

SAFETY DATA SHEET

SERONORM™ IMMUNOASSAY LYO L-1, L-2 & L-3

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE & OF THE COMPANY/UNDERTAKING

Product name: Seronorm™ Immunoassay Lyo L-1, L-2 & L-3
Application: Quality control material for *in vitro* diagnostic use
Supplier: SERO AS
 Stasjonsveien 44
 NO-1396 Billingstad, Norway
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2. HAZARDS IDENTIFICATION

Emergency overview: Non-flammable material.
 The human material, from which this product has been derived, is from controlled voluntary donors. The donors are tested negative for HBs antigen, HIV p24 antigen, HIV-I - HIV-II and HCV antibodies by CE-approved tests. No test method can offer complete assurance that products containing human material will be absent of these and of other infectious agents. Normal laboratory precautions should be taken as for potential infectious material.

Health hazard: Regarded as low health hazard

3. COMPOSITION, INFORMATION ON INGREDIENTS

Composition:	<u>Main ingredients:</u>	<u>CAS No.:</u>	<u>Content:</u>	<u>Hazard classification:</u>
	Human-based matrix	None	95-99%	None

4. FIRST-AID MEASURES

General: Miscible with water
Eyes: Flush eyes with water. If persistent irritation occurs, seek medical advice.
Skin contact: Wash with soap and water
Ingestion: Drink water to dilute the swallowed solution and contact physician for medical advice.
Inhalation: Not applicable

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use extinguishing media appropriate for the surrounding fire
Flammable properties: Not flammable. This product does not present any fire risk or explosion hazard.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Should be handled as an ordinary patient sample. The use of disposable gloves is recommended.
Clean up procedures: Spillages should be washed with soap and water

7. HANDLING AND STORAGE

Handling precautions: The product should be handled as if it was potentially infectious. The use of disposable gloves is recommended.
Storage precautions: Store according to temperature stated on the vial label or according to documentation provided. Avoid direct sunlight and temperature beyond the recommended storage conditions.

8.	EXPOSURE CONTROLS, PERSONAL PROTECTION
Ventilation:	No particular ventilation requirements
Protective gloves:	The use of disposable gloves is recommended
Eye protection:	Eye protection not normally required
Protective clothing:	Protective clothing is not necessary
9.	PHYSICAL AND CHEMICAL PROPERTIES
Appearance:	Lyophilized
Colour:	Not applicable
Solubility:	Readily miscible with water
Specific gravity:	Not applicable
pH-value:	6-10
10.	STABILITY AND REACTIVITY
Stability:	Stable and non-reactive
11.	TOXICOLOGICAL INFORMATION
Acute effects:	Unknown
Skin effects:	Not known to be a skin irritant
Eye effects:	Not known to be an eye irritant
12.	ECOLOGICAL INFORMATION
Summary:	This preparation is readily miscible with water and rated not toxic. It has no potential for bioaccumulation.
13.	DISPOSAL CONSIDERATION
General information:	Disposal should be made in accordance with existing disposal practices employed for patient serum samples or infectious waste.
14.	TRANSPORT INFORMATION
General information:	Transportation of the product is not regulated by ADR. Fragile containers; handle with care. Transport under recommended storage conditions.
15.	REGULATORY INFORMATION
	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 th December 2006 concerning the Registration, Evaluation and Authorization of Chemicals (REACH) and CLP regulation EC1272/2008.
16.	OTHER INFORMATION
Revision date:	2016-02-18
Replaces:	2013-07-26

Note: The above-mentioned data are based on our present knowledge of this product
