

# SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

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## Mobile Phase 1 Reagent

Revision 4  
Revision date 2015-05-19

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

#### 1.1. Product identifier

|              |                        |
|--------------|------------------------|
| Product name | Mobile Phase 1 Reagent |
| Product code | 01-03-0040, 01-03-0042 |

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

|             |  |
|-------------|--|
| Description | Intended for the separation and quantitation of normal and abnormal hemoglobin species as an aid in the diagnosis of hemoglobinopathies. This assay is intended to be used with automated high performance liquid chromatography (HPLC) systems employing ion exchange chromatography. For in Vitro Diagnostic Use only. |
|-------------|--|

#### 1.3. Details of the supplier of the safety data sheet

|           |   |
|-----------|---|
| Company   | Trinity Biotech                                     |
| Address   | IDA Business Park<br>Bray<br>Co. Wicklow<br>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<br>Jamestown<br>NY<br>14701<br>USA |
| Telephone | +1 800-325-3424                                  |
| Fax       | +1 716-487-1419                                  |

#### 1.4. Emergency telephone number

|  |  |
|--|--|
|  | Contact your local Emergency Health Provider.<br>Ireland-Technical Support Group 00353 -1- 276- 9800<br>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

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## 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. |
|---------------|-----------|-------------|--------|---------------------------|--------------|----------------|-----------|
| Water         |           | 7732-18-5   |        |                           | 90 - 100%    |                |           |
| Bis Tris HCL  |           | 124763-51-5 |        |                           | 0 - 0.5%     |                |           |

### EC 1272/2008

| Chemical Name | Index No. | CAS No.     | EC No. | REACH Registration Number | Conc. (%w/w) | Classification | M-factor. |
|---------------|-----------|-------------|--------|---------------------------|--------------|----------------|-----------|
| Water         |           | 7732-18-5   |        |                           | 90 - 100%    |                |           |
| Bis Tris HCL  |           | 124763-51-5 |        |                           | 0 - 0.5%     |                |           |

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

|              |   |
|--------------|---|
| Inhalation   | Not applicable.   |
| Eye contact  | Rinse immediately with plenty of water. Seek medical attention if irritation or symptoms persist. |
| Skin contact | Wash with soap and water. Seek medical attention if irritation or symptoms persist.               |
| Ingestion    | Induce vomiting. Seek medical attention.  |

### 4.2. Most important symptoms and effects, both acute and delayed

|              |   |
|--------------|---|
| Inhalation   | May cause irritation to respiratory system.   |
| Eye contact  | May cause irritation to eyes.   |
| Skin contact | May cause irritation to skin.   |
| Ingestion    | Ingestion may cause nausea and vomiting. Harmful in contact with skin and if swallowed. If swallowed, seek medical advice immediately and show this container or label. |

### General information

|  |   |
|--|---|
|  | Remove contaminated clothing. Wash with 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. |
|--|---|

### 5.2. Special hazards arising from the substance or mixture

|  |       |
|--|-------|
|  | None. |
|--|-------|

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

|  |   |
|--|---|
|  | Wear suitable protective clothing, gloves and eye/face protection. Handle and open container with care. |
|--|---|

### 6.3. Methods and material for containment and cleaning up

|  |                           |
|--|---------------------------|
|  | Wash with soap and water. |
|--|---------------------------|

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

|  |  |
|--|--|
|  | Keep tightly closed. Do not permit to freeze. Once contact with blood has occurred, handle as potentially infectious using universal safety precautions. |
|--|--|

### 7.2. Conditions for safe storage, including any incompatibilities

|  |  |
|--|--|
|  | Store in original container. Store at temperatures between 2 °C and 28 °C. |
|--|--|

### 7.3. Specific end use(s)

|  |  |
|--|--|
|  | For use with Trinity Biotech A1c and Variant assay systems. Follow instructions for use as |
|--|--|

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## 7.3. Specific end use(s)

provided in the system operator manual. No substitutions or other uses are permitted.

