

SAFETY DATA SHEET

Date of issue: May 13, 2009

Version no 2.0

Replaces: 2005-04-27

1. IDENTIFICATION OF THE PRODUCT AND COMPANY □

<p>Product name</p> <p>EDIA anti-CCP FCCP 100</p> <p>DIASTAT ENA Profile FAID200 (1050)</p> <p>DIASTAT anti-Jo-1 FAJO200 (1047)</p> <p>DIASTAT anti-La (SS-B) FALA200 (1001)</p> <p>DIASTAT ANA FANA200 (1048)</p> <p>DIASTAT anti-Ro (SS-A) FARO300 (1000)</p> <p>DIASTAT anti-Sm FASM200 (1005)</p> <p>DIASTAT anti-Thyroglobulin (Tg) FATG200 (1011)</p> <p>DIASTAT anti-β₂-Glycoprotein-1 IgM FBGP100M (1015)</p> <p>DIASTAT anti-β₂-Glycoprotein-1 IgG FBGP100G (1014)</p> <p>DIASTAT anti-Cardiolipin IgA FCAR100A (1033)</p> <p>DIASTAT anti-Cardiolipin IgG FCAR100G (1019)</p> <p>DIASTAT anti-Cardiolipin IgM FCAR100M (1023)</p> <p>DIASTAT total anti-Cardiolipin FCAR100T (1040)</p> <p>DIASTAT anti-Centromere FCEN200 (1007)</p> <p>DIASTAT anti-dsDNA FDNA100 (1003)</p> <p>DIASTAT anti-GBM FGBM200 (1012)</p> <p>DIASTAT anti-Histone FHIS200 (1006)</p> <p>DIASTAT anti-Mitochondria FMIT200 (1041)</p> <p>DIASTAT anti-Sm/RNP FRNP200 (1002)</p> <p>DIASTAT anti-Scl-70 FSCL200 (1046)</p> <p>DIASTAT ENA single well screen FSWS200 (1049)</p> <p>DIASTAT anti-Thyroid Peroxidase (TPO) FTPO300 (1013)</p> <p>DIASTAT anti-MPO (pANCA) FMPO200 (1009)</p> <p>DIASTAT anti-PR3 FPRO200 (1008)</p>	<p>Component name: Sample diluent concentrate (5 x) Sample diluent 2 concentrate (5 x) Anti-Cardiolipin sample diluent concentrate (5 x) Wash buffer concentrate (16 x)</p>
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Use of the product

In vitro diagnostic use

Manufacturer/undertaking identification

Company	Euro-Diagnostica AB
Address	P.O.Box 50117
Zip code/Place	SE-202 11 Malmö
Country	Sweden
Telephone	+46 40 53 76 00
Contact person	Åsa Anderlind
E-mail	info@eurodiagnostica.se

2. HAZARDS IDENTIFICATION



Harmful

HEALTH

Harmful if swallowed. Contact with acids liberates very toxic gas.

FIRE AND EXPLOSION HAZARDS

No danger of fire or explosion exists.

ENVIRONMENT

Harmful to aquatic organisms, may cause long-term adverse effects in aquatic environment.

3. COMPOSITION/INFORMATION ON INGREDIENTS



Components mentioned at section 1 contain following chemical ingredients.

No	Ingredient name	EC-no	CAS-no	Conc. (%)	Classification
1	sodium azide	247-852-1	540-72-7	0,5	T+, N; R28, 50/53
					--
Abbreviations: T+= Very toxic, T=Toxic, C=Corrosive, Xn=Harmful, Xi=Irritant, E=Explosive, O=Oxidizing, F+=Extremely flammable, F=Highly flammable, N=Dangerous for the environment.					

4. FIRST AID MEASURES



SKIN CONTACT

Wash properly with soap and water.

EYE CONTACT

Keep eyelids well apart. Rinse with water for several minutes. Contact a doctor if the complaints persist.

INGESTION

Wash mouth properly with water. Drink a couple of water or milk. Contact a doctor.

OTHER INFORMATION

Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES



SUITABLE EXTINGUISHING MEDIA

The product is not combustible.

