

**1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY****1.1 Product identifier**

Product Name: TSH Receptor Autoantibody ELISA 3<sup>rd</sup> generation

Catalog #: KAPD4834

Kit Components: Microtiterwells  
Incubation Buffer  
Calibrators  
Controls  
Biotin Conjugate  
Streptavidin Peroxidase  
Diluent for Streptavidin Peroxidase  
Chromogenic TMB  
Stop Solution  
Wash Solution

**1.2 Intended Use**

Components of an *in-vitro* diagnostic device

Detection of TSH Receptor antibodies in human serum.

**1.3 Company**

DIAsource ImmunoAssays S.A.

Rue du Bosquet, 2

B-1348 Louvain-la-Neuve

Belgium

Tel. Nr. +32 (0)10/84.99.11

E-mail: [products.support@diasource.be](mailto:products.support@diasource.be)

**1.4 Emergency telephone**

DIAsource (only office hours): +32 (0)10/84.99.23

Centre Anti-Poisons (BE) 070 245 245

Please refer to your local Anti-Poison Center!


**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	H360

## 2.2 Label elements

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

STREPTAVIDIN PEROXIDASE (SA-POD)	
Hazard pictogram	 <b>Signal word:</b> Warning
<b>Hazard statement(s)</b>	
H317	May cause an allergic skin reaction
<b>Precautionary statement(s)</b>	
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

CHROMOGENIC TMB	
Hazard pictogram	 <b>Signal word:</b> Danger
<b>Hazard statement(s)</b>	
H360	May damage fertility or the unborn child
<b>Precautionary statement(s)</b>	
P280	Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313	IF exposed or concerned: Get medical advice/attention

### Other labeling:

Microplate : Each well can only be used once



## 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.

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).

### 3 COMPOSITION/INFORMATION ON INGREDIENTS

#### Mixtures

#### Hazardous ingredients according to Regulation (EC) No. 1272/2008:

CHROMOGENIC TMB				
Ingredient(s)	CAS No.	EC No.	Classification (GHS)	Conc. (v/v)
SeramunBlau® Fast2	N/A	N/A	Repr. 1B; H360	≤ 100%
<u>Contains 2-pyrrolidone:</u>				
CAS No.	616-45-5			
EC No.	210-483-1			
Concentration:	1 - <5%			
Classification:	Eye Irrit. 2, H319; Repr.1B, H360			

STREPTAVIDIN PEROXIDASE (SA-POD)				
Ingredient(s)	CAS No.	EC No.	Classification	Conc. (v/v)
Stabilzyme® HRP Conjugate Stabilizer	N/A	N/A	Skin Sens. 1; H317	>99%
<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, Dermal & Inhalation) H301, H311 & H331; Skin Corr. 1B, H314; Skin Sens. 1, H317; Aquatic Acute 1, H400; Aquatic chronic 1, H410			
<u>Specific Concentration Limits:</u>				
	$C \geq 0.0015\%$		Skin Sens. 1, H317	
	$0.06\% \leq C < 0.6\%$		Eye Irrit. 2, H319	
	$0.06\% \leq C < 0.6\%$		Skin Irrit. 2, H315	
	$C \geq 0.6\%$		Skin Corr. 1B, H314	

Biotin Conjugate, Incubation Buffer, Calibrators and Controls contain animal proteins and/or human proteins and should be treated as potential biohazards.

The ingredients listed for the kit components below are considered hazardous but are not present in high enough concentrations to be classified under Regulation (EC) No 1272/2008.

Kit Component	Ingredient(s)	Concentration
Biotin Conjugate	Tergitol™	0.1% v/v
	Sodium azide	0.04% w/v
Incubation Buffer	Tergitol™	0.5% v/v
	Sodium azide	0.04% w/v
Diluent for SA-POD	2-Chloroacetamide	0.04% w/v
	N-Methylisothiazolone (MIT)	0.008% w/v
Stop Solution	Sulphuric acid (0.5M)	0.5 M (<5% v/v)
Concentrated Wash Solution	Tergitol™	0.5% v/v
	2-Chloroacetamide	0.05% w/v
	Antifoam A	0.01% v/v
	MIT	0.01% w/v
Calibrators and Controls	Oxypyron	0.2% w/v
	Sodium azide	0.05% w/v

