

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

TSH Receptor Antibody ELISA (ElisaRSR™ TRAb 2nd Generation)
 Catalogue no: EA101/96 (REF) TRE/96/2A

1.2 Relevant identified uses of the substance or mixture and uses advised against:

Quantitative determination of TSH Receptor antibodies in human serum

1.3 Details of the supplier of the safety data sheet:

DLD Diagnostika GmbH
 Adlerhorst 15
 22459 HAMBURG, GERMANY
 Phone: +49405558710; Fax: +494055587111
 Email: contact@dld-diagnostika.de

1.4 Emergency telephone number:

+49(0)40-5558710 (Mon – Fri, except public holidays, 8.00 – 15.30)


SECTION 2: Hazards identification**2.1 Classification of the substance or mixture**

Classification according to Regulation (EC) No. 1272/2008 [CLP]:

Kit Component	Hazard Classification	Hazard Statements
Streptavidin Peroxidase (SA-POD)	Skin Sensitisation, Category 1	H317
Peroxidase Substrate (TMB)	Reproductive Toxicity, Category 1B	H360D


2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]:

STREPTAVIDIN PEROXIDASE (SA-POD)	
Hazard pictogram	 Signal word: Warning
Hazard statement(s)	
H317	May cause an allergic skin reaction
Precautionary statement(s)	
P261	Avoid breathing mist, vapours
P272	Contaminated work clothing should not be allowed out of the workplace
P280	Wear protective gloves/protective clothing/eye protection/face protection
P302 + P352	IF ON SKIN: Wash with plenty of soap and water
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention
P362 + P364	Take off contaminated clothing and wash it before reuse

P501	Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation
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PEROXIDASE SUBSTRATE (TMB)

Hazard pictogram	 Signal word: Danger
Hazard statement(s)	
H360D	May damage the unborn child
Precautionary statement(s)	
P202	Do not handle until all safety precautions have been read and understood
P280	Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313	IF exposed or concerned: Get medical advice/attention
P501	Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

2.3 Other Hazards

All other kit components not listed in section 2.1 and 2.2 do not contain hazardous ingredients in concentrations which meet the criteria for classification according to Regulation (EC) No. 1272/2008. However, ingestion or exposure to large amounts from improper handling can be potentially hazardous.

This kit contains both animal and human proteins and should be treated as a potential biohazard. All animal and human sera have been tested to ensure the absence of infectious agents but all materials should be handled as though capable of transmitting infectious disease and disposed of accordingly.

TSH Receptor Antibody ELISA kit components ingredients listed in 3.2 have not been identified as having endocrine disrupting properties according to Regulation (EU) 2017/2100 and does not meet the criteria for vPvB and PBT according to Regulation (EC) No. 1907/2006 Annex XIII.

The following precautionary statements should be taken into consideration: P233, P270, P281, P301 + P330 + P331, P302 + P352, P304 + P340, P305 + P351 + P338 (see section 16 for full text).

SECTION 3: Composition/information on ingredients**3.1 Substances**

Not applicable

3.2 Mixtures

Hazardous ingredients according to Regulation (EC) No. 1272/2008:					
PEROXIDASE SUBSTRATE (TMB)					
Ingredient(s)	CAS No.	EC No.	Classification (GHS)	Conc. (v/v)	Conc. Limits
SeramunBlau® fast2	N/A	N/A	Repr. 1B; H360D	≤100%	≥0.3%
<u>Contains 2-pyrrolidone:</u> CAS No. 616-45-5 EC No. 210-483-1 Concentration: 1-3% Classification: Eye Irrit. 2, H319; Repr.1B, H360D					
STREPTAVIDIN PEROXIDASE (SA-POD)					
Ingredient(s)	CAS No.	EC No.	Classification (GHS)	Conc. (v/v)	Conc. Limits
StabilZyme® HRP Conjugate Stabilizer	N/A	N/A	Skin Sens. 1; H317	>99%	≥0.1%
<u>Contains 2-methyl-2H-isothiazol-3-one:</u> CAS No. 2682-20-4 EC No. 613-167-00-5 Concentration: 0.0126% Classification: Skin Corr. 1C, H314; Skin Sens. 1A, H317; Aquatic Acute 1, H400; Aquatic Chronic 1, H410 <u>Specific Concentration Limits:</u> C≥0.6% Skin Corr. 1C, H314					
<u>Contains CMIT/MIT: Mixture, 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):</u> CAS No. 55965-84-9 EC No. 613-167-00-5 Concentration: 0.0024% Classification: Acute Tox. 3 (Oral), H301, Acute Tox. 2 (Dermal), H310; Acute Tox. 3 (Inhalation), H330; Eye Dam. 1, H318; Skin Corr. 1C, H314; Skin Sens. 1A, H317; Aquatic Acute 1, H400; Aquatic Chronic 1, H410 <u>Specific Concentration Limits:</u> C ≥ 0.0015% Skin Sens. 1, H317 C≥0.06% Eye Dam. 1, H318					
The following kit components contain ingredients which are considered hazardous but are not present in high enough concentrations to be classified under Regulation (EC) No. 1272/2008.					

