SAFETY DATA SHEET
Rox Factor XIa, REF 110050
Revision date: September 17, 2012

1. IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

1.1 Product identifiers

Product Name: Rox Factor XIa

Kit Composition

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1110</td>
<td>Reagent 1</td>
<td>2 vials</td>
</tr>
<tr>
<td>1120</td>
<td>Reagent 2</td>
<td>2 vials</td>
</tr>
<tr>
<td>9080</td>
<td>FXa Substrate</td>
<td>1 vial</td>
</tr>
<tr>
<td>1150</td>
<td>Diluent Buffer, Stock Solution</td>
<td>1 vial</td>
</tr>
</tbody>
</table>

Product Number: 110050

1.2 Intended Use

Kit 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

None of the Kit components (Reagent 1, Reagent 2, FXa Substrate and Diluent Buffer) are hazardous mixtures according to Regulation (EC) No 1272/2008

None of the Kit components (Reagent 1, Reagent 2, FXa Substrate and Diluent Buffer) are classified as dangerous according to Directive 67/548/EEC

2.2 Other Hazards

Biological Risk

The product contains purified human coagulation factors 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.
## 3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Name</th>
<th>Cas-No.</th>
<th>EC-No.</th>
<th>Conc. % w/w</th>
<th>Classification 67/548/ECC</th>
<th>Classification 1272/2008/EC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1110 – Reagent 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human Factor IX</td>
<td>-</td>
<td>-</td>
<td>&lt; 10%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Human FVIII</td>
<td>-</td>
<td>-</td>
<td>&lt; 10%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Bovine Serum Albumin (BSA)</td>
<td>9048-46-8</td>
<td>232-936-2</td>
<td>&lt; 10%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>PEG 6000</td>
<td>25322-68-3</td>
<td>500-038-2</td>
<td>&lt; 10%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Tris HCl</td>
<td>1185-53-1</td>
<td>214-684-5</td>
<td>&lt; 1%</td>
<td>XI R36/37/38</td>
<td>Eye Irrit. 2, H319, Skin Irrit. 2, H315, STOT SE 3, H335</td>
</tr>
<tr>
<td>Tris</td>
<td>77-86-1</td>
<td>201-064-4</td>
<td>&lt; 1%</td>
<td>XI R36/38</td>
<td>Eye Irrit. 2, H319, Skin Irrit. 2, H315</td>
</tr>
<tr>
<td>Calcium Chloride Dihydrate</td>
<td>10035-04-8</td>
<td>233-140-8</td>
<td>&lt; 1%</td>
<td>XI R36</td>
<td>Eye Irrit. 2, H319</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>&lt; 10%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>1120 – Reagent 2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human Factor X</td>
<td>-</td>
<td>-</td>
<td>&lt; 10%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Bovine Thrombin</td>
<td>-</td>
<td>-</td>
<td>&lt; 10%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Bovine Serum Albumin (BSA)</td>
<td>9048-46-8</td>
<td>232-936-2</td>
<td>&lt; 10%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Phospholipids</td>
<td>-</td>
<td>-</td>
<td>&lt; 10%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>PEG 6000</td>
<td>25322-68-3</td>
<td>500-038-2</td>
<td>&lt; 10%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Tris HCl</td>
<td>1185-53-1</td>
<td>214-684-5</td>
<td>&lt; 1%</td>
<td>XI R36/37/38</td>
<td>Eye Irrit. 2, H319, Skin Irrit. 2, H315, STOT SE 3, H335</td>
</tr>
<tr>
<td>Tris</td>
<td>77-86-1</td>
<td>201-064-4</td>
<td>&lt; 1%</td>
<td>XI R36/38</td>
<td>Eye Irrit. 2, H319, Skin Irrit. 2, H315</td>
</tr>
<tr>
<td>Calcium Chloride Dihydrate</td>
<td>10035-04-8</td>
<td>233-140-8</td>
<td>&lt; 1%</td>
<td>XI R36</td>
<td>Eye Irrit. 2, H319</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>&lt; 10%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>9080 – FXa Substrate</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Z-D-Arg-Gly-Arg-pNA x 2HCl (pNA chemically bound to peptide)</td>
<td>-</td>
<td>-</td>
<td>&lt; 0.2%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>free pNA (pNA is released during assay)</td>
<td>100-01-6</td>
<td>202-810-1</td>
<td>&lt; 0.05%</td>
<td>R23/24/25 R52/53</td>
<td>Acute Tox. 3 H301, Acute Tox. 3 H311, Acute Tox. 3 H330, H413</td>
</tr>
<tr>
<td>Thrombin Inhibitor</td>
<td>-</td>
<td>-</td>
<td>&lt; 1%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>1150 – Diluent Buffer, Stock Solution</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tris HCl</td>
<td>1185-53-1</td>
<td>214-684-5</td>
<td>&lt; 10%</td>
<td>XI R36/37/38</td>
<td>Eye Irrit. 2, H319, Skin Irrit. 2, H315, STOT SE 3, H335</td>
</tr>
<tr>
<td>Tris</td>
<td>77-86-1</td>
<td>201-064-4</td>
<td>&lt; 10%</td>
<td>XI R36/38</td>
<td>Eye Irrit. 2, H319, Skin Irrit. 2, H315</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>&lt; 15%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Bovine Serum Albumin (BSA)</td>
<td>9048-46-8</td>
<td>232-936-2</td>
<td>10%</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

For phrases R and hazard statements text see ch. 16
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 CO₂.

**Special hazards arising from the mixture:** Thermal decomposition or combustion may generate toxic and hazardous fumes of COₓ and NOₓ.

**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.

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:** 2 - 8°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 (Reagent A and B).
  - Clear slightly yellow liquid (FIX Diluent Buffer).
  - Clear liquid (FXa Substrate).
- **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 when stored at 2 - 8°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.
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

<table>
<thead>
<tr>
<th>Route</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inhalation</strong></td>
<td>May be harmful if inhaled. May cause respiratory tract irritation.</td>
</tr>
<tr>
<td><strong>Ingestion</strong></td>
<td>May be harmful if swallowed.</td>
</tr>
<tr>
<td><strong>Skin</strong></td>
<td>May be harmful if absorbed through skin. May cause skin irritation.</td>
</tr>
<tr>
<td><strong>Eyes</strong></td>
<td>May cause eye irritation.</td>
</tr>
</tbody>
</table>

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. It must be stored at 2 - 8°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.
16. OTHER INFORMATION

Phrases R:
- R22/23/24: Toxic by inhalation, in contact with skin and if swallowed.
- R36/38: Irritating to eyes and skin.
- R36/37/38: Irritating to eyes, respiratory system and skin.
- R52/53: Harmful to aquatic organism may cause long-term adverse effects in the aquatic environment.

Hazard Statements:
- H301: Toxic if swallowed.
- H311: Toxic in contact with skin.
- H330: Fatal if inhaled.
- H319: Causes serious eye irritation.
- H315: Causes skin irritation.
- H335: May cause respiratory irritation.
- H413: May cause long lasting harmful effects to aquatic life.

For In Vitro Research Use Only

Last revision date: September 17, 2012

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.