

Revision Date 02-Dec-2020 Revision Number 5

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

1.1. Product identifier

Product Description: ImmunoCAP Rapid QC 1

Cat No.: 82-1027-01

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

ImmunoCAP Rapid QC 1 Page 1/10

2.3. Other hazards

This product contains human sourced material. The donors have been tested and found to be non-reactive for HBsAg, HIV-1 Ag, anti-HCV and anti HIV-1/HIV-2.

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
Pooled human sera	-		>99	-
Sodium azide	26628-22-8	EEC No. 247-852-1	<0.1	Acute Tox. 2 (H300) (EUH032) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)

Component	Specific concentration limits (SCL's)	M-Factor	Component notes
Sodium azide	-	1	-

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 Rinse mouth. If possible drink milk afterwards.

Inhalation Not applicable.

Self-Protection of the First Aider Ensure that medical personnel are aware of the material(s) involved, take precautions to

protect themselves and prevent spread of contamination.

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

ImmunoCAP Rapid QC 1 Page 2/10

Revision Date 02-Dec-2020

ImmunoCAP Rapid QC 1

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

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

7.2. Conditions for safe storage, including any incompatibilities

Observe instructions for use.

7.3. Specific end use(s)

Observe instructions for use.

ImmunoCAP Rapid QC 1 Page 3 / 10

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure limits

Component	European Union	The United Kingdom	France	Belgium	Spain
Sodium azide	TWA: 0.1 mg/m ³ (8h)	STEL: 0.3 mg/m ³ 15 min	TWA / VME: 0.1 mg/m ³	Huid	STEL / VLA-EC: 0.3
	STEL: 0.3 mg/m ³	TWA: 0.1 mg/m ³ 8 hr	(8 heures). restrictive		mg/m³ (15 minutos).
	(15min)	Skin	limit		TWA / VLA-ED: 0.1
	Skin		STEL / VLCT: 0.3		mg/m³ (8 horas)
			mg/m ³ . restrictive limit		Piel
			Peau		

Component	Italy	Germany	Portugal	The Netherlands	Finland
Sodium azide	TWA: 0.1 mg/m ³ 8 ore.	TWA: 0.2 mg/m ³ (8	STEL: 0.3 mg/m ³ 15	huid	TWA: 0.1 mg/m ³ 8
	Media Ponderata nel	Stunden). AGW -	minutos	STEL: 0.3 mg/m ³ 15	tunteina
	Tempo	exposure factor 2	Ceiling: 0.29 mg/m ³	minuten	STEL: 0.3 mg/m ³ 15
	STEL: 0.3 mg/m ³ 15	TWA: 0.2 mg/m³ (8	Ceiling: 0.11 ppm	TWA: 0.1 mg/m ³ 8 uren	minuutteina
	minuti. Breve termine	Stunden). MAK	TWA: 0.1 mg/m ³ 8 horas		lho
	Pelle	Höhepunkt: 0.4 mg/m ³	Pele		

Component	Austria	Denmark	Switzerland	Poland	Norway
Sodium azide	Haut	TWA: 0.1 mg/m ³ 8 timer	STEL: 0.4 mg/m ³ 15	STEL: 0.3 mg/m ³ 15	TWA: 0.1 mg/m ³ 8 timer
	MAK-KZW: 0.3 mg/m ³	Hud	Minuten	minutach	STEL: 0.3 mg/m ³ 15
	15 Minuten		TWA: 0.2 mg/m ³ 8	TWA: 0.1 mg/m ³ 8	minutter. value from the
	MAK-TMW: 0.1 mg/m ³ 8		Stunden	godzinach	regulation
	Stunden			_	_

Component	Bulgaria	Croatia	Ireland	Cyprus	Czech Republic
Sodium azide	TWA: 0.1 mg/m ³	kože	TWA: 0.1 mg/m ³ 8 hr.	Skin-potential for	TWA: 0.1 mg/m ³ 8
	STEL: 0.3 mg/m ³	TWA-GVI: 0.1 mg/m ³ 8	STEL: 0.3 mg/m ³ 15 min	cutaneous absorption	hodinách.
	Skin notation	satima.	Skin	STEL: 0.3 mg/m ³	Potential for cutaneous
		STEL-KGVI: 0.3 mg/m ³		TWA: 0.1 mg/m ³	absorption
		15 minutama.			Ceiling: 0.3 mg/m ³

