

SAFETY DATA SHEET IMMUNOSCAN CCPlus® kit

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

1.1 Product identifier

PRODUCT NAME:	Immunoscan CCPlus®			
Product description	Kit consisting of following reagents:			
	Reagent A: Dilution Buffer			
	Reagent B: Wash Solution (20x Conc.)			
	Reagent C: Stop Solution			
	Reagent D: Conjugate Solution			
	Reagent E: Positive Control			
	Reagent F: Reference Control			
	Reagent G: Calibrator A-E			
	Reagent H: Negative Control			
	Substrate TMB (separate SDS)			
	Antigen coated plate			
Product code	RA-96RT			

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the product	Kit consisting of different reagents for in vitro diagnostic use.	
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1.3 Details of the supplier of the safety data sheet

Company	Euro Diagnostica AB	
Address	undavägen 151	
Zip code/Place	E-212 24 Malmö, Sweden	
Telephone	+46 40 53 76 00	
Internet	www.eurodiagnostica.com	
E-mail	info@eurodiagnostica.se	

1.4 Emergency telephone number

Emergency telephone	+46 20 996000 – Poisson Information Centre, Sweden
number	

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Product definition: In vitro diagnostic kit consisting of different reagents.

Classification according to the Regulation (EC) No. 1272/2008 (CLP)

Reagent A, B, C, D, E, F, G, H and the antigen coated plate: Not classified as dangerous.

2.2 Label elements according to the Regulation (EC) No. 1272/2008 (CLP)

Reagent A, B, D, E, F, G, H and the antigen coated plate: No labeling required.

2.3 Special labelling of certain preparations

Reagent C: Safety data sheet available for professional user on request.

2.4 Other hazards

Other hazards which do	None
not result in classification	
Substance meets the	PBT: No
criteria	(refers to substances containing)
for PBT under Regulation	
EC No. 1907/2006,	



appendix XIII	
Substance meets the	vPvB: No
criteria	(refers to substances containing)
for PBT under Regulation	
EC No. 1907/2006,	
appendix XIII	

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Reagents containing following substances classified as dangerous.

No	Product/ingredient name	EC-number	CAS-	REACH	Conc.	Classification
			number	registration	(weight-	Regulation (EC) No. 1272/2008 [CLP]
				number	%)	
Rea	gent Dilution Buffer, Conjugate S	Solution, Positi	ve Control, Re	ference Control,	Calibrator A	-E and Negative Control
	Sodium azide	247-852-1	26628-22-8		0,09	Acute Tox. 2; H300
						Aquatic Acute 1;
						H400
						Aquatic Chronic 1; H410
						EUH032
Rea	Reagent Stop Solution					
	Sulphuric acid %	231-639-5	7664-93-9		4,89	Skin Corr. 1A; H314

Regent Wash Solution and the antigen coated plate contain no dangerous substances. See section 16 for the full text of the classifications declared above. Occupational exposure limits are mentioned under section 8, if such exist.

4. FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation:	Remove to fresh air, rest. Call a physician if the complaints persist.			
Skin contact:	Remove contaminated clothing and footwear. Wash the skin properly with soap and			
	water.			
Eye contact:	Keep eyelids well apart. Rinse with water for a couple of minutes. Call a physician if			
	the complaints persist.			
Ingestion	Wash mouth properly with water. If victim is conscious and alert, give 2-4 cupfuls of			
	milk/water to dilute the substance in stomach. Call a physician if the complaints persist.			

4.2 Most important symptoms and effects, both acute and delayed

Potential acute health effects

Inhalation:	Exposure to high airborne concentrations of the reagents in this kit may cause irritation
	in the respiratory tract, dizziness and sickness.
Skin contact:	Not relevant.
Eye contact:	Not relevant.
Ingestion:	Ingestion of larger amounts may cause sickness and vomiting.

4.3 Indication of any immediate medical attention and special treatment needed

Ingestion:	Treat symptomatically.	
Specific treatments:	No specific treatment.	

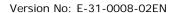
5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

511 Extinguishing incura			
Suitable extinguishing Dry chemical, foam, water spray or carbon dioxide.			
media			
Unsuitable extinguishing	Waterjet		
media			

5.2 Special hazards arising from the substance or mixture

Haza	rds from the	None
subst	ance or mixture	
Haza	rdous thermal	Decomposition products may include the following materials: carbon monoxide,
decor	nposition products	carbon dioxide and nitrous gases.





