

Revision Date 30-Apr-2025 Revision Number 2

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

1.1. Product identifier

Product Description: EliA IgA Calibrator Well

Cat No.: 14-6616-41

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

#### 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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None

#### 2.3. Other hazards

Not applicable 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**

Component	CAS No	EC No	Weight %	GHS Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567
Antigens from different sources	N/A		<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** Not an expected route of exposure.

**Skin Contact** No hazards which require special first aid measures.

**Ingestion** Not an expected route of exposure.

**Inhalation** Not an expected route of exposure.

**Self-Protection of the First Aider** No special precautions required.

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**

No information available. Use extinguishing measures that are appropriate to local circumstances and the surrounding

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environment.

Extinguishing media which must not be used for safety reasons

No information available.

5.2. Special hazards arising from the substance or mixture

None known.

#### **Hazardous Combustion Products**

None under normal use conditions.

#### 5.3. Advice for firefighters

No information available.

## **SECTION 6: ACCIDENTAL RELEASE MEASURES**

#### 6.1. Personal precautions, protective equipment and emergency procedures

No special precautions required.

#### 6.2. Environmental precautions

Dispose of in accordance with local regulations.

6.3. Methods and material for containment and cleaning up

#### 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 hands before breaks and immediately after handling the product. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use.

#### 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**

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#### **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)

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.

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

**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 special protective equipment required

Recommended Filter type:

Small scale/Laboratory use No personal respiratory protective equipment normally required.

Recommended half mask:-

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

**Environmental exposure controls** Dispose of contents/containers in accordance with local regulations.

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## **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

## 9.1. Information on basic physical and chemical properties

Physical State Solid

**Appearance** 

Odor None Odor Threshold None

Melting Point/RangeNo data availableSoftening PointNo data availableBoiling Point/RangeNo data available

Flammability (liquid) Not applicable Solid

Flammability (solid,gas)

Explosion Limits No data available

Flash Point No data available Method - No information available

No information available

Autoignition Temperature

Decomposition Temperature
pH

No data available
No data available
Not applicable
No data available

Water Solubility Insoluble

Solubility in other solvents No information available

Partition Coefficient (n-octanol/water)

Vapor PressureNo data availableDensity / Specific GravityNo data availableBulk DensityNot applicable

Vapor Density Not applicable (Air = 1.0)

Particle characteristics No data available

9.2. Other information

Evaporation Rate 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 PolymerizationNo information available.Hazardous ReactionsNo information available.

10.4. Conditions to avoid

None known.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None under normal use conditions.

## **SECTION 11: TOXICOLOGICAL INFORMATION**

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#### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

**Product Information**No acute toxicity information is available for this product.

(a) acute toxicity;

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

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

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

(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.

(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.

Symptoms / effects,both acute and delayed No information available.

11.2. Information on other hazards

Endocrine Disrupting Properties This product may contain traces of endocrine disruptors < 0.1% (w/w).

#### **SECTION 12: ECOLOGICAL INFORMATION**

12.1. Toxicity

**Ecotoxicity effects** No information available.

**12.2. Persistence and degradability** No information available.

**12.3. Bioaccumulative potential** No information available.

12.4. Mobility in soil No information available.

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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 may contain traces of endocrine disruptors < 0.1% (w/w).

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)** 

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**

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15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

International Inventories X = listed

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**

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**

#### 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

ICAO/IATA - International Civil Aviation Organization/International Air

MARPOL - International Convention for the Prevention of Pollution from

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

**ENCS** - Japanese Existing and New Chemical Substances AICS - Australian Inventory of Chemical Substances NZIoC - New Zealand Inventory of Chemicals

WEL - Workplace Exposure Limit

TWA - Time Weighted Average **ACGIH** - American Conference of Governmental Industrial Hygienists IARC - International Agency for Research on Cancer

**DNEL** - Derived No Effect Level RPE - Respiratory Protective Equipment LC50 - Lethal Concentration 50% NOEC - No Observed Effect Concentration

LD50 - Lethal Dose 50% EC50 - Effective Concentration 50%

PBT - Persistent, Bioaccumulative, Toxic

POW - Partition coefficient Octanol:Water vPvB - very Persistent, very Bioaccumulative

Predicted No Effect Concentration (PNEC)

ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road

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

Ships ATE - Acute Toxicity Estimate

Transport Association

VOC (volatile organic compound)

**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

#### **Training Advice**

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

30-Apr-2025 **Revision Date Revision Summary** Initial Release.

## This safety data sheet complies with Regulation UK SI 2019/758 and UK SI 2020/1577 as amended

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#### **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**

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