

SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

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SS-A (Ro) Conjugate 385425

Revision 2

Revision date 2015-06-16

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

1.1. Product identifier

| | |
|--------------|----------------------------|
| Product name | SS-A (Ro) Conjugate 385425 |
| Product code | 2337070 |

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

SS-A (Ro) Conjugate 385425

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3.2. Mixtures

EC 1272/2008

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

Further information

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

SECTION 4: First aid measures

4.1. Description of first aid measures

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

SECTION 5: Firefighting measures

5.1. Extinguishing media

Use extinguishing media appropriate to the surrounding fire conditions.

5.2. Special hazards arising from the substance or mixture

Burning produces irritating, toxic and obnoxious fumes.

5.3. Advice for firefighters

Wear suitable respiratory equipment when necessary.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation of the working area.

6.3. Methods and material for containment and cleaning up

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

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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

7.2. Conditions for safe storage, including any incompatibilities

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

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Ensure adequate ventilation of the working area.

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8.2. Exposure controls

8.2.2. Individual protection measures

Wear protective clothing.

Eye / face protection

In case of splashing, wear: Approved safety goggles.

Skin protection - Handprotection

Wear suitable gloves.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|------------|-----------|
| Appearance | Liquid |
| Colour | Off white |

SECTION 10: Stability and reactivity

10.2. Chemical stability

Stable under normal conditions.

SECTION 11: Toxicological information

11.1.13. Other information

No known adverse health effects.

SECTION 12: Ecological information

Further information

No known adverse environmental effects.

SECTION 13: Disposal considerations

Further information

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

SECTION 14: Transport information

Further information

The product is not classified as dangerous for carriage.

SECTION 15: Regulatory information

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

COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

Further information

This SDS is prepared according to 29 CFR 1910.1200.

SECTION 16: Other information

Other information

Revision

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

SS-A (Ro) Conjugate 385425

Revision 2

Revision date 2015-06-16

Other information

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

Further information

| | |
|--|--|
| | The information supplied in this Safety Data Sheet is designed only as guidance for the safe use, storage and handling of the product. This information is correct to the best of our knowledge and belief at the date of publication however no guarantee is made to its accuracy. This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process. |
|--|--|

SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

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SS-A (Ro) High Pos Control 3707-1

Revision 2

Revision date 2015-06-16

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

1.1. Product identifier

| | |
|--------------|-----------------------------------|
| Product name | SS-A (Ro) High Pos Control 3707-1 |
| Product code | 2337070 |

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

SS-A (Ro) High Pos Control 3707-1

Revision 2

Revision date 2015-06-16

3.2. Mixtures

EC 1272/2008

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

Hazardous ingredients

Biohazardous Material.

Further information

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

SECTION 4: First aid measures

4.1. Description of first aid measures

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

General information

If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: Firefighting measures

5.1. Extinguishing media

Use extinguishing media appropriate to the surrounding fire conditions.

5.2. Special hazards arising from the substance or mixture

Burning produces irritating, toxic and obnoxious fumes.

5.3. Advice for firefighters

Wear suitable respiratory equipment when necessary.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear suitable protective equipment.

6.3. Methods and material for containment and cleaning up

Collect spilled liquid with absorbent material and place in a container for suitable disposal. Clean area thoroughly with disinfectant. Flush down the drain with plenty of water.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handle as if capable of transmitting a disease.

7.2. Conditions for safe storage, including any incompatibilities

2-8 °C.

