# SAFETY DATA SHEET

**Revision Date** 17-Jan-2024 **Revision Number** 3

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

### 1.1. Product identifier

**Product Description:** EliA APS Positive Control 250
**Cat No. :** 83-1055-41

### 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

None

EUH208 - Contains (reaction mass of: 5-chloro-2- methyl-4-isothiazolin-3-one [EC no. 247-500-7]and 2-methyl-2H -isothiazol-3- one [EC no. 220-239-6] (3:1); (CMIT/MIT (3:1))). May produce an allergic reaction.

### 2.3. Other hazards

May produce an allergic reaction 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 |
|---|---|---|---|---|
| Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]and 2-methyl-2H -isothiazol-3- one [EC no. 220-239-6] (3:1); (CMIT/MIT (3:1)) | 55965-84-9 | | <0.0015 | Acute Tox. 3 (H301)<br>Acute Tox. 2 (H310)<br>Acute Tox. 2 (H330)<br>Skin Corr. 1C (H314)<br>Eye Dam. 1 (H318)<br>Skin Sens. 1A (H317)<br>Aquatic Acute 1 (H400)<br>Aquatic Chronic 1 (H410)<br>EUH071 |
| Human Immunoglobulins in buffer | N/A | | >99 | - |

| Component | Specific concentration limits (SCL's) | M-Factor | Component notes |
|---|---|---|---|
| Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); (CMIT/MIT (3:1)) | Eye Irrit. 2 (H319) :: 0.06%<=C<0.6%<br>Skin Corr. 1C (H314) :: C>=0.6%<br>Skin Irrit. 2 (H315) :: 0.06%<=C<0.6%<br>Skin Sens. 1A (H317) :: C>=0.0015%<br>Eye Dam. 1 (H318) :: C>=0.6% | 100 (acute)<br>100 (chronic) | - |

*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 immediately with plenty of water, also under the eyelids, for at least 15 minutes. If eye irritation persists: Get medical advice/attention.

**Skin Contact** Wash off immediately with soap and plenty of water. Wash contaminated clothing before reuse.

| | |
|---|---|
| **Ingestion** | Clean mouth with water and drink afterwards plenty of water. Consult a physician if necessary. |
| **Inhalation** | Not an expected route of exposure. |
| **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

None reasonably foreseeable.

### 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**
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

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). Clean with disinfectants. 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 hands before breaks and immediately after handling the product. 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

### 8.1. Control parameters

**Exposure limits**

| Component | Austria | Denmark | Switzerland | Poland | Norway |
|---|---|---|---|---|---|
| Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]and 2-methyl-2H -isothiazol-3- one [EC no. 220-239-6] (3:1); (CMIT/MIT (3:1)) | MAK-TMW: 0.05 mg/m³ 8 Stunden | | STEL: 0.4 mg/m³ 15 Minuten TWA: 0.2 mg/m³ 8 Stunden | | |

**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

| Component | Acute effects local (Inhalation) | Acute effects systemic (Inhalation) | Chronic effects local (Inhalation) | Chronic effects systemic (Inhalation) |
|---|---|---|---|---|
| Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]and 2-methyl-2H | DNEL = 0.04mg/m³ | | DNEL = 0.02mg/m³ | |

| | | | | |
|---|---|---|---|---|
| -isothiazol-3- one [EC no. 220-239-6] (3:1); (CMIT/MIT (3:1))<br>55965-84-9 ( <0.0015 ) | | | | |

**Predicted No Effect Concentration (PNEC)**
No information available.

| Component | Fresh water | Fresh water sediment | Water Intermittent | Microorganisms in sewage treatment | Soil (Agriculture) |
|---|---|---|---|---|---|
| Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); (CMIT/MIT (3:1))<br>55965-84-9 ( <0.0015 ) | PNEC = 3.39µg/L | PNEC = 0.027mg/kg sediment dw | PNEC = 3.39µg/L | PNEC = 0.23mg/L | PNEC = 0.01mg/kg soil dw |

| Component | Marine water | Marine water sediment | Marine water intermittent | Food chain | Air |
|---|---|---|---|---|---|
| Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); (CMIT/MIT (3:1))<br>55965-84-9 ( <0.0015 ) | PNEC = 3.39µg/L | PNEC = 0.027mg/kg sediment dw | PNEC = 3.39µg/L | | |

**8.2. Exposure controls**

**Engineering Measures**
None under normal use conditions.

**Personal protective equipment**

**Eye Protection** Wear safety glasses with side shields (or goggles).

**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 special protective equipment required.

**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** | Liquid | |
| **Appearance** | Clear Yellow | |
| **Odor** | None | |
| **Odor Threshold** | Not applicable | |
| **Melting Point/Range** | 0°C | |
| **Softening Point** | No data available | |
| **Boiling Point/Range** | 100°C | |
| **Flammability (liquid)** | No data available | |
| **Flammability (solid,gas)** | Not applicable | |
| **Explosion Limits** | Not applicable | |
| **Flash Point** | Not applicable | **Method -** No information available |
| **Autoignition Temperature** | Not applicable | |
| **Decomposition Temperature** | No information available | |
| **pH** | 7.0 - 7.3 | |
| **Viscosity** | No information available | |
| **Water Solubility** | Soluble in water | |
| **Solubility in other solvents** | No information available | |

