

according to 1907/2006/EC, Article 31

Page 1/4

PR-3 Conjugate 385425

Revision 2
Revision date 2015-06-05

| | Revision date 2015-06-05 |
|-------------------------------------|--|
| SECTION 1: Identification of | f the substance/mixture and of the company/undertaking |
| 1.1. Product identifier | |
| Product name | PR-3 Conjugate 385425 |
| Product code | 2338970 |
| 1.3. Details of the supplier of the | ne 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 nun | nber |
| | 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 identi | fication |
| 2.1. Classification of the substa | ance or mixture |
| Main hazards | No Significant Hazard |
| 2.2. Label elements | |
| Risk phrases | No Significant Hazard |
| SECTION 3: Composition/ir | nformation on ingredients |



3.2. Mixtures

PR-3 Conjugate 385425

Revision 2
Revision date 2015-06-05

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% | ó | |
| Bromonitrodioxane | | | | | 0 - 0.5% | 0 | |
| Gentatmicin Sulfate | | 1405-41-0 | | | 0 - 0.5% | Ó | |

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.



PR-3 Conjugate 385425

Revision Revision date 2015-06-05

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 (EC) 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:.



PR-3 Conjugate 385425

Revision date 2015-06-05

| 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. |





according to 1907/2006/EC, Article 31

Page 1/4

PR-3 High Pos Control 3897-1

Revision 2 Revision date 2015-06-05

| SECTION 1: Identification of | f the substance/mixture and of the company/undertaking |
|-------------------------------------|--|
| 1.1. Product identifier | |
| Product name | PR-3 High Pos Control 3897-1 |
| Product code | 2338970 |
| 1.3. Details of the supplier of the | e 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 num | ber |
| | 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 identif | fication |
| 2.1. Classification of the substa | nnce 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/in | formation on ingredients |



3.2. Mixtures

PR-3 High Pos Control 3897-1

Revision 2
Revision date 2015-06-05

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 NaN3)) | 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; | |

| ы | 979rd | Inara | dients |
|---|-------|-------|--------|
| | | | |

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 | Wear suitable protective equipment. Handle as if potentially infectious. |
|------------------------------|--|
| measures | |
| | |





PR-3 High Pos Control 3897-1

Revision 2
Revision date 2015-06-05

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 Colour Liquid 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

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 (EC) 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



PR-3 High Pos Control 3897-1

Revision 2 Revision date 2015-06-05

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 |
|---|--|
| Text of Hazard Statements in Section 3 Further information | mixture. 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. |
| | 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. |





according to 1907/2006/EC, Article 31

Page 1/4

PR-3 Calibrator 3897-2

Revision 2
Revision date 2015-06-05

| SECTION 1: Identification | of the substance/mixture and of the company/undertaking |
|---------------------------------|--|
| 1.1. Product identifier | |
| Product name | PR-3 Calibrator 3897-2 |
| Product code | 2338970 |
| 1.3. Details of the supplier of | f 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 n | umber |
| | 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 ide | ntification |
| 2.1. Classification of the sub | stance 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

PR-3 Calibrator 3897-2

Revision 2
Revision date 2015-06-05

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 NaN3)) | 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; | |

| н | 979rd | Inara | dients |
|---|-------|-------|--------|
| | | | |

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



PR-3 Calibrator 3897-2

Revision 2
Revision date 2015-06-05

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 Colour Liquid 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

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



PR-3 Calibrator 3897-2

Revision date 2015-06-05

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. |





according to 1907/2006/EC, Article 31

Page 1/4

PR-3 Negative Control 3897-3

Revision 2
Revision date 2015-06-05

| SECTION 1: Identification of | the substance/mixture and of the company/undertaking | | | |
|---|--|--|--|--|
| 1.1. Product identifier | | | | |
| Product name | PR-3 Negative Control 3897-3 | | | |
| Product code | 2338970 | | | |
| 1.3. Details of the supplier of the | e 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 num | ber I | | | |
| | 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 identifi | ication | | | |
| 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 | | | |
| 0.0 Labellahara 1 | recommended for any potentially infectious human serum or blood specimen. | | | |
| 2.2. Label elements | | | | |
| Risk phrases | No Significant Hazard | | | |