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

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

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8.2. Exposure controls

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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|------------|-----------|
| Appearance | Liquid |
| Colour | Off white |

SECTION 10: Stability and reactivity

10.2. Chemical stability

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

SECTION 11: Toxicological information

11.1.4. Toxicological Information

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

SECTION 12: Ecological information

12.1. Toxicity

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

SECTION 13: Disposal considerations

General information

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

Disposal methods

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

Disposal of packaging

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

SECTION 14: Transport information

Further information

| | |
|--|--|
| | The product is not classified as dangerous for carriage. |
|--|--|

SECTION 15: Regulatory information

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

| | |
|--|--|
| | <p>COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.</p> <p>REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.</p> |
|--|--|

Further information

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

SECTION 16: Other information

SS-A (Ro) High Pos Control 3707-1

Revision 2

Revision date 2015-06-16

Other information

| | |
|---|--|
| Revision | This document differs from the previous version in the following areas: 3 - Further information. 8 - Skin protection - Handprotection. 12 - 12.1. Toxicity. 15 - 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture. |
| Text of Hazard Statements in Section 3 | EUH032 - Contact with acids liberates very toxic gas. Acute Tox. 2: H300 - Fatal if swallowed. Aquatic Acute 1: H400 - Very toxic to aquatic life. Aquatic Chronic 1: H410 - Very toxic to aquatic life with long lasting effects. |

Further information

| | |
|--|--|
| | The information supplied in this Safety Data Sheet is designed only as guidance for the safe use, storage and handling of the product. This information is correct to the best of our knowledge and belief at the date of publication however no guarantee is made to its accuracy. This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process. |
|--|--|

SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

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SS-A (Ro) Calibrator 3707-2

Revision 2

Revision date 2015-06-16

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

1.1. Product identifier

| | |
|--------------|-----------------------------|
| Product name | SS-A (Ro) Calibrator 3707-2 |
| Product code | 2337070 |

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

SS-A (Ro) Calibrator 3707-2

Revision 2

Revision date 2015-06-16

3.2. Mixtures

EC 1272/2008

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

Hazardous ingredients

Biohazardous Material.

Further information

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

SECTION 4: First aid measures

4.1. Description of first aid measures

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

General information

If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: Firefighting measures

5.1. Extinguishing media

Use extinguishing media appropriate to the surrounding fire conditions.

5.2. Special hazards arising from the substance or mixture

Burning produces irritating, toxic and obnoxious fumes.

5.3. Advice for firefighters

Wear suitable respiratory equipment when necessary.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear suitable protective equipment.

6.3. Methods and material for containment and cleaning up

Collect spilled liquid with absorbent material and place in a container for suitable disposal. Clean area thoroughly with disinfectant. Flush down the drain with plenty of water.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handle as if capable of transmitting a disease.

7.2. Conditions for safe storage, including any incompatibilities

2-8 °C.

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

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

SS-A (Ro) Calibrator 3707-2

Revision 2

Revision date 2015-06-16

8.2. Exposure controls

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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|------------|-----------|
| Appearance | Liquid |
| Colour | Off white |

SECTION 10: Stability and reactivity

10.2. Chemical stability

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

SECTION 11: Toxicological information

11.1.4. Toxicological Information

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

SECTION 12: Ecological information

12.1. Toxicity

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

SECTION 13: Disposal considerations

General information

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

Disposal methods

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

Disposal of packaging

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

SECTION 14: Transport information

Further information

| | |
|--|--|
| | The product is not classified as dangerous for carriage. |
|--|--|

SECTION 15: Regulatory information

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

| | |
|--|--|
| | <p>COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.</p> <p>REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.</p> |
|--|--|

Further information

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

SECTION 16: Other information

SS-A (Ro) Calibrator 3707-2

Revision 2

Revision date 2015-06-16

Other information

| | |
|---|--|
| Revision | This document differs from the previous version in the following areas: 3 - Further information. 8 - Skin protection - Handprotection. 12 - 12.1. Toxicity. 15 - 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture. |
| Text of Hazard Statements in Section 3 | EUH032 - Contact with acids liberates very toxic gas. Acute Tox. 2: H300 - Fatal if swallowed. Aquatic Acute 1: H400 - Very toxic to aquatic life. Aquatic Chronic 1: H410 - Very toxic to aquatic life with long lasting effects. |

