

Revision Date 06-Sep-2024

Revision Number 4

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

1.1. Product identifier

Product Description: EliA anti-TSH-R Sample Diluent

Cat No.: 83-1122-01

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

This product does not contain any known or suspected endocrine disruptors.

Substance is not considered persistent, bioaccumulative and toxic (PBT) / very persistent and very bioaccumulative (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
Tartrazine	1934-21-0	EEC No. 217-699-5	<1	-
Sodium azide	26628-22-8	EEC No. 247-852-1	<0.1	Acute Tox. 2 (H300) (EUH032) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
Ethylenediaminetetraacetic acid, disodium salt dihydrate	6381-92-6	613-386-6	<1	Acute Tox. 4 (H332) STOT RE 2 (H373)

Component	Specific concentration limits (SCL's)	M-Factor	Component notes
Sodium azide	-	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 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 No special measures are necessary. 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.

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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). 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.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure limits

List source(s): **EU** - Commission Directive (EU) 2019/1831 of 24 October 2019 establishing a fifth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC and amending Commission Directive 2000/39/EC

Component	European Union	The United Kingdom	France	Belgium	Spain
Sodium azide	TWA: 0.1 mg/m ³ (8h)	STEL: 0.3 mg/m3 15 min	TWA / VME: 0.1 mg/m ³	TWA: 0.1 mg/m ³ 8 uren	STEL / VLA-EC: 0.3
	STEL: 0.3 mg/m ³	TWA: 0.1 mg/m ³ 8 hr	(8 heures). restrictive	Huid	mg/m ³ (15 minutos).
	(15min)	Skin	limit		TWA / VLA-ED: 0.1
	Skin		STEL / VLCT: 0.3		mg/m³ (8 horas)
			mg/m ³ . restrictive limit		Piel
			Peau		

Component	Italy	Germany	Portugal	The Netherlands	Finland
Sodium azide	TWA: 0.1 mg/m ³ 8 ore.	TWA: 0.2 mg/m ³ (8	STEL: 0.3 mg/m ³ 15	huid	TWA: 0.1 mg/m ³ 8
	Time Weighted Average	Stunden). AGW -	minutos	STEL: 0.3 mg/m ³ 15	tunteina
	STEL: 0.3 mg/m ³ 15	exposure factor 2	Ceiling: 0.29 mg/m ³	minuten	STEL: 0.3 mg/m ³ 15
	minuti. Short-term	TWA: 0.2 mg/m ³ (8	Ceiling: 0.11 ppm	TWA: 0.1 mg/m ³ 8 uren	minuutteina
	Pelle	Stunden). MAK	TWA: 0.1 mg/m ³ 8 horas	_	lho
		Höhepunkt: 0.4 mg/m ³	Pele		

Component	Austria	Denmark	Switzerland	Poland	Norway
Sodium azide	Haut	TWA: 0.1 mg/m ³ 8 timer	STEL: 0.4 mg/m ³ 15	STEL: 0.3 mg/m ³ 15	TWA: 0.1 mg/m ³ 8 timer
	MAK-KZGW: 0.3 mg/m ³	STEL: 0.3 mg/m ³ 15	Minuten	minutach	STEL: 0.3 mg/m ³ 15
	15 Minuten	minutter	TWA: 0.2 mg/m ³ 8	TWA: 0.1 mg/m ³ 8	minutter. value from the
	MAK-TMW: 0.1 mg/m ³ 8	Hud	Stunden	godzinach	regulation
	Stunden			_	_

Component	Bulgaria	Croatia	Ireland	Cyprus	Czech Republic
Sodium azide	TWA: 0.1 mg/m ³	kože	TWA: 0.1 mg/m ³ 8 hr.	Skin-potential for	TWA: 0.1 mg/m ³ 8
	STEL: 0.3 mg/m ³	TWA-GVI: 0.1 mg/m ³ 8	STEL: 0.3 mg/m ³ 15 min	cutaneous absorption	hodinách.
	Skin notation	satima.	Skin	STEL: 0.3 mg/m ³	Potential for cutaneous
		STEL-KGVI: 0.3 mg/m ³		TWA: 0.1 mg/m ³	absorption
		15 minutama.		_	Ceiling: 0.3 mg/m ³

