

# SAFETY DATA SHEET

## IMMUNOSCAN CCPlus®

### SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF 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-96Plus, RA-96Plus RUO

#### 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.

#### 1.3 Details of the Supplier of the safety data sheet

**Company** Svar Life Science AB  
**Address** Lundvägen 151  
**Zip code/Place** SE-212 24 Malmö, Sweden  
**Telephone** +46 40 53 76 00  
**Website** [www.svarlifescience.com](http://www.svarlifescience.com)  
**E-mail** [info@svarlifescience.com](mailto:info@svarlifescience.com)

#### 1.4 Emergency telephone number

**Emergency telephone number** (Sweden) Acute: 112 – Ask for "Giftinformation". If less acute call: +46 010 4566700.  
(UK) NHS (England or Wales): Dial 111 or 0845 4647 NHS 24  
(Scotland): 08454 24 24 24

### SECTION 2. HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance or mixture

Classification according to the Regulation (EC) No. 1272/2008 (CLP)  
Product definition: In vitro diagnostic kit consisting of different reagents.  
Reagent A, B, C, D, E, F, G, H and the antigen coated plate: Not classified as dangerous.

#### 2.2 Label elements

No labeling required.

#### 2.3 Other hazards

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

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Not applicable.

### 3.2 Mixtures

Solutions containing the following declarable preservative

No	Product/ingredient name	EC-number	CAS-number	REACH registration number	Conc. (weight-%)	Classification Regulation (EC) No. 1272/2008 [CLP]
<b>Reagent Dilution Buffer, Conjugate Solution, Positive Control, Reference Control, Calibrator A-E and Negative Control</b>						
	Sodium azide	247-852-1	26628-22-8	--	0,09	Acute Tox. 2; H300 Aquatic Acute 1; H400 Aquatic Chronic 1; H410, EUH032
<b>Reagent Stop Solution</b>						
	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.

## SECTION 4. FIRST AID MEASURES

### 4.1 Description of first aid measures

<b>Inhalation:</b>	Remove to fresh air, rest. Call a physician if the complaints persist.
<b>Skin contact:</b>	Remove contaminated clothing and footwear. Wash the skin properly with soap and water.
<b>Eye contact:</b>	Keep eyelids well apart. Rinse with water for a couple of minutes. Call a physician if the complaints persist.
<b>Ingestion</b>	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

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

### 4.3 Indication of any immediate medical attention and special treatment needed

<b>Ingestion:</b>	Treat symptomatically.
<b>Specific treatments:</b>	No specific treatment.

## SECTION 5. FIRE-FIGHTING MEASURES

### 5.1 Extinguishing media

<b>Suitable extinguishing media</b>	Dry chemical, foam, water spray or carbon dioxide.
<b>Unsuitable extinguishing media</b>	Waterjet

## 5.2 Special hazards arising from the substance or mixture

<b>Hazards from the substance or mixture</b>	None
<b>Hazardous thermal decomposition products</b>	Decomposition products may include the following materials: carbon monoxide, carbon dioxide and nitrous gases.

## 5.3 Advice for firefighters

<b>Special protective actions for fire-fighters</b>	Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
<b>Special protective equipment for fire-fighters</b>	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure 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.
<b>Further information</b>	Not applicable

## SECTION 6. ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

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

### 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).

### 6.3 Methods and materials for containment and cleaning up

<b>Small spill</b>	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.
<b>Large spill</b>	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

See Section 8 for information on appropriate personal protective equipment. See Section 13 for additional waste treatment information.

## SECTION 7. HANDLING AND STORAGE

### 7.1 Precautions for safe handling

<b>Protective measures</b>	Put on appropriate personal protective equipment (see Section 8).
<b>Advice on general occupational hygiene</b>	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

<b>Storage:</b>	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.
<b>Further information:</b>	Not applicable

### 7.3 Specific end use(s)

Reagents for in vitro diagnostic use.

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

#### Occupational exposure limits

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

#### Occupational exposure limits

Chemical name	EU	United Kingdom	France	Spain	Germany
Sulphuric acid (CAS No. 7664-93-9)	0,05 mg/m <sup>3</sup> thoracic fraction	--	0,05 mg/m <sup>3</sup> thoracic fraction	VLA-EC: 2 mg/m <sup>3</sup>	STEL: 0.1 mg/m <sup>3</sup> MAK: 0.1 mg/m <sup>3</sup> Inhalable aerosols
Chemical name	Italy	Sweden	Netherlands	Finland	Denmark
Sulphuric acid (CAS No. 7664-93-9)	TWA 0.05 mg/m <sup>3</sup>	TWA 0.1 mg/m <sup>3</sup> STEL 0.2mg/m <sup>3</sup>	0,05 mg/m <sup>3</sup> thoracic fraction	--	TWA 1 mg/m <sup>3</sup> STEL 2 mg/m <sup>3</sup>
Chemical name	Austria	Switzerland	Poland	Norway	Ireland
Sulphuric acid (CAS No. 7664-93-9)	MAK: 1 mg/m <sup>3</sup> STEL: 3 mg/m <sup>3</sup> Inhalable aerosols	STEL: 0.1 mg/m <sup>3</sup> MAK: 0.1 mg/m <sup>3</sup> Inhalable aerosols	NDSch: 1 mg/m <sup>3</sup> NDS: 3 mg/m <sup>3</sup>	--	--

