

**Trade name:** Control solution Hb-con low(Order number 3000-6121)

**Current version :** 4.1.0, issued: 14.07.2020

**Replaced version:** 4.0.0, issued: 12.02.2018

**Region:** GB

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

### 1.1 Product identifier

**Trade name**

**Control solution Hb-con low(Order number 3000-6121)**

**Control Solution Hb-con norm (Order number 3000-6122)**

**Control Solution Hb-con high (Order number 3000-6123)**

**Control solution Hb-con set 2-LN (Order number 3000-6127)**

**Control solution Hb-con set 2 (Order number 3000-6128)**

**Control cuvette set (Order number 3000-6138)**

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

**Relevant identified uses of the substance or mixture**

For in-vitro diagnosis

control material made of bovine haemolysate for checking the calibration of Hemo\_Control devices

**Uses advised against**

No data available.

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

**Address**

EKF-diagnostic GmbH  
Ebendorfer Chaussee 3  
39179 Barleben  
Germany

Telephone no. +49(0)39203511-0

Fax no. +49(0)39203511-171

**Information provided by / telephone**

Telephone number +49(0)39203511-0

**Advice on Safety Data Sheet**

support@ekf-diagnostic.de

### 1.4 Emergency telephone number

For medical advice (in German and English):

+49 (0)551 192 40 (Giftinformationszentrum Nord)

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

**Classification information**

This product does not meet the classification and labelling criteria given in the Regulation (EC) No 1272/2008 (CLP).

### 2.2 Label elements

Not relevant

### 2.3 Other hazards

This product is prepared from bovine material. Cattle used for bleeding are under veterinary control. Cattle have not been mixed with other cattle.

No foot-and-mouth disease or rinderpest has been observed in these cattle. However, no test method can offer complete assurance that products derived from bovine source material are free from infectious agents.

**PBT assessment**

The product is not considered to be a PBT.

**vPvB assessment**

The product is not considered to be a vPvB.

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## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Not applicable. The product is not a substance.

### 3.2 Mixtures

#### Chemical characterization

aqueous solution

Material contains Hemolized bovine red blood cells.

#### Hazardous ingredients

This product does not contain substances to be mentioned according to EU Regulation No 1907/2006 (REACH), annex II.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

#### General information

In case of persisting adverse effects, consult a physician. Remove contaminated clothing and shoes immediately, and launder thoroughly before reusing.

#### After inhalation

No data available.

#### After skin contact

Rinse with plenty of water.

#### After eye contact

Remove contact lenses. Rinse eye thoroughly under running water keeping eyelids wide open and protecting the unaffected eye (at least 10 to 15 minutes).

#### After ingestion

Drink plenty of water. Never give anything by mouth to an unconscious person. If individual is drowsy or unconscious, place in recovery position (on left side, with head down).

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

No data available.

### 4.3 Indication of any immediate medical attention and special treatment needed

No data available.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

#### Suitable extinguishing media

Product itself is non-combustible; adapt fire extinguishing measures to surrounding areas.

#### Unsuitable extinguishing media

High power water jet

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

None known.

### 5.3 Advice for firefighters

Use self-contained breathing apparatus. Wear protective clothing.

## SECTION 6: Accidental release measures

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

#### For non-emergency personnel

Refer to protective measures listed in sections 7 and 8. Ensure adequate ventilation.

#### For emergency responders

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No data available. Personal protective equipment (PPE) - see Section 8.

## 6.2 Environmental precautions

Do not discharge into the drains/surface waters/groundwater.

## 6.3 Methods and material for containment and cleaning up

Pick up with absorbent material (e.g., sand, sawdust, general-purpose binder). Send in suitable containers for recovery or disposal.

## 6.4 Reference to other sections

No data available.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

#### Advice on safe handling

Ensure adequate ventilation.

#### General protective and hygiene measures

Do not eat, drink or smoke during work time. Keep away from foodstuffs and beverages. Wash hands before breaks and after work.

#### Advice on protection against fire and explosion

No special measures necessary.

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

#### Technical measures and storage conditions

Keep container tightly closed in a cool, well-ventilated place.

#### Requirements for storage rooms and vessels

Containers which are opened must be carefully closed and kept upright to prevent leakage. Always keep in containers of same material as the original.

#### Incompatible products

Store the foodstuffs separately.

### 7.3 Specific end use(s)

No data available.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

No parameters available for monitoring.

### 8.2 Exposure controls

#### Appropriate engineering controls

No data available.

#### Personal protective equipment

##### Respiratory protection

No special measures required.

##### Eye / face protection

No special measures required.

##### Hand protection

Sufficient protection is given wearing suitable protective gloves checked according to i.e. EN 374, in the event of risk of skin contact with the product.

##### Environmental exposure controls

No data available.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

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<b>Form/Colour</b>	
Liquid	
red-brown	
<b>Odour</b>	
odourless	
<b>Odour threshold</b>	
No data available	
<b>pH value</b>	
Value	appr. 7
Source	supplier
<b>Boiling point / boiling range</b>	
Value	appr. 100 °C
Source	supplier
<b>Melting point / melting range</b>	
Value	appr. 0 °C
Source	supplier
<b>Decomposition point / decomposition range</b>	
Value	appr. 70 °C
Source	supplier
<b>Flash point</b>	
No data available	
<b>Auto-ignition temperature</b>	
No data available	
<b>Oxidising properties</b>	
No data available	
<b>Explosive properties</b>	
No data available	
<b>Flammability (solid, gas)</b>	
No data available	
<b>Lower flammability or explosive limits</b>	
No data available	
<b>Upper flammability or explosive limits</b>	
No data available	
<b>Vapour pressure</b>	
No data available	
<b>Vapour density</b>	
No data available	
<b>Evaporation rate</b>	
No data available	
<b>Relative density</b>	
No data available	
<b>Density</b>	
Value	appr. 1.0 g/cm <sup>3</sup>
<b>Solubility in water</b>	
Comments	soluble
<b>Solubility(ies)</b>	
No data available	

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**Partition coefficient: n-octanol/water**

No data available

**Viscosity**

No data available

**9.2 Other information**

**Other information**

No data available.