Component	Estonia	Gibraltar	Greece	Hungary	Iceland
Sodium azide	Nahk	Skin notation	STEL: 0.1 ppm	STEL: 0.3 mg/m ³ 15	STEL: 0.3 mg/m ³
	TWA: 0.1 mg/m ³ 8	TWA: 0.1 mg/m ³ 8 hr	STEL: 0.3 mg/m ³	percekben. CK	TWA: 0.1 mg/m ³ 8
	tundides.	STEL: 0.3 mg/m ³ 15 min	TWA: 0.1 ppm	TWA: 0.1 mg/m ³ 8	klukkustundum.
	STEL: 0.3 mg/m ³ 15	_	TWA: 0.3 mg/m ³	órában. ÁK	Skin notation
	minutites.		_		ļ

Component	Latvia	Lithuania	Luxembourg	Malta	Romania
Sodium azide	skin - potential for	TWA: 0.1 mg/m ³ IPRD	Possibility of significant	possibility of significant	Skin notation
	cutaneous exposure	Oda	uptake through the skin	uptake through the skin	TWA: 0.1 mg/m ³ 8 ore
	STEL: 0.3 mg/m ³	STEL: 0.3 mg/m ³	TWA: 0.1 mg/m ³ 8	TWA: 0.1 mg/m ³	STEL: 0.3 mg/m ³ 15
	TWA: 0.1 mg/m ³		Stunden	STEL: 0.3 mg/m ³ 15	minute
			STEL: 0.3 mg/m ³ 15	minuti	
			Minuten		

Component	Russia	Slovak Republic	Slovenia	Sweden	Turkey
Tartrazine	MAC: 5 mg/m ³				
Sodium azide		Ceiling: 0.3 mg/m ³	TWA: 0.1 mg/m ³ 8 urah	Binding STEL: 0.3	Deri
		Potential for cutaneous	Koža	mg/m ³ 15 minuter	TWA: 0.1 mg/m ³ 8 saat
		absorption	STEL: 0.3 mg/m ³ 15	TLV: 0.1 mg/m ³ 8	STEL: 0.3 mg/m ³ 15
		TWA: 0.1 mg/m ³	minutah	timmar. NGV	dakika

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)

See table for values

Component	Acute effects local (Oral)	Acute effects systemic (Oral)	Chronic effects local (Oral)	Chronic effects systemic (Oral)
Ethylenediaminetetraacetic				DNEL = 25 mg/kg
acid, disodium salt dihydrate				
6381-92-6 (<1)				

Component	Acute effects local (Dermal)	Acute effects systemic (Dermal)	Chronic effects local (Dermal)	Chronic effects systemic (Dermal)
Tartrazine 1934-21-0 (<1)				DNEL = 52.82mg/kg bw/day
Sodium azide 26628-22-8 (<0.1)				DNEL = 46.7µg/kg bw/day

Component	Acute effects local (Inhalation)	Acute effects systemic (Inhalation)	Chronic effects local (Inhalation)	Chronic effects systemic (Inhalation)
Tartrazine 1934-21-0 (<1)				DNEL = 372.52mg/m ³
Sodium azide 26628-22-8 (<0.1)				DNEL = 0.164mg/m ³
Ethylenediaminetetraacetic acid, disodium salt dihydrate 6381-92-6 (<1)	DNEL = 3 mg/m ³	DNEL = 3 mg/m ³	DNEL = 0,6 mg/m ³	DNEL = 1,5 mg/m ³

Predicted No Effect Concentration (PNEC)

See values below.

Component	Fresh water	Fresh water	Water Intermittent	Microorganisms in	Soil (Agriculture)
		sediment		sewage treatment	
Tartrazine	PNEC = 0.12mg/L	PNEC =	PNEC = 1.2mg/L	PNEC = 10mg/L	PNEC =
1934-21-0 (<1)	_	0.46992mg/kg	_	_	0.02353mg/kg soil
		sediment dw			dw
Sodium azide	$PNEC = 0.35 \mu g/L$	$PNEC = 16.7 \mu g/kg$	$PNEC = 3.5 \mu g/L$	PNEC = 30µg/L	
26628-22-8 (<0.1)		sediment dw			
Ethylenediaminetetraacetic	PNEC = 2,5 mg/l				PNEC = 1,1 mg/kg
acid, disodium salt	-				
dihydrate					
6381-92-6 (<1)					