Stop Solution	Sulphuric Acid	CAS No. 7664-93-9 EC No. 231-639-5	Met. Corr. 1, Skin Corr. 1A; H290, H314	<5%	Skin Corr. 1A C≥15% Skin Irrit. 2 5%≤C<15% Eye Irrit. 2 5%≤C<15% Met. Corr. 1* C≥0.3%
Concentrated Wash Solution	2-Methyl-4-isothiazolin-3-one hydrochloride (MIT)	CAS No. 26172-54-3 EC No. 247-499-3	Acute Tox. 3 (Oral & Dermal), Acute Tox. 2 (inhalation), Skin Corr. 1A, Skin Sens. 1A, Aquatic Chronic 1; H301, H311, H314, H317, H330, H410	<0.1%	Acute Tox. 3 (Oral & Dermal) C≥0.1% Acute Tox. 2 (Inhalation) C≥0.1% Skin Corr 1A C≥5% Skin Irrit. 2 1%≤C<5% Skin Sens. 1A C≥0.1% Aquatic Chronic 1 C≥0.1%
Diluent for SA-POD Concentrated Wash Solution	2-Chloroacetamide	CAS No. 79-07-2 EC No. 201-174-2	Acute Tox. 3 (Oral), Skin Sens. 1. Repr. 2; H301, H317, H361f	<0.1%	Acute Tox. 3 (Oral) C≥0.1% Skin Sens. 1 C≥0.1% Repr. 2 C≥3%
Reconstitution Buffer for TSHR-Biotin Start Buffer Calibrators Controls	Sodium Azide	CAS No. 26628-22-8 EC No. 247-852-1	Acute Tox. 2 (Oral & Inhalation), Acute Tox. 1 (Dermal), STOT RE 2, Aquatic Acute 1, Aquatic Chronic 1; H300, H310, H330, H373, H400, H410, EUH032	<0.1%	Acute Tox. 2 (Oral & Inhalation) C≥0.1% Acute Tox. 1 (Dermal) C≥0.1% STOT RE 2 C≥10% Aquatic Acute 1 C≥0.1% Aquatic Chronic 1 C≥0.1%

*Please note that corrosive to metals does not need to be on the label of Stop Solution as it is exempt under 1.5.2.1.3. of Regulation (EC) No. 1272/2008.

TSH receptor coated wells, TSH-Biotin, reconstitution buffer for TSH-Biotin, calibrators and controls contain animal proteins and/or human proteins and should be treated as potential biohazards.

The full text for the hazard statements can be found in section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

After skin contact

Wash off skin thoroughly with water for at least 15 minutes. Remove contaminated clothing. In severe cases or if skin is broken, OBTAIN MEDICAL ATTENTION.

After eye contact

Separate eyelids with fingers and flush eye with copious amounts of water for at least 15 minutes. OBTAIN MEDICAL ATTENTION.

Component(s)	Ingredient	Number	Classification (GHS)	Conc. (v/v)	Conc. Limits (v/v)

After Inhalation

Remove from exposure, rest and keep warm. If breathing becomes difficult, OBTAIN MEDICAL ATTENTION.