<b>Ingredient</b>	<b>CAS No.</b>	<b>EC No.</b>	<b>Classification GHS</b>
Antifoam A	N/A	N/A	Eye Irrit. 2, STOT SE 3; <i>H319, H335</i>
2-Chloroacetamide	79-07-2	201-174-2	Acute Tox. 3 (Oral), Skin Sens. 1, Repr. 2; <i>H301, H317, H361f</i>
MIT	26172-54-3	247-499-3	Acute Tox. 3 (Oral & Dermal), Acute Tox. 2 (inhalation), Skin Corr. 1A, Skin Sens. 1A, Aquatic Chronic 1; <i>H301, H311, H314, H317, H330, H410</i>
Oxypyrrion	822-89-9	215-506-0	Acute Tox. 4, Eye Irrit. 2, STOT SE 3; <i>H302, H319, H335</i>
Sodium Azide	26628-22-8	247-852-1	Acute Tox. 2 (Oral), Acute Tox. 1 (Dermal), STOT RE 2, Aquatic Acute 1, Aquatic Chronic 1; <i>H300, H310, H373, H400, H410, EUH302</i>
Sulphuric Acid	7664-93-9	231-639-5	Met. Corr. 1, Skin Corr. 1A; <i>H290, H314</i>
Tergitol™	84133-50-6	617-534-0	Acute Tox. 4 (Oral & Inhalation), Skin Irrit. 2, Eye Dam. 1; <i>H302, H315, H318, H332</i>

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

## **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.

#### **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.

## **5 FIRE FIGHTING MEASURES**

### **5.1 Suitable 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:

<b>Ingredient</b>	<b>Hazardous Combustion Product(s)</b>
Antifoam A	Nature of decomposition products not known.
2-Chloroacetamide	Carbon oxides, nitrogen oxides (NOx) and hydrogen chloride gas
MIT	Carbon oxides, nitrogen oxides (NOx), sulphur oxides and hydrogen chloride gas
Oxyprion	No data available
Sodium Azide	Nitrogen oxides (NOx)
Stabilzyme® HRP Conjugate Stabilizer	Carbon oxides and nitrogen oxides (NOx)
Sulphuric Acid	Sulphur oxides
Tergitol™	Nature of decomposition products not known

### **5.3 Advice for firefighters**

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

## **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.

## **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 II 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 °C and +8 °C.

### **7.3 Specific end use**

The 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.

## 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
<b>Sodium Azide</b>		
TWA	0.1 mg/m <sup>3</sup>	UK: EH40 Workplace Exposure Limits (WEL)
STEL	0.3 mg/m <sup>3</sup>	Europe: Commission Directive 2000/39/EC
<b>Sulphuric Acid</b>		
TWA	0.05 mg/m <sup>3</sup>	UK: EH40 Workplace Exposure Limits (WEL)
		Europe: Commission Directive 2009/161/EU
<b>Stabilzyme® HRP Conjugate Stabilizer</b>		
TRGS 900 Occupational exposure limit value		0.2 mg/m <sup>3</sup> inhalable fraction
TRGS 900 Limitation of exposure peaks		0.4 mg/m <sup>3</sup> inhalable fraction

\*Definitions can be found in section 16

<b>Stabilzyme® HRP Conjugate Stabilizer</b>		
TRGS 900 Occupational exposure limit value		0.2 mg/m <sup>3</sup> inhalable fraction
TRGS 900 Limitation of exposure peaks		0.4 mg/m <sup>3</sup> inhalable fraction

### 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:  $\geq 0.4$  mm thickness

Permeation Time:  $\geq 480$  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.

## 9 PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Kit component	Appearance	Odour	pH	Solubility
Microtiterwells Wells	Colourless polystyrene microplate	None	N/A	N/A
Biotin conjugate	Pink liquid	None	N/A	In water
Streptavidin Peroxidase	Pale brown liquid	None	N/A	N/A
Diluent for Streptavidine Peroxidase	Colourless liquid	None	~7.5	N/A
Chromogenic TMB	Colourless to slight blue liquid	None	N/A	N/A
Stop Solution (0.5M sulphuric acid)	Colourless liquid	May be slightly sulphurous	<1.0	N/A
Wash Solution	Colourless liquid	None	~7.8	N/A
Incubation Buffer	Yellow 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, vapour density, relative density, partition coefficient, autoignition temperature, decomposition temperature, viscosity, explosive properties or oxidising properties.