5.3 Advice for firefighters

Special protective actions	Promptly isolate the scene by removing all persons from the vicinity of the incident if			
for fire-fighters	there is a fire. No action shall be taken involving any personal risk or without suitable			
	training.			
Special protective	Fire-fighters should wear appropriate protective equipment and self-contained			
equipment for fire-	oreathing apparatus (SCBA) with a full face-piece operated in positive pressure			
fighters	mode. Clothing for fire-fighters (including helmets, protective boots and gloves)			
	conforming to European standard EN 469 will provide a basic level of protection			
	for chemical incidents.			
Further information	Not applicable			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

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For non-emergency	No action shall be taken involving any personal risk or without suitable training.		
personnel	Evacuate surrounding areas. Keep unnecessary and unprotected personnel from		
	entering. Do not touch or walk through spilt material. Put on appropriate personal		
	protective equipment.		
For emergency	If specialized clothing is required to deal with the spillage, take note of any		
responders	information in Section 8 on suitable and unsuitable materials. See also Section 8 for		

6.2 Environmental precautions

Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

additional information on hygiene measures.

6.3 Methods and materials for containment and cleaning up

old intentions und indictions	s for containment and eleaning up			
Small spill	Stop leak if without risk. Move containers from spill area. Dilute with water and mop			
	up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry			
	material and place in an appropriate waste disposal container. Dispose of via a			
	licensed waste disposal contractor.			
Large spill	Stop leak if without risk. Move containers from spill area. Prevent entry into sewers,			
	water courses, basements or confined areas. Wash spillages into an effluent			
	treatment plant or proceed as follows. Contain and collect spillage with			
	noncombustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous			
	earth and place in container for disposal according to local regulations. Dispose of			
	via a licensed waste disposal contractor.			

6.4 Reference to other sections

Reference to other	See Section 8 for information on appropriate personal protective equipment.			
sections	See Section 13 for additional waste treatment information.			

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Protective measures	Put on appropriate personal protective equipment (see Section 8).
Advice on general occupational hygiene	Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

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Storage:	Store in original container protected from direct sunlight in a dry, cool and well-
	ventilated area, away from incompatible materials (see section 10), food and drink.
	Keep container tightly closed and sealed until ready for use. Containers that have
	been opened must be carefully resealed and kept upright to prevent leakage.



Further information: Not applicable

7.3 Specific end use(s)

Reagents for in vitro diagnostic use.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limits

Chemical name	European Union	United Kingdom	France	Spain	Germany
Sodium azide	TWA 0.1 mg/m ³	STEL: 0.3 mg/m ³	VME: 0.1 mg/m ³	VLA-EC: 0.3	MAK: 0.2 mg/m ³
(CAS No. 26628-22-8)	STEL 0.3 mg/m ³	TWA: 0.1 mg/m ³	VLCT: 0.3	mg/m3 VLA-ED:	Ceiling/Peak: 0.4
		Skin	mg/m ³	0.1 mg/m^3	mg/m3
					TWA: 0.2 mg/m ³
Chemical name	Italy	Portugal	Netherlands	Finland	Denmark
Sodium azide	TWA: 0.1 mg/m ³	Ceiling: 0.29	STEL: 0.3 mg/m ³	TWA: 0.1 mg/m ³	TWA: 0.1 mg/m ³
(CAS No. 26628-22-8)	STEL: 0.3 mg/m ³	mg/m ³ Ceiling:	TWA: 0.1 mg/m ³	STEL: 0.3 mg/m ³	Skin
	Skin	0.11 ppm	Skin	Skin	
Chemical name	Austria	Switzerland	Poland	Norway	Ireland
Sodium azide	STEL: 0.3 mg/m ³	STEL: 0.4 mg/m ³	NDSCh: 0.3	Ceiling: 0.3	TWA: 0.1 mg/m ³
(CAS No. 26628-22-8)	MAK: 0.1 mg/m ³	MAK: 0.2 mg/m ³	mg/m3	mg/m ³	STEL: 0.3 mg/m ³
	Skin		NDS: 0.1 mg/m ³	Skin	Skin
			Skin		

Occupational exposure limits

Chemical name	EU	United Kingdom	France	Spain	Germany
Sulphuric acid	0.05 mg/m^3		0.05 mg/m^3	VLA-EC: 2	STEL: 0.1 mg/m ³
(CAS No. 7664-93-9)	thoracic fraction		thoracic fraction	mg/m ³	MAK: 0.1 mg/m ³
					Inhalable aerosols
Chemical name	Italy	Sweden	Netherlands	Finland	Denmark
Sulphuric acid	TWA 0.05 mg/m ³	TWA 0.1 mg/m ³	0.05 mg/m^3		TWA 1 mg/m ³
(CAS No. 7664-93-9)		STEL 0.2mg/m ³	thoracic fraction		STEL 2 mg/m ³
Chemical name	Austria	Switzerland	Poland	Norway	Ireland
Sulphuric acid	MAK: 1 mg/m ³	STEL: 0.1 mg/m ³	NDSCh: 1		
(CAS No. 7664-93-9)	STEL: 3 mg/m ³	MAK: 0.1 mg/m ³	mg/m ³		
	Inhalable aerosols	Inhalable aerosols	NDS: 3 mg/m ³		

