

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

Product Description: EliA β 2-Glycoprotein I IgM Well
Cat No. : 14-5533-01

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

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None

2.3. Other hazards

This material is prepared from a human source base. Donors have been tested by FDA approved methods and found negative for antibodies to HIV-1 and HIV-2, non-reactive for HBsAg, and non-reactive for HCV. Handle as potentially infectious material. 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 %	CLP Classification - Regulation (EC) No 1272/2008
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.
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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.

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 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/Range	No data available	
Softening Point	No data available	
Boiling Point/Range	No data available	
Flammability (liquid)	Not applicable	Solid
Flammability (solid,gas)	No information available	
Explosion Limits	No data available	
Flash Point	No data available	Method - No information available
Autoignition Temperature	No data available	
Decomposition Temperature	No data available	
pH	Not applicable	
Viscosity	No data available	
Water Solubility	Insoluble	
Solubility in other solvents	No information available	
Partition Coefficient (n-octanol/water)		
Vapor Pressure	No data available	
Density / Specific Gravity	No data available	
Bulk Density	Not applicable	
Vapor Density	Not applicable	(Air = 1.0)
Particle characteristics	No data available	

9.2. Other information

Evaporation Rate	Not applicable
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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	No information available.
Hazardous Reactions	No 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) 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

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

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

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)

Training Advice

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

Revision Date 23-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**

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Disclaimer

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End of Safety Data Sheet