Safety glasses.
Skin protection - Handprotection	Wear suitable gloves.
Skin protection - Other	Wear suitable protective clothing.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid
Colour	Blue

SECTION 10: Stability and reactivity

10.2. Chemical stability

Macra Lp(a) 0 Standard 9100-5

Revision 2

Revision date 2015-05-27

10.2. Chemical stability

Stable under normal conditions.

SECTION 11: Toxicological information

11.1.4. Toxicological 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

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

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.

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.

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Macra Lp(a) 5 Standard 9100-6

Revision 2

Revision date 2015-05-27

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

1.1. Product identifier

Product name	Macra Lp(a) 5 Standard 9100-6
Product code	2339100

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
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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.
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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

Macra Lp(a) 5 Standard 9100-6

Revision 2

Revision date 2015-05-27

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
Goat Serum, Heat Inactivated					1 - 10%		
Sodium phosphate monobasic monohydrate		10049-21-5	231-449-2		0 - 0.5%		
Human Serum					0 - 0.5%		
Disodium EDTA		6381-92-6	205-358-3		0 - 0.5%		
Bromophenol Blue		62625-28-9	263-653-2		0 - 0.5%		

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

Macra Lp(a) 5 Standard 9100-6

Revision 2

Revision date 2015-05-27

8.2. Exposure controls

Eye / face protection	Face shield. Safety glasses.
Skin protection - Handprotection	Wear suitable gloves.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid
Colour	Blue

SECTION 10: Stability and reactivity

10.2. Chemical stability

	Stable under normal conditions.
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SECTION 11: Toxicological information

11.1.4. Toxicological Information

	No data is available on this product.
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SECTION 12: Ecological information

12.1. Toxicity

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

General information

	Dispose of in compliance with all local and national regulations.
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Disposal methods

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

	Do NOT reuse empty containers.
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SECTION 14: Transport information

Further information

	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

	<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>
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Further information

	This SDS is prepared according to 29 CFR 1910.1200.
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Macra Lp(a) 5 Standard 9100-6

Revision 2

Revision date 2015-05-27

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. 9 - 9.1. Information on basic physical and chemical properties (Colour). 15 - 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.
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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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SAFETY DATA SHEET

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Macra Lp(a) 10 Standard 9100-7

Revision 2

Revision date 2015-05-27

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

1.1. Product identifier

Product name	Macra Lp(a) 10 Standard 9100-7
Product code	2339100

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
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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.
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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

Macra Lp(a) 10 Standard 9100-7

Revision 2
Revision date 2015-05-27

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
Goat Serum, Heat Inactivated					1 - 10%		
Sodium phosphate monobasic monohydrate		10049-21-5	231-449-2		0 - 0.5%		
Human Serum					0 - 0.5%		
ProClin 300					0 - 0.5%		
Disodium EDTA		6381-92-6	205-358-3		0 - 0.5%		
Bromophenol Blue		62625-28-9	263-653-2		0 - 0.5%		

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

Macra Lp(a) 10 Standard 9100-7

Revision 2

Revision date 2015-05-27

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.

Skin protection - Handprotection

Wear suitable gloves.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid
Colour	Blue

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

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.

Macra Lp(a) 10 Standard 9100-7

Revision 2

Revision date 2015-05-27

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:.

3 - Further information.

8 - Skin protection - Handprotection.

9 - 9.1. Information on basic physical and chemical properties (Colour).

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.

