

## Material Safety Data Sheet

### 1. Identification of substance

Product name: CueSee® HbA1c  
Product code: REF 011.001.010, 011.002.010, 011.003.010  
Manufacturer: Eurotrol B.V., Keplerlaan 20, 6716 BS, Ede, The Netherlands.

In emergency call **+31 318 695777** for further information.  
For **US and Canadian customers**: in emergency call: **+1-978-598-3779** for further information.

### 2. Components

Component	Classification	Concentration
Hemolyzed and lyophilized human whole blood	None	100%

The product does not contain components at concentrations of 0.1% or higher that are classified as toxic according to regulation (EC) No 1272/2008 [EU-GHS/CLP].

### 3. Hazardous characteristics

Appearance: red powder  
Odour: none  
Physical State: lyophilized powder

This product is prepared from human material obtained from thoroughly controlled voluntary unpaid blood donors. Each donor is tested negative for HbsAg, HCV, HIV-I and HIV-II antibodies by approved tests. No test method can offer complete assurance that products containing human source material will be absent of these and other infectious agents. Precautions should be taken as for any potentially bio hazardous materials.

### 4. Emergency first aid procedures

General advice:  
Consult a physician. Show this safety data sheet to the doctor in attendance.

Inhalation: Not applicable

Skin contact: Remove contaminated clothing. Wash off with disinfectant or soap and plenty of water.

Eye contact: Flush eyes with water for at least 10 minutes, occasionally lifting upper and lower eyelids.. If persistent irritation occurs, seek medical advice.

Ingestion: Wash mouth thoroughly with water and drink water. If substance has been swallowed, drink large quantities of water and seek medical advice. Never give anything by mouth to an unconscious person.

### 5. Actions in case of fire

Not flammable.  
Follow general fire fighting procedures.  
This product does not present any fire or explosion hazard.

### 6. Actions in case of spill of material

Wear appropriate protective gloves. Clean up, contaminated area should be washed with disinfectant or soap and water.

### 7. Handling and storage

Handling:  
Avoid contact with skin and eyes. Ensure good ventilation/exhaustion at work place. Have an immediate availability of an eye wash in case of emergency. The product should be handled as potentially biohazardous material. Use Good Laboratory Practice when working with any chemical whether it is considered hazardous or not.

**Storage:**

Store as indicated in product insert to maintain proper performance of the product.

**8. Limitation of the exposure / personal protective measures**

Use Good Laboratory Practice. Wear goggles, protective apron and chemical resistant gloves. Ensure good ventilation/exhaustion at work place.

**9. Physical / chemical characteristics**

pH	N/A
Boiling point (°C)	~100
Melting point (°C)	~ 0
Decomposition temperature (°C)	N/A
Flash-point (°C)	Not flammable.
Spontaneous combustion temp (°C)	N/A
Combustibility (solid, gas)	N/A
Explosive characteristics	Not explosive
Explosion limits	N/A
Oxidizing characteristics	N/A
Vapor pressure (kPa)	N/A
Vapor density	N/A
Appearance	Lyophilized, red
Odour	None
Physical state	Liquid
Solubility in water	Soluble

**10. Stability and reactive hazard data**

Expiry date is stated on each vial. Stored as indicated in product insert, product performance is guaranteed until stated expiration date.

Conditions to avoid: Boiling the product; exposure to temperatures above 30°C.

**11. Toxicological information**

Product does not contain components at levels greater than or equal to 0.1% that are identified as probable, possible, or confirmed to be toxic.

Product does not contain components at levels greater than or equal to 0.1% that are identified as probable, possible, or confirmed human carcinogen.

This product is prepared from human material obtained from thoroughly controlled voluntary unpaid blood donors. Each unit is tested negative for HbsAg, HCV, HIV-I and HIV-II antibodies by approved tests. No test method can offer complete assurance that products containing human source material will be absent of these and other infectious agents. Precautions should be taken as for any potentially bio hazardous materials.

**12. Ecological Toxicological information**

No information is found on environmental toxicity for this solution.

**13. Waste disposal methods**

Do not dispose of in general waste. Consult local environmental authorities for proper disposal.

**14. Transport information**

The product is not subject to transport regulation. Fragile containers, handle with care. Protect from temperatures above 30°C.



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#### 15. Valid regulations

- EU:
  - o Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH);
  - o Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (EU-GHS);
- US:
  - o Guidelines for Importation #1121;
  - o Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

#### 16. Other information

For in-vitro diagnostic use only.

Further information:

The opinions expressed herein are those of qualified experts within Eurotrol B.V. We believe that the information contained herein is current as of the date of this Material Safety Data Sheet. Since the use of this information and these opinions and the conditions of use of the product are not within the control of Eurotrol B.V., it is the users' obligation to assure safe use of the product.

Date of issue:

April 13, 2015