Component	Estonia	Gibraltar	Greece	Hungary	Iceland
Sodium azide	Nahk	Skin notation	STEL: 0.1 ppm	STEL: 0.3 mg/m ³ 15	STEL: 0.3 mg/m ³
	TWA: 0.1 mg/m ³ 8	TWA: 0.1 mg/m ³ 8 hr	STEL: 0.3 mg/m ³	percekben. CK	TWA: 0.1 mg/m ³ 8
	tundides.	STEL: 0.3 mg/m ³ 15 min	TWA: 0.1 ppm	TWA: 0.1 mg/m ³ 8	klukkustundum.
	STEL: 0.3 mg/m ³ 15		TWA: 0.3 mg/m ³	órában. AK	Skin notation
	minutites.		-		

Component	Latvia	Lithuania	Luxembourg	Malta	Romania
Sodium azide	skin - potential for	TWA: 0.1 mg/m ³ IPRD	Possibility of significant	possibility of significant	Skin notation
	cutaneous exposure	Oda	uptake through the skin	uptake through the skin	TWA: 0.1 mg/m ³ 8 ore
	STEL: 0.3 mg/m ³	STEL: 0.3 mg/m ³	TWA: 0.1 mg/m ³ 8	TWA: 0.1 mg/m ³	STEL: 0.3 mg/m ³ 15
	TWA: 0.1 mg/m ³		Stunden	STEL: 0.3 mg/m ³ 15	minute
	_		STEL: 0.3 mg/m ³ 15	minuti	
			Minuten		

Component	Russia	Slovak Republic	Slovenia	Sweden	Turkey
Sodium azide		Ceiling: 0.3 mg/m ³	TWA: 0.1 mg/m ³ 8 urah	Binding STEL: 0.3	Deri
		Potential for cutaneous	Koža	mg/m ³ 15 minuter	TWA: 0.1 mg/m ³ 8 saat
		absorption	STEL: 0.3 mg/m ³ 15	TLV: 0.1 mg/m ³ 8	STEL: 0.3 mg/m ³ 15
		TWA: 0.1 mg/m ³	minutah	timmar. NGV	dakika

Biological limit values

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

ImmunoCAP Rapid QC 1 Page 4/10

ImmunoCAP Rapid QC 1 Revision Date 02-Dec-2020

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 No Effect Level (DNEL)No information available.

Predicted No Effect Concentration

(PNEC)

No information available.

8.2. Exposure controls

Engineering Measures

None under normal use conditions.

Personal protective equipment

Eye Protection No special protective equipment required.

Hand Protection Protective gloves.

Glove material	Breakthrough time	Glove thickness	EU standard	Glove comments
Nitrile rubber	See manufacturers	-	EN 374	(minimum requirement)
	recommendations			

Skin and body protectionNo 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 Yellow Odor None Odor Threshold None

Melting Point/RangeNo data availableSoftening PointNo data availableBoiling Point/RangeNo data availableFlammability (liquid)No data availableFlammability (solid,gas)Not flammableExplosion LimitsNot applicable

Flash Point Not applicable Method - No information available

Autoignition TemperatureNot applicableDecomposition TemperatureNot applicablepHNo data availableViscosityNo data available

ImmunoCAP Rapid QC 1 Page 5 / 10

ImmunoCAP Rapid QC 1 Revision Date 02-Dec-2020

Water Solubility Soluble in water
Solubility in other solvents No information available

Partition Coefficient (n-octanol/water)

Componentlog PowSodium azide0.3

Vapor Pressure
Density / Specific Gravity
Bulk Density
No data available
No data available
No data available

Vapor Density No data available (Air = 1.0)

Particle characteristics Not applicable (liquid)

9.2. Other information

Explosive PropertiesNot applicable
Not applicable

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;

OralNo data available.DermalNo data available.InhalationNo data available.