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Macra Lp(a) 20 Standard 9100-8

Revision 2

Revision date 2015-05-27

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

1.1. Product identifier

Product name	Macra Lp(a) 20 Standard 9100-8
Product code	2339100

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
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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.
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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

Macra Lp(a) 20 Standard 9100-8

Revision 2

Revision date 2015-05-27

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
Goat Serum, Heat Inactivated					1 - 10%		
Human Serum					0 - 0.5%		
ProClin 300					0 - 0.5%		
Disodium EDTA		6381-92-6	205-358-3		0 - 0.5%		
Bromophenol Blue		62625-28-9	263-653-2		0 - 0.5%		

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

Macra Lp(a) 20 Standard 9100-8

Revision 2

Revision date 2015-05-27

8.2. Exposure controls

Eye / face protection	Face shield. Safety glasses.
Skin protection - Handprotection	Wear suitable gloves.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid
Colour	Blue

SECTION 10: Stability and reactivity

10.2. Chemical stability

	Stable under normal conditions.
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SECTION 11: Toxicological information

11.1.4. Toxicological Information

	No data is available on this product.
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SECTION 12: Ecological information

12.1. Toxicity

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

General information

	Dispose of in compliance with all local and national regulations.
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Disposal methods

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

	Do NOT reuse empty containers.
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SECTION 14: Transport information

Further information

	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

	<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>
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Further information

	This SDS is prepared according to 29 CFR 1910.1200.
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Macra Lp(a) 20 Standard 9100-8

Revision 2

Revision date 2015-05-27

SECTION 16: Other information**Other information****Revision**

This document differs from the previous version in the following areas:.
9 - 9.1. Information on basic physical and chemical properties (Colour).

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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Macra Lp(a) 40 Standard 9100-9

Revision 2

Revision date 2015-05-27

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

1.1. Product identifier

Product name	Macra Lp(a) 40 Standard 9100-9
Product code	2339100

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.
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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

Macra Lp(a) 40 Standard 9100-9

Revision 2

Revision date 2015-05-27

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
Goat Serum, Heat Inactivated					1 - 10%		
Human Serum					0 - 0.5%		
Sodium phosphate monobasic monohydrate		10049-21-5	231-449-2		0 - 0.5%		
ProClin 300					0 - 0.5%		
Disodium EDTA		6381-92-6	205-358-3		0 - 0.5%		
Bromophenol Blue		62625-28-9	263-653-2		0 - 0.5%		

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

Macra Lp(a) 40 Standard 9100-9

Revision 2

Revision date 2015-05-27

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.

Skin protection - Handprotection

Wear suitable gloves.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid
Colour	Blue

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

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.

Macra Lp(a) 40 Standard 9100-9

Revision 2

Revision date 2015-05-27

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:.

3 - Further information.

8 - Skin protection - Handprotection.

9 - 9.1. Information on basic physical and chemical properties (Colour).

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.

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Macra Lp(a) 80 Standard 9100-10

Revision 2

Revision date 2015-05-27

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

1.1. Product identifier

Product name	Macra Lp(a) 80 Standard 9100-10
Product code	2339100

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
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SECTION 3: Composition/information on ingredients

3.2. Mixtures

Macra Lp(a) 80 Standard 9100-10

Revision 2

Revision date 2015-05-27

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
Goat Serum, Heat Inactivated					1 - 10%		
Human Serum					1 - 10%		
Sodium phosphate monobasic monohydrate		10049-21-5	231-449-2		0 - 0.5%		
ProClin 300					0 - 0.5%		
Bromophenol Blue		62625-28-9	263-653-2		0 - 0.5%		

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

Macra Lp(a) 80 Standard 9100-10

Revision 2

Revision date 2015-05-27

8.2. Exposure controls

Eye / face protection	Face shield. Safety glasses.
Skin protection - Handprotection	Wear suitable gloves.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid
Colour	Blue

SECTION 10: Stability and reactivity

10.2. Chemical stability

	Stable under normal conditions.
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SECTION 11: Toxicological information

11.1.4. Toxicological Information

	No data is available on this product.
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SECTION 12: Ecological information

12.1. Toxicity

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

General information

	Dispose of in compliance with all local and national regulations.
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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>
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Further information

	This SDS is prepared according to 29 CFR 1910.1200.
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Macra Lp(a) 80 Standard 9100-10