3.2. Mixtures

SECTION 3: Composition/information on ingredients

PR-3 Negative Control 3897-3

Revision 2
Revision date 2015-06-05

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 NaN3)) | 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; | |

| inaredients |
|-------------|
| |

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



PR-3 Negative Control 3897-3

Revision 2
Revision date 2015-06-05

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 Colour Liquid 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

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



PR-3 Negative Control 3897-3

Revision 2 Revision date 2015-06-05

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. |





according to 1907/2006/EC, Article 31

Page 1/4

PR-3 Low Pos Control 3897-4

Revision 2 Revision date 2015-06-05

| SECTION 1: Identification of | f the substance/mixture and of the company/undertaking |
|------------------------------------|--|
| 1.1. Product identifier | |
| Product name | PR-3 Low Pos Control 3897-4 |
| Product code | 2338970 |
| 1.3. Details of the supplier of th | e 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 num | ber |
| | 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 identif | ication |
| 2.1. Classification of the substa | nce 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/in | formation on ingredients |



3.2. Mixtures

PR-3 Low Pos Control 3897-4

Revision 2
Revision date 2015-06-05

3.2. Mixtures

| | 72 | | |
|--|----|--|--|
| | | | |
| | | | |

| 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 NaN3)) | 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; | |

| | | | -12 4 - |
|------|--------|-------|---------|
| ната | เตดเเร | Inare | dients |
| | | | |

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 | |

SECTION 5: Firefighting measures

5.1. Extinguishing media

Use extinguishing media appropriate to the surrounding fire conditions.

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

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



PR-3 Low Pos Control 3897-4

Revision 2
Revision date 2015-06-05

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 Colour

Liquid 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

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



PR-3 Low Pos Control 3897-4

Revision 2 Revision date 2015-06-05

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. |





according to 1907/2006/EC, Article 31

Page 1/4

PR-3 Serum Diluent Type III 616434

Revision 2 Revision date 2015-06-05

| SECTION 1: Identification of the substance/mixture and of the company/undertaking | | | | |
|---|---|--|--|--|
| 1.1. Product identifier | | | | |
| Product name | PR-3 Serum Diluent Type III 616434 | | | |
| Product code | 2338870 | | | |
| 1.3. Details of the supplier of the | e 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 num | | | | |
| The Line going, toophone ham | 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 identif | ication | | | |
| 2.1. Classification of the substa | nce 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 | | | | |



PR-3 Serum Diluent Type III 616434

Revision 2
Revision date 2015-06-05

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% | Ó | |
| Bovine Serum Albumin | | 9048-46-8 | | | 1 - 10% | 0 | |
| ProClin 300 | | | | | 0 - 0.5% | , b | |
| Tween 20 CH016 | | 9005-64-5 | 500-018-3 | | 0 - 0.5% | , b | |
| Potassium Chloride CH037 | | 7447-40-7 | 231-211-8 | | 0 - 0.5% | Ó | |
| Sodium Phosphate, Monobasic CH012A | | 7558-80-7 | 231-449-2 | | 0 - 0.5% | , | |

Description

Non Hazardous.

Further information

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

SECTION 4: First aid measures

4.1. Description of first aid measures

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

SECTION 5: Firefighting measures

5.1. Extinguishing media

Use extinguishing media appropriate to the surrounding fire conditions.

5.3. Advice for firefighters

Wear suitable respiratory equipment when necessary

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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

6.2. Environmental precautions

Do not allow product to enter drains.

6.3. Methods and material for containment and cleaning up

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

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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

7.2. Conditions for safe storage, including any incompatibilities

Store in correctly labelled containers

Further information



PR-3 Serum Diluent Type III 616434

Revision 2 Revision date 2015-06-05

Further information

2-8 °C

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

8.2.1. Appropriate engineering controls Ensure adequate ventilation of the working area.

8.2.2. Individual protection

measures

Wear suitable protective clothing.