After Ingestion

If patient is conscious, wash out mouth with water and give plenty of water to drink. OBTAIN MEDICAL ATTENTION.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: Firefighting measures**5.1 Extinguishing media**

Use water, dry powder or foam as appropriate to supporting fire.

5.2 Special hazards arising from the substance or mixture

May evolve toxic fumes in fire. Hazardous combustion products are not known for kit components but combustion products for the ingredients listed in subsection 3.2 can be found in the following table:

Ingredient	Hazardous Combustion Product(s)
2-Chloroacetamide	Carbon oxides, nitrogen oxides (NO _x) and hydrogen chloride gas
MIT	Carbon oxides, nitrogen oxides (NO _x), sulphur oxides and hydrogen chloride gas
SeramunBlau® Fast2	Carbon oxides and nitrogen oxides (NO _x)
Sodium Azide	Nitrogen oxides (NO _x)
StabilZyme® HRP Conjugate Stabilizer	Carbon oxides and nitrogen oxides (NO _x)
Sulphuric Acid	Sulphur oxides

5.3 Advice for firefighters

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Wear appropriate protective clothing as described in subsection 8.2. Ventilate area and avoid breathing vapours, mist or gas.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Prevent any reagents from entering drains.

6.3 Methods and material for containment and cleaning up

Wipe up liquid spills with absorbent paper. For solid spills, sweep up without raising dust. Once pick up is complete. Wash site with detergent and water.

Decontaminate with a suitable disinfectant solution.

6.4 Reference to other sections

See sections 8 and 13.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Material of human origin has been tested and found non-reactive for HIV 1 and 2 and HCV antibodies and HBsAg. All animal sourced material has been obtained from animals certified as healthy and free from disease. However all potentially biohazardous components should be considered as potentially infectious. Level 2 containment should be applied.

Do not eat, drink or smoke in the laboratory. Do not pipette by mouth. Avoid skin and eye contact. Wear appropriate protective clothing as described in subsection 8.2. Avoid the use of needles or other sharp implements. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Avoid release into drains; in case of accidental spillage, refer to section 6.

7.2 Conditions for safe storage, including any incompatibilities

Keep containers tightly closed. Store in a dry place in the box supplied at a temperature between +2 and +8°C.

7.3 Specific end use(s)

The TSH Receptor Antibody ELISA kit is intended for professional use only and to be used solely for the purpose as specified in subsection 1.2. Refer to kit instructions for details.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters**

No occupational exposure limits exist for any kit components. However, exposure limits apply to the following ingredients (see subsection 3.2 for components containing these substances):

Value*	Control Parameters	Basis
Sodium Azide		
TWA	0.1 mg/m ³	UK: EH40 Workplace Exposure Limits (WEL)
STEL	0.3 mg/m ³	Europe: Commission Directive 2000/39/EC
Sulphuric Acid		
TWA	0.05 mg/m ³	UK: EH40 Workplace Exposure Limits (WEL) Europe: Commission Directive 2009/161/EU

Stabilzyme® HRP Conjugate Stabilizer

TRGS 900 Occupational exposure limit value	0.2 mg/m ³ inhalable fraction
TRGS 900 Limitation of exposure peaks	0.4 mg/m ³ inhalable fraction

*Definitions can be found in section 16

8.2 Exposure controls**Appropriate engineering controls**

Good laboratory practice should be followed (see Section 7). Avoid contact with skin or eyes. Wash hands after use.

Individual protection measures (personal protective equipment)**Eye/face protection**

Chemical safety glasses or goggles conforming to appropriate government standards such as EN166 (EU) or NIOSH (US).

Skin and body protection

Chemical resistant gloves to be used in accordance with standard EN374 derived from Regulation (EU) 2016/425. Inspect gloves for damage prior to use and change if any sign of degradation. Proper glove removal technique must be used. Wash hands after use.

The following are suitable as protective gloves:

Glove materials: Nitrile rubber

Glove Thickness: ≥ 0.4 mm thickness

Permeation Time: ≥ 480 min

This recommendation is advisory only and should be evaluated by the customer for suitability in their specific situation.

Respiratory protection

Local exhaust.