Further information

| | |
|--|--|
| | The information supplied in this Safety Data Sheet is designed only as guidance for the safe use, storage and handling of the product. This information is correct to the best of our knowledge and belief at the date of publication however no guarantee is made to its accuracy. This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process. |
|--|--|

SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

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SS-A (Ro) Negative Control 3707-3

Revision 2

Revision date 2015-06-16

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

1.1. Product identifier

| | |
|--------------|-----------------------------------|
| Product name | SS-A (Ro) Negative Control 3707-3 |
| Product code | 2337070 |

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

SS-A (Ro) Negative Control 3707-3

Revision 2

Revision date 2015-06-16

3.2. Mixtures

EC 1272/2008

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

Hazardous ingredients

Biohazardous Material.

Further information

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

SECTION 4: First aid measures

4.1. Description of first aid measures

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

General information

If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: Firefighting measures

5.1. Extinguishing media

Use extinguishing media appropriate to the surrounding fire conditions.

5.2. Special hazards arising from the substance or mixture

Burning produces irritating, toxic and obnoxious fumes.

5.3. Advice for firefighters

Wear suitable respiratory equipment when necessary.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear suitable protective equipment.

6.3. Methods and material for containment and cleaning up

Collect spilled liquid with absorbent material and place in a container for suitable disposal. Clean area thoroughly with disinfectant. Flush down the drain with plenty of water.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handle as if capable of transmitting a disease.

7.2. Conditions for safe storage, including any incompatibilities

2-8 °C.

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

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

SS-A (Ro) Negative Control 3707-3

Revision 2

Revision date 2015-06-16

8.2. Exposure controls

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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|------------|-----------|
| Appearance | Liquid |
| Colour | Off white |

SECTION 10: Stability and reactivity

10.2. Chemical stability

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

SECTION 11: Toxicological information

11.1.4. Toxicological Information

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

SECTION 12: Ecological information

12.1. Toxicity

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

SECTION 13: Disposal considerations

General information

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

Disposal methods

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

Disposal of packaging

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

SECTION 14: Transport information

Further information

| | |
|--|--|
| | The product is not classified as dangerous for carriage. |
|--|--|

SECTION 15: Regulatory information

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

| | |
|--|--|
| | <p>COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.</p> <p>REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.</p> |
|--|--|

Further information

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

SECTION 16: Other information

SS-A (Ro) Negative Control 3707-3

Revision 2

Revision date 2015-06-16

Other information

| | |
|---|--|
| Revision | This document differs from the previous version in the following areas: 3 - Further information. 8 - Skin protection - Handprotection. 12 - 12.1. Toxicity. 15 - 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture. |
| Text of Hazard Statements in Section 3 | EUH032 - Contact with acids liberates very toxic gas. Acute Tox. 2: H300 - Fatal if swallowed. Aquatic Acute 1: H400 - Very toxic to aquatic life. Aquatic Chronic 1: H410 - Very toxic to aquatic life with long lasting effects. |

Further information

| | |
|--|--|
| | The information supplied in this Safety Data Sheet is designed only as guidance for the safe use, storage and handling of the product. This information is correct to the best of our knowledge and belief at the date of publication however no guarantee is made to its accuracy. This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process. |
|--|--|

SAFETY DATA SHEET

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SS-A (Ro) Low Pos Control 3707-4

Revision 2

Revision date 2015-06-16

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

1.1. Product identifier

| | |
|--------------|----------------------------------|
| Product name | SS-A (Ro) Low Pos Control 3707-4 |
| Product code | 2337070 |

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

SS-A (Ro) Low Pos Control 3707-4

Revision 2

Revision date 2015-06-16

3.2. Mixtures

EC 1272/2008

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

Hazardous ingredients

Biohazardous Material.

Further information

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

SECTION 4: First aid measures

4.1. Description of first aid measures

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

General information

If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: Firefighting measures

5.1. Extinguishing media

Use extinguishing media appropriate to the surrounding fire conditions.

