

# SAFETY DATA SHEET IMMUNOSCAN CCPlus®

## SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/ UNDERTAKING

## 1.1 Product identifier

Product name: Product description Immunoscan CCPlus®

Kit consisting of the following components:

- 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

CompanySvar Life Science ABAddressLundvägen 151

**Zip code/Place** SE-212 24 Malmö, Sweden

**Telephone** +46 40 53 76 00

Website www.svarlifescience.com 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** 

distributed in the US/Canada by: EAGLE BIOSCIENCES, INC.

20A NW Blvd, Suite 112 Nashua, NH 03063 Phone: 617-419-2019 FAX: 617-419-1110 www.EagleBio.com info@eaglebio.com



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 None

not result in classification

Substance meets the PBT: No criteria for PBT / vPvB vPvB: No

under Regulation EC No. 1907/2006, appendix XIII

**Endocrine disrupting** 

properties accordance with the criteria set out in Regulation 2017/2100 or Regulation 2018/605.

The substances are not identified as having endocrine disrupting properties in

## **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

231-639-5

7664-93-9

## 3.1 Substances

Not applicable.

**Stop Solution** 

Sulphuric acid %

3.2 Mixtures Solutions containing the foll Product / ingredient name	lowing declara	able substan	ces: REACH	Conc.	Classification
rioduct/ingredient name	Lo-number	number	registration number	(weight-%)	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)  (= CMI/MI)	247-500-7 and 220-239-6	55965-84-9	-	0.0024	Acute Tox. 3; H301 ATE = $100 \text{mg/kg}$ Acute Tox. 2; H310 ATE = $50 \text{mg/kg}$ Acute Tox. 3; H331 (ATE = $0.05 \text{mg/l/4H}$ ) Eye Dam. 1; H318 Skin Corr. 1C; H314 SCL: Skin Corr. 1C; H314: $C \ge 0.6\%$ Eye Dam. 1; H318: $C \ge 0.6\%$ 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 = $100$ )
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 C	ontrol, Positiv	e Control, Ne	gative Control	and Dilution I	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

Skin Corr. 1A; H314

Eye Irrit. 2; H319: 5% ≤ C < 15% Skin Corr. 1A; H314: C ≥ 15% Skin Irrit. 2; H315: 5% ≤ C < 15%

SCL:

2.5-2.66



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.

**Eve 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** Dry chemical, foam, water spray or carbon dioxide.

media

**Unsuitable** Waterjet

extinguishing media

5.2 Special hazards arising from the substance or mixture

Hazards from the None

substance or mixture

Hazardous thermal Decomposition products may include the following materials: carbon monoxide, carbon

**decomposition** dioxide and nitrous gases.

products

5.3 Advice for firefighters

**Special protective** Promptly isolate the scene by removing all persons from the vicinity of the incident if

actions 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 breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for

fighters 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



For emergency

#### **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

surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Put on appropriate personal protective equipment.

If specialized clothing is required to deal with the spillage, take note of any information in

responders Section 8 on suitable and unsuitable materials. See also Section 8 for additional

Section of the suitable and unsuitable materials. See also Section of the addition

