

Revision Date 28-Dec-2023 Revision Number 25

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

1.1. Product identifier

Product Description: ImmunoCAP Specific IgE Anti-IgE

**Cat No.**: 14-4417-08

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

#### GHS Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567

#### 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

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 %	GHS Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567
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))	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	M-Factor	Component notes
	(SCL's)		
Reaction mass of: 5-chloro-2-	Eye Irrit. 2 (H319) ::	100 (acute)	-
methyl-4-isothiazolin-3-one [EC no.	0.06%<=C<0.6%	100 (chronic)	
247-500-7]and 2-methyl-2H -isothiazol-3-	Skin Corr. 1C (H314) :: C>=0.6%		
one [EC no. 220-239-6] (3:1); (CMIT/MIT	Skin Irrit. 2 (H315) ::		
(3:1))	0.06%<=C<0.6%		
	Skin Sens. 1A (H317) ::		
	C>=0.0015%		
	Eye Dam. 1 (H318) :: C>=0.6%		

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.

ImmunoCAP Specific IgE Anti-IgE Revision Date 28-Dec-2023

Ingestion Clean mouth with water and drink afterwards plenty of water.

**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**

## ImmunoCAP Specific IgE Anti-IgE

Revision Date 28-Dec-2023

#### 7.1. Precautions for safe handling

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):

Component	Austria	Denmark	Switzerland	Poland	Norway
Reaction mass of:	MAK-TMW: 0.05 mg/m <sup>3</sup>		STEL: 0.4 mg/m <sup>3</sup> 15		
5-chloro-2-	8 Stunden		Minuten		
methyl-4-isothiazolin-			TWA: 0.2 mg/m <sup>3</sup> 8		
3-one [EC no.			Stunden		
247-500-7]and					
2-methyl-2H					
-isothiazol-3- one					
[EC no. 220-239-6]					
(3:1); (CMIT/MIT					
(3:1))					

## **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	Acute effects	Chronic effects local	Chronic effects
	(Inhalation)	systemic (Inhalation)	(Inhalation)	systemic (Inhalation)
Reaction mass of: 5-chloro-2-	DNEL = $0.04$ mg/m <sup>3</sup>		DNEL = $0.02$ mg/m <sup>3</sup>	
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				

#### ImmunoCAP Specific IgE Anti-IgE

(3:1))		
55965-84-9 ( <0.0015 )		

#### **Predicted No Effect Concentration (PNEC)**

See values below.

Component	Fresh water	Fresh water	Water Intermittent	Microorganisms in	Soil (Agriculture)
		sediment		sewage treatment	
Reaction mass of:	PNEC = 3.39µg/L	PNEC =	PNEC = $3.39\mu g/L$	PNEC = 0.23mg/L	PNEC = 0.01 mg/kg
5-chloro-2-		0.027mg/kg			soil dw
methyl-4-isothiazolin-3-one		sediment dw			
[EC no. 247-500-7]and					
2-methyl-2H -isothiazol-3-					
one [EC no. 220-239-6]					
(3:1); (CMIT/MIT (3:1))					
55965-84-9 ( <0.0015 )					

Component	Marine water	Marine water sediment	Marine water intermittent	Food chain	Air
Reaction mass of:	$PNEC = 3.39 \mu g/L$	PNEC =	PNEC = 3.39µg/L		
5-chloro-2-		0.027mg/kg			
methyl-4-isothiazolin-3-one		sediment dw			
[EC no. 247-500-7]and					
2-methyl-2H -isothiazol-3-					
one [EC no. 220-239-6]					
(3:1); (CMIT/MIT (3:1))					
55965-84-9 ( < 0.0015 )					

#### 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

No personal respiratory protective equipment normally required. Small scale/Laboratory use

**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**

Revision Date 28-Dec-2023

ImmunoCAP Specific IgE Anti-IgE

Revision Date 28-Dec-2023

## 9.1. Information on basic physical and chemical properties

**Physical State** Liquid

Transparent **Appearance** 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 No information available Flammability (solid,gas) No data available **Explosion Limits** 

**Flash Point** No data available Method - No information available

**Autoignition Temperature** No data available No data available **Decomposition Temperature** 

7.2-7.6 Hq

No data available **Viscosity** Water Solubility Soluble in water Solubility in other solvents No information available

Partition Coefficient (n-octanol/water)

log Pow Component Reaction mass of: 5-chloro-2-< 0.401

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))

No data available **Vapor Pressure** Density / Specific Gravity 1.1 g/cm3 **Bulk Density** No data available No data available **Vapor Density** 

Not applicable (liquid)

**Particle characteristics** 

## 9.2. Other information

## **SECTION 10: STABILITY AND REACTIVITY**

(Air = 1.0)

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.

Revision Date 28-Dec-2023

## **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
Reaction mass of: 5-chloro-2-	LD50 = 53 mg/kg (Rat)	LD50 = 87.12 mg/kg (Rabbit)	4h 0.33 mg/l ( Rat )
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))			

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

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

(d) respiratory or skin sensitization;

**Respiratory**Skin
No data available.
No data available.

(e) germ cell mutagenicity; No data available.