Environmental exposure controls

Prevent further leakage or spillage if safe to do so. Prevent any reagents from entering drains.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Kit component	Appearance	Odour	pH	Solubility
TSH Receptor Coated Wells	Colourless polystyrene microplate	None	N/A	N/A
TSH-Biotin	White solid	None	N/A	In water
Reconstitution Buffer for TSH-Biotin	Pink liquid	None	~7.8	N/A
Streptavidin Peroxidase (SA-POD)	Pale brown liquid	None	N/A	N/A

Kit component	Appearance	Odour	pH	Solubility
Diluent for SA-POD	Colourless liquid	None	~7.5	N/A

Peroxidase Substrate (TMB)	Colourless to slight blue liquid	None	N/A	N/A
Start Buffer	Yellow liquid	None	~7.8	N/A
Stop Solution (0.5M sulphuric acid)	Colourless liquid	May be slightly sulphurous	<1.0	N/A
Concentrated Wash Solution	Colourless liquid	None	~7.8	N/A
Calibrators and Controls	Colourless to pale yellow liquid	None	N/A	N/A

There is no information available for the following categories: odour threshold, melting/freezing point, initial boiling point/boiling range, flash point, evaporation rate, flammability (solid, gas), upper/lower flammability or explosive limits, vapour pressure, relative vapour density, relative density, particle characteristics, partition coefficient, autoignition temperature, decomposition temperature, kinematic viscosity, explosive properties or oxidising properties.

9.2 Other information

All liquid components are miscible with water in all proportions.

SECTION 10: Stability and reactivity**10.1 Reactivity**

Data is not available on the reactivity of individual kit components but is given, where available, on ingredients listed in subsection 3.2.

Sulphuric acid is a strong oxidising agent and has a corrosive effect. There is no data available on the other ingredients.

10.2 Chemical stability

All components of the TSH Receptor Antibody ELISA kit have been found stable for stated shelf life when stored under the recommended conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known for kit components although, hazardous reactions occur for the following ingredients listed in subsection 3.2:

Ingredient	Hazardous Reaction
Sodium Azide	Risk of explosion and/or toxic gas formation exists with heavy metals, bromine, lead, chromyl chloride, dichloromethane, dimethylsulfate, halogenated hydrocarbon, acid, carbon disulphide, sulphuric acid, copper and nitric acid. Generates dangerous gases or fumes with acids and water, leading to the release of hydrazoic acid. Violent reactions possible with nitrates, benzoyl chloride and potassium nitrate.

Sulphuric Acid	Violent reactions possible with: Water, alkali metals, alkali compounds, ammonia, aldehydes, acetonitrile, alkaline earth metals, alkalines, acids, alkaline earth compounds, metals, metal alloys, oxides of phosphorus, phosphorus, hydrides, halogen-halogen compounds, oxyhalogenic compounds, permanganates, nitrates, carbides, combustible substances, organic solvent, acetylidene, nitriles, organic nitro compounds, anilines, peroxides, picrates, nitrides, lithium silicide, iron (III) compounds, bromates, chlorates, amines, perchlorates and hydrogen peroxide.
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10.4 Conditions to avoid

Peroxidase substrate (TMB) is light, heat and moisture sensitive, exposure to these conditions will reduce the quality of the product. Therefore the bottle should be kept tightly closed when not in use and stored in a dark place. Proteins, sodium azide and sulphuric acid are heat sensitive and storage or use at the improper temperature may compromise the integrity of the kit.

10.5 Incompatible materials

No data is known for kit components but the following data is known for ingredients listed in subsection 3.2:

Ingredient	Incompatible Materials
2-Chloroacetamide	Strong oxidising agents, strong acids, strong bases and strong reducing agents
MIT	Strong oxidising agents
SeramunBlau® Fast2	Strong oxidising agents and metals
Sodium Azide	Aluminium and heavy metals
StabilZyme® HRP Conjugate Stabilizer	None known
Sulphuric Acid	Animal and vegetable tissues. Metals. Contact with metals liberates hydrogen gas

10.6 Hazardous decomposition products

No decomposition products are formed if kit is stored and used under the specified storage and handling conditions. May evolve toxic fumes in fire. Thermal decomposition products are not known for the kit components but hazardous combustion products of the ingredients listed in subsection 3.2 can be found in subsection 5.2.