Skin protection -Handprotection

Eye / face protection

Approved safety goggles. Wear suitable gloves.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance Colour

Aqueous solution 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,

PR-3 Serum Diluent Type III 616434

Revision 2 Revision date 2015-06-05

| 15.1. Safety, health and environ | nmental regulations/legislation specific for the substance or mixture |
|----------------------------------|--|
| | 93/105/EC and 2000/21/EC. |
| Further information | |
| | This SDS is prepared according to 29 CFR 1910.1200. |
| SECTION 16: Other information | ation |
| 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. |





according to 1907/2006/EC, Article 31

Page 1/4

PR-3 Wash Buffer Type II 827402

Revision 2
Revision date 2015-06-08

| SECTION 1: Identification of | the substance/mixture and of the company/undertaking |
|-------------------------------------|--|
| 1.1. Product identifier | . , , , , , , , , , , , , , , , , , , , |
| Product name | PR-3 Wash Buffer Type II 827402 |
| Product code | 2338970 |
| 1.3. Details of the supplier of the | e 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 num | ber T |
| | 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 identif | ication |
| 2.1. Classification of the substa | nce or mixture |
| Main hazards | No Significant Hazard |
| 2.2. Label elements | |
| Risk phrases | No Significant Hazard |
| SECTION 3: Composition/in | formation on ingredients |
| 2.2 Mindrage | |



3.2. Mixtures

PR-3 Wash Buffer Type II 827402

Revision 2
Revision date 2015-06-08

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 | | | Skin Corr. 1B: H314; STOT SE 3: H335; | |
| Tween 80 005-392 | | 9005-65-6 | | | | | |
| Tris Base | | 77-86-1 | 201-064-4 | | | | |
| EDTA DINA (ED2SS) 006-436 | | 6381-92-6 | 205-358-3 | | | | |
| ProClin 300 | | | | | | | |

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



PR-3 Wash Buffer Type II 827402

Revision 2 Revision date 2015-06-08

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Ensure adequate ventilation of the working area.

8.2.2. Individual protection

Wear protective clothing.

measures
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 Colour Aqueous solution

r 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

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 (EC) 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



PR-3 Wash Buffer Type II 827402

Revision 2 Revision date 2015-06-08

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 | Skin Corr. 1B: H314 - Causes severe skin burns and eye damage. | | | | | |
| Section 3 | 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. | | | | | |





according to 1907/2006/EC, Article 31

Page 1/3

PR-3 Substrate Solution 525600

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 | PR-3 Substrate Solution 525600 | | | | | | | |
| Product code | 2338970 | | | | | | | |
| 1.3. Details of the supplier of the | e 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 | <u>+1 716-487-1419</u> | | | | | | | |
| 1.4. Emergency telephone num | | | | | | | | |
| | 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 identif | ication | | | | | | | |
| 2.1. Classification of the substa | nce or mixture | | | | | | | |
| Main hazards | No Significant Hazard | | | | | | | |
| 2.2. Label elements | 2.2. Label elements | | | | | | | |
| Risk phrases | No Significant Hazard | | | | | | | |
| SECTION 3: Composition/information on ingredients | | | | | | | | |
| 3.1. Substances | | | | | | | | |



PR-3 Substrate Solution 525600

Revision 2
Revision date 2015-06-15

3.1. Substances

| FC | | | | |
|----|--|--|--|--|
| | | | | |
| | | | | |
| | | | | |

| Chemical Name | Index No. | CAS No. | EC No. | REACH Registration Number | Conc. (%w/w) | Classification | M-factor. |
|--------------------------------|-----------|---------|--------|------------------------------|-----------------|----------------|-----------|
| SureBlue Reserve TMB Microwell | | | | | 90 - 100% | 6 | |
| Peroxidase Substrate | | | | | | | |

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. If breathing is difficult give oxygen. Seek medical attention |
|--------------|---|
| | if irritation or symptoms persist. |
| Eye contact | Rinse immediately with plenty of water for 15 minutes holding the eyelids open. |
| Skin contact | Wash with soap and water. Wash contaminated clothing before reuse. |

SECTION 5: Firefighting measures

5.1. Extinguishing media

Use extinguishing media appropriate to the surrounding fire conditions.