Revision 2

Revision date 2015-05-27

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. 9 - 9.1. Information on basic physical and chemical properties (Colour). 15 - 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.
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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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Macra Lp(a) Control 1 9100-1

Revision 2

Revision date 2015-05-27

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

1.1. Product identifier

Product name	Macra Lp(a) Control 1 9100-1
Product code	2339100

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
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SECTION 3: Composition/information on ingredients

3.2. Mixtures

Macra Lp(a) Control 1 9100-1

Revision 2

Revision date 2015-05-27

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
Goat Serum, Heat Inactivated					1 - 10%		
Sodium phosphate monobasic monohydrate		10049-21-5	231-449-2		0 - 0.5%		
Human Serum					0 - 0.5%		
ProClin 300					0 - 0.5%		
Disodium EDTA		6381-92-6	205-358-3		0 - 0.5%		
Bromophenol Blue		62625-28-9	263-653-2		0 - 0.5%		

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

Macra Lp(a) Control 1 9100-1

Revision 2

Revision date 2015-05-27

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.

Skin protection - Handprotection

Wear suitable gloves.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid
Colour	Blue

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

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.

Macra Lp(a) Control 1 9100-1

Revision 2

Revision date 2015-05-27

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:.

3 - Further information.

8 - Skin protection - Handprotection.

9 - 9.1. Information on basic physical and chemical properties (Colour).

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.

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Macra Lp(a) Control 2 9100-2

Revision 2

Revision date 2015-05-27

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

1.1. Product identifier

Product name	Macra Lp(a) Control 2 9100-2
Product code	2339100

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

Macra Lp(a) Control 2 9100-2

Revision 2
Revision date 2015-05-27

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
Goat Serum, Heat Inactivated					1 - 10%		
Human Serum					0 - 0.5%		
Sodium phosphate monobasic monohydrate		10049-21-5	231-449-2		0 - 0.5%		
ProClin 300					0 - 0.5%		
Disodium EDTA		6381-92-6	205-358-3		0 - 0.5%		
Bromophenol Blue		62625-28-9	263-653-2		0 - 0.5%		

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

Macra Lp(a) Control 2 9100-2

Revision 2

Revision date 2015-05-27

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.

Skin protection - Handprotection

Wear suitable gloves.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid
Colour	Blue

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

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.

Macra Lp(a) Control 2 9100-2

Revision 2

Revision date 2015-05-27

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:.

3 - Further information.

8 - Skin protection - Handprotection.

9 - 9.1. Information on basic physical and chemical properties (Colour).

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

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Macra Lp(a) Sample Diluent 617487

Revision 2

Revision date 2015-05-27

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

1.1. Product identifier

Product name	Macra Lp(a) Sample Diluent 617487
Product code	2339100

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
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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

2.2. Label elements

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

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Macra Lp(a) Sample Diluent 617487

Revision 2

Revision date 2015-05-27

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
Goat Serum, Heat Inactivated					1 - 10%		
Sodium phosphate monobasic monohydrate		10049-21-5	231-449-2		0 - 0.5%		
Disodium EDTA		6381-92-6	205-358-3		0 - 0.5%		
Bromophenol Blue		62625-28-9	263-653-2		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	No known adverse health effects.
Eye contact	Rinse immediately with plenty of water for 15 minutes holding the eyelids open. Seek medical attention.
Skin contact	Wash with soap and water. Seek medical attention.
Ingestion	Immediate medical attention is required.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Use extinguishing media appropriate to the surrounding fire conditions.

SECTION 6: Accidental release measures

6.3. Methods and material for containment and cleaning up

Absorb with inert, absorbent material. Clean spillage area thoroughly with plenty of water.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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

7.2. Conditions for safe storage, including any incompatibilities

2-8 °C.

