

SAFETY DATA SHEET

Revision Date 18-Dec-2020 Revision Number 8

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

1.1. Product identifier

Product Description: ImmunoCAP Rapid Developer Solution

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

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2.3. Other hazards

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 |
|--------------|------------|-------------------|----------|---|
| 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 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

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

| 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/m ³ 15 min TWA: 0.1 mg/m ³ 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 |
| | | Ι . | | | |
| 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 |

| 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 |
| | Time Weighted Average | Stunden). AGW - | minutos | STEL: 0.3 mg/m ³ 15 | tunteina |
| | STEL: 0.3 mg/m ³ 15 | exposure factor 2 | Ceiling: 0.29 mg/m ³ | minuten | STEL: 0.3 mg/m ³ 15 |
| | minuti. Short-term | TWA: 0.2 mg/m ³ (8 | Ceiling: 0.11 ppm | TWA: 0.1 mg/m ³ 8 uren | minuutteina |
| | Pelle | Stunden). MAK | TWA: 0.1 mg/m ³ 8 horas | | lho |
| | | 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-KZGW: 0.3 mg/m ³ | STEL: 0.3 mg/m ³ 15 | Minuten | minutach | STEL: 0.3 mg/m ³ 15 |
| | 15 Minuten | minutter | 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 | Hud | 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 tundides. | TWA: 0.1 mg/m ³ 8 hr STEL: 0.3 mg/m ³ 15 min | STEL: 0.3 mg/m ³ TWA: 0.1 ppm | percekben. CK TWA: 0.1 mg/m ³ 8 | TWA: 0.1 mg/m³ 8 klukkustundum. |
| | STEL: 0.3 mg/m ³ 15 | STEE. 0.3 mg/m² 13 mm | TWA: 0.3 mg/m ³ | órában. AK | Skin notation |
| | minutites. | | _ | | |

| 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 | |

| 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

Monitoring methods

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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 | | | | DNEL = 0.164mg/m^3 |
| 26628-22-8 (<0.1) | | | | |

Predicted No Effect Concentration (PNEC)

See values below.

| Component | Fresh water | Fresh water | Water Intermittent | Microorganisms in | Soil (Agriculture) |
|---------------------|-----------------|------------------------|---------------------------|-------------------|--------------------|
| | | sediment | | sewage treatment | |
| Sodium azide | PNEC = 0.35µg/L | $PNEC = 16.7 \mu g/kg$ | PNEC = $3.5\mu g/L$ | PNEC = 30µg/L | |
| 26628-22-8 (<0.1) | | sediment dw | | | |

| Component | Marine water | Marine water | Marine water | Food chain | Air |
|---------------------|----------------------------|--------------|----------------|------------|-----|
| | | sediment | intermittent | | |
| Sodium azide | Sodium azide PNEC = 15ng/L | | PNEC = 150ng/L | | |
| 26628-22-8 (<0.1) | | sediment dw | _ | | |

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 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 Clear 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 applicable

pH 7.2

Viscosity

Water Solubility

Soluble in water

No information available

No information available

Partition Coefficient (n-octanol/water)

Componentlog PowSodium azide0.3

Vapor PressureNo data availableDensity / Specific GravityNo data availableBulk DensityNo 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 SkinNo data available.
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).

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

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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

| Г | Component | EINECS | ELINCS | NLP | TSCA | DSL | NDSL | PICCS | ENCS | IECSC | AICS | KECL |
|---|--------------|-----------|--------|-----|------|-----|------|-------|------|-------|------|---------|
| Γ | Sodium azide | 247-852-1 | - | | Х | Х | - | Χ | Χ | Χ | Х | KE-3135 |
| | | | | | | | | | | | | 7 |

| Component | Seveso III Directive (2012/18/EC) - Qualifying | Seveso III Directive (2012/18/EC) - Qualifying Quantitie | | | |
|--------------|--|--|--|--|--|
| | Quantities for Major Accident Notification | 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

ImmunoCAP Rapid Developer Solution

EUH032 - Contact with acids liberates very toxic gas

Legend

CAS - Chemical Abstracts Service

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

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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

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

IECSC - Chinese Inventory of Existing Chemical Substances **KECL** - Korean Existing and Evaluated Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

WEL - Workplace Exposure Limit

ACGIH - American Conference of Governmental Industrial Hygienists

TWA - Time Weighted Average

DNEL - Derived No Effect Level

IARC - International Agency for Research on Cancer

RPE - Respiratory Protective Equipment LC50 - Lethal Concentration 50%

Predicted No Effect Concentration (PNEC) LD50 - Lethal Dose 50%

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

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

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

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

MARPOL - International Convention for the Prevention of Pollution from Shins

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 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 Calculation method **Environmental hazards**

Training Advice

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

18-Dec-2020 **Revision Date**

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