

# SAFETY DATA SHEET

## SERONORM™ HUMAN & HUMAN HIGH

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

**Product name:** Seronorm™ Human & Human High  
**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 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 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  
**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.

<b>8.</b>	<b>EXPOSURE CONTROLS, PERSONAL PROTECTION</b>
<b>Ventilation:</b>	No particular ventilation requirements
<b>Protective gloves:</b>	The use of disposable gloves is recommended
<b>Eye protection:</b>	Eye protection not normally required
<b>Protective clothing:</b>	Protective clothing is not necessary
<b>9.</b>	<b>PHYSICAL AND CHEMICAL PROPERTIES</b>
<b>Appearance:</b>	Lyophilized
<b>Colour:</b>	Not applicable
<b>Solubility:</b>	Readily miscible with water
<b>Specific gravity:</b>	Not applicable
<b>pH-value:</b>	6-10
<b>10.</b>	<b>STABILITY AND REACTIVITY</b>
<b>Stability:</b>	Stable and non-reactive
<b>11.</b>	<b>TOXICOLOGICAL INFORMATION</b>
<b>Acute effects:</b>	Unknown
<b>Skin effects:</b>	Not known to be skin irritant
<b>Eye effects:</b>	Not known to be eye irritant
<b>12.</b>	<b>ECOLOGICAL INFORMATION</b>
<b>Summary:</b>	This preparation is readily miscible with water and rated not toxic. It has no potential for bioaccumulation.
<b>13.</b>	<b>DISPOSAL CONSIDERATION</b>
<b>General information:</b>	Disposal should be made in accordance with existing disposal practices employed for patient serum samples or infectious waste.
<b>14.</b>	<b>TRANSPORT INFORMATION</b>
<b>General information:</b>	Transportation of the product is not regulated by ADR. Fragile containers; handle with care. Transport under recommended storage conditions.
<b>15.</b>	<b>REGULATORY INFORMATION</b>
	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 <sup>th</sup> December 2006 concerning the Registration, Evaluation and Authorization of Chemicals (REACH) and CLP regulation EC 1272/2008
<b>16.</b>	<b>OTHER INFORMATION</b>
<b>Revision Date:</b>	2016-02-01
<b>Replaces:</b>	2013-10-25

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

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