

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**1.1. Product identifier**

Product Description: ImmunoCAP Total IgE Anti-IgE
Cat No. : 14-4509-22

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

Recommended Use In vitro diagnostic
Uses advised against All other uses

1.3. Details of the supplier of the safety data sheet

Company Phadia AB
Rapsgatan 7P
P.O. Box 6460
751 37 UPPSALA
Sweden
+46 18 16 50 00
E-mail address safetydatasheet.idd@thermofisher.com

1.4. Emergency telephone number

CHEMTREC Ireland (Dublin) +(353)-19014670
CHEMTREC Belgium (Brussels) +(32)-28083237
Malta 112 Emergency phone number

SECTION 2: HAZARDS IDENTIFICATION**2.1. Classification of the substance or mixture****CLP Classification - Regulation (EC) No 1272/2008****Physical hazards**

Based on available data, the classification criteria are not met

Health hazards

Based on available data, the classification criteria are not met

Environmental hazards

Based on available data, the classification criteria are not met

For the full text of the H-statements mentioned in this Section, see Section 16.

2.2. Label elements

SAFETY DATA SHEET

ImmunoCAP Total IgE Anti-IgE

Revision Date 28-Dec-2023

EUH208 - 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); (CMIT/MIT (3:1))). May produce an allergic reaction.

2.3. Other hazards

May produce an allergic reaction This product does not contain any known or suspected endocrine disruptors.
This preparation contains no substance considered to be persistent, bioaccumulating nor toxic (PBT). This preparation contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

3.2. Mixtures

Component	CAS No	EC No	Weight %	CLP Classification - Regulation (EC) No 1272/2008
5-Chloro-2-methyl-3(2H)-isothiazol one, mixture with 2-methyl-3(2H)-isothiazolone	55965-84-9		<0.0015	Acute Tox. 3 (H301) Acute Tox. 2 (H310) Acute Tox. 2 (H330) Skin Corr. 1C (H314) Eye Dam. 1 (H318) Skin Sens. 1A (H317) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) EUH071

Component	Specific concentration limits (SCL's)	M-Factor	Component notes
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	Eye Irrit. 2 (H319) :: 0.06%≤C<0.6% Skin Corr. 1C (H314) :: C≥0.6% Skin Irrit. 2 (H315) :: 0.06%≤C<0.6% Skin Sens. 1A (H317) :: C≥0.0015% Eye Dam. 1 (H318) :: C≥0.6%	100 (acute) 100 (chronic)	-

For the full text of the H-statements mentioned in this Section, see Section 16.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Eye Contact	Rinse thoroughly with plenty of water, also under the eyelids.
Skin Contact	Wash off immediately with soap and plenty of water.
Ingestion	Clean mouth with water and drink afterwards plenty of water.

SAFETY DATA SHEET

ImmunoCAP Total IgE Anti-IgE

Revision Date 28-Dec-2023

Inhalation Not applicable.

Self-Protection of the First Aider Not Applicable.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

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

Notes to Physician Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Extinguishing media which must not be used for safety reasons

None known.

5.2. Special hazards arising from the substance or mixture

None known.

Hazardous Combustion Products

None known.

5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Wear protective gloves/clothing and eye/face protection.

6.2. Environmental precautions

Dispose of in accordance with local regulations.

6.3. Methods and material for containment and cleaning up

Wipe up with adsorbent material (e.g. cloth, fleece). Dispose of waste product or used containers according to local regulations.

6.4. Reference to other sections

Refer to protective measures listed in Sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

SAFETY DATA SHEET

ImmunoCAP Total IgE Anti-IgE

Revision Date 28-Dec-2023

Wash thoroughly after handling. Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Keep at temperatures between 2 and 8°C.

7.3. Specific end use(s)

Observe instructions for use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure limits

List source(s): **CH** - The Government of Switzerland has set a directive on limit values for working materials (Grenzwerte am Arbeitsplatz) which is based on the Swiss Federal Regulation "Verordnung über die Verhütung von Unfällen und Berufskrankheiten". This directive is administered, periodically revised and enforced by SUVA (Swiss National Accident Insurance Fund).

Component	Austria	Denmark	Switzerland	Poland	Norway
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	MAK-TMW: 0.05 mg/m ³ 8 Stunden		STEL: 0.4 mg/m ³ 15 Minuten TWA: 0.2 mg/m ³ 8 Stunden		

Biological limit values

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Monitoring methods

BS EN 14042:2003 Title Identifier: Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents.