**Recommended monitoring procedure** Not relevant

#### Derived effect levels

Product/ingredient name	Type	Exposure	Value	Population	Effects
--	--	--	--	--	--

**Predicted effect concentrations** Not available

**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 exposurecontrols

Not applicable

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**
**9.1 Information on basic physical and chemical properties of the reagents**

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

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

**9.2 Other information**

Not applicable

**SECTION 10. STABILITY AND REACTIVITY**

**10.1 Reactivity** Non-reactive

**10.2 Chemical stability** Stable under normal conditions of use and storage.

**10.3 Possibility of hazardous reactions** Under normal conditions of storage and use, hazardous reactions will not occur.

**10.4 Condition to avoid** Avoid direct sunlight.

**10.5 Incompatible materials** None

**10.6 Hazardous decomposition products** Carbon monoxide, carbon dioxide and nitrous gases.

## SECTION 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:

LD<sub>50</sub> oral, rat: > 2000 mg/kg

LD<sub>50</sub> 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 doesn't indicate any mutagenic effects.

#### Carcinogenicity

Assessment of carcinogenicity for the different reagents: The chemical structure of the different reagents doesn't indicate any carcinogenic effects.

#### Reproduction toxicity

Assessment of reproduction toxicity for the different reagents:

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

#### Developmental toxicity

Assessment of teratogenicity for the different reagents:

The chemical structure of the different reagents doesn'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.

## SECTION 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 LC <sub>50</sub>	0.8-1.6	--	96	Rainbow trout
Daphnia EC <sub>50</sub>	4.2	--	48	Daphnia pulex

Not readily biodegradable.

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

Test	Value/unit (mg/l)	Test method	Exp. time (h)	Species
Fish LC <sub>50</sub>	> 100	--	96	--
Daphnia EC <sub>50</sub>	> 100	--	48	Daphnia magna
Algae IC <sub>50</sub>	> 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.

**12.2 Persistence and degradability**

**Conclusion/Summary** The reagents will be classified as readily biodegradable.

**12.3 Bioaccumulative potential**

**Conclusion/Summary** The reagents will not be classified as bioaccumulative.

**12.4 Mobility in soil**

**Soil/water partition coefficient (KOC)** Not available

**Mobility** Not available

**12.5 Results of PBT and vPvB assessment**

**PBT** Not applicable

**vPvB** Not applicable

**12.6 Summary – ecological information**

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

**SECTION 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 and 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 hazardous waste.

**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)**

<b>EWC Waste Code</b>	<b>Type of waste</b>
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.

**SECTION 14. TRANSPORT INFORMATION**

Product classified as dangerous goods:  Yes  No  Not decided

	<b>ADR/RID</b>	<b>ADN/ADNR</b>	<b>IMDG</b>	<b>IATA</b>
<b>14.1 UN number</b>	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.2 UN proper shipping name</b>	--	--	--	--
<b>14.3 Transport hazard class(es)</b>	--	--	--	--
<b>14.4 Packing Group</b>	--	--	--	--
<b>14.5 Environmental hazards</b>	--	--	--	--
<b>14.6 Special precautions for user</b>	Not available	Not available	Not available	Not available

**Additional information** Used kit is dangerous goods by transportation in class 6.2, UN 3291. Contact the manufacturer for further information.

**14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable

**SECTION 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**

<b>Tariff Code – harmonized system</b>	Not applicable
<b>The EU Seveso Directive</b>	Not applicable

**International regulations****Chemical Weapons Convention  
List****Schedule I Chemicals**

Not regulated

**Chemical Weapons Convention  
List****Schedule II Chemicals**

Not regulated

**Chemical Weapons Convention  
List****Schedule III Chemicals**

Not regulated

**SECTION 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**

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**LIST OF HAZARD STATEMENTS MENTIONED UNDER SECTION 3**

<b>No.</b>	<b>H-Statements</b>
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.

The following document :

**SDS Immunoscan CCPlus RA-96Plus EN**

has been signed as follows

Approval	Signatures
Author Approval	Julia Selmani [gxpihosted\jus] [ 01-Oct-2019 14:41 +01, Author Approver ] Outcome: Approve
Management Approval	Anna Pramhed [gxpihosted\apr] [ 01-Oct-2019 16:36 +01, Management ] Outcome: Approve
QA Approval	My Tran [gxpihosted\myt] [ 02-Oct-2019 09:36 +01, Quality Assurance ] Outcome: Approve

Revision History
1.0 Document E-31-0008-02EN migrated to x-docs with new document number LABEL-DOC-0265 v1.0. 2.0: According to CR-00019 - New Svar logo and updated Svar address. New layout. Correction from RA-96RT to RA-96Plus. Revision removed from SDS, all revisionshistory can be found in the x.docs' archive. A new Product RA-96 Plus RUO has been added according to CR-00140.