

SAFETY DATA SHEET

Euro-Diagnostica AB

Date of issue: April 11, 2011

Version no: 7.0

Replaces: January 20, 2010

1. IDENTIFICATION OF THE PRODUCT AND COMPANY □

PRODUCT NAME:	<p>Wieslab® ASCA IgA semi quant. ASCA 150</p> <p>Wieslab® ASCA IgG semi quant. ASCA 151</p> <p>Wieslab® Cap MPO-ANCA semi quant. ap MPO 110</p> <p>Wieslab® Cap PR3-ANCA semi quant. Cap PR3 108X</p> <p>Wieslab® Complement system Screen COMPL 300</p> <p>Wieslab® Complement system Alternative pathway COMPL AP 330</p> <p>Wieslab® Complement system Classical pathway COMPL CP 310</p> <p>Wieslab® Complement system MBL pathway COMPL MP 320</p> <p>Wieslab® a-GBM semi quant. GP 104X</p> <p>Wieslab® MPO-ANCA semi quant. MPO 103X</p> <p>Wieslab® ANCA panel PAN 106</p> <p>Wieslab® PR3-ANCA semi quant. PR3 102X</p> <p>Wieslab® ANCA screen CP 111</p> <p>Wieslab® a-GBM, ANCA screen GCP 100</p> <p>Wieslab® a-GBM qualitative GP 114</p> <p>Wieslab® SS-A p200 SSA p200</p> <p>Wieslab® MPO-ANCA MPO IU</p> <p>Wieslab® Capture MPO-ANCA CapMPO IU</p> <p>Wieslab® PR3-ANCA PR3 IU</p> <p>Wieslab® Capture PR3-ANCA CapPR3 IU</p> <p>Wieslab® hCOMP quantitative COMP 200</p> <p>Wieslab® Vasculitis screen GCP-CAP</p> <p>Wieslab® Complement system Ficolin 3 COMPLF3</p>	COMPONENT NAME:	<p>Diluent buffer</p> <p>Wash solution</p> <p>Calibrator</p> <p>Positive control</p> <p>Negative control</p> <p>Reference control</p> <p>Stop solution</p> <p>Substrate solution</p> <p>Conjugate solution</p>
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Use of the product	In vitro diagnostic use.
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Company	Euro-Diagnostica AB
Address	P.O.Box 50117
Zip code/Place	SE-202 11 Malmö
Telephone	+46 40 53 76 00
Contact person	Åsa Anderlind
E-mail	info@eurodiagnostica.se

2. HAZARDS IDENTIFICATION

Classification according to the EU preparation directive 1999/45/EC.



Irritating

HEALTH

May cause sensitization by skin contact.

FIRE AND EXPLOSION HAZARDS

No danger of fire or explosion exists.

ENVIRONMENT

No adverse environmental impact is expected from the preparation.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Preparation containing following ingredients classified as dangerous substances.

Components mentioned under section 1 contain the following chemical ingredients:

No	Ingredient name	EC-no	CAS-no	Conc. (%)	Classification
1	5-chloro-2-methyl-4-isothiazolin-3-one	247-500-7	26172-55-4	0,0015-0,015	T, Xn; R23/24/25, 34, 43 50/53
2	2-methyl-4-isothiazolin-3-one	--	2682-20-4	0,0006 – 0,006	T, Xn; R23/24/25, 34, 43 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.

See section 16 for the full text of the classification declared above. Occupational exposure limits are mentioned under section 8, if such exist.

4. FIRST AID MEASURES

INHALATION

Fresh air, rest.

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. Give two cupfuls of water or milk to drink. Contact a doctor if larger amount has been swallowed.

5. FIRE-FIGHTING MEASURES

SUITABLE EXTINGUISHING MEDIA

Dry chemical, foam, water spray or carbon dioxide.

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FIRE AND EXPLOSION HAZARDS

No danger of fire or explosion exists.

PROTECTION OF FIRE-FIGHTERS

Wear respiratory protection and full protective gear.

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.

METHOD FOR CLEANING UP

Absorb larger spill with inert material (e.g. vermiculite, sand or soil), then place in a sealable container. The collected material is hazardous waste. Smaller spill can be cleaned up with a scouring-cloth, or something similar, which should be placed in a sealable container and disposed as hazardous waste.

7. HANDLING AND STORAGE

HANDLING

Use only in well-ventilated areas. Avoid contact with skin and eyes.

STORAGE

The preparation should be stored dry and cool at a temperature between 2-8°C in well sealed containers.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

OCCUPATIONAL EXPOSURE CONTROLS

Use only in well-ventilated areas. When necessary use local ventilation or good general extraction. Avoid contact with skin and eyes. Wash hands after working with the product.

HAND PROTECTION

Wear safety gloves. Recommended materials for gloves are latex rubber.

EYE PROTECTION

Wear tightly fitted safety glasses.

SKIN PROTECTION

Wear suitable protective clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

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

10. STABILITY AND REACTIVITY

STABILITY

Stable under normal conditions of use and storage.

11. TOXICOLOGICAL INFORMATION

SKIN CONTACT

May cause sensitization by skin contact.

EYE CONTACT

Splash in the eyes may cause reversible irritation and redness.

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INGESTION

Ingestion of larger amount may cause nausea, stomach pains and vomiting.

12. ECOLOGICAL INFORMATION

This preparation contains substances classified as dangerous for the environment. But the concentration of These substances are very low, so the preparation as such is not classified as dangerous for the environment, according to the EU classification rules in force.

13. DISPOSAL CONSIDERATIONS

METHOD OF DISPOSAL

Spill, leakage and not cleaned containers are hazardous waste and should be incinerated in an approved incineration plant for hazardous waste.

EWC-CODE

Proposed EWC code: 18 01 06

14. TRANSPORT INFORMATION

Product classified as dangerous goods:

Yes

No

Not decided

15. REGULATORY INFORMATION

Classification according to the EU preparation directive 1999/45/EC.



Irritating

EU label:

Yes

No

Not decided

Contains:

5-chloro-2-methyl-4-isothiazolin-3-one
2-methyl-4-isothiazolin-3-one

R-PHRASES

R43 May cause sensitization by skin contact.

S-PHRASES

S24 Avoid contact with skin.
S28 After contact with skin, wash immediately with plenty of water.
S37 Wear suitable gloves.

16. OTHER INFORMATION

THE PRODUCER'S NOTES

Safety data sheet approved by Euro-Diagnostica AB.

LIST OF R-PHRASES MENTIONED UNDER SECTION 2

Nr.	R-phrases
R23/24/25	Toxic by inhalation, in contact with skin and if swallowed.
R34	Corrosive.
R36/37/38	Irritating to eyes, respiratory system and skin.
R43	May cause sensitization by skin contact.
R50/53	Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment.

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REVISIONS HISTORY

Version 2.0: changes in section 1

Version 3.0: changes in section 2

Version 4.0: changes in section 1; five products have been added to the product list

Version 5.0: added Substrate solution to the list of components at section 1;

company contact information has been updated.

Sections 2 and 3 are inverted according to **REACH**.

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

YES at EU label under section 15.

Version 6.0: Wieslab Vasculitis screen kit has been added to the product list under section 1.

Version 7.0: Wieslab Complement system Ficolin 3 kit has been added to the product list under section 1. Conjugate solution has been added under Component Name section 1.