

SAFETY DATA SHEET

SERONORM™ URINE L-1 & L-2

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

Product name: Seronorm™ Urine L-1 & L-2
Application: Quality control material for *in vitro* diagnostic use
Supplier: SERO AS
Stasjonsveien 44
NO-1396 Billingstad, Norway
Telephone: +47 66 85 89 00
Telefax: +47 66 98 22 01
E-mail: seronorm@sero.no
Emergency Telephone Number: +47 22 59 13 00

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 24p 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:	Main ingredients:	CAS No.:	Content:	Hazard classification:
	Human-based matrix	None	95-99%	None

Hazardous ingredients:

This product is sterile filtered and ProClin 300 preservative is added to prevent microbial growth once the product is opened.

Chemical name:

Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one

CAS NO:	WT:
55965-84-9	<0, 0015%



H317: May cause an allergic skin reaction

4. FIRST-AID MEASURES

General: Miscible with water
Eyes: Flush eyes with water. If persistent irritation occurs seek medical advice.
Skin contact: Immediately wash skin 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. Avoid contact with eyes, skin and clothing.
Storage precautions:	Store according to temperature stated on the vial label or according to documentations 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 is not normally required.
Protective clothing:	Protective clothing is not necessary.
9.	PHYSICAL AND CHEMICAL PROPERTIES
Appearance:	Liquid
Colour:	Light yellow
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:	May cause an allergic skin reaction
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 EC 1272/2008.
16.	OTHER INFORMATION
Revision date:	2018-11-12
Replaces:	2018-07-31

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