5.2. Special hazards arising from the substance or mixture

Burning produces irritating, toxic and obnoxious fumes.

5.3. Advice for firefighters

Wear suitable respiratory equipment when necessary.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear suitable protective equipment.

6.3. Methods and material for containment and cleaning up

Collect spilled liquid with absorbent material and place in a container for suitable disposal. Clean area thoroughly with disinfectant. Flush down the drain with plenty of water.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handle as if capable of transmitting a disease.

7.2. Conditions for safe storage, including any incompatibilities

2-8 °C.

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

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

SS-A (Ro) Low Pos Control 3707-4

Revision 2

Revision date 2015-06-16

8.2. Exposure controls

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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|------------|-----------|
| Appearance | Liquid |
| Colour | Off white |

SECTION 10: Stability and reactivity

10.2. Chemical stability

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

SECTION 11: Toxicological information

11.1.4. Toxicological Information

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

SECTION 12: Ecological information

12.1. Toxicity

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

SECTION 13: Disposal considerations

General information

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

Disposal methods

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

Disposal of packaging

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

SECTION 14: Transport information

Further information

| | |
|--|--|
| | The product is not classified as dangerous for carriage. |
|--|--|

SECTION 15: Regulatory information

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

| | |
|--|--|
| | <p>COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.</p> <p>REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.</p> |
|--|--|

Further information

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

SECTION 16: Other information

SS-A (Ro) Low Pos Control 3707-4

Revision 2

Revision date 2015-06-16

Other information

| | |
|---|--|
| Revision | This document differs from the previous version in the following areas: 3 - Further information. 8 - Skin protection - Handprotection. 12 - 12.1. Toxicity. 15 - 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture. |
| Text of Hazard Statements in Section 3 | EUH032 - Contact with acids liberates very toxic gas. Acute Tox. 2: H300 - Fatal if swallowed. Aquatic Acute 1: H400 - Very toxic to aquatic life. Aquatic Chronic 1: H410 - Very toxic to aquatic life with long lasting effects. |

Further information

| | |
|--|--|
| | The information supplied in this Safety Data Sheet is designed only as guidance for the safe use, storage and handling of the product. This information is correct to the best of our knowledge and belief at the date of publication however no guarantee is made to its accuracy. This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process. |
|--|--|

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SS-A (Ro) Serum Diluent Type III 616434

Revision 2

Revision date 2015-06-15

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

1.1. Product identifier

| | |
|--------------|---|
| Product name | SS-A (Ro) Serum Diluent Type III 616434 |
| Product code | 2337070 |

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

SS-A (Ro) Serum Diluent Type III 616434

Revision 2

Revision date 2015-06-15

3.2. Mixtures

EC 1272/2008

| Chemical Name | Index No. | CAS No. | EC No. | REACH Registration Number | Conc. (%w/w) | Classification | M-factor. |
|---------------------------------|-----------|-----------|-----------|---------------------------|--------------|----------------|-----------|
| N-Z-Amine CH001A | | | | | 1 - 10% | | |
| Sodium Phosphate, Dibasic CH012 | | 7558-79-4 | 231-448-7 | | 0 - 0.5% | | |
| ProClin 300 | | | | | 0 - 0.5% | | |
| Tween 20 CH016 | | 9005-64-5 | 500-018-3 | | 0 - 0.5% | | |
| Potassium Chloride CH037 | | 7447-40-7 | 231-211-8 | | 0 - 0.5% | | |

Description

Non Hazardous.

Further information

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

SECTION 4: First aid measures

4.1. Description of first aid measures

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

SECTION 5: Firefighting measures

5.1. Extinguishing media

Use extinguishing media appropriate to the surrounding fire conditions.

5.3. Advice for firefighters

Wear suitable respiratory equipment when necessary.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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

6.2. Environmental precautions

Do not allow product to enter drains.

