

## SAFETY DATA SHEET

Factor XIa Calibrator, REF 1199  
Revision date: March 01, 2013

### 1. IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

#### 1.1 Product identifiers

Product Name: **Factor XIa Calibrator**  
Product Composition  
10 vials with lyophilized Factor XIa.

Product Number: **1199**

#### 1.2 Intended Use

Product for In Vitro Research Use

#### 1.3 Company Identification

Rossix AB  
Taljegardsgatan 3B  
S-43153 Molndal  
Sweden

Tel: +46 (0)31 706 8965

Fax: +46 (0)31 706 8966

info@rossix.com

www.rossix.com

#### 1.4 Emergency Telephone Number

European Union: 112

US: 911

Other countries: Call national emergency phone number

### 2. HAZARDS IDENTIFICATION

#### 2.1 Mixture Classification

The Factor XIa Calibrator is not a hazardous mixtures according to Regulation (EC) No 1272/2008

The Factor XIa Calibrator is not classified as dangerous according to Directive 67/548/EEC

#### 2.2 Other Hazards

##### Biological Risk



The product contains a purified human coagulation factor extracted from human plasma. Each donor unit used for the preparation has been tested by FDA approved methods for the presence of Hepatitis B surface antigen and antibodies to HIV 1 and 2 and Hepatitis C and found to be negative.

Bovine Serum Albumin (BSA) were prepared from bovine plasma of Australian and New Zealand origin and hence from countries demonstrated to be free from transmissible spongiform encephalopathies (TSEs) affecting animals, including bovine spongiform encephalopathy (BSE) and scrapie.

**However, no biological test may totally exclude the presence of any infectious agent. This product, as with all human based specimens, should be handled with proper laboratory safety procedures and disposal procedures to minimize the risk of transmission of infectious disease.**

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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Name	Cas-No.	EC-No.	Conc. % w/w	Classification 67/548/ECC	Classification 1272/2008/EC
<b>1199 – Factor XIa Calibrator</b>					
Human Factor XIa	-	-	< 1%	-	-
Bovine Serum Albumin (BSA)	9048-46-8	232-936-2	< 5%	-	-
PEG 6000	25322-68-3	500-038-2	< 5%	-	-
Tris HCl	1185-53-1	214-684-5	< 1%	Xi R36/37/38	Eye Irrit. 2, H319 Skin Irrit. 2, H315 STOT SE 3, H335
Tris	77-86-1	201-064-4	< 1%	Xi R36/38	Eye Irrit. 2, H319 Skin Irrit. 2, H315
Sodium Chloride	7647-14-5	231-598-3	< 10%	-	-

### 4. FIRST AID MEASURES

Ingestion:	Never give anything by mouth to an unconscious person. If swallowed rinse mouth with plenty of water provided person is conscious. Get medical advice.
Inhalation exposure:	If inhaled, move person to fresh air. Get medical advice if adverse symptoms appear.
Contact with skin:	Wash off with soap or mild detergent and plenty of water. Get medical advice if adverse symptoms appear.
Contact with eyes:	Wash immediately with plenty of water or normal saline. Get medical advice if adverse symptoms appear.

### 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media:	Use water spray or regular foam, dry powder or CO <sub>2</sub> .
Special hazards arising from the mixture:	Thermal decomposition or combustion may generate toxic and hazardous fumes of CO <sub>x</sub> and NO <sub>x</sub> .
Equipment for self-protection (fire fighters):	Self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves.

### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions:	Suitable protective clothing, gloves, safety glasses.
Environmental precautions:	Comply with local environmental regulations on waste handling and disposal. Do not empty into drains.
Method for containment and cleaning up:	Soak up with inert absorbent material and clean with plenty of water. Keep in suitable closed containers for disposal.

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**7. HANDLING AND STORAGE**

**7.1 Handling**

Must be used only by suitably trained and informed personnel.

P280	Wear chemical resistant gloves, chemical safety glasses and protective laboratory clothing.
P264	Wash hands with soap thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.

**7.2 Storage**

Room ventilation:	Well ventilated workspace.
Storage temperature:	≤ -20°C
Humidity, light and other environmental factors:	Do not store in direct sunlight, protect from heat.
Containers:	Keep containers tightly closed.

**8. EXPOSURE CONTROLS /PERSONAL PROTECTION**

Ventilation:	Provide adequate ventilation.
Respiratory protection:	Respiratory protection is not required.
Skin protection:	Protective clothing.
Eye protection:	Safety glasses.
Hand protection:	Protective gloves.
Hygienic measures:	General industrial hygiene practice.
Environmental protection:	Avoid any release into the environment.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance:	Lyophilized, solid
Odour:	no data available
Odour Threshold:	no data available
pH:	no data available
Melting point:	no data available
Boiling point:	no data available
Flash point:	no data available
Evaporation rate:	no data available
Vapour pressure:	no data available
Vapour density:	no data available
Relative density:	no data available
Water solubility:	Miscible
Viscosity:	no data available

**10. STABILITY AND REACTIVITY**

The product is stable until the expiry date printed on the label when stored at ≤ -20 °C

No known hazardous reactions when handled and stored according to provisions.

Conditions to avoid:	Keep away from heat and light
Materials to avoid:	no data available
Hazardous decomposition products:	Does not decompose when used for intended uses. Hazardous decomposition products formed under fire conditions: Carbon oxides and nitrogen oxides.

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### 11. TOXICOLOGICAL INFORMATION

The product's toxicological properties have not been thoroughly investigated and quantitative toxicological data are not available.

The product is intended for in vitro research use only, by experienced and suitably trained personal. There is no known special risk when used under these conditions.

Potential health effects

<b>Inhalation</b>	May be harmful if inhaled. May cause respiratory tract irritation.
<b>Ingestion</b>	May be harmful if swallowed.
<b>Skin</b>	May be harmful if absorbed through skin. May cause skin irritation.
<b>Eyes</b>	May cause eye irritation.

Acute toxicity:	no data available
Skin corrosion/irritation:	no data available
Serious eye damage/eye irritation:	no data available
Respiratory or skin sensitization:	no data available
Germ cell mutagenicity	no data available
Carcinogenicity	no data available
Reproductive toxicity	no data available

### 12. ECOLOGICAL INFORMATION

Data regarding the product's ecotoxicology are not available. Do not empty product into waters or drains.

### 13. DISPOSAL CONSIDERATIONS

National and local laws on disposal must be considered. Used waste product, surplus product or spillage product shall be disposed of in accordance with (where applicable) national, state and local laws respectively.

### 14. TRANSPORT INFORMATION

Not classified as dangerous for transport in accordance with ADR/RID, IMDG, IATA and DOT regulations.

The product can be shipped at ambient temperature for a short period, not exceeding 7 days, when packed in a foam box containing cold packs. It must be stored at  $\leq -20$  °C upon receipt.

### 15. REGULATORY INFORMATION

Not a hazardous mixture according to Regulation (EC) No 1272/2008.

This mixture is not classified as dangerous according to Directive 67/548/EEC.

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**16. OTHER INFORMATION**

**Phrases R:** R36/38: Irritating to eyes and skin.  
R36/37/38: Irritating to eyes, respiratory system and skin.

**Hazard Statements:** H319: Causes serious eye irritation.  
H315: Causes skin irritation.  
H335: May cause respiratory irritation.

**For In Vitro Research Use Only**

Last revision date: March 01, 2013

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Rossix AB and its appointed agents/distributors shall not be held liable for any damage resulting from handling or from contact with the above product.

Rossix AB reserves the right to revise this SDS periodically as new information becomes available.