

Version 1 2 3

Engelsk

# SAFETY DATASHEET

## 1. Identification of the substance/preparation and of the company/undertaking

Date issued	06/07-2004
Product name	Thrombotest 2.2 mL and 11 mL
Use of the substance/preparation	PT-reagent: To be used for control of oral anticoagulant therapy. For in vitro diagnostic use.

### Manufacturer

Company name	Axis-Shield PoC AS
Office address	Marstrandgate 6
Postal address	PO Box 6863 Rodeløkka
Postcode	0504
Place name	Oslo
Country	Norway
Tel	+47 22 04 20 00
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E-mail	<b>hege.ronning@no.axis-shield.com</b>
Prepared by	LR Kjemikalierådgivning, Norway

## 2. Composition/information on ingredients

CAS no.	EC no.	Component name	Contents	HH	HF	HE	R phrases
		Bovine plasma					
		Bovine brain					
Column headings	CAS no. = Chemical Abstracts Service; EU (Einecs or Elincs number) = European inventory of Existing Commercial Chemical Substances; Ingredient name = Name as specified in the substance list (substances that are not included in the substance list must be translated, if possible). Contents given in; %, %wt/wt, %vol/wt, %vol/vol, mg/m3, ppb, ppm, weight%, vol%; HF/HH/HE = Hazard class fire/health/environment; R-phrases = Ingredients' risk phrases.						
HH/HF/HE	T+ = Very toxic, T = Toxic, C = Corrosive, Xn = Harmful, Xi = Irritating, E = Explosive, O = Oxidizing, F+ = Extremely flammable, F = Very flammable, N = Environmental hazard						
Component comments	Bovine plasma and bovine brain.						

## 3. Hazards identification

Hazard description	<p>Regarded as having very low health hazard. Presents little hazard if spilled or in fire. No ecotoxicological data available.</p> <p>Freeze dried bovine thromboplastin from bovine brain and bovine plasma to be reconstituted with Calcium Chloride 3.2 mmol/L or water. This product has been derived from Norwegian healthy bovine animals approved for human consumption. Norway is known to be free from most contagious diseases, and BSE has never been reported in Norway. There is no known risk of HIV and Hepatitis in animal sera. We recommend however to take precautions as for any potentially infectious material.</p>
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## 4. First aid measures

General	Miscible with water.
Inhalation	Not applicable.
Skin contact	Wash with water.
Eye contact	Flush eyes with water for at least 10 minutes. If persistent irritation occurs, seek medical advice.
Ingestion	Wash mouth thoroughly with water and drink water. If substance has been swallowed, drink large quantities of water.

## 5. Fire-fighting measures

Suitable extinguishing media	Use extinguishing media appropriate for surrounding fire.
Improper extinguishing media	None.
Fire and explosion hazards	Not flammable. This product does not present any fire or explosion hazard.

## 6. Accidental release measures

Personal precautions	Wear gloves, other protection is not necessary, see section 8.
Environmental precautions	No special precautions necessary.
Methods for cleaning	Clean up, contaminated area should be washed with soap and water.

## 7. Handling and storage

Handling	The product should be handled as if it was potentially infectious.
Storage	Store in original container according to temperature stated on container.

## 8. Exposure controls/personal protection

### Exposure controls

Occupational exposure controls	Eye Washing Station should be available.
Respiratory protection	Respiratory protection not required.
Hand protection	Hand protection is recommended. (Nitrile gloves).
Eye protection	Eye protection is not necessary.
Skin protection (other than of the hands)	Protective clothing is not necessary.

## 9. Physical and chemical properties

Physical state	Freeze dried
Colour	Light yellow
Solubility in water	Miscible with Calcium Chloride 3.2 mmol/L or water.
Specific gravity	Not applicable
pH (as supplied)	7.5

### Other physical and chemical properties

## 10. Stability and reactivity

Conditions to avoid	None.
Materials to avoid	None.
Hazardous decomposition products	No hazardous decomposition products are known.
Stability	Stable and not reactive under normal conditions. Stable for two years in freeze dried conditions when stored at <20°C

## 11. Toxicological information

### Toxicological Information:

General	The product itself does not represent any health hazard.
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## 12. Ecological information

Aquatic, comments	No potential for bioaccumulation.
Ecotoxicity	No ecotoxicological data available.
Mobility	This product is miscible with water.
Bioaccumulative potential	No potential for bioaccumulation.

## 13. Disposal considerations

Specify the appropriate methods of disposal	To be disposed according to local regulations.
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## 14. Transport information

Other applicable information.	The product is not subject to transport regulation. Fragile containers, handle with care. Protect from direct sunlight and temperatures above 25°C.
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## 15. Regulatory information

R phrases	Not classified.
References (laws/regulations)	EU Regulations, 2004. ADR, RID, IMDG, IATA. Micromedex Tomes CPS System.

## 16. Other information

Sources of key data used to compile the safety datasheet	Exact composition and Safety Data Sheet from the Manufacturer (March 2000).
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Supplier's notes	The MSDS is according to current regulations. LR Kjemikalierådgivning is not responsible for errors or lack in information given
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