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

Eye / face protection	Safety glasses.
Skin protection - Handprotection	Wear suitable gloves.
Skin protection - Other	Wear suitable protective clothing.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid
Colour	Blue

SECTION 10: Stability and reactivity

10.2. Chemical stability

Stable under normal conditions.

Macra Lp(a) Sample Diluent 617487

Revision 2

Revision date 2015-05-27

SECTION 11: Toxicological information**11.1.4. Toxicological 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**

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**

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.

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.

SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

Page 1/3

Macra Lp(a) Wash Buffer 20X 827602

Revision 2

Revision date 2015-05-27

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

1.1. Product identifier

Product name	Macra Lp(a) Wash Buffer 20X 827602
Product code	2339100

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
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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
--------------	-----------------------

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Macra Lp(a) Wash Buffer 20X 827602

Revision 2

Revision date 2015-05-27

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
Tween 20 CH016		9005-64-5	500-018-3		1 - 10%		
Sodium phosphate monobasic monohydrate		10049-21-5	231-449-2		0 - 0.5%		
ProClin 300					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	No known adverse health effects.
Eye contact	Rinse immediately with plenty of water for 15 minutes holding the eyelids open. Seek medical attention.
Skin contact	Wash with soap and water. Seek medical attention.
Ingestion	Immediate medical attention is required.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Use extinguishing media appropriate to the surrounding fire conditions.

SECTION 6: Accidental release measures

6.3. Methods and material for containment and cleaning up

Absorb with inert, absorbent material. Clean spillage area thoroughly with plenty of water.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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

7.2. Conditions for safe storage, including any incompatibilities

2-8 °C.

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

Eye / face protection	Safety glasses.
Skin protection - Handprotection	Wear suitable gloves.
Skin protection - Other	Wear suitable protective clothing.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid
Colour	Clear

SECTION 10: Stability and reactivity

10.2. Chemical stability

Stable under normal conditions.

SECTION 11: Toxicological information

Macra Lp(a) Wash Buffer 20X 827602

Revision 2

Revision date 2015-05-27

11.1.4. Toxicological Information

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

	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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	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.
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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.
--	--

Revision

	This document differs from the previous version in the following areas: 3 - Further information. 8 - Skin protection - Handprotection. 9 - 9.1. Information on basic physical and chemical properties (Colour). 15 - 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.
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SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

Page 1/3

Macra Lp(a) Colorimetric Reagent (Substrate) 517873

Revision 2

Revision date 2015-05-27

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

1.1. Product identifier

Product name	Macra Lp(a) Colorimetric Reagent (Substrate) 517873
Product code	2339100

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

Macra Lp(a) Colorimetric Reagent (Substrate) 517873

Revision 2

Revision date 2015-05-27

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%		
Citric Acid Trisodium Dihydrate		6132-04-3			0.5 - 1%		

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	Rinse immediately with plenty of water for 15 minutes holding the eyelids open. Seek medical attention.
Skin contact	Wash off immediately with plenty of soap and water.
Ingestion	Rinse mouth thoroughly. Seek medical attention.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Use extinguishing media appropriate to the surrounding fire conditions.

5.3. Advice for firefighters

Protective equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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

6.3. Methods and material for containment and cleaning up

Absorb with inert, absorbent material. Wash with water.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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

7.2. Conditions for safe storage, including any incompatibilities

2-8 °C.

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

Eye / face protection	Safety glasses.
Skin protection - Handprotection	Wear suitable gloves.
Skin protection - Other	Wear suitable protective clothing.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Aqueous solution
Colour	Colourless

SECTION 10: Stability and reactivity

10.2. Chemical stability

Macra Lp(a) Colorimetric Reagent (Substrate) 517873

Revision 2

Revision date 2015-05-27

10.2. Chemical stability

Stable under normal conditions.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

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

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

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:.

3 - Further information.

8 - Skin protection - Handprotection.

