

SAFETY DATASHEET

NycoCard® D-Dimer, TD/Test Device

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

Date issued	23/01-2007
Product name	NycoCard® D-Dimer, TD/Test Device
Use of the substance/preparation	A component included in the NycoCard® D-Dimer products: 1114300 and 1114301. NycoCard® D-Dimer are rapid tests for determination of D-Dimer in human plasma. For in vitro diagnostic use.

Manufacturer

Company name	Axis-Shield PoC AS
Office address	Marstrandgata 6
Postal address	PO Box 6863 Rodeløkka
Postcode	0504
Place name	Oslo
Country	Norway
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Prepared by	Alfheim Kjemikalie Consult, Norway

2. Composition/information on ingredients

Component comments	Contains Monoclonal anti D-Dimer antibodies.
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3. Hazards identification

Hazard description	This safety data sheet is valid for the solution used to coat the membrane. Regarded as having very low health hazard. Presents little hazard if spilled or in fire. No ecotoxicological data available.
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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	No special precautions necessary.
Storage	Store in original container according to temperature stated on container. Avoid exposure to temperatures above 25°C and direct sunlight.

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	A white polypropylen test device with an antibody coated membrane. The device is sealed with an aluminium foil.
Colour	White with aluminium foil.

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.

11. Toxicological information

Other information regarding health hazards

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

Toxicological Information:

Aquatic, comments	No potential for bioaccumulation.
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Other ecological information

Ecotoxicity	No ecotoxicological data available.
Bioaccumulative potential	No potential for bioaccumulation.
Other adverse effects / Remarks	The device contains recycable PP plastic.

13. Disposal considerations

Specify the appropriate methods of disposal	To be disposed according to local regulations.
Other Information	Used device with specimens from human blood should be disposed as infectious material.

14. Transport information

Other applicable information.	The product is not subject to transport regulation. Fragile containers, handle with care. Protect from freezing, 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.

Supplier's notes

The MSDS is according to current regulations. Alfheim Kjemikalie Consult is not responsible for errors or lack in information given by the manufacturer/importer. Manufacturer/importer given in section 1 is legally responsible for the content of the MSDS.