

SAFETY DATA SHEET

Revision Date 24-Jan-2024 Revision Number 10

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

1.1. Product identifier

Product Description: EliA FLC Kappa Research Calibrator Well

Cat No.: 14-5626-01

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

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

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.

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

Skin and body protectionNo special protective equipment required.

Respiratory ProtectionNo 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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical State Solid

Appearance

Odor None **Odor Threshold** None

No data available **Melting Point/Range 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

No data available **Flash Point** Method - No information available

Autoignition Temperature No data available **Decomposition Temperature** No data available Not applicable pН No data available Viscosity

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

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

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

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

(a) acute toxicity;

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

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

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

(d) respiratory or skin sensitization;

No data available. Respiratory 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.

No data available. (h) STOT-single exposure;

(i) STOT-repeated exposure; No data available.

No data available. (j) aspiration hazard;

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. EliA FLC Kappa Research Calibrator Well

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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

<u>proper</u>ties

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.

Dispose of in accordance with local regulations. **Contaminated Packaging**

European Waste Catalogue (EWC)

18 01 07 Chemicals other than those mentioned in 18 01 06. No information available.

Other Information

SECTION 14: TRANSPORT INFORMATION

Not regulated IMDG/IMO

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

No hazards identified. 14.5. Environmental hazards

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

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

Predicted No Effect Concentration (PNEC) LD50 - Lethal Dose 50% EC50 - Effective Concentration 50%

IARC - International Agency for Research on Cancer

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

ATE - Acute Toxicity Estimate

VOC (volatile organic compound)

Transport Association

TWA - Time Weighted Average

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

Training Advice

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

Ships

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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