Toxicology data for the components

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Sodium azide	LD50 = 27 mg/kg (Rat)	20 mg/kg (Rabbit)	37 mg/l (Rat)

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

(c) serious eye damage/irritation;

ImmunoCAP Rapid QC 1 Page 6/10

ImmunoCAP Rapid QC 1

(d) respiratory or skin sensitization;

Respiratory No data available. Skin No data available.

(e) germ cell mutagenicity; No data available.

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

<u>. ,</u>	_	·	
Component	Test method	Test species / Duration	Study result
Sodium azide			No ingredient of this product
			present at levels greater than or
			equal to 0.1% is identified as
			probable, possible or confirmed
			human carcinogen by IARC.

(g) reproductive toxicity; No data available.

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

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

(j) aspiration hazard; No data available.

Component	Other Adverse Effects
Sodium azide	Symptoms of overexposure are dizziness, headache, tiredness,
	nausea, unconsciousness, cessation of breathing. Harmful to
	central nervous system and heart. Fatal if swallowed.

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 No information available.

Component	Freshwater Fish	Water Flea	Freshwater Algae	Microtox
Sodium azide	LC50 96 h 0.7 mg/L	EC50 4.2 mg/l 48 h (EC50 38.5 mg/l (
	LC50 96 h	Daphnia pulex)	IC50 272 mg/l (green	Photobacterium
	LC50 0.7 mg/l 96 H (algae)	phosphoreum)
	Lepomis macrochirus)		,	, ,

12.2. Persistence and degradability No information available.

12.3. Bioaccumulative potential No information available.

Component	log Pow	Bioconcentration factor (BCF)
Sodium azide	0.3	

ImmunoCAP Rapid QC 1 Page 7/10

ImmunoCAP Rapid QC 1 Revision Date 02-Dec-2020

12.4. Mobility in soilNo 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

No information available 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

<u>IATA</u> Not regulated

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.

ImmunoCAP Rapid QC 1 Page 8 / 10

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
Sodium azide	247-852-1	-		Х	Х	-	Х	Х	Х	Χ	KE-3135
											7

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 (VwVwS)	Germany - TA-Luft Class
Sodium azide	WGK2	

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

H300 - Fatal if swallowed

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

EUH032 - Contact with acids liberates very toxic gas

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

Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances **IECSC** - Chinese Inventory of Existing Chemical Substances

ENCS - Japanese Existing and New Chemical Substances AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

WEL - Workplace Exposure Limit

TWA - Time Weighted Average IARC - International Agency for Research on Cancer

DNEL - Derived No Effect Level

ACGIH - American Conference of Governmental Industrial Hygienists Predicted No Effect Concentration (PNEC)

RPE - Respiratory Protective Equipment LC50 - Lethal Concentration 50%

EC50 - Effective Concentration 50% POW - Partition coefficient Octanol:Water

NOEC - No Observed Effect Concentration PBT - Persistent, Bioaccumulative, Toxic

vPvB - very Persistent, very Bioaccumulative

ADR - European Agreement Concerning the International Carriage of

ICAO/IATA - International Civil Aviation Organization/International Air

LD50 - Lethal Dose 50%

Transport Association

Dangerous Goods by Road IMO/IMDG - International Maritime Organization/International Maritime

MARPOL - International Convention for the Prevention of Pollution from Ships

Dangerous Goods Code OECD - Organisation for Economic Co-operation and Development

ATE - Acute Toxicity Estimate VOC (volatile organic compound)

BCF - Bioconcentration factor Key literature references and sources for data

ImmunoCAP Rapid QC 1 Page 9/10

ImmunoCAP Rapid QC 1 Revision Date 02-Dec-2020

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

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

Physical hazardsOn basis of test dataHealth HazardsCalculation methodEnvironmental hazardsCalculation method

Training Advice

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

Revision Date 02-Dec-2020

Revision Summary Update to CLP Format, SDS sections updated, 1, 3, 16.

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

ImmunoCAP Rapid QC 1 Page 10 / 10