**Partition Coefficient (n-octanol/water)**

| **Component** | **log Pow** |
|---|---|
| Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]and 2-methyl-2H -isothiazol-3- one [EC no. 220-239-6] (3:1); (CMIT/MIT (3:1)) | <0.401 |

| | | |
|---|---|---|
| **Vapor Pressure** | No information available | |
| **Density / Specific Gravity** | No information available | |
| **Bulk Density** | Not applicable | |
| **Vapor Density** | No information available | No information available |
| **Particle characteristics** | Not applicable (liquid) | |

### 9.2. Other information

| | |
|---|---|
| **Explosive Properties** | Not applicable |
| **Oxidizing Properties** | Not applicable |
| **Evaporation Rate** | Not applicable - Not Available |

## SECTION 10: STABILITY AND REACTIVITY

### 10.1. Reactivity

There are no known reactivity hazards associated with this product.

### 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 under normal use conditions.

## 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.

| Component | LD50 Oral | LD50 Dermal | LC50 Inhalation |
|---|---|---|---|
| Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); (CMIT/MIT (3:1)) | LD50 = 53 mg/kg ( Rat ) | LD50 = 87.12 mg/kg ( Rabbit ) | 4h 0.33 mg/l ( Rat ) |

**(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.

| Component | Test method | Test species | Study result |
|---|---|---|---|
| Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); (CMIT/MIT (3:1)) | in vivo<br>in vitro | | negative |

**(f) carcinogenicity;** There are no known carcinogenic chemicals in this product.

| Component | Test method | Test species / Duration | Study result |
|---|---|---|---|
| Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); (CMIT/MIT (3:1)) | | | negative |

**(g) reproductive toxicity;** No data available.

| Component | Test method | Test species / Duration | Study result |
|---|---|---|---|
| Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); (CMIT/MIT (3:1)) | | | negative<br>Animal testing did not show any effects on fetal development |

**(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 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 |
|---|---|---|---|---|
| Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); (CMIT/MIT (3:1)) | Acute toxicity: LC50 96 h 0.19mg/l (Oncorhynchus mykiss) EPA OPP 72-1<br><br>Chronic toxicity: NOEC 35 days 0.02 mg/l (Pimephales promelas) OECD 210 | Acute toxicity: EC50 48 h 0.126 mg/l (Daphnia magna) OECD Test 202<br><br>Chronic toxicity: NOEC 21 days 0.10 mg/l (Daphnia magna) | Acute toxicity: ERC50 72 h 0.027 mg/l (Selenastrum capricornutum)<br><br>Chronic toxicity: NOEC 96h 0.004 mg/l, (Skeletonema costatum) OECD 201 | Chronic toxicity: NOEC 3h 0.91 mg/l (Activated sludge) OECD 209 |

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

| Component | Degradability |
|---|---|
| Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); (CMIT/MIT (3:1)) | Biodegradable <50 % 10 days<br>Atmospheric half-life: 0.38-1.3 Days |

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

| Component | log Pow | Bioconcentration factor (BCF) |
|---|---|---|
| Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); (CMIT/MIT (3:1)) | <0.401 | <54 |

**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** This product does not contain any known or suspected substance.
**Ozone Depletion Potential** This product does not contain any known or suspected substance.

## 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

**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 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]and 2-methyl-2H -isothiazol-3- one [EC no. 220-239-6] (3:1); (CMIT/MIT (3:1)) | - | - | | - | X | - | X | X | X | - | KE-05738 |

| Component | REACH (1907/2006) - Annex XIV - Substances Subject to | REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous | REACH Regulation (EC 1907/2006) article 59 - Candidate |
|---|---|---|---|

| | Authorization | Substances | List of Substances of Very High Concern (SVHC) |
|---|---|---|---|
| Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]and 2-methyl-2H -isothiazol-3- one [EC no. 220-239-6] (3:1); (CMIT/MIT (3:1)) | | Use restricted. See entry 75. (see link for restriction details) | |

| 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 |
|---|---|---|
| Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]and 2-methyl-2H -isothiazol-3- one [EC no. 220-239-6] (3:1); (CMIT/MIT (3:1)) | H1: 5-100 ton, E1: 20-200 ton | H1: 5-100 ton, E1: 20-200 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 |
|---|---|---|
| Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]and 2-methyl-2H -isothiazol-3- one [EC no. 220-239-6] (3:1); (CMIT/MIT (3:1)) | WGK3 | |

**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

**Full text of H-Statements referred to under sections 2 and 3**
H301 - Toxic if swallowed
H310 - Fatal in contact with skin
H314 - Causes severe skin burns and eye damage
H317 - May cause an allergic skin reaction
H318 - Causes serious eye damage
H330 - Fatal if inhaled
H400 - Very toxic to aquatic life
H410 - Very toxic to aquatic life with long lasting effects
EUH071 - Corrosive to the respiratory tract
EUH208 - May produce an allergic reaction

**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
**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)

**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.

| | |
|---|---|
| **Revision Date** | 17-Jan-2024 |
| **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