### 9.2 Other information

All liquid components are miscible with water in all proportions.

## 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 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 substances listed in subsection 3.2:



<b>Ingredient</b>	<b>Hazardous Reaction</b>
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.

#### 10.4 Conditions to avoid

Chromogenic 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, oxypyrion, 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 components listed in subsection 3.2:

<b>Ingredient</b>	<b>Incompatible Materials</b>
Antifoam A	Strong oxidising agents and strong acids
2-Chloroacetamide	Strong oxidising agents, strong acids, strong bases and strong reducing agents
MIT	Strong oxidising agents
Oxypyrion	No data available
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
Tergitol™	Strong acids, strong bases and strong oxidising agents

#### 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.

## 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 <sub>50</sub> (Oral)	138 mg/kg	Rat
MIT	LD <sub>50</sub> (Oral)	175 mg/kg	Rat
	LC <sub>50</sub> (Inhalation)	0.11 mg/L (4h)	Rat
	LD <sub>50</sub> (Dermal)	246 mg/kg	Rat
Oxypyrron	LD <sub>50</sub> (Oral)	1765 mg/kg	Rat
	LD <sub>50</sub> (Dermal)	>2000 mg/kg	Rat
Sodium Azide	LD <sub>50</sub> (Oral)	27 mg/kg	Rat
	LC <sub>50</sub> (Inhalation)	0.054 – 0.52 mg/L (4h)	Rat
	LD <sub>50</sub> (Dermal)	20 mg/kg	Rabbit
Sulphuric Acid	No data available. Acute inhalation toxicity : mucosal irritations, cough, shortness of breath, possible damage to respiratory tract.		

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
Oxypyrron	Not classified base on available information. May cause skin irritation in susceptible persons
Sodium Azide	In vitro study, human skin model test – No skin irritation
Sulphuric Acid	Causes severe burns
Tergitol™	Irritating to skin

No data available for other ingredients listed in subsection 3.2.

**(c) Serious eye damage/irritation**

Ingredient	Test/Result
MIT	Causes serious eye damage
Oxypyrron	Causes serious eye irritation
Sodium Azide	In vitro study, exposure time 4 hours – No eye irritation
Sulphuric Acid	Causes serious eye damage – risk of blindness
Tergitol™	Causes severe eye irritation

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
Oxypyrron	Not classified based on available information
Sodium Azide	Sensitisation test, Mouse – Negative
Stabilzyme® HRP Conjugate Stabilizer	May cause an allergic skin reaction
Tergitol™	Patch test on human volunteers did not demonstrate sensitisation properties.

No data available for other ingredients listed in subsection 3.2.

**(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
Oxypyrron	Not classified based on available information

No data available for other ingredients listed in subsection 3.2.

**(f) Carcinogenicity**

Ingredient	Test/Result
Antifoam A	IARC: No component of this product present at levels $\geq 0.1\%$ is identified as probable, possible or confirmed human carcinogen by IARC
2-Chloroacetamide	
MIT	
Tergitol™	
Oxypyryon	Not classified based on available information

No data available for other ingredients listed in subsection 3.2.

**(g) Reproductive toxicity**

Ingredient	Test/Result
2-Chloroacetamide	Suspected human reproductive toxicant
Oxypyryon	Not classified based on available information

No data available for other ingredients listed in subsection 3.2.

**(h) STOT-single exposure**

Ingredient	Test/Result
Oxypyryon	May cause respiratory irritation

No data available for other ingredients listed in subsection 3.2.

**(i) STOT-repeated exposure**

Ingredient	Test/Result
Oxypyryon	Not classified based on available information

No data available for other ingredients listed in subsection 3.2.

**(j) Aspiration hazard**

Ingredient	Test/Result
Oxypyryon	Not classified based on available information

No data available for other ingredients listed in subsection 3.2.