Recommended	Not relevant
monitoring procedures	

Derived effect levels

Product/ingredient name	Type	Exposure	Value	Population	Effects

Predicted effect	Not available
concentrations	
PNEC Summary	Not available

8.2 Exposure controls

Appropriate engineering controls	Good general ventilation should be sufficient to control worker exposure to airborne contaminants. Otherwise, use local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.
Hygiene measures	Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.



Respiratory protection	Not relevant during normal condition.
Eye/face protection	Safety glasses or face shield shall be worn.
Hand protection	Chemical-resistant, impervious gloves in butyl rubber or nitril rubber complying with an approved standard shall be worn.
Body protection	Wear suitable protective clothing.

Environmental exposure	Not applicable
controls	

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1.1 Information on basic physical and chemical properties of the reagents

7.1.1 Information on b	Reagent A	Reagent B	Reagent C	Reagent D	Reagent E	Reagent F	Reagent G	Reagent H
Physical state	Liquid							
Colour	Blue	Colourless	Colourless	Red	Blue	Blue	Blue	Blue
Odour	Odourless							
Odour threshold	n.a							
Solubility(ies)	Soluble in							
Solubine (105)	water							
pH (product)	7,3-7,5	7,3-7,5	n.d.	n.d.	7,3-7,5	7,3-7,5	7,3-7,5	7,3-7,5
Melting point/freezing	n.d							
point								
Initial boiling point and	n.d							
boiling range								
Flash point	> 100°C							
Evaporation rate (butyl	< 1	< 1	< 1	< 1	< 1	< 1	< 1	< 1
acetate = 1)								
Flammability (solid, gas)	n.a							
Upper/lower flammability	n.a							
or explosive limits								
Combustion rate	n.a							
Upper/lower flammability	Upper: n.a							
or explosive limits	Lower: n.a							
Vapour pressure	n.d							
(at 20°C)								
Vapour density	n.a							
Relative density (Water =	n.d							
1)								
Partition coefficient:	n.a							
n-octanol/water								
Autoignition temperature	n.d							
Decomposition	n.d							
temperature			_					
Viscosity	n.d							
Explosive properties	n.a							
Oxidising properties	n.a							

n.a = not applicable. n.d = not determined

9.2 Other information

hazardous reactions

10. STABILITY AND REACTIVITY

10.1 Reactivity	Non-reactive
10.2 Chemical stability	Stabile under normal conditions of use and storage.
10.3 Possibility of	Under normal conditions of storage and use hazardous reactions will not occur

10.4 Conditions to avoid	Avoid direct sunlight.
10.5 Incompatible	None



materials	
10 C TT 1	G. 1

10.6 Hazardous Carbon monoxide, carbon dioxide and nitrous gases.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Assessment of acute toxicity for the different reagents:

Not harmful if inhaled. Not harmful in contact with skin. Not harmful if swallowed.

Calculated data:

LD50 oral, rat: > 2000 mg/kgLD50 dermal, rat: > 2000 mg/kg

Irritation/Corrosion

Assessment of irritating effect for the different reagents

Experimental/calculated data:

Corrosive or irritating to the skin, rabbit: Not irritating. Serious eye damage/eye irritation, rabbit: Not irritating

Sensitization by inhalation/skin contact

Assessment of sensibility for the different reagents:

May not cause any sensitizing effects.

Germ cell mutagenicity

Assessment of mutagenicity for the different reagents:

The chemical structure of the different reagents don't indicate any mutagenic effects.

Carcinogenicity

Assessment of carcinogenicity for the different reagents:

The chemical structure of the different reagents don't indicate any carcinogenic effects.

Reproduction toxicity

Assessment of reproduction toxicity for the different reagents:

The chemical structure of the different reagents don't indicate any reproduction toxic effects.

Developmental toxicity

Assessment of teratogenicity for the different reagents:

The chemical structure of the different reagents don't indicate any teratogenic effects.

Specific target organ toxicity (single exposure)

STOT assessment single dos toxicity:

Based on available information an organ specific toxicity is not expected for the different reagents.

Repeated dose toxicity and specific organ toxicity (repeated exposure)

Based on available information an organ specific toxicity is not expected for the different reagents.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

12.1.1 Acute toxicity in the aquatic environment for sodium azide

Test	Value/unit (mg/l)	Test method	Exp. time (h)	Species
Fish LC50	0.8-1.6		96	Rainbow trout
Daphnia EC50	4.2		48	Daphnia pulex
Not readily biodegradable.				

