SAFETY DATA SHEET

Revision Date 08-Dec-2023 **Revision Number** 10

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

1.1. Product identifier

Product Description: ImmunoCAP ECP Control
Cat No. : 10-9269-41

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

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 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). 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.

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
Human proteins in buffer	-		>99	-
Sodium azide	26628-22-8	EEC No. 247-852-1	<0.05	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

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

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): **EU** - Commission Directive (EU) 2019/1831 of 24 October 2019 establishing a fifth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC and amending Commission Directive 2000/39/EC **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	European Union	The United Kingdom	France	Belgium	Spain
Sodium azide	TWA: 0.1 mg/m³ (8h) STEL: 0.3 mg/m³ (15min) Skin	STEL: 0.3 mg/m³ 15 min TWA: 0.1 mg/m³ 8 hr Skin	TWA / VME: 0.1 mg/m³ (8 heures). restrictive limit STEL / VLCT: 0.3 mg/m³. restrictive limit Peau	TWA: 0.1 mg/m³ 8 uren Huid	STEL / VLA-EC: 0.3 mg/m³ (15 minutos). TWA / VLA-ED: 0.1 mg/m³ (8 horas) Piel

Component	Italy	Germany	Portugal	The Netherlands	Finland
Sodium azide	TWA: 0.1 mg/m³ 8 ore. Time Weighted Average STEL: 0.3 mg/m³ 15 minuti. Short-term Pelle	TWA: 0.2 mg/m³ (8 Stunden). AGW - exposure factor 2 TWA: 0.2 mg/m³ (8 Stunden). MAK Höhepunkt: 0.4 mg/m³	STEL: 0.3 mg/m³ 15 minutos Ceiling: 0.29 mg/m³ Ceiling: 0.11 ppm TWA: 0.1 mg/m³ 8 horas Pele	huid STEL: 0.3 mg/m³ 15 minuten TWA: 0.1 mg/m³ 8 uren	TWA: 0.1 mg/m³ 8 tunteina STEL: 0.3 mg/m³ 15 minuutteina Iho

Component	Austria	Denmark	Switzerland	Poland	Norway
Sodium azide	Haut MAK-KZGW: 0.3 mg/m³ 15 Minuten MAK-TMW: 0.1 mg/m³ 8 Stunden	TWA: 0.1 mg/m³ 8 timer STEL: 0.3 mg/m³ 15 minutter Hud	STEL: 0.4 mg/m³ 15 Minuten TWA: 0.2 mg/m³ 8 Stunden	STEL: 0.3 mg/m³ 15 minutach TWA: 0.1 mg/m³ 8 godzinach	TWA: 0.1 mg/m³ 8 timer STEL: 0.3 mg/m³ 15 minutter. value from the regulation

Component	Bulgaria	Croatia	Ireland	Cyprus	Czech Republic
Sodium azide	TWA: 0.1 mg/m³ STEL : 0.3 mg/m³ Skin notation	kože TWA-GVI: 0.1 mg/m³ 8 satima. STEL-KGVI: 0.3 mg/m³ 15 minutama.	TWA: 0.1 mg/m³ 8 hr. STEL: 0.3 mg/m³ 15 min Skin	Skin-potential for cutaneous absorption STEL: 0.3 mg/m³ TWA: 0.1 mg/m³	TWA: 0.1 mg/m³ 8 hodinách. Potential for cutaneous absorption Ceiling: 0.3 mg/m³

Component	Estonia	Gibraltar	Greece	Hungary	Iceland
Sodium azide	Nahk TWA: 0.1 mg/m³ 8 tundides. STEL: 0.3 mg/m³ 15 minutites.	Skin notation TWA: 0.1 mg/m³ 8 hr STEL: 0.3 mg/m³ 15 min	STEL: 0.1 ppm STEL: 0.3 mg/m³ TWA: 0.1 ppm TWA: 0.3 mg/m³	STEL: 0.3 mg/m³ 15 percekben. CK TWA: 0.1 mg/m³ 8 órában. AK	STEL: 0.3 mg/m³ TWA: 0.1 mg/m³ 8 klukkustundum. Skin notation

