

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

**Product Description:** Specific IgE Control

**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  
Rapskatan 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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## 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).

## 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

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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

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## 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/m <sup>3</sup> (8h) STEL: 0.3 mg/m <sup>3</sup> (15min) Skin	STEL: 0.3 mg/m <sup>3</sup> 15 min TWA: 0.1 mg/m <sup>3</sup> 8 hr Skin	TWA / VME: 0.1 mg/m <sup>3</sup> (8 heures). restrictive limit STEL / VLCT: 0.3 mg/m <sup>3</sup> . restrictive limit Peau	TWA: 0.1 mg/m <sup>3</sup> 8 uren Huid	STEL / VLA-EC: 0.3 mg/m <sup>3</sup> (15 minutos). TWA / VLA-ED: 0.1 mg/m <sup>3</sup> (8 horas) Piel

Component	Italy	Germany	Portugal	The Netherlands	Finland
Sodium azide	TWA: 0.1 mg/m <sup>3</sup> 8 ore. Time Weighted Average STEL: 0.3 mg/m <sup>3</sup> 15 minuti. Short-term Pelle	TWA: 0.2 mg/m <sup>3</sup> (8 Stunden). AGW - exposure factor 2 TWA: 0.2 mg/m <sup>3</sup> (8 Stunden). MAK Höhepunkt: 0.4 mg/m <sup>3</sup>	STEL: 0.3 mg/m <sup>3</sup> 15 minutos Ceiling: 0.29 mg/m <sup>3</sup> Ceiling: 0.11 ppm TWA: 0.1 mg/m <sup>3</sup> 8 horas Pele	huid STEL: 0.3 mg/m <sup>3</sup> 15 minuten TWA: 0.1 mg/m <sup>3</sup> 8 uren	TWA: 0.1 mg/m <sup>3</sup> 8 tunteina STEL: 0.3 mg/m <sup>3</sup> 15 minuutteina Iho

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

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

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

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

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

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## 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 ( <0.1 )				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 ( <0.1 )				DNEL = 0.164mg/m <sup>3</sup>

## 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 ( <0.1 )	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 ( <0.1 )	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.

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**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

<b>Physical State</b>	Liquid	
<b>Appearance</b>	No information available	
<b>Odor</b>	None	
<b>Odor Threshold</b>	None	
<b>Melting Point/Range</b>	No data available	
<b>Softening Point</b>	No data available	
<b>Boiling Point/Range</b>	No data available	
<b>Flammability (liquid)</b>	No data available	
<b>Flammability (solid,gas)</b>	Not flammable	
<b>Explosion Limits</b>	Not applicable	
<b>Flash Point</b>	Not applicable	<b>Method -</b> No information available
<b>Autoignition Temperature</b>	Not applicable	
<b>Decomposition Temperature</b>	Not applicable	
<b>pH</b>	No data available	
<b>Viscosity</b>	No data available	
<b>Water Solubility</b>	Soluble in water	
<b>Solubility in other solvents</b>	No information available	
<b>Partition Coefficient (n-octanol/water)</b>		
<b>Component</b>	<b>log Pow</b>	
Sodium azide	0.3	
<b>Vapor Pressure</b>	No data available	
<b>Density / Specific Gravity</b>	No data available	
<b>Bulk Density</b>	No data available	
<b>Vapor Density</b>	No data available	(Air = 1.0)
<b>Particle characteristics</b>	Not applicable (liquid)	

### 9.2. Other information

<b>Explosive Properties</b>	Not applicable
<b>Oxidizing Properties</b>	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

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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.

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## 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).

### 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



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## 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-3135 7

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

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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/NDL** - 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

**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**

03-Jan-2024

**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**