Safety data sheet
According to regulation (EC) No. 1907/2006, Article 31

Section 1: Identification of the substance/ mixture and of the company/ undertaking	
1.1 Product identifiers	
Product name	Seronorm™ Trace Elements Whole Blood L-1, L-2 & L-3
Article number	210105, 210205 & 210305
1.2 Relevant identified uses of the substance or mixture and uses advised against	
Identified uses	SU20 Health services.
	Quality control material for in-vitro diagnostics.
1.3 Details of the supplier of the safety data sheet	
Manufacturer	SERO AS Stasjonsveien 44 NO-1396, Billingstad, Norge Telephone: +47 66 85 89 00 E-mail: seronorm@sero.no
1.4 Emergency telephone number	+47 22 59 13 00

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	The product is not classified according to the CLP regulation.
Hazard pictograms	Not applicable.
Signal word	Not applicable.
Hazard statements	Not applicable.
2.3 Other hazards	
Other information	 The material is a human- based control produced from blood collected from voluntary blood donors. The material has been tested by CE- marked or FDA- approved methods to be negative for HBs antigen, HIV p24- antigen and HIV I, II and HCV antibodies. However, since no method can completely exclude the presence of infectious agents, this material should be handled as an ordinary patient sample.

Section 3: Composition/ information on ingredients	
3.1 Substances	
3.2 Mixture of substances	
Description	Mixture of the substances listed below.
Dangerous components	**Hazardous ingredients:** This product is sterile filtered and an anti foaming agent is added. The concentration of the added component is below the generic cut-off value according to Regulation (EC) No. 1272/2008. **Chemical Name:** Ethylene oxide-propylene oxide copolymer mono(2-ethylhexyl) ether **CAS Nr**.: 64366-70-7 **WT %:** <0.7%
Other information	Main substances: Human whole blood Content: 95-99%

Section 4: First aid measures	
4.1 Description of first aid measures	
General information	Water soluble.
Eye contact	Rinse under running water.
Skin contact	Wash with soap and water.
Swallowing	Drink water to dilute the swallowed material and seek medical attention.
Inhalation	Not applicable.
4.2 Most important symptoms and effects, both acute and delayed	Undetermined.
4.3 Indication of any immediate medical attention and special treatment needed	Not applicable.

Section 5: Firefighting measures	
5.1 Extinguishing media	
Suitable extinguishing media	Use extinguishing media appropriate for the surrounding fire.
5.2 Special hazards arising from the substance or mixture	Not flammable. The product does not present any fire risk or explosion hazard.
5.3 Advice for firefighters	Use extinguishing media appropriate for the surrounding fire.

Section 6: Accidental release measures	
6.1 Personal precautions, protective equipment and emergency procedures	
Protective equipment	Handle as potentially infectious. Gloves recommended.
6.2 Environmental precautions	Do not allow the material or contaminated washing water to enter sewers/ surface or ground water.
6.3 Methods and material for containment and cleaning up	Absorb with liquid-binding material. Pick up mechanically. Clean with soap and water. Use desinfectant.
6.4 Reference to other sections	See Section 13 for disposal information.

Section 7: Handling and storage	
7.1 Precautions for safe handling	Handle as potentially infectious. No special precautions are necessary if used correctly.
7.2 Conditions for safe storage, including any incompatibilities	Store according to documentation provided.
7.3 Specific end use(s)	See Section 1.2

Section 8: Exposure controls/ personal protection

8.1 Control parameters

Components with limit values that require monitoring at the workplace	Does not contain any relevant quantities of materials with critical values that requires monitoring at the workplace. In accordance with the Norwegian national regulation; FOR-2011-12-06-1358.

8.2 Exposure controls

8.2.1 Personal protective equipment

Breathing equipment	Not required.
Skin protection	Gloves recommended.
Eye protection	Not required.
Protective clothing	Not required.
8.2.2 Control of environmental exposure	See section 6.2

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance/ Form	Lyophilized
Color	Red.
Odour	Light.
pH- value	6-10
Melting point / feezingpoint	Undetermined.
Bioling point / boiling range	Undetermined.
Flash point	Undetermined.
Danger of exposion	Product does not present an explosion hazard.
Vapour pressure	Undetermined.
Density	Undetermined.
Solubility	Water soluble.
9.2 Other information	Not applicable.

Section 10: Stability and reactivity

10.1 Reactivity	No expected reactivity hazard.
10.2 Chemical stability	Stable.
10.3 Possibility of hazardous reactions	No expected reactivity hazard.
10.4 Conditions to avoid	Not applicable.
10.5 Incompatible materials	Not applicable.
10.6 Hazardous decompositions products	Not applicable.

Section 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity	Undetermined.
Skin corrosion / irritation	Undetermined.
Serious eye damage / irritation	Undetermined.
Respiratory or skin sensitisation	Undetermined.
Germ cell mutagenicity	Undetermined.
Carcinogenicity	Undetermined.
Reproductive toxicity	Undetermined.
STOT – single exposure	Undetermined.
STOT – repeated	Undetermined.
Aspiration hazard	Undetermined.

Section 12: Ecological information

12.1 Toxicity	Undetermined.
12.2 Persistence and degradability	Undetermined.
12.3 Bioaccumulative potential	No potential of bioaccumulation.
12.4 Mobility in soil	Water soluble.
12.5 Results of PBT and vPvB assessment	Undetermined.
12.6 Other adverse effects	Undetermined.

Section 13: Disposal considerations

13.1 Waste treatment methods	Dispose of waste in accordance to applicable national, regional or local regulations. Waste should be handled with the same care as potentially infected biological waste.

Section 14: Transport information

14.1 UN - number	Not applicable. Transport of the product not regulated according to **ADN, ADR, RID, IMDG, or IATA**.
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 MARPOL73/78 and IBC Code	Not applicable.

Section 15: Regulatory information

15.1 Safety, health and environmental regulations/ legislation specific for the substance or mixture	Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.
15.2 Chemical safety assessment	Not applicable.

Section 16: Other information

The above information is based on our current knowledge about the product. However, this shall not constitute a guarantee for any specific product features and shall not establish a legal valid contractual relationship.

Revision history:
Version 1.0: In accordance with current standard.

Abbreviations and acronyms
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of
Dangerous Goods by Road)
IATA: International Air Transport Association
IMDG: International Maritime Code for Dangerous Goods
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
RID: European Agreements Concerning the International Carriage of Dangerous Goods by Rail
STOT: Specific Target Organ Toxicant