6.3. Methods and material for containment and cleaning up

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

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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

7.2. Conditions for safe storage, including any incompatibilities

Store in correctly labelled containers.

Further information

2-8 °C.

SS-A (Ro) Serum Diluent Type III 616434

Revision 2

Revision date 2015-06-15

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

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

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

| | |
|------------|------------------|
| Appearance | Aqueous solution |
| Colour | Yellow |

SECTION 10: Stability and reactivity**10.1. Reactivity**

Stable under normal conditions.

SECTION 11: Toxicological information**Further information**

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

SECTION 12: Ecological information**Further information**

No known adverse environmental effects.

SECTION 13: Disposal considerations**Disposal methods**

Dispose of in compliance with all local and national regulations.

SECTION 14: Transport information**Further information**

The product is not classified as dangerous for carriage.

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

Further information

This SDS is prepared according to 29 CFR 1910.1200.

SS-A (Ro) Serum Diluent Type III 616434

Revision 2

Revision date 2015-06-15

SECTION 16: Other information**Further information**

The information supplied in this Safety Data Sheet is designed only as guidance for the safe use, storage and handling of the product. This information is correct to the best of our knowledge and belief at the date of publication however no guarantee is made to its accuracy. This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process.

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SS-A (Ro) Wash Buffer Type II 827402

Revision 2

Revision date 2015-06-16

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

1.1. Product identifier

| | |
|--------------|--------------------------------------|
| Product name | SS-A (Ro) Wash Buffer Type II 827402 |
| Product code | 2337070 |

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

SS-A (Ro) Wash Buffer Type II 827402

Revision 2

Revision date 2015-06-16

3.2. Mixtures

EC 1272/2008

| Chemical Name | Index No. | CAS No. | EC No. | REACH Registration Number | Conc. (%w/w) | Classification | M-factor. |
|-----------------------|--------------|-----------|-----------|---------------------------|--------------|---------------------------------------|-----------|
| Hydrochloric acid...% | 017-002-01-X | | 231-595-7 | | 0 - 0.5% | Skin Corr. 1B: H314; STOT SE 3: H335; | |
| Tween 80 CH016A | | 9005-65-6 | | | 1 - 10% | | |
| EDTA | | 6381-92-6 | 205-358-3 | | 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 | May cause irritation to mucous membranes. Move the exposed person to fresh air. |
| Eye contact | May cause irritation to eyes. Rinse immediately with plenty of water for 15 minutes holding the eyelids open. Seek medical attention if irritation or symptoms persist. |
| Skin contact | May cause irritation to skin. Wash off immediately with plenty of soap and water. Remove contaminated clothing. Seek medical attention if irritation or symptoms persist. |
| Ingestion | May cause irritation to mucous membranes. DO NOT INDUCE VOMITING. Seek medical attention if irritation or symptoms persist. |

SECTION 5: Firefighting measures

5.1. Extinguishing media

Use extinguishing media appropriate to the surrounding fire conditions.

5.2. Special hazards arising from the substance or mixture

Burning produces irritating, toxic and obnoxious fumes.

5.3. Advice for firefighters

Wear suitable respiratory equipment when necessary.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation of the working area.

6.2. Environmental precautions

Do not allow product to enter drains.

6.3. Methods and material for containment and cleaning up

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

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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

7.2. Conditions for safe storage, including any incompatibilities

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

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

SS-A (Ro) Wash Buffer Type II 827402

Revision 2

Revision date 2015-06-16

8.2. Exposure controls

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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|------------|------------------|
| Appearance | Aqueous solution |
| Colour | Blue |

SECTION 10: Stability and reactivity

10.2. Chemical stability

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

SECTION 11: Toxicological information

11.1.13. Other information

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

SECTION 12: Ecological information

Further information

| | |
|--|---|
| | No known adverse environmental effects. |
|--|---|

SECTION 13: Disposal considerations

General information

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

SECTION 14: Transport information

Further information

| | |
|--|--|
| | The product is not classified as dangerous for carriage. |
|--|--|