Component	Test method	Test species	Study result
Reaction mass of: 5-chloro-2-	in vivo		negative
methyl-4-isothiazolin-3-one [EC no.	in vitro		_
247-500-7]and 2-methyl-2H -isothiazol-3-			
one [EC no. 220-239-6] (3:1); (CMIT/MIT			
(3:1))			

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

Component	Test method	Test species / Duration	Study result
Reaction mass of: 5-chloro-2-			negative
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))			

(g) reproductive toxicity; No data available.

L	Component	Test method	Test species / Duration	Study result
Ī	Reaction mass of: 5-chloro-2-			negative
-	methyl-4-isothiazolin-3-one [EC no.			Animal testing did not show any
-	247-500-7]and 2-methyl-2H -isothiazol-3-			effects on fetal development
-	one [EC no. 220-239-6] (3:1); (CMIT/MIT			-
L	(3:1))			

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

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

(j) aspiration hazard; No data available.

ImmunoCAP Specific IgE Anti-IgE

Revision Date 28-Dec-2023

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
Reaction mass of: 5-chloro-2-	Acute toxicity:	Acute toxicity:	Acute toxicity:	Chronic toxicity:
methyl-4-isothiazolin-3-one [EC no.	LC50 96 h 0.19mg/l	EC50 48 h 0.126 mg/l	ERC50 72 h 0.027 mg/l	NOEC 3h 0.91 mg/l
247-500-7]and 2-methyl-2H -isothiazol-3-	(Oncorhynchus mykiss)	(Daphnia magna)	(Selenastrum	(Activated sludge)
one [EC no. 220-239-6] (3:1); (CMIT/MIT	EPA OPP 72-1	OECD Test 202	capricornutum)	OECD 209
(3:1))				
	Chronic toxicity:	Chronic toxicity:	Chronic toxicity:	
	NOEC 35 days 0.02	NOEC 21 days	NOEC 96h 0.004 mg/l,	
	mg/l (Pimephales	0.10 mg/l	(Skeletonema costatum)	
	promelas) OECD 210	(Daphnia magna)	OECD 201	

## 12.2. Persistence and degradability Product is biodegradable.

Component	Degradability
Reaction mass of: 5-chloro-2-	Biodegradable <50 % 10 days
methyl-4-isothiazolin-3-one [EC no.	Atmospheric half-life: 0.38-1.3 Days
247-500-7]and 2-methyl-2H -isothiazol-3-	
one [EC no. 220-239-6] (3:1); (CMIT/MIT	
(3:1))	

#### **12.3. Bioaccumulative potential** Bioaccumulation is unlikely.

Component	log Pow	Bioconcentration factor (BCF)
Reaction mass of: 5-chloro-2-	<0.401	<54
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))		

12.4. Mobility in soil No information available.

12.5. Results of PBT and vPvB

<u>assessment</u>

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**

ImmunoCAP Specific IgE Anti-IgE Revision Date 28-Dec-2023

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)** 

Other Information

18 01 07 Chemicals other than those mentioned in 18 01 06.

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

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

No hazards identified. 14.5. Environmental hazards

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
Reaction mass of: 5-chloro-2-	-	-		-	Х	-	Х	Х	Х	-	KE-0573
methyl-4-isothiazolin-3-one											8
[EC no. 247-500-7]and											
2-methyl-2H -isothiazol-3- one											
[EC no. 220-239-6] (3:1);											
(CMIT/MIT (3:1))											

Component	. , ,	REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous Substances	• • • • • • • • • • • • • • • • • • • •
Reaction mass of: 5-chloro-2- methyl-4-isothiazolin-3-one [EC no. 247-500-7]and 2-methyl-2H		Use restricted. See item 75. (see link for restriction details)	

#### ImmunoCAP Specific IgE Anti-IgE

-isothiazol-3- one [EC no.		
220-239-6] (3:1); (CMIT/MIT		
(3.1))		

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
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))	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
Reaction mass of: 5-chloro-2-	WGK3	
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))		

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

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

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

EINECS/ELINCS - European Inventory of Existing Commercial Chemical DSL/NDSL - Canadian Domestic Substances List/Non-Domestic 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

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%

TWA - Time Weighted Average

IARC - International Agency for Research on Cancer

Predicted No Effect Concentration (PNEC)

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50%

Revision Date 28-Dec-2023

#### ImmunoCAP Specific IgE Anti-IgE

NOEC - No Observed Effect Concentration POW - Partition coefficient Octanol:Water

**NOEC** - No Observed Effect Concentration **POW** - Partition coefficient Octanol:Water **PBT** - Persistent, Bioaccumulative, Toxic **POW** - Partition coefficient Octanol:Water **vPvB** - very Persistent, very Bioaccumulative

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

**IMO/IMDG** - International Maritime Organization/International Maritime Dangerous Goods Code

**OECD** - Organisation for Economic Co-operation and Development

**BCF** - Bioconcentration factor

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

Revision Date 28-Dec-2023

 $\mbox{\bf MARPOL}$  - International Convention for the Prevention of Pollution from Ships

ATE - Acute Toxicity Estimate
VOC (volatile organic compound)

## Key literature references and sources for data

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

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

Physical hazards
Health Hazards
Calculation method
Environmental hazards
Cn basis of test data
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 Regulation UK SI 2019/758 and UK SI 2020/1577 as amended

#### **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**