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

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

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Macra Lp(a) OPD Reagent 51-

Revision 2

Revision date 2015-06-22

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

1.1. Product identifier

Product name Macra Lp(a) OPD Reagent 51-

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

2.1.1. Classification - 1999/45/EC T; R25 Xn; R20/21-40-68 Xi; R36-43 N; R50/53
Symbols:

Main hazards Harmful by inhalation and in contact with skin. Toxic if swallowed. Irritating to eyes. Limited evidence of a carcinogenic effect. May cause sensitisation by skin contact. Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Possible risk of irreversible effects.

2.1.2. Classification - EC 1272/2008 Acute Tox. 3: H301; Skin Sens. 1: H317; Eye Irrit. 2: H319; Acute Tox. 4: H332; Muta. 2: H341; Carc. 2: H351;



2.2. Label elements

Macra Lp(a) OPD Reagent 51-

Revision 2

Revision date 2015-06-22

2.2. Label elements

Hazard pictograms	 
Signal Word	Danger
Hazard Statement	Acute Tox. 3: H301 - Toxic if swallowed. Skin Sens. 1: H317 - May cause an allergic skin reaction. Eye Irrit. 2: H319 - Causes serious eye irritation. Acute Tox. 4: H332 - Harmful if inhaled. Muta. 2: H341 - Suspected of causing genetic defects . Carc. 2: H351 - Suspected of causing cancer .
Precautionary Statement: Prevention	P201 - Obtain special instructions before use. P202 - Do not handle until all safety precautions have been read and understood. P261 - Avoid breathing dust/fume/gas/mist/vapours/spray. P264 - Wash thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P271 - Use only outdoors or in a well-ventilated area. 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+P310 - IF SWALLOWED: IF SWALLOWED: Immediately call a POISON CENTER/doctor/ . P302+P352 - IF ON SKIN: Wash with plenty of water/ . 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. P312 - Call a POISON CENTER/doctor/ /if you feel unwell. P321 - Specific treatment (see on this label). P330 - Rinse mouth. P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P337+P313 - If eye irritation persists: Get medical advice/attention.
Precautionary Statement: Storage	P405 - Store locked up.
Precautionary Statement: Disposal	P501 - Dispose of contents/container to an appropriate waste site or reclaim (in accordance with local/regional/national/international regulation).

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.
o-Phenylenediamine dihydrochloride	612-146-00-8	615-28-1	210-418-7		40 - 50%	Carc. Cat. 3; R40 Muta. Cat. 3; R68 T; R25 Xn; R20/21 Xi; R36 R43 N; R50/53	
Sodium metabisulphite (Disodium disulphite)	016-063-00-2	7681-57-4	231-673-0		0.5 - 1%	Xn; R22 Xi; R41 R31	

Macra Lp(a) OPD Reagent 51-

Revision 2

Revision date 2015-06-22

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
o-Phenylenediamine dihydrochloride	612-146-00-8	615-28-1	210-418-7		40 - 50%	Carc. 2: H351; Muta. 2: H341; Acute Tox. 3: H301; Acute Tox. 4: H332; Acute Tox. 4: H312; Eye Irrit. 2: H319; Skin Sens. 1: H317; Aquatic Acute 1: H400; Aquatic Chronic 1: H410;	
Sodium metabisulphite (Disodium disulphite)	016-063-00-2	7681-57-4	231-673-0		0.5 - 1%	Acute Tox. 4: H302; Eye Dam. 1: H318;	

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Move the exposed person to fresh air. If breathing stops, provide artificial respiration. Seek medical attention.
Eye contact	Rinse immediately with plenty of water for 15 minutes holding the eyelids open. Seek medical attention.
Skin contact	Wash with soap and water. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Rinse mouth. Seek medical attention.

