

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

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

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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	M-Factor	Component notes
	(SCL's)		
5-Chloro-2-methyl-3(2H)-isothiazolone,	Eye Irrit. 2 (H319) ::	100 (acute)	=
mixture with 2-methyl-3(2H)-isothiazolone	0.06%<=C<0.6%	100 (chronic)	
	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%		

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.

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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

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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(MAK-TMW: 0.05 mg/m ³		STEL: 0.4 mg/m ³ 15		
2H)-isothiazolone,	8 Stunden		Minuten		
mixture with			TWA: 0.2 mg/m ³ 8		
2-methyl-3(2H)-isothi			Stunden		
azolone					

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)
5-Chloro-2-methyl-3(2H)-isothia zolone, 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)

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		sediment		sewage treatment	
5-Chloro-2-methyl-3(2H)-is	$PNEC = 3.39 \mu g/L$	PNEC =	PNEC = $3.39\mu g/L$	PNEC = 0.23mg/L	PNEC = 0.01 mg/kg
othiazolone, mixture with 2-methyl-3(2H)-isothiazolo		0.027mg/kg sediment dw			soil dw
ne					
55965-84-9 (<0.0015)					

Component	Marine water	Marine water sediment	Marine water Intermittent	Food chain	Air
5-Chloro-2-methyl-3(2H)-is othiazolone, mixture with 2-methyl-3(2H)-isothiazolo	. •	PNEC = 0.027mg/kg sediment dw	PNEC = 3.39µg/L		
ne 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

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/RangeNo data availableSoftening PointNo data availableBoiling Point/RangeNo data availableFlammability (liquid)No data availableFlammability (solid,gas)No information availableExplosion LimitsNo data available

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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

Water Solubility

Soluble in water

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 PressureNo data availableDensity / Specific Gravity1.1 g/cm3Bulk DensityNo 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,	LD50 = 53 mg/kg (Rat)	LD50 = 87.12 mg/kg (Rabbit)	4h 0.33 mg/l (Rat)
mixture with 2-methyl-3(2H)-isothiazolone			

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

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

(d) respiratory or skin sensitization;

RespiratorySkin
No data available.
No data available.

(e) germ cell mutagenicity; No data available.

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

(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,			negative
mixture with 2-methyl-3(2H)-isothiazolone			_

(g) reproductive toxicity; No data available.

Component	Test method	Test species / Duration	Study result
5-Chloro-2-methyl-3(2H)-isothiazolone,			negative
mixture with 2-methyl-3(2H)-isothiazolone			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,	Acute toxicity:	Acute toxicity:	Acute toxicity:	Chronic toxicity:
mixture with 2-methyl-3(2H)-isothiazolone	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
	(Oncorhynchus mykiss)	(Daphnia magna)	(Selenastrum	(Activated sludge)
	EPA OPP 72-1	OECD Test 202	capricornutum)	OECD 209
	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	

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12.2. Persistence and degradability Product is biodegradable.

Component	Degradability
5-Chloro-2-methyl-3(2H)-isothiazolone,	Biodegradable <50 % 10 days
mixture with 2-methyl-3(2H)-isothiazolone	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,	<0.401	<54
mixture with 2-methyl-3(2H)-isothiazolone		

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

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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 Ozone Depletion Potential No known effect. 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)

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

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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)-isothi	-	-		-	Х	-	Х	Х	Х	-	KE-0573
azolone, mixture with											8
2-methyl-3(2H)-isothiazolone											

Component	,	REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous Substances	· · · · · · · · · · · · · · · · · · ·
5-Chloro-2-methyl-3(2H)-isothiaz olone, 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)-isothiaz	H1: 5-100 ton, E1: 20-200 ton	H1: 5-100 ton, E1: 20-200 ton
olone, mixture with		
2-methyl-3(2H)-isothiazolone		

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)-isothiaz	WGK3	
olone, mixture with		
2-methyl-3(2H)-isothiazolone		

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

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H317 - May cause an allergic skin reaction

H318 - Causes serious eve 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 DSL/NDSL - Canadian Domestic Substances List/Non-Domestic

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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

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/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

MARPOL - International Convention for the Prevention of Pollution from

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

On basis of test data Physical hazards **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.

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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