

Safety Data Sheet

according to 1907/2006/EC, Article 31

Section 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Tradename HemoTrol® Duo Low
HemoTrol® Duo Normal
HemoTrol® Duo High

Article number **REF** AN01637A01
REF AN01637A02
REF AN01637A03

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

HemoTrol® Duo is an assayed quality control material for professional use to verify the performance characteristics of the HemoCue® Hb 301 and the HemoCue® Hb 801 System. HemoTrol® Duo is intended for the quantitative determination of hemoglobin.

1.2.1 Application of the substance / the mixture

HemoTrol® Duo is a quality control material containing a known hemoglobin concentration in three clinically relevant ranges. When measured like a patient sample, the regular use of the quality control material can provide proof for proper functioning of the HemoCue® Hb 301 and the HemoCue® Hb 801 System.

Quality control materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Eurotrol B.V.
Keplerlaan 20
6716 BS Ede
The Netherlands
Mail: office@eurotrol.com
Phone: +31 (0) 318 695777

Information department

Eurotrol B.V. Customer Service
Mail: office@eurotrol.com
Phone: +31 (0) 318 695777

1.4 Emergency telephone number

In case of an emergency call **+31 (0) 318 695777** for any further information (only during office hours).

Section 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008: The product is not classified according to the CLP regulation.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008:	Not applicable
Hazard pictograms:	Not applicable
Signal word:	Not applicable
Hazard statements:	Not applicable

2.3 Other hazards

Results of PBT and vPvB assessment: Not applicable

HemoTrol® Duo contains material of bovine origin. Bovine based materials do not carry Hepatitis B Surface Antigen (HbsAg), Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV-1/HIV-2). The product is free from transmissible spongiform encephalopathies (TSEs). However, no test method can offer complete assurance that products derived from bovine source material are free from infectious agents and may transmit infectious agents.

Section 3: Composition/information on ingredients

3.1 Substances

Description:	Purified stroma-free bovine hemolysate and stabilizers.
Dangerous components:	Not applicable
Additional information:	None

Section 4: First-aid measures

4.1 Description of first aid measures

Inhalation: Not applicable

Skin contact: Normal hygiene

Eye contact: Flush with water for >15 minutes in case reagent contacts eyes

Ingestion: Get medical attention

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

Section 5: Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing agents: Use water, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

No data on specific hazards available.

5.3 Advice for firefighters

Standard precautions and protective equipment should be used.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

No personal precautions, protective equipment and emergency procedures are required.

6.2 Environmental precautions

Do not dispose in the general waste. Consult local environmental authorities for proper disposal. In case of contaminated packaging, dispose the unused product.

6.3 Methods and material for containment and cleaning up

In case of spill of material, clean with water. Keep left over waste in suitable, closed containers for disposal.

6.4 Reference to other sections

No dangerous substances are released. See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

Section 7: Handling and storage

7.1 Precautions for safe handling

Follow Good Laboratory Practice (GLP).

7.1.1 Information about protection against explosions and fires

No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Store the product as indicated on the product label.

7.3 Specific end use(s)

No further relevant information available.

Section 8: Exposure controls/personal protection

8.1 Control parameters

Components with limit values that require monitoring at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.1.1 Additional information

Applicable lists valid during the creation of this safety data sheet were used as basis.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Follow Good Laboratory Practice (GLP).

8.2.2 Individual protection measures, such as personal protective equipment

Eye/face protection: Use equipment for eye protection tested under appropriate government standards

Skin protection: Use protective gloves

Body protection: Wear protective clothing

Respiratory protection: Respiratory protection not required

8.2.3 Environmental exposure controls

The usual precautionary measures should be adhered to when handling chemicals.

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Appearance	Reddish liquid
b) Odor	Odorless
c) Odor threshold	Data not available
d) pH	7.0 – 9.0
e) Melting point/freezing point	Data not available
f) Initial boiling point and boiling range	Data not available
g) Flash point	Data not available
h) Evaporation rate	Data not available
i) Flammability (solid, gas)	Product is nonflammable
j) Upper/lower flammability or explosive limits	Not applicable
k) Vapor pressure	Data not available
l) Vapor density	Data not available
m) Relative density	Data not available
n) Solubility(ies)	Product is an aqueous solution
o) Partition coefficient: n-octanol/water	Product is an aqueous solution
p) Auto-ignition temperature	Data not available
q) Decomposition temperature	Data not available
r) Viscosity	Data not available
s) Explosive properties	Data not available
t) Oxidizing properties	Data not available

9.2 Other information

No further relevant information available.

Section 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

The product has been validated to be chemically stable at least up until the expiration date.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

The product should not be used past expiration date. Avoid exposure to temperatures below 0 °C or above 30 °C.

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

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| a) acute toxicity | No relevant information available. |
| b) skin corrosion/irritation | No relevant information available. |
| c) serious eye damage/irritation | No relevant information available. |
| d) respiratory or skin sensitization | No relevant information available. |
| e) germ cell mutagenicity | No relevant information available. |
| f) carcinogenicity | No relevant information available. |
| g) reproductive toxicity | No relevant information available. |
| h) STOT-single exposure | No relevant information available. |
| i) STOT-repeated exposure | No relevant information available. |
| j) aspiration hazard | No relevant information available. |

Section 12: Ecological information

12.1 Toxicity

No relevant information available.

12.2 Persistence and degradability

No relevant information available.

12.3 Bioaccumulative potential

No relevant information available.

12.4 Mobility in soil

No relevant information available.

12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

12.6 Other adverse effects

No relevant information available.

Section 13: Disposal considerations

13.1 Waste treatment methods

Do not dispose of in general waste. Consult local environmental authorities for proper disposal. In case of contaminated packaging, disposition of the unused product.

Section 14: Transport information

According to ADR, ADN, RID, IMDG and IATA the product is not classified as dangerous good.

14.1 UN number	Not applicable
14.2 UN 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 for user	Not applicable
14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code	Not applicable

Section 15: Regulatory information

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

This Safety Data Sheet complies with the following regulations:

- Regulation (EC) No. 1907/2006 (REACH)
- Regulation (EC) No. 453/2010 (REACH)
- Regulation (EC) No. 1272/2008 (EU-GHS/CLP)

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this product.

Section 16: Other information

The information in this Safety Data Sheet are based on our current knowledge. This SDS has been compiled exclusively for this product and is intended exclusively for this product. It guaranties no product characteristics and does not ensure a legal relationship. Since the implementation of the information and the operating conditions of the product given in this SDS are not controlled by Eurotrol B.V., the user is responsible for the safe use of the product.

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route

ADN: Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

IATA: International Air Transport Association

IBC Code: International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk

IMDG: International Maritime Code for Dangerous Goods

MARPOL: International Convention for the Prevention of Pollution from Ships

REACH: Registration, Evaluation, Authorization and Restriction of Chemicals

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer

Revision history

Revision	Effective date	Change to previous revision
01	2019-11-04	First revision.

Effective date: 2019-11-04