SECTION 5: Firefighting measures

5.1. Extinguishing media

	Water spray. Alcohol resistant foam. Dry chemical. Carbon dioxide (CO2).
--	--

5.2. Special hazards arising from the substance or mixture

	Carbon dioxide (CO2). Nitrogen oxides. Sulphur oxides. Hydrogen chloride. Sodium oxides.
--	--

5.3. Advice for firefighters

	Self-contained breathing apparatus.
--	-------------------------------------

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

	Avoid formation of dust. Do not breathe gas/fumes/vapour/spray. Ensure adequate ventilation of the working area. Evacuate personnel to a safe area. Avoid breathing dust/fume/gas/mist/vapours/spray.
--	---

6.2. Environmental precautions

	Prevent further spillage if safe. Do not allow product to enter drains. Avoid release to the environment.
--	---

6.3. Methods and material for containment and cleaning up

	Avoid formation of dust. Sweep up.
--	------------------------------------

SECTION 7: Handling and storage

7.1. Precautions for safe handling

	Avoid contact with eyes and skin. Avoid formation of dust. Ensure adequate ventilation of the working area.
--	---

7.2. Conditions for safe storage, including any incompatibilities

	Keep container dry. Keep container tightly closed and in a well-ventilated place.
--	---

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. Exposure Limit Values

Macra Lp(a) OPD Reagent 51-

Revision 2

Revision date 2015-06-22

8.1.1. Exposure Limit Values

o-Phenylenediamine dihydrochloride	WEL 8-hr limit ppm:	WEL 8-hr limit mg/m3: 5
	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:
Sodium metabisulphite (Disodium disulphite)	WEL 8-hr limit ppm: -	WEL 8-hr limit mg/m3: 5
	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	Wash hands after handling the product.
Eye / face protection	Face shield. Safety glasses.
Skin protection - Handprotection	Wear suitable gloves. Wash hands after handling the product.
Skin protection - Other	Wear suitable protective clothing.
8.2.3. Environmental exposure controls	Prevent further spillage if safe. Do not allow product to enter drains. Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Tablet
Colour	White
Flash point	No data available
Solubility	No data available

SECTION 10: Stability and reactivity

10.2. Chemical stability

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

SECTION 11: Toxicological information

11.1.4. Toxicological Information

	No data available
--	-------------------

SECTION 12: Ecological information

Further information

	Toxic to aquatic organisms.
--	-----------------------------

SECTION 13: Disposal considerations

General information

	Contact a licensed waste disposal company.
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SECTION 14: Transport information

SECTION 15: Regulatory information

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

Macra Lp(a) OPD Reagent 51-

Revision 2

Revision date 2015-06-22

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. Classification of the substance or mixture.
- 2 - 2.1.2. Classification - EC 1272/2008.
- 2 - Hazard pictograms.
- 2 - Signal Word.
- 2 - Precautionary Statement: Prevention.
- 2 - Precautionary Statement: Response.
- 2 - Precautionary Statement: Storage.
- 2 - Precautionary Statement: Disposal.
- 4 - Skin contact.
- 4 - Eye contact.
- 4 - Inhalation.
- 4 - Ingestion.
- 5 - 5.1. Extinguishing media.
- 5 - 5.2. Special hazards arising from the substance or mixture.
- 5 - 5.3. Advice for firefighters.
- 6 - 6.1. Personal precautions, protective equipment and emergency procedures.
- 6 - 6.2. Environmental precautions.
- 6 - 6.3. Methods and material for containment and cleaning up.
- 7 - 7.1. Precautions for safe handling.
- 7 - 7.2. Conditions for safe storage, including any incompatibilities.
- 8 - 8.2.1. Appropriate engineering controls.
- 8 - Skin protection - Handprotection.
- 8 - Eye / face protection.
- 8 - 8.2.3. Environmental exposure controls.
- 8 - Skin protection - Other.
- 9 - 9.1. Information on basic physical and chemical properties (Appearance).
- 9 - 9.1. Information on basic physical and chemical properties (Colour).
- 9 - 9.1. Information on basic physical and chemical properties (Flash point).
- 9 - 9.1. Information on basic physical and chemical properties (Solubility).
- 10 - 10.2. Chemical stability.
- 11 - 11.1.4. Toxicological Information.
- 12 - 12.1. Toxicity.
- 12 - Further information.
- 13 - General information.
- 14 - ADR/RID.
- 14 - IMDG.

