

Safety Data Sheet

1. Identification of substance/mixture and of the company/undertaking

1.1 Product identifier:

Product name	Code / REF
Eurotrol HemoTrol, Low (Level 1)	022.001.002
Eurotrol HemoTrol, Normal (Level 2)	022.002.002
Eurotrol HemoTrol, High (Level 3)	022.003.002

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

Eurotrol HemoTrol is an assayed hemoglobin control intended for use in the verification of the precision and accuracy of the HemoCue Hb 201+ system.

1.3 Details of the manufacturer and importer of the safety data sheet:

Manufacturer: Eurotrol B.V., Keplerlaan 20, 6716 BS, Ede, The Netherlands, (+31) 318 695777

Australian customers	New Zealand customers
Distributor:	Distributor:
Radiometer Pacific Pty Ltd	Radiometer Pacific
1 st Floor, 96 Ricketts Road	3/33 Spartan Road
Mt Waverley, Vic. 3149	Takanini, 2105
Australia	Auckland
	New Zealand
Phone: 1800 247 254	Phone: 0800 723 287
www.radiometer.com.au	www.radiometer.co.nz

1.4 Emergency telephone number:

Australian customers	New Zealand customers
Emergency contacts;	Emergency contacts;
Phone: 000 (mobile phones 112)	Phone: 111
Australian Poisons Information Centre Phone 13 11 26	New Zealand Poisons Centre Phone: 0800 764 766

2. Hazards identification

2.1 Classification of the substance or mixture:

Hemolysed bovine blood material in a plastic dropper bottle. The cattle used for bleeding is under veterinary control. The cattle has not been mixed with other cattle, and no foot-and-mouth disease or rinderpest has been observed. However, no test method can offer complete assurance that products derived from bovine source material are free from infectious agents.

2.2 Label elements:

Precautionary statements:

- Caution: Eurotrol Hemotrol is an Animal Blood Product. Bovine based materials do not carry biohazards for man, such as Hepatitis B Surface Antigen (HbsAg). Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV-1/HIV-2)). This product is free from TSE.
- It is Good Laboratory Practice to follow the same precautions as for patient samples when handling or disposing vials.
- This product should not be disposed in the general waste. Consult local environmental authorities for proper disposal.

2.3 Other hazards:

Not applicable.

3. Composition and Information on Ingredients:

3.1 Disclosure of ingredient names

The only component of the product is hemolyzed red blood cells of bovine origin, which is dissolved in an aqueous solution containing salts.

3.2 CAS number and other unique identifiers:

Not applicable.

3.3 Concentrations of ingredients:

Not applicable.

4. First aid measures

4.1 Description of first aid measures:

Inhalation: Not applicable.

Skin contact: Normal hygiene, wash off with disinfectant or soap and plenty of water.

Eye contact: Flush eyes with water for at least 15 minutes, occasionally lifting upper and lower eyelids.

Ingestion: Wash mouth thoroughly with water. If substance has been swallowed, drink large quantities of water and seek medical advice.

4.2 Symptoms caused by exposure:

Not applicable.

4.3 Medical attention and special treatment:

Consult a physician after ingestion of the product. Show this safety data sheet to the doctor in attendance.

5. Fire-fighting measures

5.1 Suitable extinguishing media:

The primary container and its contents are not flammable, but the packaging used is. Follow general fire fighting procedures. This product does not present any fire or explosion hazard.

5.2 Special hazards arising from the substance or mixtures:

None.

5.3 Special protective equipment and precautions for fire-fighters:

None.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Always wear protective gloves and a lab coat.

6.2 Environmental precautions:

The product does not provide an environmental hazard.

6.3 Methods and material for containment and cleaning up

Contaminated area should be washed with disinfectant or soap and water.

7. Handling and storage

7.1 Precautions for safe handling:

Use Good Laboratory Practice when working with any chemical whether it is considered hazardous or not.