## SECTION 8: Exposure controls/personal protection

### 8.2. Exposure controls

|                                  |  |
|----------------------------------|--|
| Eye / face protection            | Wear suitable protective clothing, gloves and eye/face protection. |
| Skin protection - Handprotection | Wear suitable gloves.  |
| Respiratory protection           | Not normally required.   |

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

|                       |                     |
|-----------------------|---------------------|
| Appearance            | Liquid              |
| Colour                | Clear               |
| Freezing Point        | 0 °C                |
| Initial boiling point | 100 °C              |
| Evaporation rate      | 1 g/min             |
| Vapour pressure       | 2200 Pa             |
| Vapour density        | 1 g/cm <sup>3</sup> |
| Solubility            | Soluble in water    |

### 9.2. Other information

|                  |       |
|------------------|-------|
| Specific gravity | 0.998 |
| Total Solids     | 0 g/l |

## SECTION 10: Stability and reactivity

### 10.4. Conditions to avoid

Avoid use near acids, metallic salts, strong oxidizing agents iodine, peroxides, alkaloids, and chloral hydrates. Avoid incidental and accidental mixing with acids, metallic salts, strong oxidizing agents iodine, peroxides, alkaloids, and chloral hydrates.

### 10.5. Incompatible materials

Acids. Alkalis. Chloral hydrate. Iodine. Oxidising agents. Peroxides. Metal Salts.

### 10.6. Hazardous decomposition products

None.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

|                                   |  |
|-----------------------------------|--|
| Acute toxicity                    | Hazardous in case of skin contact, eye contact, or ingestion. May be absorbed through the skin. Exposed areas may redden and experience itching with watering of eyes. Seek medical attention in case of ingestion. Severe exposure may result in death. |
| Skin corrosion/irritation         | Irritating to skin.  |
| Serious eye damage/irritation     | May cause irritation to eyes.  |
| Respiratory or skin sensitisation | No Significant Hazard.   |
| Repeated or prolonged exposure    | Mutagenic of mammalian somatic cells.  |

#### 11.1.13. Other information

Hazardous in case of skin contact, eye contact, or ingestion. May be absorbed through the skin. Exposed areas may redden and experience itching with watering of eyes. Seek medical attention in case of ingestion. Severe exposure may result in death.

## SECTION 12: Ecological information

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## 12.2. Persistence and degradability

|  |  |
|--|--|
|  | This product is not known to present any environmental hazards related to persistence in the environment, resistance to biodegradability, or hazardous degradation intermediates. The plastic container consists of polypropylene and may be recycled. |
|--|--|

## 12.3. Bioaccumulative potential

|  |       |
|--|-------|
|  | None. |
|--|-------|

## 12.4. Mobility in soil

|  |       |
|--|-------|
|  | None. |
|--|-------|

## 12.6. Other adverse effects

|  |  |
|--|--|
|  | This material is expected to be slightly toxic to aquatic life. This product does not present an environmental hazard in the terrestrial, atmospheric, or food-chain via accumulation. |
|--|--|

## SECTION 13: Disposal considerations

### General information

|  |   |
|--|---|
|  | Disposal should be made in accordance with local and national regulations. Trinity Biotech analyzer systems discharge no more than 2 mL per minute. Consult local wastewater discharge requirements. Discharge only to public waste water treatment (POTW) systems. The preservative used is toxic to fish and wildlife. Do not discharge to lakes, streams, ponds, or surface watershed. The reagent is biodegradable. Once used with patient blood samples, handle under universal precautions as potentially infectious waste. |
|--|---|

## SECTION 14: Transport information

### Further information

|  |   |
|--|---|
|  | Transportation of this product is not regulated. Fragile containers, handle with care. Protect from freezing. Protect from extended storage at elevated temperatures. |
|--|---|

## SECTION 15: Regulatory information

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

|  |                                   |
|--|-----------------------------------|
|  | For in Vitro Diagnostic Use only. |
|--|-----------------------------------|

## SECTION 16: Other information

### Other information

|          |  |
|----------|--|
|          | The information contained in this MSDS does not purport to be all-inclusive and is provided for general guidance only. The manufacturer is not liable for any damage resulting from mishandling or unprotected contact with the above product. |
| Revision | This document differs from the previous version in the following areas:<br>12 - 12.1. Toxicity.<br>13 - General information.   |