



# Safety Data Sheet

## CA 15-3

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

1.1 COMMERCIAL PRODUCT NAME: **CA 15-3**  
 PRODUCT NUMBER **DNOV062**

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
<b>STD 0 CA 15-3 1 mL</b>	<b>DCE002/55 06-0</b>		
Sodium phosphate bibasic		1,3 %	<b>NOT DANGEROUS</b>
CA 15-3		0 IU/mL	
Proclin300		0,0015%	
EDTA Bisodium		0,55 %	
BSA		0,1 %	
<b>STD 1 CA 15-3 1 mL</b>	<b>DCE002/55 07-0</b>		
Sodium phosphate bibasic		1,3 %	<b>NOT DANGEROUS</b>
CA 15-3		15,0 IU/mL	
Proclin300		0,0015%	
EDTA Bisodium		0,55 %	
BSA		0,1 %	
<b>STD 2 CA 15-3 1 mL</b>	<b>DCE002/55 08-0</b>		
Sodium phosphate bibasic		1,3 %	<b>NOT DANGEROUS</b>
CA 15-3		30,0 IU/mL	
Proclin300		0,0015%	
EDTA Bisodium		0,55 %	
BSA		0,1 %	
<b>STD 3 CA 15-3 1 mL</b>	<b>DCE002/55 09-0</b>		
Sodium phosphate bibasic		1,3 %	<b>NOT DANGEROUS</b>
CA 15-3		60,0 IU/mL	
Proclin300		0,0015%	
EDTA Bisodium		0,55 %	
BSA		0,1 %	
<b>STD 4 CA 15-3 1 mL</b>	<b>DCE002/55 10-0</b>		
Sodium phosphate bibasic		1,3 %	<b>NOT DANGEROUS</b>
CA 15-3		120,0 IU/mL	
Proclin300		0,0015%	

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EDTA Bisodium	0,55 %	
BSA	0,1 %	
<b>STD 5 CA 15-3 1 mL DCE002/55 11-0</b>		
Sodium phosphate bibasic	1,3 %	<b>NOT DANGEROUS</b>
CA 15-3	240,0 IU/mL	
Proclin300	0,0015%	
EDTA Bisodium	0,55 %	
BSA	0,1 %	
<b>SERUM DILUENT CONCENTRATE R. 1 DCE002/5518-0</b>		<b>NOT DANGEROUS</b>
Phosphate buffer	0,0001 %	
BSA	0,01 %	
<b>CONJUGATE R. 3 DCE002/55 03-0</b>		
Anti Human IgG-Peroxldase	0,0001 %	<b>NOT DANGEROUS</b>
Proclin 300	0,01 %	
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<b>COATED MICROPLATE R. 4 DCE002/55 04-0</b>		<b>NOT DANGEROUS</b>
Anti Ca 15-3	0,01%	
Other ingredients		
<b>CONCENTRATE WASH SOLUTION R. 1 30 mL DCE006-0</b>		
Sodium phosphate bibasic	1,3 %	<b>NOT DANGEROUS</b>
NACL	1,8 %	
Proclin300	0,015 %	
TWEEN 20%	2,0 %	
<b>TMB Substrate R.5 DCE004-0</b>		<b>NOT DANGEROUS</b>
33,55 tetramethylbenzidine	0,03 %	
hydrogen peroxide	0,015%	
DimethylsulfoXide	< 5%	
<b>Stop solution DCE005-0</b>		<b>NOT DANGEROUS</b>
Sulphuric Acid	1,5 %	

Make reference to safety data sheet of dangerous chemical compounds and preparations written according to 67/548/CE and 88/55 9/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 15-3 6 X 1 ML	liquid
	SERUM DILUENT	liquid
	CONJUGATE R. 3	liquid
	COATED MICROPLATE R. 4	
	TMB SUBSTRATE	liquid
9.2 COLOUR	STD CA 15-3 6 X 1 ML	uncolour
	SERUM DILUENT	orange
	CONJUGATE R. 3	orange
	COATED MICROPLATE R. 3	
	WASH SOLUTION R. 4	uncolour
9.3 COLOUR	TMB SUBSTRATE	uncolour
	STOP SOLUTION	uncolour
	STD CA 15-3 6 X 1 ML	odourless
	SERUM DILUENT	odourless
	CONJUGATE R. 2	odourless
9.4 pH	COATED MICROPLATE R. 3	odourless
	WASH SOLUTION R. 4	odourless
	TMB SUBSTRATE	odourless
	STOP SOLUTION	odourless
	STD CA 15-3 6 X 1 ML	7.4
9.5 MELTING POINT	SERUM DILUENT	liquid
	CONJUGATE R. 2	7.4
	COATED MICROPLATE R. 3	
	WASH SOLUTION R. 4	7.4
	TMB SUBSTRATE	4.0
9.6 BOILING POINT	STOP SOLUTION	0
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

LD50 oral: not known.

LD50: not known.

LD50 skin: not known.

LD50 inhalation: not known.

Toxicological information: intoxication has so 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.

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**15.REGULATORY INFORMATION**

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

**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](mailto:info@novatec-id.com);  
[www.novatec-id.com](http://www.novatec-id.com)