SECTION 15: Regulatory information

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

| | |
|--|--|
| | <p>COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.</p> <p>REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.</p> |
|--|--|

Further information

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

SS-A (Ro) Wash Buffer Type II 827402

Revision 2

Revision date 2015-06-16

SECTION 16: Other information

Other information

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

General information

| | |
|--|--|
| | The information supplied in this Safety Data Sheet is designed only as guidance for the safe use, storage and handling of the product. This information is correct to the best of our knowledge and belief at the date of publication however no guarantee is made to its accuracy. This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process. |
|--|--|

SAFETY DATA SHEET

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SS-A (Ro) Substrate Solution 525700

Revision 2

Revision date 2015-06-16

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

1.1. Product identifier

| | |
|--------------|-------------------------------------|
| Product name | SS-A (Ro) Substrate Solution 525700 |
| Product code | 2337070 |

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

SS-A (Ro) Substrate Solution 525700

Revision 2

Revision date 2015-06-16

3.2. Mixtures

EC 1272/2008

| Chemical Name | Index No. | CAS No. | EC No. | REACH Registration Number | Conc. (%w/w) | Classification | M-factor. |
|---|-----------|-------------|--------|---------------------------|--------------|----------------|-----------|
| SureBlue TMB Microwell Peroxidase Substrate (1-component) | | Proprietary | | | 10 - 20% | | |
| Hydrogen Peroxide | | 7722-84-1 | | | 0 - 0.5% | | |

Further information

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

SECTION 4: First aid measures

4.1. Description of first aid measures

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

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

5.3. Advice for firefighters

Self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear suitable protective equipment.

6.3. Methods and material for containment and cleaning up

Transfer to suitable, labelled containers for disposal.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Wear protective clothing.

7.2. Conditions for safe storage, including any incompatibilities

2-8 °C.

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

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

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SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

| | |
|------------------------------|------------------|
| Appearance | Aqueous solution |
| Colour | Clear |
| Initial boiling point | 100 |

SECTION 10: Stability and reactivity**10.2. Chemical stability**

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

10.4. Conditions to avoid

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

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

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

SECTION 12: Ecological information**Further information**

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

SECTION 13: Disposal considerations**General information**

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

SECTION 14: Transport information**Further information**

| | |
|--|--|
| | The product is not classified as dangerous for carriage. |
|--|--|

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

| | |
|--|--|
| | <p>COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.</p> <p>REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.</p> |
|--|--|

Further information

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

SECTION 16: Other information**Other information**

| | |
|-----------------|---|
| Revision | <p>This document differs from the previous version in the following areas:</p> <p>3 - Further information.</p> <p>8 - Skin protection - Handprotection.</p> <p>8 - 8.2.2. Individual protection measures.</p> |
|-----------------|---|

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Other information

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

1.1. Product identifier

| | |
|--------------|--------------------------------|
| Product name | SS-A (Ro) Stop Solution 915401 |
| Product code | 2337070 |

1.3. Details of the supplier of the safety data sheet

| | |
|-----------|---|
| Company | Trinity Biotech |
| Address | IDA Business Park Bray Co. Wicklow Ireland |
| Web | www.trinitybiotech.com |
| Telephone | +353 1 276 9800 |
| Fax | +353 1 276 9883 |
| Email | info@trinitybiotech.com |

Local Supplier

| | |
|-----------|--|
| Company | Trinity Biotech USA |
| Address | 2823 Girts Rd Jamestown NY 14701 USA |
| Telephone | +1 800-325-3424 |
| Fax | +1 716-487-1419 |

1.4. Emergency telephone number


| | |
|--|--|
| | Contact your local Emergency Health Provider. Ireland-Technical Support Group 00353 -1- 276- 9800 USA-Technical Support Group 1-800-325-3424 |
|--|--|