**SECTION 10: Stability and reactivity**

**10.1 Reactivity**

Dangerous reactions are not expected if the product is handled according to its intended use.

**10.2 Chemical stability**

Stable under recommended storage and handling conditions (See section 7).

**10.3 Possibility of hazardous reactions**

None, when used as directed.

**10.4 Conditions to avoid**

Keep from freezing. Protect from heat and direct sunlight.

**10.5 Incompatible materials**

No data available.

**10.6 Hazardous decomposition products**

No data available.

**SECTION 11: Toxicological information**

**11.1 Information on toxicological effects**

**Acute oral toxicity**

No data available

**Acute dermal toxicity**

No data available

**Acute inhalational toxicity**

No data available

**Skin corrosion/irritation**

No data available

**Serious eye damage/irritation**

No data available

**Respiratory or skin sensitisation**

No data available

**Germ cell mutagenicity**

No data available

**Reproduction toxicity**

No data available

**Carcinogenicity**

No data available

**STOT - single exposure**

No data available

**STOT - repeated exposure**

No data available

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## Aspiration hazard

No data available

## Delayed and immediate effects as well as chronic effects from short and long-term exposure

Product specific toxicological data are not available.

## Other information

No health-damaging effects to be expected if used properly.

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Toxicity to fish (acute)

No data available

#### Toxicity to fish (chronic)

No data available

#### Toxicity to Daphnia (acute)

No data available

#### Toxicity to Daphnia (chronic)

No data available

#### Toxicity to algae (acute)

No data available

#### Toxicity to algae (chronic)

No data available

#### Bacteria toxicity

No data available

### 12.2 Persistence and degradability

No data available.

### 12.3 Bioaccumulative potential

No data available.

### 12.4 Mobility in soil

No data available.

### 12.5 Results of PBT and vPvB assessment

#### Results of PBT and vPvB assessment

PBT assessment

The product is not considered to be a PBT.

vPvB assessment

The product is not considered to be a vPvB.

### 12.6 Other adverse effects

No data available.

### 12.7 Other information

#### Other information

Do not discharge into the drains or waters and do not store on public depositories.

Ecological data are not available.

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

#### Product

Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

For disposal follow your local regulations for infectious medical waste.

#### Packaging

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Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse. Packaging that cannot be cleaned should be disposed of in agreement with the regional waste disposal company.

## SECTION 14: Transport information

### 14.1 Transport ADR/RID/ADN

The product is not subject to ADR/RID/ADN regulations.

### 14.2 Transport IMDG

The product is not subject to IMDG regulations.

### 14.3 Transport ICAO-TI / IATA

The product is not subject to ICAO-TI / IATA regulations.

### 14.4 Other information

No data available.

### 14.5 Environmental hazards

Information on environmental hazards, if relevant, please see 14.1 - 14.3.

### 14.6 Special precautions for user

No data available.

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not relevant

## SECTION 15: Regulatory information

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

#### Regulation (EC) No 1907/2006 (REACH) Annex XIV (List of substances subject to authorisation)

According to the data available and/or specifications supplied by upstream suppliers, this product does not contain any substances considered as substances requiring authorisation as listed on Annex XIV of the REACH regulation (EC) 1907/2006.

#### REACH candidate list of substances of very high concern (SVHC) for authorisation

According to available data and the information provided by preliminary suppliers, the product does not contain substances that are considered substances meeting the criteria for inclusion in annex XIV (List of Substances Subject to Authorisation) as laid down in Article 57 and article 59 of REACH (EC) 1907/2006.

#### Regulation (EC) No 1907/2006 (REACH) Annex XVII: RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, PREPARATIONS AND ARTICLES

According to the data available and/or specifications supplied by upstream suppliers, this product does not contain any substances requiring authorisation as listed on Annex XVII of the REACH regulation (EC) 1907/2006.

#### Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances

This product is not subject to Part 1 or 2 of Annex I.

### 15.2 Chemical safety assessment

No data available.

## SECTION 16: Other information

#### Sources of key data used to compile the data sheet:

Regulation (EC) No 1907/2006 (REACH), 1272/2008 (CLP) as amended in each case.

Directives 2000/39/EC, 2006/15/EC, 2009/161/EU, (EU) 2017/164.

National Threshold Limit Values of the corresponding countries as amended in each case.

Transport regulations according to ADR, RID, IMDG, IATA as amended in each case.

The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding section.

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## **Department issuing safety data sheet**

UMCO GmbH

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This information is based on our present knowledge and experience.

The safety data sheet describes products with a view to safety requirements.

It does not however, constitute a guarantee for any specific product properties and shall not establish a legally valid contractual relationship.

**Alterations/supplements:**

Alterations to the previous edition are marked in the left-hand margin.

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