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** Eating, drinking and smoking should be prohibited in areas where this material is **occupational hygiene** 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	France	Spain	Germany
		Kingdom			
Sodium azide	TWA 0.1 mg/m <sup>3</sup>	STEL: 0.3 mg/m <sup>3</sup>	VME: 0.1 mg/m <sup>3</sup>	VLA-EC: 0.3 mg/m <sup>3</sup>	MAK: 0.2 mg/m <sup>3</sup>
(CAS No. 26628-22-8)	STEL 0.3 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup>	VLCT: 0.3 mg/m <sup>3</sup>	VLA-ED: 0.1 mg/m <sup>3</sup>	Ceiling/Peak: 0.4 mg/m <sup>3</sup>
		Skin		Skin	TWA: 0.2 mg/m <sup>3</sup>
Chemical name	Italy	Portugal	Netherlands	Finland	Denmark
Sodium azide	TWA: 0.1 mg/m <sup>3</sup>	Ceiling: 0.29 mg/m <sup>3</sup>	STEL: 0.3 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup>
(CAS No.26628-22-8)	STEL: 0.3 mg/m <sup>3</sup>	Ceiling: 0.11 ppm	TWA: 0.1 mg/m <sup>3</sup>	STEL: 0.3 mg/m <sup>3</sup>	STEL: 0.2 mg/m <sup>3</sup>
(6/16/10:20020/22/0)	Skin		Skin	Skin	Skin
Chemical name	Austria	Switzerland	Poland	Norway	Ireland
Sodium azide	STEL: 0.3 mg/m <sup>3</sup>	STEL: 0.4 mg/m <sup>3</sup>	NDSCh: 0.3 mg/m <sup>3</sup>	Ceiling: 0.3 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup>
(CAS No. 26628-22-8)	MAK: 0.1 mg/m <sup>3</sup> Skin	MAK: 0.2 mg/m <sup>3</sup>	NDS: 0.1 mg/m <sup>3</sup>	Skin	STEL: 0.3 mg/m <sup>3</sup>
(3/13/143. 20020-22-0)			Skin		Skin

Occupational exposure limits

Chemical name	EU	United Kingdom	France	Spain	Germany
Sulphuric acid (CAS No. 7664-93-9)	0,05 mg/m³ thoracic fraction	0,05 mg/m³ thoracic fraction	0,05 mg/m³ thoracic fraction	0,05 mg/m <sup>3</sup>	STEL: 0.1 mg/m³ MAK: 0.1 mg/m³ 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 0.05 mg/m³ STEL 0.1 mg/m³ thoracic fraction	TWA 0.05 mg/m <sup>3</sup> STEL 0.1 mg/m <sup>3</sup>
Chemical name	Austria	Switzerland	Poland	Norway	Ireland
Sulphuric acid (CAS No. 7664-93-9)	MAK: 0.1 mg/m³ STEL: 0.2 mg/m³ Inhalable aerosols	STEL: 0.2 mg/m³ MAK: 0.1 mg/m³ Inhalable aerosols	NDSCh: 1 mg/m <sup>3</sup> NDS: 3 mg/m <sup>3</sup>	-	0,05 mg/m <sup>3</sup>

Recommended monitoring procedure

Not relevant

**Derived effect levels** 

Product/ingredient Type Exposure Value Population Effects name

Predicted effect concentrations

Not available

PNEC Summary Not available

8.2 Exposure controls
Appropriate engineering

Appropriate engineerii

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							
	Α	В	С	D	E	F	G	Н
Physical state	Liquid							
Colour	Blue	Colourless	Colourless	Red	Blue	Blue	Blue	Blue
Odour	Odourless							
Melting point/freezing point	n.d							
Boiling point or initial	n.d							
boiling point								
Flammability (solid, gas)	n.a							
Lower and upper explosion	n.a							
limit								
Flash point	> 100°C							
Auto-ignition temperature	n.d							
Decomposition	n.d							
temperature								
pН	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							
Solubility	Soluble in water							
Partition coefficient	n.a							
n-octanol/water (log value)								
Vapour pressure	n.d							
Density and/or relative	n.d							
density								
Relative vapour density	n.a							
Particle characteristics	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** Stabile 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

None

materials

products

10.6 Hazardous decomposition

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:

 $LD_{50}$  oral, rat: > 2000 mg/kg  $LD_{50}$  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 <sub>50</sub>	0.19		96	Salmo gairdneri
Daphnia EC <sub>50</sub>	0.028		48	Crassostrea virg.
Algae EC <sub>50</sub>	0.018		96	Selenastrum cap.

## 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

## 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 EC50	> 100		48	Daphnia magna
Algae IC50	> 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

Not available Soil/water partition

coefficient (KOC)

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	<b>X</b> No	☐ Not decided	
14.1 UN number or ID number	ADR/RID Not regulated	ADN/ADNR Not regulated	IMDG Not regulated	IATA 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 Sched

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

	IAZARD STATEMENTS MENTIONED UNDER SECTION 5
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.