

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

ElisaRSR™ AChRab
Catalogue no: ACE/96 (96 well)

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

Detection of AChR antibodies in human serum

1.3 Details of the supplier of the safety data sheet:

RSR Limited
Parc Ty Glas, Llanishen, Cardiff, CF14 5DU, United Kingdom
Phone: +4429 2068 9299 (Office hours only)
Fax: +4429 2075 7770 Email: info@rsrltd.com

1.4 Emergency telephone number:

MHRA Medical Devices Adverse Incident Centre: +4420 3080 7080

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
Reconstitution buffer for AChR	Eye Irritation, Category 2	H319
Reconstitution buffer for MAb-Biotin	Eye Irritation, Category 2	H319
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)	
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


RECONSTITUTION BUFFER FOR AChR

Hazard pictogram	 Signal word: Warning
Hazard statement(s)	
H319	Causes serious eye irritation
Precautionary statement(s)	
P280	Wear protective gloves/protective clothing/eye protection/face protection
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313	If eye irritation persists: Get medical advice/attention

RECONSTITUTION BUFFER FOR MAb-BIOTIN

Hazard pictogram	 Signal word: Warning
Hazard statement(s)	
H319	Causes serious eye irritation
Precautionary statement(s)	
P280	Wear protective gloves/protective clothing/eye protection/face protection
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313	If eye irritation persists: Get medical advice/attention

PEROXIDASE SUBSTRATE (TMB)

Hazard pictogram	 Signal word: Danger
Hazard statement(s)	
H360D	May damage the unborn child
Precautionary statement(s)	
P280	Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313	IF exposed or concerned: Get medical advice/attention

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).

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

Not applicable

3.2 Mixtures

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

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%

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):

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

Specific Concentration Limits:

$C \geq 0.0015\%$ 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

PEROXIDASE SUBSTRATE (TMB)

Ingredient(s)	CAS No.	EC No.	Classification	Conc. (v/v)
SeramunBlau® Fast	N/A	N/A	Repr. 1B; H360D	100%

Contains N-methyl-2-pyrrolidone:

Included in the Candidate List of Substances of Very High Concern (SVHC) for

Authorisation according to Regulation (EC) No. 1907/2006 (REACH).

CAS No. 872-50-4

EC No. 212-828-1

Concentration: <5%

Classification: Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335; Repr. 1B, H360D

RECONSTITUTION BUFFER FOR AChR**RECONSTITUTION BUFFER FOR MAb-BIOTIN**

Ingredient(s)	CAS No.	EC No.	Classification (GHS)	Concentration (v/v)
Triton™ X-100	9002-93-1	N/A	Acute Tox. 4 (Oral), Skin Irrit. 2, Eye Dam. 1, Aquatic Acute 1; Aquatic Chronic 1; H302, H315, H318, H400, H410	1.0%

Contains p-tertiary-octylphenoxy polyethyl alcohol:

Included in Candidate List of Substances of Very High Concern (SVHC) for Authorisation (Article 59). Listed in Annex XIV of REACH Regulation (EC) No. 1907/2006.

CAS No. 9002-93-1

EC No. N/A

Concentration: $\geq 90 - 100\%$

Classification: Acute Tox. 4 (Oral), H302; Skin Irrit. 2, H315; Eye Dam. 1, H318; Aquatic Acute 1, H400; Aquatic Chronic 1, H410

Foetal/adult type AChR, reconstitution buffer for AChR, AChR MAb-Biotin, reconstitution buffer for MAb-Biotin, calibrators and controls contain animal proteins and/or human proteins and should be treated as potential biohazards.

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.