12.1.2 Acute toxicity in the aquatic environment for all reagents (calculated)



Fish LC50	> 100	 96	
Daphnia EC50	> 100	 48	Daphnia magna
Algae IC50	> 100	 72	Green algae

12.1.3 Ecotoxicity

Reagent A, D, E, F, G and H contains only a low concentration of sodium azide. This concentration is below the lowest concentration limit for classification as harmful to aquatic organisms. Thus, all reagents in the kit are classified as not harmful to aquatic organisms.

122	Persistence	and door	odobility
12.2	Persistence	and degr	adabiiitv

Conclusion/Summary	The reagents will be classified as readily biodegradable.		
12.3 Bioaccumulative pote	ential		
Conclusion/Summary	The reagents will not be classified as bioaccumulative.		
12.4 Mobility in soil			
Soil/water partition	Not available		
coefficient (KOC)			
Mobility	Not available		
12.5 Results of PBT and v	12.5 Results of PBT and vPvB assessment		
PBT	Not applicable		
vPvB	Not applicable		
12.6 Summary – ecological information			

The reagents will not be classified as dangerous for the environment.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Method of disposal	The generation of waste should be avoided or minimized wherever possible. This material and its container must be disposed of in a safe way. Dispose of surplus a non-recyclable products via a licensed waste disposal contractor. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Used kit may be potentially infectious material and shall be disposed as a hazardowaste. Within the present knowledge of the supplier, this product is regarded as	
Hazardous waste	Within the present knowledge of the supplier, this product is regarded as hazardous waste, as defined by EU Directive 2008/98/EC.	

European Waste Catalogue (EWC)

EWC Waste Code	Type of waste		
18 01 06*	Chemicals consisting of or containing dangerous substances		
15 01 10*	Packaging containing residues of or contaminated by dangerous substances		

Packaging

Method of disposal	Incineration.
Special precautions	None.

14. TRANSPORT INFORMATION

Product classified as dangerous goods:

Yes

No

Not decided

	ADR/RID	ADN/ADNR	IMDG	IATA
14.1 UN number	Not regulated	Not regulated	Not regulated	Not regulated
14.2 UN proper				
shipping name				



14.3 Transport				T
_				
hazard				
class(es)				
14.4 Packing Group				
14.5 Environmental				
hazards				
14.6 Special	Not available	Not available	Not available	Not available
precautions for user				
Additional	Used kit is dangerous goods by transportation in class 6.2, UN 3291. Contact the manufacturer for			
information	further information.			

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture EU Regulation (EC) No. 1907/2006 (REACH)

REACH Status	In compliance.
	Pre-registration status: All components are listed or exempted.

Annex XIV - List of substances subject to authorization

Substances of very high concern

None of the components are listed.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

Not applicable.

15.2 Chemical Safety Assessment

The reagents in this kit contain substances for which Chemical Safety Assessments still are required.

15.3 Other information

Tariff Code –	Not applicable	
harmonized system		
The EU Seveso Directive	Not applicable	

International regulations

Chemical Weapons Convention List	Chemical Weapons Convention List	Chemical Weapons Convention List
Schedule I Chemicals	Schedule II Chemicals	Schedule III Chemicals
Not regulated	Not regulated	Not regulated

16. OTHER INFORMATION

Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II

Disclaimer: The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties, protections and disposal which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.



THE PRODUCER'S NOTES

--LIST OF HAZARD STATEMENTS MENTIONED UNDER SECTION 3

No.	H-Statements	
H300	Fatal if swallowed.	
H314	Causes severe skin burns and eye damage.	
H400	Very toxic to aquatic life.	
H410	Very toxic to aquatic life with long lasting effects.	
EUH032	Contact with acids liberates very toxic gas.	

Revisions

Version	Valid from (date)	Changes
00EN	October 30, 2013	New MSDS according to Regulation (EC) No. 1907/2006 (REACH), Annex
		II. Replaces: SDS Immunoscan version no: 3.0, dated December 10, 2009
		and SDS Immunoscan Stop solution version no: 2.0, dated June 04, 2009.
01EN	January 30, 2015	Concentration of Sulphuric acid under section 3.1 has been corrected.
02EN	June 1, 2015	From June 1, 2015 the Regulation (EU) No: 453/2010, Annex II applies and
		CLP enters into force for mixtures.
		All information in SDS related to classification according to KIFS 2005:7 has
		been removed, sections 2, 3.1 and 16 (the producer's notes) have been
		updated.