

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 the following components: <ul style="list-style-type: none"> • Calibrator A-E • Reference Control • Positive Control • Negative Control • Wash Buffer Solution (20x Conc.) • Dilution Buffer • Conjugate Solution • Substrate TMB (separate SDS) • Stop Solution • 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
E-mail	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)

Conjugate Solution: Skin Sens.1; H317

The remaining reagents are not classified as dangerous.

2.2 Label elements

Conjugate Solution:



WARNING

Contains: Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

H317 May cause an allergic skin reaction

P261 Avoid breathing spray.

P280 Wear protective gloves.

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

The remaining reagents require no CLP labelling.

Additional labelling:



Biohazard

IVD contains plasma which is derived from human donors. The plasma has been tested for hepatitis B, hepatitis C and antibodies for HIV, and found to be negative. The product is considered to be biological agents in group 2.

2.3 Other hazards

Other hazards which do not result in classification

Substance meets the criteria for PBT / vPvB under Regulation EC No. 1907/2006, appendix XIII

Endocrine disrupting properties The substances are not identified as having endocrine disrupting properties in accordance with the criteria set out in Regulation 2017/2100 or Regulation 2018/605.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

Solutions containing the following declarable substances:

Product / ingredient name	EC-number	CAS-number	REACH registration number	Conc. (weight-%)	Classification Regulation (EC) No. 1272/2008 [CLP]
Conjugate Solution					
Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	247-500-7 and 220-239-6	55965-84-9	-	0.0024	Acute Tox. 3; H301 ATE = 100mg/kg Acute Tox. 2; H310 ATE = 50mg/kg Acute Tox. 3; H331 (ATE = 0.05mg/l/4H) Eye Dam. 1; H318 Skin Corr. 1C; H314 SCL: Skin Corr. 1C; H314: C ≥ 0.6% Eye Dam. 1; H318: C ≥ 0.6% Eye Irrit. 2; H319: 0.06% < C < 0.6% Skin Irrit. 2; H315: 0.06% < C < 0.6% Skin Sens. 1A; H317 (SCL = 0.0015%) Aquatic Acute 1; H400 (M = 100) Aquatic Chronic 1; H410 (M = 100)
(= CMI/MI)					
2-methyl-2H-isothiazol-3-one	220-239-6	2682-20-4	-	0.0126	Acute Tox. 3; H301 (ATE = 100mg/kg) Acute Tox. 2; H310 (ATE = 50mg/kg) Eye Dam. 1; H318 Skin Corr. 1C; H314 Skin Sens. 1A; H317 (SCL = 0.0015%) Aquatic Acute 1; H400 (M = 10) Aquatic Chronic 1; H410
Calibrator A-E, Reference Control, Positive Control, Negative Control and Dilution Buffer.					
Sodium azide	247-852-1	26628-22-8	-	0.09	Acute Tox. 2; H300 (ATE = 5mg/kg) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032
Stop Solution					
Sulphuric acid %	231-639-5	7664-93-9	-	2.5-2.66	Skin Corr. 1A; H314 SCL: Eye Irrit. 2; H319: 5% ≤ C < 15% Skin Corr. 1A; H314: C ≥ 15% Skin Irrit. 2; H315: 5% ≤ C < 15%

Remark: Sodium azide has an EC limit value. Occupational exposure limits are mentioned under section 8. Wash Buffer Solution and the antigen coated plate contain no dangerous substances. See section 16 for the full text of the classifications declared above.

SECTION 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. Call a physician if irritation persists.
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:	Exposure to the skin may cause an allergic skin reaction.
Eye contact:	May cause mild eye irritation.
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.

SECTION 5. FIREFIGHTING MEASURES

5.1 Extinguishing media

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

5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

Special protective actions for fire-fighters	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.
Special protective equipment for fire-fighters	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.
Further information	Not applicable

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	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.
For emergency responders	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

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

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

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

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.

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

Occupational exposure limits

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

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

Wear chemical-resistant, impervious gloves in butyl rubber or nitril rubber complying with an approved standard (EN374).

