# SAFETY DATA SHEET

according to 1907/2006/EC, Article 31



## A2+F Control Material Kit

**Revision** 3
**Revision date** 2014-10-14

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

### 1.1. Product identifier

| | |
|---|---|
| **Product name** | A2+F Control Material Kit |
| **Product code** | 01-04-0043 |

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

| | |
|---|---|
| **Description** | Intended for use as a quality control material to monitor the precision of laboratory testing procedures for HbF and HbA2 quantitation. Design primarily for high performance liquid chromatography (HPLC) based analyses. 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 |

### 2.3. Other hazards

| | |
|---|---|
| **Other hazards** | All blood donor units have been tested and found non-reactive for Hepatitis B surface antigen and HIV 1 and 2 and HCV antibodies when tested by FDA accepted methods. However, no known test method can assure that a product derived from blood does not contain Hepatitis or HIV virus. |

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### 2.3. Other hazards

| | |
|---|---|
| | Handle as if potentially infectious. |

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

**67/548/EEC / 1999/45/EC**

| Chemical Name | Index No. | CAS No. | EC No. | REACH Registration Number | Conc. (%w/w) | Classification | M-factor. |
|---|---|---|---|---|---|---|---|
| Human Whole Blood | | | | | 90 - 100% | | |

**EC 1272/2008**

| Chemical Name | Index No. | CAS No. | EC No. | REACH Registration Number | Conc. (%w/w) | Classification | M-factor. |
|---|---|---|---|---|---|---|---|
| Human Whole Blood | | | | | 90 - 100% | | |

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

| | |
|---|---|
| **Inhalation** | No Significant Hazard. |
| **Eye contact** | May cause irritation to eyes. Wear eye/face protection. Rinse immediately with plenty of water. |
| **Skin contact** | Wash with soap and water. |
| **Ingestion** | No Significant Hazard. Wear suitable gloves. Avoid contact with skin. Seek medical attention. |

**General information**

| | |
|---|---|
| | Use universal precautions for handling as with human blood. Remove contaminated clothing. Wash with soap and water. |

## 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 gloves and eye/face protection. Wear suitable protective clothing. Handle spilled material under universal precautions and protections, as with patient blood samples. |

### 6.2. Environmental precautions

| | |
|---|---|
| | This product readily biodegrades and does not present an environmental hazard in the (1) aquatic (including sediment), (2) terrestrial, (3) atmospheric, or (4) food-chain via accumulation. |

### 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. Keep frozen until used. Glass container is fragile. Read and review the package insert for additional handling instructions. All blood donor units have been tested and found non-reactive for Hepatitis B surface antigen and HIV 1 and 2 and HCV antibodies when tested by FDA accepted methods. However, no known test method can assure that a product derived from blood does not contain Hepatitis or HIV virus. Handle as if potentially infectious. |

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

| | |
|---|---|
| | Store in original container. |

### 7.3. Specific end use(s)

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### 7.3. Specific end use(s)

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

## SECTION 8: Exposure controls/personal protection

### 8.2. Exposure controls

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

## SECTION 9: Physical and chemical properties

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

| | |
|---|---|
| **Appearance** | Powder |
| **Colour** | Red |
| **Solubility** | Soluble in water |

## SECTION 10: Stability and reactivity

### 10.4. Conditions to avoid

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

### 10.5. Incompatible materials

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

### 10.6. Hazardous decomposition products

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

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

| | |
|---|---|
| **Acute toxicity** | None. |
| **Skin corrosion/irritation** | Avoid contact with skin. |
| **Serious eye damage/irritation** | Avoid contact with eyes. |
| **Respiratory or skin sensitisation** | None. |
| **Repeated or prolonged exposure** | None. |

## SECTION 12: Ecological information

### 12.2. Persistence and degradability

| | |
|---|---|
| | The blood component of this product readily biodegrades and does not present any environmental hazard related to persistence in the environment or hazardous degradation intermediates. The glass vial does not present any environmental hazard related to persistence in the environment or hazardous degradation intermediates. The empty glass vial is typically collected for disposal with biohazard waste under universal precautions. |

### 12.3. Bioaccumulative potential

| | |
|---|---|
| | This product readily biodegrades and does not present an environmental hazard in the (1) aquatic (including sediment), (2) terrestrial, (3) atmospheric, or (4) food-chain via accumulation. |

### 12.4. Mobility in soil

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

### 12.6. Other adverse effects

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

## SECTION 13: Disposal considerations

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**Further information**

| | |
|---|---|
| | Disposal should be made in accordance with local and national regulations. |

## SECTION 14: Transport information

**Further information**

| | |
|---|---|
| | This product is not regulated during transportation, except where regulations apply to blood products. Keep frozen and protect from elevated temperatures. Return to freezer immediately upon receipt. Glass containers are fragile, handle with care. |

## SECTION 15: Regulatory information

**Further information**

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

## SECTION 16: Other information

**Other information**

| | |
|---|---|
| | Caution: Contains human blood source material. All blood donor units have been tested and found non-reactive for Hepatitis B surface antigen and HIV 1 and 2 and HCV antibodies when tested by FDA accepted methods. No known test method can assure that a product derived from blood does not contain Hepatitis or HIV virus. Handle as if potentially infectious. |
| **Revision** | This document differs from the previous version in the following areas:.<br>16 - Other information. |