Derived Minimum Effect Level (DMEL) / Derived No Effect Level (DNEL)

See table for values

Component	Acute effects local (Inhalation)	Acute effects systemic (Inhalation)	Chronic effects local (Inhalation)	Chronic effects systemic (Inhalation)
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9 (<0.0015)	DNEL = 0.04mg/m ³		DNEL = 0.02mg/m ³	

Predicted No Effect Concentration (PNEC)

See values below.

Component	Fresh water	Fresh water	Water Intermittent	Microorganisms in	Soil (Agriculture)
-----------	-------------	-------------	--------------------	-------------------	--------------------

SAFETY DATA SHEET

ImmunoCAP Total IgE Anti-IgE

Revision Date 28-Dec-2023

		sediment		sewage treatment	
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9 (<0.0015)	PNEC = 3.39µg/L	PNEC = 0.027mg/kg sediment dw	PNEC = 3.39µg/L	PNEC = 0.23mg/L	PNEC = 0.01mg/kg soil dw

Component	Marine water	Marine water sediment	Marine water Intermittent	Food chain	Air
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9 (<0.0015)	PNEC = 3.39µg/L	PNEC = 0.027mg/kg sediment dw	PNEC = 3.39µg/L		

8.2. Exposure controls

Engineering Measures

None under normal use conditions.

Personal protective equipment

Eye Protection

No special protective equipment required.

Hand Protection

No special protective equipment required.

Glove material	Breakthrough time	Glove thickness	EU standard	Glove comments
		-		

Skin and body protection

No special protective equipment required.

Respiratory Protection

No protective equipment is needed under normal use conditions.

Large scale/emergency use

No protective equipment is needed under normal use conditions

Small scale/Laboratory use

No personal respiratory protective equipment normally required.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls

Dispose of contents/containers in accordance with local regulations.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical State	Liquid
Appearance	Transparent
Odor	None
Odor Threshold	None
Melting Point/Range	No data available
Softening Point	No data available
Boiling Point/Range	No data available
Flammability (liquid)	No data available
Flammability (solid,gas)	No information available
Explosion Limits	No data available

SAFETY DATA SHEET

ImmunoCAP Total IgE Anti-IgE

Revision Date 28-Dec-2023

Flash Point	No data available	Method - No information available
Autoignition Temperature	No data available	
Decomposition Temperature	No data available	
pH	7.2-7.6	
Viscosity	No data available	
Water Solubility	Soluble in water	
Solubility in other solvents	No information available	
Partition Coefficient (n-octanol/water)		
Component	log Pow	
5-Chloro-2-methyl-3(2H)-isothiazolone, <0.401 mixture with 2-methyl-3(2H)-isothiazolone		
Vapor Pressure	No data available	
Density / Specific Gravity	1.1 g/cm ³	
Bulk Density	No data available	
Vapor Density	No data available	(Air = 1.0)
Particle characteristics	Not applicable (liquid)	

9.2. Other information

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

None known.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous Polymerization	Hazardous polymerization does not occur.
Hazardous Reactions	None under normal processing.

10.4. Conditions to avoid

None known.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Product Information Product does not present an acute toxicity hazard based on known or supplied information.

(a) acute toxicity;

Oral	No data available.
Dermal	No data available.
Inhalation	No data available.

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	LD50 = 53 mg/kg (Rat)	LD50 = 87.12 mg/kg (Rabbit)	4h 0.33 mg/l (Rat)

SAFETY DATA SHEET

ImmunoCAP Total IgE Anti-IgE

Revision Date 28-Dec-2023

(b) skin corrosion/irritation; No data available.

(c) serious eye damage/irritation; No data available.

(d) respiratory or skin sensitization;

Respiratory

No data available.

Skin

No data available.

(e) germ cell mutagenicity; No data available.

Component	Test method	Test species	Study result
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	in vivo in vitro		negative

(f) carcinogenicity; There are no known carcinogenic chemicals in this product.

Component	Test method	Test species / Duration	Study result
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone			negative

(g) reproductive toxicity; No data available.

Component	Test method	Test species / Duration	Study result
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone			negative Animal testing did not show any effects on fetal development

(h) STOT-single exposure; No data available.

(i) STOT-repeated exposure; No data available.

(j) aspiration hazard; No data available.

Symptoms / effects, both acute and delayed No information available.