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
Physical state	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid
Colour	Blue	Colourless	Colourless	Red	Blue	Blue	Blue	Blue
Odour	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless
Melting point/freezing point	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d
Boiling point or initial boiling point	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d
Flammability (solid, gas)	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Lower and upper explosion limit	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Flash point	> 100°C	> 100°C	> 100°C	> 100°C	> 100°C	> 100°C	> 100°C	> 100°C
Auto-ignition temperature	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d
Decomposition temperature	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d
pH	7,3-7,5	7,3-7,5	< 1	n.d.	7,3-7,5	7,3-7,5	7,3-7,5	7,3-7,5
Kinematic viscosity	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d
Solubility	Soluble in water	Soluble in water	Soluble in water	Soluble in water	Soluble in water	Soluble in water	Soluble in water	Soluble in water
Partition coefficient n-octanol/water (log value)	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Vapour pressure	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d
Density and/or relative density	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d
Relative vapour density	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Particle characteristics	n.a	n.a	n.a	n.a	n.a	n.a	n.a	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 hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Based on available data, the classification criteria are not met.

Calculated data:

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

Irritation/Corrosion

Based on available data, the classification criteria are not met.

Experimental/calculated data: Corrosive or irritating to the skin, rabbit: Not irritating.

Serious eye damage/irritation

Based on available data, the classification criteria are not met.

Experimental/calculated data: Serious eye damage/eye irritation, rabbit: Not irritating

Respiratory or skin sensitization

Skin Sens. 1;H317 May cause an allergic skin reaction.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Carcinogenicity

Based on available data, the classification criteria are not met.

Reproductive toxicity

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

11.2. Information on other hazards

None known.

SECTION 12. ECOLOGICAL INFORMATION

12.1 Toxicity

12.1.1 Acute toxicity in the aquatic environment

For CMI/MI

Test	Value/unit (mg/l)	Test method	Exp. time (h)	Species
Fish LC ₅₀	0.19	--	96	Salmo gairdneri
Daphnia EC ₅₀	0.028	--	48	Crassostrea virg.
Algae EC ₅₀	0.018	--	96	Selenastrum cap.

For sodium azide

Test	Value/unit (mg/l)	Test method	Exp. time (h)	Species
Fish LC ₅₀	0.8-1.6	--	96	Rainbow trout
Daphnia EC ₅₀	4.2	--	48	Daphnia pulex

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 ₅₀	> 100	--	96	--
Daphnia EC ₅₀	> 100	--	48	Daphnia magna
Algae IC ₅₀	> 100	--	72	Green algae

12.1.3 Ecotoxicity

All reagents in the kit are classified as not harmful to aquatic organisms.

12.2 Persistence and degradability

Conclusion/Summary The reagents are classified as readily biodegradable.

12.3 Bioaccumulative potential

Conclusion/Summary The reagents are not 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 Endocrine disrupting properties

Conclusion None known.

12.7. Other adverse effects

Conclusion None known.

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)

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.

SECTION 14. TRANSPORT INFORMATION

Product classified as dangerous goods: Yes No Not decided

	ADR/RID	ADN/ADNR	IMDG	IATA
14.1 UN number or ID number	Not regulated	Not regulated	Not regulated	Not regulated
14.2 UN proper shipping name	--	--	--	--
14.3 Transport hazard class(es)	--	--	--	--
14.4 Packing Group	--	--	--	--
14.5 Environmental hazards	--	--	--	--
14.6 Special precautions for user	Not available	Not available	Not available	Not available
14.7 Maritime transport in bulk according to IMO instruments	Not applicable	Not applicable	Not applicable	Not applicable
Additional information	Used kit is dangerous goods by transportation in class 6.2, UN 3291. Contact the manufacturer for further information.			

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

Tariff Code – Not applicable

harmonized system

The EU Seveso Not applicable

Directive

International regulations

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

No.	H-Statements
H300	Fatal if swallowed.
H310	Fatal if in contact with skin.
H301	Toxic if swallowed.
H311	Toxic if in contact with skin.
H331	Toxic if inhaled.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious 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.

DOCUMENT HISTORY

Version	Valid from (date)	Changes
3.0	2021-06-16	Format updates according to Regulation 2020/878.
4.0	{{2023-05-11}}	DEV-00594 Missing symbols in SDS, correction of content of Conjugate solution throughout the document. Clarification of section 1.1 Included information related to 2000/54/EC – Biological agents at work, biohazard symbol.