Kit Component	Ingredient(s)	Concentration
Reconstitution Buffer for AChR	Antifoam A Sodium azide	0.05% v/v 0.05% w/v
Reconstitution Buffer for MAb-Biotin	Sodium azide	0.05% w/v
Diluent for SA-POD	2-Chloroacetamide N-Methylisothiazolone (MIT)	0.04% w/v 0.008% w/v
Stop Solution	Sulphuric acid	0.5M (<5% v/v)
Concentrated Wash Solution	Triton™ X-100	0.5% v/v
Calibrators and Controls	Oxypyron Sodium azide	0.2% w/v 0.05% w/v

Ingredient	CAS No.	EC No.	Classification GHS/CLP
2-Chloroacetamide	79-07-2	201-174-2	Acute Tox. 3 (Oral), Skin Sens. 1, Repr. 2; <i>H301, H317, H361f</i>
Antifoam A	N/A	N/A	Asp. Tox. 1, Repr. 2; <i>H304, H361</i>
MIT	26172-54-3	247-499-3	Skin Corr. 1B, Eye Dam. 1, Skin Sens. 1, Resp. Sens. 1; <i>H314, H317, H318, H334</i>
Oxypyrrion	822-89-9	212-506-0	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 & Inhalation), Acute Tox. 1 (Dermal), STOT RE 2, Aquatic Acute 1, Aquatic Chronic 1; <i>H300, H310, H330, H373, H400, H410, EUH302</i>
Sulphuric Acid	7664-93-9	231-639-5	Met. Corr. 1, Skin Corr. 1A; <i>H290, H314</i>
Triton™ X-100	For chemical information – See “RECONSTITUTION BUFFER FOR AChR” & “RECONSTITUTION BUFFER FOR MAb-BIOTIN”		

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.

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)
Antifoam A	Carbon oxides and silicon oxides
2-Chloroacetamide	Carbon oxides, nitrogen oxides (NOx) and hydrogen chloride gas
MIT	Carbon oxides, nitrogen oxides (NOx) and sulphur oxides
Oxypyrrion	No data available
SeramunBlau® Fast	None known
Sodium Azide	Nitrogen oxides (NOx)
Stabilzyme® HRP Conjugate Stabilizer	Carbon oxides and nitrogen oxides (NOx)
Sulphuric Acid	Sulphur oxides
Triton™ X-100	Carbon 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 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 hands 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 ElisaRSR™ AChRAB 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
SeramunBlau® Fast		
MAK	82 mg/m ³	TRGS 900
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 EU Directive 89/686/EEC. Latex or vinyl gloves will provide sufficient protection. 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.

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
AChR MAb1 Coated Wells	Colourless polystyrene microplate	None	N/A	N/A
Foetal/Adult Type AChR	White solid	None	N/A	In water
Reconstitution Buffer for AChR	Yellow liquid	None	~7.6	N/A
AChR MAb-Biotin	White solid	None	N/A	In water
Reconstitution Buffer for MAb-Biotin	Red liquid	None	~7.6	N/A
Streptavidin Peroxidase (SA-POD)	Pale brown/ yellow liquid	None	N/A	N/A
Diluent for SA-POD	Colourless liquid	None	~7.5	N/A
Peroxidase Substrate (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
Concentrated Wash Solution	Colourless liquid	None	~7.7	N/A
Calibrators and Controls	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.

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 ElisaRSR™ AChRAB 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.

10.4 Conditions to avoid

Peroxidase substrate (TMB) is light sensitive and therefore the bottle should be kept tightly closed when not in use and stored in a dark place.

Proteins, oxyprion, 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
Antifoam A	Strong oxidising agents
2-Chloroacetamide	Strong oxidising agents, strong acids, strong bases and strong reducing agents
MIT	Strong oxidising agents
Oxyprion	No data available
SeramunBlau® Fast	Heavy metal salts, complex forming agents and catalases (will not cause a dangerous reaction but destroys the quality of the product)
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
Triton™ X-100	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 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

Ingredient	Measurement*	Value	Species
Oxyprion	LD ₅₀ (Oral)	1.765 mg/kg	Rat
	LD ₅₀ (Dermal)	>2000 mg/kg	Rat
SeramunBlau® Fast (N-Methyl-2-pyrrolidone)	LD ₅₀ (Oral)	3598 mg/kg	Rat
	LD ₅₀ (Dermal)	8000 mg/kg	Rabbit
	LC ₅₀ (Inhalation)	>5.1 mg/L	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	No data available. Acute inhalation toxicity: mucosal irritations, cough, shortness of breath, possible damage to respiratory tract		
Triton™ X-100	LD ₅₀ (Dermal)	>3000 mg/kg	Rabbit

No data available for Antifoam A or Stabilzyme® HRP Conjugate Stabilizer.