SECTION 11: Toxicological information**11.1 Information on toxicological effects**

The kit components have not been directly tested for their toxicological effects, therefore no information is known for these mixtures. The following toxicological data is known for ingredients listed in subsection 3.2:

(a) Acute toxicity

*Definitions can be found in section 16

Ingredient	Measurement*	Value	Species
2-Chloroacetamide	LD ₅₀ (Oral)	138 mg/kg	Rat
MIT	LD ₅₀ (Oral)	175 mg/kg	Rat
	LC ₅₀ (Inhalation)	0.11 mg/L (4h)	Rat
	LD ₅₀ (Dermal)	242 mg/kg	Rat
Sodium Azide	LD ₅₀ (Oral)	27 mg/kg	Rat
	LC ₅₀ (Inhalation)	0.054 – 0.52 mg/L (4h)	Rat
	LD ₅₀ (Dermal)	20 mg/kg	Rabbit
Sulphuric Acid	LD ₅₀ (Oral)	>2140 mg/kg	Rat
	LC ₅₀ (Inhalation)	>0.51 mg/L	Rat

No data available for other ingredients listed in subsection 3.2.

(b) Skin corrosion/irritation

Ingredient	Test/Result
MIT	Skin (reconstructed human epidermis (RhE) – Corrosive
SeramunBlau® Fast2	Based on available data, classification criteria are not met
Sodium Azide	<i>In vitro</i> study, human skin model test – No skin irritation
Sulphuric Acid	Skin – Rabbit – Result: Extremely destructive to tissue

No data available for other ingredients listed in subsection 3.2.

(c) Serious eye damage/irritation

Ingredient	Test/Result
MIT	Causes serious eye damage
SeramunBlau® Fast2	Based on available data, classification criteria are not met
Sodium Azide	Bovine cornea, exposure time 4 hours – No eye irritation
Sulphuric Acid	Causes serious eye damage – risk of blindness

No data available for other ingredients listed in subsection 3.2.

(d) Respiratory or skin sensitisation

Ingredient	Test/Result
2-Chloroacetamide	Maximisation test, Guinea pig – May cause sensitisation by skin contact
MIT	Maximisation test, Guinea pig – Result: Positive Local lymph node assay (LLNA) – Result: Positive – Sub-category 1A
SeramunBlau® Fast2	Based on available data, classification criteria are not met
Sodium Azide	Sensitisation test (dermal), Local lymph node assay (LLNA) – Mouse – Result: Negative
StabilZyme® HRP Conjugate Stabilizer	May cause an allergic skin reaction

(e) Germ cell mutagenicity

Ingredient	Test/Result
2-Chloroacetamide	Hamster, lungs – Negative

	Mouse, male and female – Negative
MIT	Ames test: Salmonella typhimurium – Negative, Mouse – Negative, Rat – Negative
SeramunBlau® Fast2 Sodium Azide	Based on available data, classification criteria are not met Chromosome aberration: Chinese hamster ovary cells – Negative Unscheduled DNA Synthesis assay: Chinese hamster lung cells – Negative Sister Chromatid exchange assay: Chinese hamster ovary cells – Negative
Sulphuric Acid	Ames test: Salmonella typhimurium – Negative

No data available for other ingredients listed in subsection 3.2.

(f) Carcinogenicity

Ingredient	Test/Result
2-Chloroacetamide	IARC: No component of this product present at levels $\geq 0.1\%$ is identified as probable, possible or confirmed human carcinogen by IARC
MIT	
SeramunBlau® Fast2	Based on available data, classification criteria are not met

No data available for other ingredients listed in subsection 3.2.

(g) Reproductive toxicity

Ingredient	Test/Result
2-Chloroacetamide	Suspected human reproductive toxicant
SeramunBlau® Fast2	Toxic for reproduction category 1 - May damage fertility or the unborn child.
MIT	Effects on foetal development – Rat – Oral 40 mg/kg bw/day – Result: Negative

No data available for other ingredients listed in subsection 3.2.