11.2. Information on other hazards

Endocrine Disrupting Properties This product does not contain any known or suspected endocrine disruptors.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity effects

Component	Freshwater Fish	Water Flea	Freshwater Algae	Microtox
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	Acute toxicity: LC50 96 h 0.19mg/l (Oncorhynchus mykiss) EPA OPP 72-1 Chronic toxicity: NOEC 35 days 0.02 mg/l (Pimephales promelas) OECD 210	Acute toxicity: EC50 48 h 0.126 mg/l (Daphnia magna) OECD Test 202 Chronic toxicity: NOEC 21 days 0.10 mg/l (Daphnia magna)	Acute toxicity: ERC50 72 h 0.027 mg/l (Selenastrum capricornutum) Chronic toxicity: NOEC 96h 0.004 mg/l, (Skeletonea costatum) OECD 201	Chronic toxicity: NOEC 3h 0.91 mg/l (Activated sludge) OECD 209

SAFETY DATA SHEET

ImmunoCAP Total IgE Anti-IgE

Revision Date 28-Dec-2023

12.2. Persistence and degradability Product is biodegradable.

Component	Degradability
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	Biodegradable <50 % 10 days Atmospheric half-life: 0.38-1.3 Days

12.3. Bioaccumulative potential Bioaccumulation is unlikely.

Component	log Pow	Bioconcentration factor (BCF)
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	<0.401	<54

12.4. Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment This preparation contains no substance considered to be persistent, bioaccumulating nor toxic (PBT). This preparation contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

12.6. Endocrine disrupting properties

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors

12.7. Other adverse effects

Persistent Organic Pollutant No known effect.
Ozone Depletion Potential No known effect.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from Residues/Unused Products Dispose of in accordance with local regulations.

Contaminated Packaging Dispose of in accordance with local regulations.

European Waste Catalogue (EWC) 18 01 07 Chemicals other than those mentioned in 18 01 06.
Other Information No information available.

SECTION 14: TRANSPORT INFORMATION

IMDG/IMO Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

ADR Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

IATA Not regulated

SAFETY DATA SHEET

ImmunoCAP Total IgE Anti-IgE

Revision Date 28-Dec-2023

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

14.5. Environmental hazards

No hazards identified.

14.6. Special precautions for user

No special precautions required.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable, packaged goods.

SECTION 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

International Inventories

X = listed

Component	EINECS	ELINCS	NLP	TSCA	DSL	NDSL	PICCS	ENCS	IECSC	AICS	KECL
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	-	-		-	X	-	X	X	X	-	KE-05738

Component	REACH (1907/2006) - Annex XIV - Substances Subject to Authorization	REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous Substances	REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC)
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone		Use restricted. See item 75. (see link for restriction details)	

Component	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	H1: 5-100 ton, E1: 20-200 ton	H1: 5-100 ton, E1: 20-200 ton

Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals

Not applicable

National Regulations

Component	Germany - Water Classification (AwSV)	Germany - TA-Luft Class
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	WGK3	

UK - Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment.

15.2. Chemical safety assessment

A Chemical Safety Assessment/Report (CSA/CSR) is not required.

SECTION 16: OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3

H301 - Toxic if swallowed

H310 - Fatal in contact with skin

H314 - Causes severe skin burns and eye damage

SAFETY DATA SHEET

ImmunoCAP Total IgE Anti-IgE

Revision Date 28-Dec-2023

H317 - May cause an allergic skin reaction
H318 - Causes serious eye damage
H330 - Fatal if inhaled
H400 - Very toxic to aquatic life
H410 - Very toxic to aquatic life with long lasting effects
EUH071 - Corrosive to the respiratory tract
EUH208 - May produce an allergic reaction

Legend

CAS - Chemical Abstracts Service

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

IECSC - Chinese Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

ENCS - Japanese Existing and New Chemical Substances

AICS - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

WEL - Workplace Exposure Limit

ACGIH - American Conference of Governmental Industrial Hygienists

DNEL - Derived No Effect Level

RPE - Respiratory Protective Equipment

LC50 - Lethal Concentration 50%

NOEC - No Observed Effect Concentration

PBT - Persistent, Bioaccumulative, Toxic

TWA - Time Weighted Average

IARC - International Agency for Research on Cancer
Predicted No Effect Concentration (PNEC)

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50%

POW - Partition coefficient Octanol:Water

vPvB - very Persistent, very Bioaccumulative

ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road

IMO/MDG - International Maritime Organization/International Maritime Dangerous Goods Code

OECD - Organisation for Economic Co-operation and Development

BCF - Bioconcentration factor

Key literature references and sources for data

<https://echa.europa.eu/information-on-chemicals>

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

ICAO/IATA - International Civil Aviation Organization/International Air Transport Association

MARPOL - International Convention for the Prevention of Pollution from Ships

ATE - Acute Toxicity Estimate

VOC (volatile organic compound)

Physical hazards

On basis of test data

Health Hazards

Calculation method

Environmental hazards

Calculation method

Training Advice

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Revision Date

28-Dec-2023

Revision Summary

SDS sections updated, 7.

**This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006
COMMISSION REGULATION (EU) 2020/878 amending Annex II to Regulation (EC) No
1907/2006**

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of Safety Data Sheet