(b) Skin corrosion/irritation

Ingredient	Test/Result
MIT	Skin (reconstructed human epidermis (RhE)) – Corrosive
Oxyprion	Not classified based on available information. May cause skin irritation in susceptible persons
SeramunBlau® Fast (N-Methyl-2-pyrrolidone)	Risk of skin resorption
Sodium Azide	In vitro study, human skin model test – No skin irritation
Sulphuric Acid	Causes severe burns

No data available for Antifoam A, 2-chloroacetamide, Stabilzyme® HRP Conjugate Stabilizer or Triton™ X-100.

(c) Serious eye damage/irritation

Ingredient	Test/Result
Oxyprion	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

No data available for Antifoam A, 2-chloroacetamide, MIT, SeramunBlau® Fast, Stabilzyme® HRP Conjugate Stabilizer or Triton™ X-100.

(d) Respiratory or skin sensitisation

Ingredient	Test/Result
2-Chloroacetamide	Maximisation test, Guinea pig – May cause sensitisation by skin contact
Oxyprion	Not classified based on available information
Sodium Azide	Sensitisation test, Mouse – Negative
Stabilzyme® HRP Conjugate Stabilizer	May cause an allergic skin reaction

No data available for Antifoam A, MIT, SeramunBlau® Fast, sulphuric acid or Triton™ X-100.

(e) Germ cell mutagenicity

Ingredient	Test/Result
2-Chloroacetamide	Hamster, lungs – Negative Mouse, male and female – Negative
MIT	Ames test, Salmonella typhimurium – Negative
Oxyprion	Not classified based on available information

No data available for Antifoam A, SeramunBlau® Fast, sodium azide, Stabilzyme® HRP Conjugate Stabilizer, sulphuric acid or Triton™ X-100.

(f) Carcinogenicity

Ingredient	Test/Result
Antifoam A	IARC: No component of this product present at levels ≥0.1% is identified as probable, possible or confirmed human carcinogen by IARC
2-Chloroacetamide	
MIT	
Triton™ X-100	Not classified based on available information
Oxyprion	

No data available for SeramunBlau® Fast, sodium azide, Stabilzyme® HRP Conjugate Stabilizer or sulphuric acid.

(g) Reproductive toxicity

Ingredient	Test/Result
2-Chloroacetamide	Suspected human reproductive toxicant
Oxyprion	Not classified based on available information
SeramunBlau® Fast (N-Methyl-2-pyrrolidone)	May damage the unborn child

No data available for Antifoam A, MIT, sodium azide, Stabilzyme® HRP Conjugate Stabilizer, sulphuric acid or Triton™ X-100.

(h) STOT-single exposure

Ingredient	Test/Result
Oxyprion	May cause respiratory irritation
SeramunBlau® Fast (N-Methyl-2-pyrrolidone)	May cause respiratory irritation

No data available for Antifoam A, 2-chloroacetamide, MIT, sodium azide, Stabilzyme® HRP Conjugate Stabilizer, sulphuric acid or Triton™ X-100.

(i) STOT-repeated exposure

Ingredient	Test/Result
Oxyprion	Not classified based on available information
SeramunBlau® Fast (N-Methyl-2-pyrrolidone)	No specific target organ toxicant, repeated exposure

No data available for Antifoam A, 2-chloroacetamide, MIT, sodium azide, Stabilzyme® HRP Conjugate Stabilizer, sulphuric acid or Triton™ X-100.

(j) Aspiration hazard

Ingredient	Test/Result
Oxyprion	Not classified based on available information

No data available for Antifoam A, 2-chloroacetamide, MIT, SeramunBlau® Fast, sodium azide, Stabilzyme® HRP Conjugate Stabilizer, sulphuric acid or Triton™ X-100.