7.2 Conditions for safe storage, including any incompatibilities:

Store as indicated in the product documentation to maintain proper performance of the product up to the expiration date as indicated on the box label. Store unopened in the refrigerator at 2 – 8° C. After opening the vial, the product is stable for 1 month when properly recapped and stored at 2 – 30° C.

8. Exposure controls / personal protection

8.1 Control parameters:

Follow Good Laboratory Practice.

8.2 Appropriate engineering controls:

No special engineering controls required.

8.3 Personal protective equipment:

No personal protective equipment required.

9. Physical and chemical Properties

Appearance	Clear red liquid in a plastic dropper bottle.
Odour	No odour.
Odour threshold	Not applicable.
pH	~ 7 (neutral).
Melting point (°C)	~ 0° C.
Boiling point (°C)	~ 100° C.
Flash-point (°C)	No flash point.
Evaporation rate	Similar to water, but product is placed in a closed container.
Flammability	Product not flammable.
Upper/lower flammability or explosive limits	Not applicable.
Vapour pressure (kPa)	Unknown.
Vapour density	Unknown.
Relative density	~ 1 g/mL.
Solubility(ies)	Soluble in water.
Partition coefficient: <i>n</i> -octanol/water	Unknown, but solution should be considered hydrophilic.
Auto-ignition temperatures	Unknown.
Decomposition temperatures	Unknown.
Viscosity	Unknown.
Biodurability	Compounds present are not biodurable.

10. Stability and reactivity

10.1 Reactivity:

The product is not considered to have reactive hazards.

10.2 Chemical Stability:

When stored as indicated in the product insert, the product performance is guaranteed until the expiration date stated on each vial. Even beyond this date, the product is not expected to provide additional health risks.

10.3 Possibility of hazardous reactions:

Unknown.

10.4 Conditions to avoid:

Exposing the product to temperatures below 0° C or temperatures above 30° C.

10.5 Incompatible materials:

Unknown.

10.6 Hazardous decomposition products:

Unknown.

11. Toxicological information

11.1 Information on routes of exposure

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. Nevertheless, product should not be ingested.

11.2 Symptoms related to exposure

Unknown.

11.3 Numerical measures of toxicity

Not applicable.

11.4 Immediate, delayed and chronic health effects from exposure

Not applicable.

11.5 Exposure levels

Not applicable.

11.6 Interactive effects

Not applicable.

11.7 Data limitations

Not applicable.

12. Ecological information

12.1 Ecotoxicity

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

12.2 Persistence and degradability

Product is biodegradable

12.3 Bioaccumulative potential

Unknown.

12.4 Mobility in soil

Unknown.

12.5 Other adverse effects

Not applicable.

13. Disposal considerations

13.1 Safe handling and disposal methods

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

13.2 Disposal of any contaminated packaging

After spilling of the product on the packing, do not dispose of in general waste. Consult local environmental authorities for proper disposal.

13.3 Environmental regulations

Not applicable.

14. Transport information

14.1 UN number

Not applicable, according to DOT and IATA, the product is considered NON-HAZARDOUS and is therefore not subject to transport regulation.

14.2 Proper shipping name

Not applicable.

14.3 Transport hazard class(es)

Not applicable.

14.4 Packing group

Not applicable.

14.5 Environmental hazards

Not applicable.

14.6 *Special precautions during transport*

Fragile containers, handle with care. Protect from temperatures above 30°C.

14.7 *Hazchem code*

Not applicable.

15. Regulatory information

15.1 *Safety, health and environmental regulations/legislation specific for the product in question*

No additional regulatory information.

15.2 *Poisons schedule number*

Not applicable.

16. Other information

16.1 *Date of preparation or reviewed*

Revision	Change	Date of issue
0.1	First issue	2015-09-16
1.0	Acquired new regulations	2016-12-23

16.2 *Key abbreviations or acronyms used*

Not applicable.

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.