Component	Marine water	Marine water	Marine water	Food chain	Air
		sediment	intermittent		
Tartrazine	PNEC = 0.012mg/L	PNEC =			
1934-21-0 (<1)		0.046992mg/kg			
		sediment dw			
Sodium azide	PNEC = 15ng/L	$PNEC = 0.72 \mu g/kg$	PNEC = 150ng/L		
26628-22-8 (<0.1)		sediment dw	-		
Ethylenediaminetetraacetic	PNEC = 0,25 mg/l				
acid, disodium salt					
dihydrate					
6381-92-6 (<1)					

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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 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)
Flammability (solid,gas)
Not applicable
Explosion Limits
Not applicable

Flash Point Not applicable Method - No information available

Autoignition Temperature Not applicable

Decomposition TemperatureNo information available

pH 7.0-7.2

Viscosity No data available

Water Solubility Soluble

Solubility in other solvents No information available

Partition Coefficient (n-octanol/water)
Component log Pow

Tartrazine -1.572
Sodium azide 0.3

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Vapor Pressure No data available
Density / Specific Gravity No data available

Bulk Density
No data available
No data available
No data available

Vapor DensityNo data available(Air = 1.0)Particle characteristicsNot applicable (liquid)

9.2. Other information

Explosive PropertiesOxidizing Properties
Not explosive Not oxidising

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 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
Tartrazine	LD50 > 2000 mg/kg (Rat)		
Sodium azide	LD50 = 27 mg/kg (Rat)	20 mg/kg (Rabbit)	37 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.

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Skin No data available.

(e) germ cell mutagenicity; No data available.

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

Component	Test method	Test species / Duration	Study result
Sodium azide			No ingredient of this product
			present at levels greater than or
			equal to 0.1% is identified as
			probable, possible or confirmed
			human carcinogen by IARC.

(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.

Component	Other Adverse Effects
Sodium azide	Symptoms of overexposure are dizziness, headache, tiredness,
	nausea, unconsciousness, cessation of breathing. Harmful to
	central nervous system and heart. Fatal if swallowed.

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
Sodium azide	LC50 96 h 0.7 mg/L	EC50 4.2 mg/l 48 h (EC50 38.5 mg/l (
	LC50 96 h	Daphnia pulex)	IC50 272 mg/l (green	Photobacterium
	LC50 0.7 mg/l 96 H (algae)	phosphoreum)
	Lepomis macrochirus)			

12.2. Persistence and degradability No information available.

12.3. Bioaccumulative potential No information available.

Component	log Pow	Bioconcentration factor (BCF)
Tartrazine	-1.572	
Sodium azide	0.3	

12.4. Mobility in soil No information available.

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12.5. Results of PBT and vPvB

assessment

Substance is not considered persistent, bioaccumulative and toxic (PBT) / very persistent

and very bioaccumulative (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 Ozone Depletion Potential This product does not contain any known or suspected substance. 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

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Component	EINECS	ELINCS	NLP	TSCA	DSL	NDSL	PICCS	ENCS	IECSC	AICS	KECL
Tartrazine	217-699-5	-		Х	Х	-	Х	Х	Χ	Х	KE-0685
											7
Sodium azide	247-852-1	-		Х	Х	-	Х	Х	Χ	Χ	KE-3135
											7
Ethylenediaminetetraacetic	-	-		-	Х	-	X	X	Х	Х	-
acid, disodium salt dihydrate											

Component	REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous Substances	
Tartrazine	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
Sodium azide	H2 50-200 ton, E1 100-200 ton	H2 50-200 ton, E1 100-200 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
Tartrazine	WGK1	
Sodium azide	WGK2	
Ethylenediaminetetraacetic acid,	WGK2	
disodium salt dihydrate		

UK - Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment. Take note of Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values .

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

H300 - Fatal if swallowed

H332 - Harmful if inhaled

H373 - May cause damage to organs through prolonged or repeated exposure if inhaled

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

EUH032 - Contact with acids liberates very toxic gas

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

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

ENCS - Japanese Existing and New Chemical Substances AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

WEL - Workplace Exposure Limit

TWA - Time Weighted Average

ACGIH - American Conference of Governmental Industrial Hygienists **DNEL** - Derived No Effect Level

IARC - International Agency for Research on Cancer

Predicted No Effect Concentration (PNEC)

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RPE - Respiratory Protective Equipment LD50 - Lethal Dose 50%

LC50 - Lethal Concentration 50%EC50 - Effective Concentration 50%NOEC - No Observed Effect ConcentrationPOW - Partition coefficient Octanol:WaterPBT - Persistent, Bioaccumulative, ToxicvPvB - 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.

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Revision Summary SDS sections updated, 3, 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