FIRE AND EXPLOSION HAZARDS

No danger of fire or explosion exists.

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6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS

Use proper personal protective equipment as indicated in section 8. Avoid contact with skin and eyes.

ENVIRONMENTAL PRECAUTIONS

Don't let the leakage reach sewage, waterways or surface water. Don't let the leakage contaminate soil and vegetation. In case of release to the environment, immediately inform the local competent authority and emergency personnel.

METHOD FOR CLEANING UP

Absorb with material (e.g. vermiculite, sand or soil), then place in a sealable container. The collected material is hazardous waste.

7. HANDLING AND STORAGE

HANDLING

Avoid contact with skin and eyes.

STORAGE

No special conditions exist.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

OCCUPATIONAL EXPOSURE CONTROLS

Wash hands after working with the product.

Occupational exposure limit:

Substance	CAS no.	Range	ppm	mg/m ³	Year	Anm
Sodium azide	26628-22-8	8 h		0,1		Exposure limit - EU
Sodium azide	26628-22-8	15 min.		0,3		Exposure limit - EU

HAND PROTECTION

Wear safety gloves. Recommended materials for gloves are natural rubber, butyle and nitrile rubber.

EYE PROTECTION

Wear safety glasses.

SKIN PROTECTION

Wear suitable protective clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	Liquid.
Colour	Colourless.
Solubility in water	Unlimited.

Physical and chemicals parameters

Parameter	Value/unit	Method / Reference	Note
Boiling point	100°C		
Melting point	0°C		
Flash point	not applicable		
pH	App. 7		
Density	1,0 g/cm ³		

10. STABILITY AND REACTIVITY

STABILITY

Stable under normal conditions of use and storage.

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HAZARDOUS REACTIONS

Contact with acids liberates very toxic gas.

11. TOXICOLOGICAL INFORMATION

INGESTION

A product containing 0,5% sodium azide has to be classified as harmful if swallowed, according to the mandatory classification rules in the EU Directive in force. Ingestion of greater amount of the product may cause dizziness, headache, blood pressure fall and severe systemic effects.

12. ECOLOGICAL INFORMATION

A product containing 0,5% sodium azide has to be classified as harmful to the aquatic organisms, may cause long-term adverse effects in aquatic environment, according to the mandatory classification rules in the EU Directive in force.

Sodium azide has a bactericidal effect. Thus, the process water may have an adverse effect on the micro organisms in the wastewater treatment.

13. DISPOSAL CONSIDERATIONS

METHOD OF DISPOSAL

A waste containing 0,1% or more of sodium azide has to be classified as dangerous waste, according to the EU Directive in force.

EWC-CODE

Proposed EWC code: 070501.

14. TRANSPORT INFORMATION

Product classified as dangerous goods: Yes No Not decided

15. REGULATORY INFORMATION



Harmful

EU LABEL No Yes Not decided

Content

Sodium azide 0,5%.

R-FRASER

Nr.	R-phrases
R22	Harmful if swallowed.
R32	Contact with acids liberates very toxic gas.
R52/53	Harmful to aquatic organisms, may cause long-term adverse effects in aquatic environment.

S-FRASER

Avoid contact with skin and eyes. Wear suitable gloves and eye/face protection.

If swallowed, seek medical advice immediately and show this safety data sheet.

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16. OTHER INFORMATION



THE PRODUCER'S NOTES

Safety data sheet prepared by: Eco-Tech AB.

Approved by Euro-Diagnostica AB.

LIST OF RELEVANT R-PHRASES

Nr.	R-phrases
R28	Very toxic if swallowed.
R32	Contact with acids liberates very toxic gas.
R52/53	Harmful to aquatic organisms, may cause long-term adverse effects in aquatic environment.

REVISIONS HISTORY

Version 2.0: EDIA anti-CCP has been added to the product list at section 1.

Company contact information has been updated.

Sections 2 and 3 are inverted according to REACH.

The following phrase has been added under section 3: Components mentioned at section 1 contain following chemical ingredients.

YES is checked at EU label under section 15.