

SAFETY DATA SHEET

Rox Factor IX, REF 900020
Revision date: March 1, 2012

1. IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

1.1 Product identifiers

Product Name:

Rox Factor IX

Kit Composition

9010	Reagent A	2 vials
9020	Reagent B	2 vials
9080	FXa Substrate	1 vial
9050	FIX Diluent Buffer, Stock Solution	1 vial

Product Number:

900020

1.2 Intended Use

Kit for In Vitro Research Use

1.3 Company Identification

Rossix AB
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S-43153 Molndal
Sweden

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Fax: +46 (0)31 706 8966
info@rossix.com
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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 A, Reagent B, FXa Substrate and FIX Diluent Buffer) are hazardous mixtures according to Regulation (EC) No 1272/2008

None of the Kit components (Reagent A, Reagent B, FXa Substrate and FIX 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.

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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
9010 – Reagent A					
Human Factor VIII	-	-	< 10%	-	-
Human Factor X	-	-	< 10%	-	-
Inhibitor	-	-	< 10%	-	-
Bovine Serum Albumin (BSA)	9048-46-8	232-936-2	< 10%	-	-
PEG 6000	25322-68-3	500-038-2	< 10%	-	-
MES	4432-31-9	224-632-3	< 1%	Xi R36/37/38	Eye Irrit. 2, H319 Skin Irrit. 2, H315 STOT SE 3, H335
Sodium Chloride	7647-14-5	231-598-3	< 10%	-	-
9020 – Reagent B					
Human Factor XIa	-	-	< 10%	-	-
Bovine Serum Albumin (BSA)	9048-46-8	232-936-2	< 10%	-	-
Phospholipids	-	-	< 10%	-	-
PEG 6000	25322-68-3	500-038-2	< 10%	-	-
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
Calcium Chloride Dihydrate	10035-04-8	233-140-8	< 1%	Xi R36	Eye Irrit. 2, H319
Sodium Chloride	7647-14-5	231-598-3	< 10%	-	-
9080 – FXa Substrate					
Z-D-Arg-Gly-Arg-pNA x 2HCl (pNA chemically bound to peptide)	-	-	< 0.2%	-	-
free pNA (pNA is released during assay)	100-01-6	202-810-1	< 0.05%	R23/24/25 R52/53	Acute Tox. 3 H301 Acute Tox. 3 H311 Acute Tox. 3 H330 H413
Thrombin Inhibitor	-	-	< 1%	-	-
9050 – FIX Diluent Buffer, Stock Solution					
Tris HCl	1185-53-1	214-684-5	< 10%	Xi R36/37/38	Eye Irrit. 2, H319 Skin Irrit. 2, H315 STOT SE 3, H335
Tris	77-86-1	201-064-4	< 10%	Xi R36/38	Eye Irrit. 2, H319 Skin Irrit. 2, H315
Sodium Chloride	7647-14-5	231-598-3	< 15%	-	-
Bovine Serum Albumin (BSA)	9048-46-8	232-936-2	10%	-	-

for phrases R and hazard statements text see ch. 16

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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 ₂ .
Special hazards arising from the mixture:	Thermal decomposition or combustion may generate toxic and hazardous fumes of CO _x and NO _x .
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.

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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.

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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

Inhalation	May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion	May be harmful if swallowed.
Skin	May be harmful if absorbed through skin. May cause skin irritation.
Eyes	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. 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.

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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: March 1, 2011
Revision was made in sections: 3. Bovine Factor Xla has been changed to Human Factor Xia in Reagent B (REF 9020)

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.