Macra Lp(a) OPD Reagent 51-

Revision 2

Revision date 2015-06-22

Other information

	14 - IATA. 15 - Labelling. 15 - Symbols. 15 - Risk phrases. 15 - Safety phrases. 15 - Further information. 15 - 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.
Text of risk phrases in Section 3	R20/21 - Harmful by inhalation and in contact with skin. R22 - Harmful if swallowed. R25 - Toxic if swallowed. R31 - Contact with acids liberates toxic gas. R36 - Irritating to eyes. R40 - Limited evidence of a carcinogenic effect. R41 - Risk of serious damage to eyes. R43 - May cause sensitisation by skin contact. R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R68 - Possible risk of irreversible effects.
Text of Hazard Statements in Section 3	Acute Tox. 3: H301 - Toxic if swallowed. Acute Tox. 4: H312 - Harmful in contact with skin. Skin Sens. 1: H317 - May cause an allergic skin reaction. Eye Irrit. 2: H319 - Causes serious eye irritation. Acute Tox. 4: H332 - Harmful if inhaled. Muta. 2: H341 - Suspected of causing genetic defects . Carc. 2: H351 - Suspected of causing cancer . Aquatic Chronic 1: H410 - Very toxic to aquatic life with long lasting effects. EUH031 - Contact with acids liberates toxic gas. Acute Tox. 4: H302 - Harmful if swallowed. Eye Dam. 1: H318 - Causes serious eye damage.

SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

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

1.1. Product identifier

Product name	Macra Lp(a) Stop Solution 914601
Product code	2339100

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
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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

2.1.2. Classification - EC 1272/2008	Skin Corr. 1A: H314;
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2.2. Label elements

Hazard pictograms	
Signal Word	Danger
Hazard Statement	Skin Corr. 1A: H314 - Causes severe skin burns and eye damage.

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2.2. Label elements

Precautionary Statement: Prevention	P260 - Do not breathe dust/fume/gas/mist/vapours/spray. P264 - Wash thoroughly after handling. P280 - Wear protective gloves/protective clothing/eye protection/face protection.
Precautionary Statement: Response	P301+P330+P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting. 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. P310 - Immediately call a POISON CENTER/doctor/ . P321 - Specific treatment (see on this label). P363 - Wash contaminated clothing before reuse.
Precautionary Statement: Storage	P405 - Store locked up.
Precautionary Statement: Disposal	P501 - Dispose of contents/container to an appropriate waste site or reclaim (in accordance with local/regional/national/international regulation).

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.
sulfuric 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.
sulfuric 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.

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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

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

	Do not allow product to enter drains.
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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.
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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.
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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.
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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. Exposure Limit Values

sulfuric 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.
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8.2.2. Individual protection measures

	Wear suitable protective clothing.
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Eye / face protection

	Approved safety goggles.
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Skin protection -
Handprotection

	Wear suitable gloves.
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Respiratory protection

	Wear suitable respiratory equipment when necessary.
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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.
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SECTION 11: Toxicological information**11.1.4. Toxicological Information**

sulfuric 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.	

SECTION 12: Ecological information**12.1. Toxicity**

sulfuric acid	Fish LC50/96h: 42.00000 mg/l
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12.4. Mobility in soil

	When released into soil, this material may leach into groundwater.
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SECTION 13: Disposal considerations**General information**

	Dispose of in compliance with all local and national regulations.
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SECTION 14: Transport information**Further information**

	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**

	<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>
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Further information

	This SDS is prepared according to 29 CFR 1910.1200.
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SECTION 16: Other information**Other information**

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 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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