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

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

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 %	CLP Classification - Regulation (EC) No 1272/2008
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	55965-84-9		<0.0015	Acute Tox. 3 (H301) Acute Tox. 2 (H310) Acute Tox. 2 (H330) Skin Corr. 1C (H314) Eye Dam. 1 (H318) Skin Sens. 1A (H317) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) EUH071
Human Immunoglobulins in buffer	N/A		>99	-

Component	Specific concentration limits (SCL's)	M-Factor	Component notes
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	Eye Irrit. 2 (H319) :: 0.06%<=C<0.6% Skin Corr. 1C (H314) :: C>=0.6% Skin Irrit. 2 (H315) :: 0.06%<=C<0.6% Skin Sens. 1A (H317) :: C>=0.0015% Eye Dam. 1 (H318) :: C>=0.6%	100 (acute) 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
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	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)
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9 (<0.0015)	DNEL = 0.04mg/m³		DNEL = 0.02mg/m³	

Predicted No Effect Concentration (PNEC)
No information available.

Component	Fresh water	Fresh water	Water Intermittent	Microorganisms in	Soil (Agriculture)

		sediment		sewage treatment	
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 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
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 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**	
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	<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
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	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
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	in vivo in vitro		negative

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

Component	Test method	Test species / Duration	Study result
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone			negative

(g) reproductive toxicity; No data available.

Component	Test method	Test species / Duration	Study result
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone			negative 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
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	Acute toxicity: LC50 96 h 0.19mg/l (Oncorhynchus mykiss) EPA OPP 72-1	Acute toxicity: EC50 48 h 0.126 mg/l (Daphnia magna) OECD Test 202	Acute toxicity: ERC50 72 h 0.027 mg/l (Selenastrum capricornutum)	Chronic toxicity: NOEC 3h 0.91 mg/l (Activated sludge) OECD 209

	Chronic toxicity: NOEC 35 days 0.02 mg/l (Pimephales promelas) OECD 210	Chronic toxicity: NOEC 21 days 0.10 mg/l (Daphnia magna)	Chronic toxicity: NOEC 96h 0.004 mg/l, (Skeletonema costatum) OECD 201	

12.2. Persistence and degradability No information available.

Component	Degradability
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	Biodegradable <50 % 10 days Atmospheric half-life: 0.38-1.3 Days

12.3. Bioaccumulative potential No information available.

Component	log Pow	Bioconcentration factor (BCF)
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	<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
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	-	-		-	X	-	X	X	X	-	KE-05738

Component	REACH (1907/2006) - Annex XIV - Substances Subject to Authorization	REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous Substances	REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC)
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone		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
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	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
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	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 the requirements of Regulation (EC) No. 1907/2006 COMMISSION REGULATION (EU) 2020/878 amending Annex II to Regulation (EC) No 1907/2006

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