## 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 <sub>50</sub>	19.8 mg/L (96h)
	Daphnia ( <i>Daphnia magna</i> (water flea))	EC <sub>50</sub>	14 mg/L (48h)
MIT	Fish ( <i>Oncorhynchus mykiss</i> (rainbow trout))	LC <sub>50</sub>	4.77 mg/L (96h)
	Daphnia ( <i>Daphnia magna</i> (water flea))	EC <sub>50</sub>	2.33 mg/L (48h)
	Algae ( <i>Pseudokirchneriella subcapitata</i> (green algae))	ErC <sub>50</sub>	0.289 mg/L (72h)
Oxypyryon	Fish ( <i>Oncorhynchus mykiss</i> (rainbow trout))	LC <sub>50</sub>	70.7 mg/L (96h)
	Fish ( <i>Lepomis macrochirus</i> (bluegill sunfish))	LC <sub>50</sub>	>97.8 mg/L (96h)
	Daphnia ( <i>Daphnia magna</i> (water flea))	EC <sub>50</sub>	78.6 mg/L (48h)
Sodium Azide	Fish ( <i>Lepomis macrochirus</i> (bluegill sunfish))	LC <sub>50</sub>	0.70 mg/L (96h)

	Daphnia ( <i>Daphnia pulex</i> (water flea))	EC <sub>50</sub>	4.2 mg/L (48h)
	Algae (mixed culture of green algae)	IC <sub>50</sub>	272 mg/L
	Microorganisms ( <i>Photobacterium phosphoreum</i> )	EC <sub>50</sub>	38.5 mg/L
Stabilzyme® HRP Conjugate Stabilizer	Fish ( <i>Oncorhynchus mykiss</i> (rainbow trout))	LC <sub>50</sub>	0.19 mg/L
	Daphnia & other aquatic invertebrates ( <i>Crassostrea virginica</i> (eastern oyster))	EC <sub>50</sub>	0.028 mg/L
	Algae ( <i>Raphidocelis subcapitata</i> (green algae))	EC <sub>50</sub>	0.018 mg/L (72h)

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
Oxyprion	Biodegradability: 94% - Readily degradable
Stabilzyme® HRP Conjugate Stabilizer	Not rapidly degradable
Tergitol™	Result: >60% - Readily biodegradable

No data available for other ingredients listed in subsection 3.2.

## 12.3 Bioaccumulative potential

Ingredient	Test/Result
Oxyprion	Log Pow: -0.64
Sodium Azide	Partition coefficient: n-octanol/water - log Pow: 0.3 (Bioaccumulation is not expected)
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.

## 12.5 Results of PBT and vPvB assessment

Ingredient	Test/Result
Antifoam A	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 ≥0.1%
2-Chloroacetamide	
MIT	
Oxyprion	
Sodium Azide	
Tergitol™	

No data available for other ingredients listed in subsection 3.2.

## 12.6 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.

**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.

**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 °C to 8 °C with all reagents contained within the packaging provided.

<b>UN number</b>	Not applicable.
<b>UN proper shipping name</b>	Not applicable.
<b>Transport hazard class(es)</b>	Not applicable.
<b>Packing group</b>	Not applicable.
<b>Environmental hazards</b>	Not applicable.
<b>Special precautions for user</b>	See sections 6 to 8.
<b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.

**15 REGULATORY INFORMATION****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

None known.

**15.2 Chemical safety assessment**

Not applicable.

**16 OTHER INFORMATION**

This SDS has been compiled in accordance with Commission Regulation (EC) No. 1907/2006 as amended by Commission Regulation (EU) 2015/830.

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:

P233: Keep container tightly closed.

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

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.

H290: May be corrosive to metals.

H300: Fatal if swallowed.

H301: Toxic if swallowed.

H302: Harmful if swallowed.

H310: Fatal in contact with skin.

H311: Toxic in contact with skin.

H314: Causes severe skin burns and eye damage.

H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

H318: Causes serious eye damage.

H319: Causes serious eye irritation.

H330 : Fatal if inhaled.

H331: Toxic if inhaled.

H332: Harmful if inhaled.

H335: May cause respiratory irritation.

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 concentration of a substance which results in 50% reduction in growth rate of the test population relative to the control within 72 hours exposure.

**IC50:** The inhibition concentration of a substance that causes a 50% inhibition of growth of the test population relative to the control within a designated period.

**NOEC:** No-observed-effect-concentration. The highest concentration at which no toxic effects are observed.

**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. DIAsource ImmunoAssays 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.

**Notification:**

English is acceptable for our MSDS as the following conditions are met:

- Medical specialists (users) are well educated in the English language

**MSDS established** : 07/01/2022

**Revision number** : 12



## MATERIEL SAFETY DATA SHEET

(According to regulation (EC) 1907/2006 and amendments)

Product Name: TSH Receptor Autoantibody ELISA

Catalog #: KAPD4834