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

Clean spillage area thoroughly with plenty of water.

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. Keep container tightly closed.

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 | Wear protective clothing. |
| measures | |
| Eye / face protection | Safety glasses. |
| Skin protection - | Wear suitable gloves. |
| Handprotection | |
| Respiratory protection | In case of insufficient ventilation, wear suitable respiratory equipment. |
| 8.2.3. Environmental | Do not eat, drink or smoke in areas where this product is used or stored. |
| exposure controls | |

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties



PR-3 Substrate Solution 525600

Revision Revision date 2015-06-15

9.1. Information on basic physical and chemical properties

Liquid **Appearance** Colour Clear

SECTION 10: Stability and reactivity

10.2. Chemical stability

Stable under normal conditions.

10.5. Incompatible materials

Strong oxidising agents. Metal articles

SECTION 11: Toxicological information

11.1. Information on toxicological effects

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

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

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.





according to 1907/2006/EC, Article 31

Page 1/5

PR-3 Stop Solution 915401

Revision 2 Revision date 2015-06-05

| SECTION 1: Ident | tification of the substance/mixtur | e and of the company/undertaking |
|------------------------|------------------------------------|----------------------------------|
| 1.1. Product identifie | er | |

Product name PR-3 Stop Solution 915401
Product code 2338970

1.3. Details of the supplier of the safety data sheet

Company Address Trinity Biotech

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 Address

Fax

Trinity Biotech USA

2823 Girts Rd Jamestown

NY

14701

USA

Telephone

+1 800-325-3424

+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

Hazard Statement

Warning

Skin Irrit. 2: H315 - Causes skin irritation.

Eye Irrit. 2: H319 - Causes serious eye irritation.



Revision 2 Revision date 2015-06-05

2.2. Label elements

| Precautionary Statement: | P264 - Wash thoroughly after handling. |
|--------------------------|--|
| Prevention | P280 - Wear protective gloves/protective clothing/eye protection/face protection. |
| Precautionary Statement: | P302+P352 - IF ON SKIN: Wash with plenty of water/ . |
| Response | 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 | 016-020-00-8 | 7664-93-9 | 231-639-5 | | 1 - 10% | C; R35 | |
| (mist)) | | | | | | | |

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 | |

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

require these extensive first aid procedures.

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



Revision 2 Revision date 2015-06-05

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 - | WEL 15 min limit mg/m3 total - |
| | inhalable dust: | inhalable dust: |
| | WEL 8-hr limit mg/m3 total - | WEL 15 min limit mg/m3 total - |
| | respirable dust: | respirable dust: |

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Ensure adequate ventilation of the working area.

8.2.2. Individual protection measures

Wear chemical protective clothing.

Eye / face protection

Skin protection -

Approved safety goggles. Wear suitable gloves.

Handprotection 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 specifical effect. | ations, the solution does not have a toxicological |



Revision 2
Revision date 2015-06-05

SECTION 12: Ecological information

12.1. Toxicity

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

12.4. Mobility in soil

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

SECTION 13: Disposal considerations

General information

Dispose of in compliance with all local and national regulations.

SECTION 14: Transport information

Further information

The product is not classified as dangerous for carriage.

SECTION 15: Regulatory information

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

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

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

Further information

This SDS is prepared according to 29 CFR 1910.1200.

SECTION 16: Other information

Other information

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

- 2 2.1.2. Classification EC 1272/2008.
- 2 Hazard pictograms.
- 2 Signal Word.
- 2 Precautionary Statement: Prevention.
- 2 Precautionary Statement: Response.
- 3 Further information.
- 8 Skin protection Handprotection.

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

Text of risk phrases in Section 3

R35 - Causes severe burns.

Text of Hazard Statements in Section 3

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

Further information

The information supplied in this Safety Data Sheet is designed only as guidance for the safe use, storage and handling of the product. This information is correct to the best of our knowledge and belief at the date of publication however no guarantee is made to its accuracy. This information



Revision 2 Revision date 2015-06-05

| Further information | |
|---------------------|---|
| | relates only to the specific material designated and may not be valid for such material used in |
| | combination with any other materials or in any other process. |