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

| | |
|--------------------------------------|--|
| 2.1.2. Classification - EC 1272/2008 | Skin Irrit. 2: H315; Eye Irrit. 2: H319; |
|--------------------------------------|--|

2.2. Label elements

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

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2.2. Label elements

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

SECTION 3: Composition/information on ingredients

3.2. Mixtures

67/548/EEC / 1999/45/EC

| Chemical Name | Index No. | CAS No. | EC No. | REACH Registration Number | Conc. (%w/w) | Classification | M-factor. |
|--|--------------|-----------|-----------|---------------------------|--------------|----------------|-----------|
| Sulphuric acid...% (Sulphuric acid (mist)) | 016-020-00-8 | 7664-93-9 | 231-639-5 | | 1 - 10% | C; R35 | |

EC 1272/2008

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

Further information

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

SECTION 4: First aid measures

4.1. Description of first aid measures

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

General information

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

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

Burning produces irritating, toxic and obnoxious fumes.

5.3. Advice for firefighters

Wear suitable respiratory equipment when necessary.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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

6.2. Environmental precautions

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6.2. Environmental precautions

Do not allow product to enter drains.

6.3. Methods and material for containment and cleaning up

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

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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

7.2. Conditions for safe storage, including any incompatibilities

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

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. Exposure Limit Values

| | | |
|--|--|--|
| Sulphuric acid...% (Sulphuric acid (mist)) | WEL 8-hr limit ppm: - | WEL 8-hr limit mg/m3: 0.05 |
| | WEL 15 min limit ppm: - | WEL 15 min limit mg/m3: - |
| | WEL 8-hr limit mg/m3 total - inhalable dust: | WEL 15 min limit mg/m3 total - inhalable dust: |
| | WEL 8-hr limit mg/m3 total - respirable dust: | WEL 15 min limit mg/m3 total - respirable dust: |

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Ensure adequate ventilation of the working area.

8.2.2. Individual protection measures

Wear suitable protective clothing.

Eye / face protection

Approved safety goggles.

Skin protection - Handprotection

Wear suitable gloves.

Respiratory protection

Wear suitable respiratory equipment when necessary.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|-----------------------|------------------|
| Appearance | Aqueous solution |
| Colour | Colourless |
| Initial boiling point | 100 |

SECTION 10: Stability and reactivity

10.2. Chemical stability

Stable under normal conditions.

SECTION 11: Toxicological information

11.1.4. Toxicological Information

| | | |
|--------------------|------------------------------|---------------------|
| Sulphuric acid...% | Inhalation Rat LC50/2 h: 510 | Oral Rat LD50: 2140 |
|--------------------|------------------------------|---------------------|

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

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

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

12.4. Mobility in soil

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

SECTION 13: Disposal considerations**General information**

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

SECTION 14: Transport information**Further information**

| | |
|--|--|
| | The product is not classified as dangerous for carriage. |
|--|--|

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

| | |
|--|--|
| | <p>COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.</p> <p>REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.</p> |
|--|--|

Further information

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

SECTION 16: Other information**Other information**

| | |
|---|--|
| Revision | <p>This document differs from the previous version in the following areas:.</p> <ul style="list-style-type: none"> 2 - 2.1.2. Classification - EC 1272/2008. 2 - Hazard pictograms. 2 - Signal Word. 2 - Precautionary Statement: Prevention. 2 - Precautionary Statement: Response. 3 - Further information. 8 - Skin protection - Handprotection. 8 - 8.2.2. Individual protection measures. 15 - 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture. |
| Text of risk phrases in Section 3 | R35 - Causes severe burns. |
| Text of Hazard Statements in Section 3 | Skin Corr. 1A: H314 - Causes severe skin burns and eye damage. |

Further information

| | |
|--|---|
| | The information supplied in this Safety Data Sheet is designed only as guidance for the safe use, storage and handling of the product. This information is correct to the best of our knowledge and |
|--|---|

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Further information

| | |
|--|--|
| | 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. |
|--|--|