(h) STOT-single exposure

Ingredient	Test/Result
SeramunBlau® Fast2	Based on available data, classification criteria are not met

No data available for other ingredients listed in subsection 3.2.

(i) STOT-repeated exposure

Ingredient	Test/Result
SeramunBlau® Fast2	Based on available data, classification criteria are not met
Sodium Azide	Oral – may cause damage to organs through prolonged or repeated exposure - Brain

No data available for other ingredients listed in subsection 3.2.

(j) Aspiration hazard

Ingredient	Test/Result
SeramunBlau® Fast2	Based on available data, classification criteria are not met

No data available for other ingredients listed in subsection 3.2.

11.2 Information on other hazards

(a) Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to Commission Regulations (EU) 2017/2100 and (EU) 2018/605.

(b) Other information

As the kit components have not been tested for their toxicological effects, other hazardous properties cannot be excluded but are unlikely when the product is handled appropriately.

SECTION 12: Ecological information

The kit components have not been tested for their ecological effects, therefore no information is known for these mixtures. The following ecological data is known for ingredients listed in subsection 3.2:

12.1 Toxicity

*Definitions can be found in section 16

Ingredient	Toxicity to	Measurement*	Value
2-Chloroacetamide	Fish (<i>Carassius auratus</i> (goldfish))	LC ₅₀	19.8 mg/L (96h)
	Daphnia (<i>Daphnia magna</i> (water flea))	EC ₅₀	14 mg/L (48h)
MIT	Fish (<i>Oncorhynchus mykiss</i> (rainbow trout))	LC ₅₀	4.77 mg/L (96h)
	Daphnia (<i>Daphnia magna</i> (water flea))	EC ₅₀	2.33 mg/L (48h) (Static)
	Daphnia (<i>Daphnia magna</i> (water flea))	EC ₅₀	0.998 mg/L (48h) (Flow through)
	Algae (<i>Pseudokirchneriella subcapitata</i> (green algae))	ErC ₅₀	0.289 mg/L (72h)
Sodium Azide	Fish (<i>Oncorhynchus mykiss</i> (rainbow trout))	LC ₅₀	2.75 mg/L (96h)
	Algae (<i>Pseudokirchneriella subcapitata</i>)	ErC ₅₀	0.35 mg/L (96h)
StabilZyme® HRP Conjugate Stabilizer	Fish (<i>Oncorhynchus mykiss</i> (rainbow trout))	LC ₅₀	0.19 mg/L
	Daphnia & other aquatic invertebrates (<i>Crassostrea virginica</i> (eastern oyster))	EC ₅₀	0.028 mg/L
	Algae (<i>Raphidocelis subcapitata</i> (green algae))	EC ₅₀	0.018 mg/L (72h)
Sulphuric Acid	Daphnia & other aquatic invertebrates (<i>Daphnia magna</i> (water flea))	EC ₅₀	>100 mg/L (48h)

Algae (<i>Desmodesmus subspicatus</i> (green algae))	ErC ₅₀	>100 mg/L (72h)
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No data available for other ingredients listed in subsection 3.2.

12.2 Persistence and degradability

Ingredient	Test/Result
2-Chloroacetamide	Biodegradability: aerobic, exposure time 28 days Results: 94% - Readily degradable
MIT	Biodegradability: aerobic, exposure time 28 days Results: 0% - Not readily degradable
StabilZyme® HRP Conjugate Stabilizer	Not rapidly degradable

No data available for other ingredients listed in subsection 3.2.

12.3 Bioaccumulative potential

Ingredient	Test/Result
MIT	Partition coefficient: n-octanol/water – log Pow: -0.44
StabilZyme® HRP Conjugate Stabilizer	Log Kow: >5 (significant bioaccumulation)

No data available for other ingredients listed in subsection 3.2.

12.4 Mobility in soil

No data available for ingredients listed in subsection 3.2.

12.5 Results of PBT and vPvB assessment

Ingredient	Test/Result
2-Chloroacetamide MIT, Sodium Azide	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of $\geq 0.1\%$

No data available for other ingredients listed in subsection 3.2.