Component	Latvia	Lithuania	Luxembourg	Malta	Romania
Sodium azide	skin - potential for cutaneous exposure STEL: 0.3 mg/m³ TWA: 0.1 mg/m³	TWA: 0.1 mg/m³ IPRD Oda STEL: 0.3 mg/m³	Possibility of significant uptake through the skin TWA: 0.1 mg/m³ 8 Stunden STEL: 0.3 mg/m³ 15 Minuten	possibility of significant uptake through the skin TWA: 0.1 mg/m³ STEL: 0.3 mg/m³ 15 minuti	Skin notation TWA: 0.1 mg/m³ 8 ore STEL: 0.3 mg/m³ 15 minute

Component	Russia	Slovak Republic	Slovenia	Sweden	Turkey
Sodium azide		Ceiling: 0.3 mg/m³ Potential for cutaneous absorption TWA: 0.1 mg/m³	TWA: 0.1 mg/m³ 8 urah Kože STEL: 0.3 mg/m³ 15 minutah	Binding STEL: 0.3 mg/m³ 15 minuter TLV: 0.1 mg/m³ 8 timmar. NGV	Deri TWA: 0.1 mg/m³ 8 saat STEL: 0.3 mg/m³ 15 dakika

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 (Dermal)	Acute effects systemic (Dermal)	Chronic effects local (Dermal)	Chronic effects systemic (Dermal)
Sodium azide 26628-22-8 (<0.05)				DNEL = 46.7µg/kg bw/day

Component	Acute effects local (Inhalation)	Acute effects systemic (Inhalation)	Chronic effects local (Inhalation)	Chronic effects systemic (Inhalation)
Sodium azide 26628-22-8 (<0.05)				DNEL = 0.164mg/m³

Predicted No Effect Concentration (PNEC)
See values below.

Component	Fresh water	Fresh water sediment	Water Intermittent	Microorganisms in sewage treatment	Soil (Agriculture)
Sodium azide 26628-22-8 (<0.05)	PNEC = 0.35µg/L	PNEC = 16.7µg/kg sediment dw	PNEC = 3.5µg/L	PNEC = 30µg/L	

Component	Marine water	Marine water sediment	Marine water Intermittent	Food chain	Air
Sodium azide 26628-22-8 (<0.05)	PNEC = 15ng/L	PNEC = 0.72µg/kg sediment dw	PNEC = 150ng/L		

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 recommendations	-	EN 374	(minimum requirement)

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	Colorless to yellow	
Odor	None	
Odor Threshold	None	
Melting Point/Range	No data available	
Softening Point	No data available	
Boiling Point/Range	100 °C	
Flammability (liquid)	No data available	
Flammability (solid,gas)	Not flammable	
Explosion Limits	Not applicable	
Flash Point	Not applicable	**Method -** No information available
Autoignition Temperature	Not applicable	
Decomposition Temperature	Not applicable	
pH	7.0	
Viscosity	No data available	
Water Solubility	Soluble in water	
Solubility in other solvents	No information available	

Partition Coefficient (n-octanol/water)

Component	**log Pow**
Sodium azide	0.3

Vapor Pressure	No data available	
Density / Specific Gravity	1 g/cm3	
Bulk Density	No data available	
Vapor Density	No data available	(Air = 1.0)
Particle characteristics	Not applicable (liquid)	

9.2. Other information

Explosive Properties	Not applicable
Oxidizing Properties	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;

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

(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.

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 LC50 96 h LC50 0.7 mg/l 96 H (Lepomis macrochirus)	EC50 4.2 mg/l 48 h (Daphnia pulex)	IC50 272 mg/l (green algae)	EC50 38.5 mg/l (Photobacterium phosphoreum)

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	

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). 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.

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

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
Sodium azide	247-852-1	-		X	X	-	X	X	X	X	KE-31357

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
Sodium azide	H2 50-200 ton, E1 100-200 ton	H2 50-200 ton, E1 100-200 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
Sodium azide	WGK2	

UK - Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment.
Take note of Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values .

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
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/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 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	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	08-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