



Safety Data Sheet

CA 125

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY

1.1 COMMERCIAL PRODUCT NAME: **CA 125**
 PRODUCT NUMBER **DNOV061**

1.2 COMPANY NovaTec Immundiagnostica GmbH
 Waldstr. 23 A6
 D-63128 Dietzenbach (Germany)
 Tel.: 06074/48760

1.3 IN EMERGENCY Turn to nearest First Aid Station

2. COMPOSITION/INFORMATION ON INGREDIENTS

KIT CONTENTS:

REAGENTS	N ° CODE	INITIAL CONCENTRATION	CLASSIFICATION
STD 0 CA-125 1 MI	DCE002/5406-0		
Sodium phosphate bibasic		1,3 %	NOT DANGEROUS
CA-125		0 IU/mL	
Proclin300		0,0015%	
EDTA Bisodium		0,46 %	
BSA		0,1 %	
STD 1 CA-125 1 mL DCE002/5407-0			
Sodium phosphate bibasic		1,3 %	NOT DANGEROUS
CA-125		15,0 IU/mL	
Proclin300		0,0015%	
EDTA Bisodium		0,46 %	
BSA		0,1 %	
STD 2 CA-125 1 mL DCE002/5408-0			
Sodium phosphate bibasic		1,3 %	NOT DANGEROUS
CA-125		50,0 IU/mL	
Proclin300		0,0015%	
EDTA Bisodium		0,46 %	
BSA		0,1 %	
STD 3 CA-125 1 mL DCE002/5409-0			
Sodium phosphate bibasic		1,3 %	NOT DANGEROUS
CA-125		100,0 IU/mL	
Proclin300		0,0015%	
EDTA Bisodium		0,46 %	
BSA		0,1 %	
STD 4 CA-125 1 mL DCE002/5410-0			
Sodium phosphate bibasic		1,3 %	NOT DANGEROUS
CA-125		200,0 IU/mL	
Proclin300		0,0015%	

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EDTA Bisodium	0,46 %	
BSA	0,1 %	
STD 5 CA-125 1 mL DCE002/5411-0		
Sodium phosphate bibasic	1,3 %	NOT DANGEROUS
CA-125	400,0 IU/mL	
Proclin300	0,0015%	
EDTA Bisodium	0,46 %	
BSA	0,1 %	
CONJUGATE R. 2 DCE002/5402-0		
Anti -CA-125-Peroxldase	0,0001 %	NOT DANGEROUS
Anti -CA-125-Biotilinate	0,0001 %	NOT DANGEROUS
Proclin 300	0,01 %	
COATED MICROPLATE R. 3 DCE002/5403-0		
Streptavidine	0,01%	NOT DANGEROUS
Other ingredients		
CONCENTRATE WASH SOLUTION R. 1 20 mL DCE006-0		
Sodium phosphate bibasic	1,3 %	NOT DANGEROUS
NACL	1,8 %	
Proclin300	0,015 %	
TWEEN 20%	2,0 %	
TMB Substrate R.5 DCE004-0		
33,55 tetramethylbenzidine	0,03 %	NOT DANGEROUS
hydrogen peroxlde	0,015%	
Other ingredients		
Stop solution DCE005-0		
Sulphuric Acid	1,5 %	NOT DANGEROUS

Make reference to safety data sheet of dangerous chemical compounds and preparations written according to 67/548/CE and 88/549/CE directives and following modifications and amendments.

3.HAZARDS IDENTIFICATION

Reagent 1, Reagent 2, Reagent 3, Reagent 4, Reagent 5,Standard :The usual precautions taken when handling chemicals should be observed.

4.FIRST AID MEASURES

Eye contact:flush eyes with water.
Skin contact:wash off with water.
Ingestion:seek medical advice.
Direction for physician:symptomatic treatment by a physician

5.FIRE-FIGHTING MEASURES

Extinguishing media:no restriction.
Thermal decomposition:dangerous decomposition is not anticipated.

6.ACCIDENTAL RELEASE MEASURES

After spillage:dilute liquid with water and absorb.
Absorbent material:no restriction.
Special measures to limit damage are not necessary.

7.HANDLING AND STORAGE

7.1 HANDLING No special requirements.

7.2 STORAGE Store in tightly closed containers under cool conditions.
Do not store together:no restriction

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8.EXPOSURE CONTROL/PERSONAL PROTECTION

TLV:no

Respiratory protection:none

Eye protection:no

Hand protection:disposable gloves.Wash hands before breaks and at the end of work

9.PHYSICAL AND CHEMICAL PROPERTIES

9.1 APPEARANCE	STD CA-125 6 X 1 ML	liquid
	CONJUGATE R. 2	liquid
	COATED MICROPLATE R. 3	
	TMB SUBSTRATE	liquid
9.2 COLOUR	STOP SOLUTION	liquid
	WASH SOLUTION R. 4	liquid
	STD CA-125 6 X 1 ML	uncolour
	CONJUGATE R. 2	green
9.3 ODOUR	COATED MICROPLATE R. 3	
	WASH SOLUTION R. 4	uncolour
	TMB SUBSTRATE	uncolour
	STOP SOLUTION	uncolour
9.4 pH	STD CA-125 6 X 1 ML	odourless
	CONJUGATE R. 2	odourless
	COATED MICROPLATE R. 3	odourless
	WASH SOLUTION R. 4	odourless
9.5 MELTING POINT	TMB SUBSTRATE	odourless
	STOP SOLUTION	odourless
	STD CA-125 6 X 1 ML	7.4
	CONJUGATE R. 2	7.4
9.6 BOILING POINT	COATED MICROPLATE R. 3	
	WASH SOLUTION R. 4	7.4
	TMB SUBSTRATE	4.0
	STOP SOLUTION	0
9.5 MELTING POINT	N.D.	
9.6 BOILING POINT	N.D.	
9.5 MELTING POINT	N.D.	
9.7 IGNITION TEMPERATURE	N.D.	
9.8 FLASH POINT	N.D.	
9.9 EXPLOSION LIMIT	N.D.	
9.10 VAPOR TENSION	N.D.	
9.12 DENSITY	N.D.	
9.11 VAPOR PRESSURE	N.D.	
9.13 SOLUBILITY IN WATER	SOLUBLE	

10.STABILITY AND REACTIVITY

Hazardous reactions:none known when used appropriately.

Hazardous decomposition products:no

11.TOXICOLOGICAL INFORMATION

LD54 oral:not known.

LD54:skin:not known.

LD54 skin:not known.

LD54 inhalation:not known.

Toxicological information:intoxification has no far not become known.

12. ECOLOGICAL INFORMATION

No data yet available.

13.DISPOSAL CONSIDERATION

Used reagents must be disposed off in accordance with local, national and federal regulations.

14.TRANSPORT INFORMATION

This product is not subject to current regulations for transportation of hazardous goods.

15.REGULATORY INFORMATION

This Product does not require special labelling, in accordance with the appropriate EEC directives related to dangerous

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16.OTHER INFORMATION

This product is intended for IN VITRO diagnostic use only. NOT FOR USE IN HUMANS.

The information herein is believed to be correct as of the date hereof and excludes any guarantee related with the final use given to the product, being the recipient the last responsible for observing the local Laws applicable in each case

Date of issue: 01.12.2008

For further information about the preparation please contact NovaTec: info@novatec-id.com;
www.novatec-id.com