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	Daphnia (<i>Daphnia magna</i> (water flea))	EC ₅₀	2.33 mg/L (48h)
	Algae (<i>Pseudokirchneriella subcapitata</i> (green algae))	ErC ₅₀	0.289 mg/L (72h)
		NOEC	0.047 mg/L (72h)
Oxyprion	Fish (<i>Oncorhynchus mykiss</i> (rainbow trout))	LC ₅₀	70.7 mg/L (96h)
	Fish (<i>Lepomis macrochirus</i> (bluegill sunfish))	LC ₅₀	>97.8 mg/L (96h)
	Daphnia (<i>Daphnia magna</i> (water flea))	EC ₅₀	78.6 mg/L (48h)
	SeramunBlau® Fast (N-Methyl-2-pyrrolidone)	Fish (<i>Lepomis macrochirus</i> (bluegill sunfish))	LC ₅₀
Fish (<i>Leuciscus idus</i> (golden orfe))		LC ₅₀	>500 mg/L (96h)
Algae (<i>Desmodesmus subspicatus</i>)		IC ₅₀	>500 mg/L (72h)
Daphnia (<i>Daphnia magna</i> (water flea))		EC ₅₀	4897 mg/L (48h)
Sodium Azide	Fish (<i>Lepomis macrochirus</i> (bluegill sunfish))	LC ₅₀	0.70 mg/L (96h)
	Daphnia (<i>Daphnia pulex</i> (water flea))	EC ₅₀	4.2 mg/L (48h)
	Algae (mixed culture of green algae)	IC ₅₀	272 mg/L
	Microorganisms (<i>Photobacterium phosphoreum</i>)	EC ₅₀	38.5 mg/L
Stabilzyme® HRP Conjugate Stabilizer	Fish (<i>Oncorhynchus mykiss</i> (rainbow trout))	LC ₅₀	0.19 mg/L

Ingredient	Toxicity to	Measurement*	Value
Stabilzyme® HRP Conjugate Stabilizer	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)
Triton™ X-100	Fish (<i>Pimephales promelas</i> (fathead minnow))	LC ₅₀	4 – 8.9 mg/L (96h)
	Daphnia (<i>Daphnia magna</i> (water flea))	LC ₅₀	18 – 26 mg/L (48h)

No data available for Antifoam A or sulphuric acid.

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
SeramunBlau® Fast (N-Methyl-2-pyrrolidone)	Biodegradability: exposure time 20 days Results: >90% - Readily degradable
Stabilzyme® HRP Conjugate Stabilizer	Not rapidly degradable

No data available for Antifoam A, sodium azide, sulphuric acid or Triton™ X-100.

12.3 Bioaccumulative potential

Ingredient	Test/Result
Oxyprion	Log Pow: -0.64
SeramunBlau® Fast (N-Methyl-2-pyrrolidone)	Log Pow: ≤4. (No bioaccumulation expected)
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 Antifoam A, 2-chloroacetamide, MIT, sulphuric acid or Triton™ X-100.

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	
Oxyprion	
Sodium Azide	
Triton™ X-100	
SeramunBlau® Fast (N-Methyl-2-pyrrolidone)	Not listed as PBT or vPvB relevant

No data available for MIT, Stabilzyme® HRP Conjugate Stabilizer or sulphuric acid.

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.

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

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 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code

Not applicable.

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture.**

Triton™ X -100 contains p-tertiary-octylphenoxy polyethyl alcohol which is included in Candidate List of Substances of Very High Concern (SVHC) for Authorisation (Article 59). Listed in Annex XIV of REACH Regulation (EC) No. 1907/2006.

SeramunBlau® Fast contains N-methyl-2-pyrrolidone which is included in the Candidate List of Substances of Very High Concern (SVHC) for Authorisation according to Regulation (EC) No. 1907/2006 (REACH).

15.2 Chemical safety assessment

Not applicable.

SECTION 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.

H304: May be fatal if swallowed and enters airways.

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.

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H335: May cause respiratory irritation.

H360D: May damage the unborn child.

H361: Suspected of damaging fertility or 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 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.

MAK: Maximum workplace concentration.

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. RSR Limited 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.