12.6 Endocrine disrupting properties

The ingredients listed in subsection 3.2 do not have endocrine disrupting properties with respect to non-target organisms as it does not meet the criteria set out in section B of Regulation (EU) No 2017/2100.

12.7 Other adverse effects

The concentrations of ingredients listed in subsection 3.2 are below the acceptable limit for hazardous substances; the ecological risk is minimal. However, it is recommended that reagents do not enter drains in large quantities

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Chemical and biological residues are classified as special waste and as such, are covered by regulations which may vary according to location. Contact your local waste disposal authority for advice or pass to a licensed disposal company. Observe all national and local environmental regulations. Contaminated packaging should be disposed of using the same routes.

SECTION 14: Transport information

This product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID).

Transport of this product can be carried out at ambient temperature but in the event of delays store at 2 – 8°C with all reagents contained within the packaging provided.

14.1 UN number or ID number

Not applicable.

14.2 UN proper shipping name

Not applicable.

14.3 Transport hazard class(es)

Not applicable.

14.4 Packing group

Not applicable.

14.5 Environmental hazards

Not applicable.

14.6 Special precautions for user

See sections 6 to 8.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture.

None known.

15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for the TSH Receptor Antibody ELISA kit by the manufacturer.

SECTION 16: Other information

This SDS has been compiled in accordance with Commission Regulation (EC) No. 1907/2006 as amended by Commission Regulation (EU) 2020/878.

All information provided on ingredients listed in subsection 3.2 has been obtained from the appropriate chemical safety data sheets.

Full text of precautionary statements (listed in subsection 2.3) and hazard statements (listed in subsection 3.2) according to Regulation (EC) No. 1272/2008:

P202: Do not handle until all safety precautions have been read and understood.

P233: Keep container tightly closed.

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.

P270: Do not eat, drink or smoke when using this product.

P272: Contaminated work clothing should not be allowed out of the workplace.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P281: Use personal protective equipment as required.
 P301 + P330 + P331: IF SWALLOWED rinse mouth. Do NOT induce vomiting.
 P302 + P352: IF ON SKIN: Wash with plenty of soap and water.
 P304 + P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
 P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing.
 P308 + P313: IF exposed or concerned: Get medical advice/attention.
 P333 + P313: If skin irritation or rash occurs: Get medical advice/attention.
 P362 + P364: Take off contaminated clothing and wash before reuse.
 P501: Dispose of contents/container in accordance with local / regional / national / international regulations.

H290: May be corrosive to metals.
 H300: Fatal if swallowed.
 H301: Toxic if swallowed.
 H310: Fatal in contact with skin.
 H311: Toxic in contact with skin.
 H314: Causes severe skin burns and eye damage.
 H317: May cause an allergic skin reaction.
 H318: Causes serious eye damage.
 H319: Causes serious eye irritation.
 H330: Fatal if inhaled.
 H360D: May damage the unborn child.
 H361f: Suspected of damaging fertility.
 H373: May cause damage to organs through prolonged or repeated exposure.
 H400: Very toxic to aquatic life.
 H410: Very toxic to aquatic life with long lasting effects.
 EUH032: Contact with acids liberates toxic gas.

Definitions:

LC50: The lethal concentration of a substance that kills 50% of the test population within a designated period.

LD50: Lethal dose for 50% of the test population.

EC50: The effective concentration of a substance that causes adverse effects in 50% of the test population within a designated period.

ErC50: The effective concentration of a substance that causes 50% reduction in growth rate of the test population within a designated period.

STEL: Short term exposure limit (15 minute reference period).

TWA: Time weighted average, long term exposure limit (8 hour reference period).

The above information is believed to be correct but does not purport to be all-inclusive and is provided for guidance only. DLD Diagnostika GmbH shall not be held liable for any damage or injury resulting from handling or from contact with the above product and assumes no responsibility to the accuracy or completeness of the data contained herein. It is the responsibility of the purchaser to ensure that laboratory workers who

use this product are aware of its hazards and take all necessary precautions to prevent contact, ingestion, inhalation or any other mode of exposure.

REVISION INFORMATION

Revision Number	Effective Date	Description of Changes
18	22 nd May 2023	Revision of SDS to meet (EU) 2020/878 – changes throughout.