

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

ElisaRSR™ 21-OH Ab
 Catalogue no: 21E/96 (96 well)
 21E/96/R (96 well)

1.2 Relevant identified uses and uses advised against (if any):

Detection of 21-OH antibodies in human serum

1.3 Details of the supplier of the safety data sheet:

RSR Limited
 Avenue Park, Pentwyn, Cardiff, UK
 CF23 8HE
 Phone: +4429 2073 2076 (Office hours only)
 Fax: +4429 2073 2704
 Email: info@rsrltd.com

1.4 Emergency telephone number:

+4420 3080 7080

2. Hazards identification**2.1 Classification of mixture**

The ElisaRSR™ 21-OH Ab Kit is not considered hazardous in accordance with Regulation (EC) No. 1272/2008.

2.2 Label elements

This product does not require a hazard warning label according to EC directives.

2.3 Other Hazards

No single component of the kit contains a hazardous ingredient in a concentration which qualifies the product as hazardous 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 phrases should be taken into consideration:
 P233, P270, P281, P301 + P330, P302 + P352, P304 + P340, P305 + P351 + P338 (see section 16 for full text)

3. Composition/information on ingredients**3.1 Substances**

Not applicable

3.2 Mixtures

21-OH-Biotin, reconstitution buffer for 21-OH-Biotin, reference preparation, calibrators and positive and negative controls contain animal 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 21-OH-Biotin	Sodium azide TCEP.HCl	0.05% w/v 0.007% w/v
Diluent for SA-POD	2-Chloroacetamide N-Methylisothiazolone (MIT)	0.05% w/v 0.01% w/v
Reaction Enhancer	MIT Oxyprion	0.2% w/v 0.2% w/v
Stop Solution	Sulphuric acid	0.25M (<5%)
Reference Preparation, Controls and Calibrators (if applicable)	Oxyprion Sodium azide	0.2% w/v 0.05% w/v

Ingredient	CAS No.	EC No.	Classification GHS/CLP
2-Chloroacetamide	79-07-02	201-174-2	Acute Tox. 3, Skin Sens. 1, Repr. 2; <i>H301, H317, H361f</i>
MIT	26172-54-3	247-499-3	Skin Corr. 1B, Resp. Sens. 1, Skin Sens. 1; <i>H314, H317, H334</i>
Oxyprion	822-89-9	212-506-0	Acute Tox. 4, Eye Dam. 1, STOT SE 3; <i>H302, H318, H335</i>
Sodium Azide	26628-22-8	247-852-1	Acute Tox. 2, Aquatic Acute 1, Aquatic Chronic 1; <i>H300, H400, H410, EUH032</i>
Sulphuric Acid	7664-93-9	231-639-5	Met Corr. 1, Skin Corr. 1A; <i>H290, H314</i>
TCEP.HCl	51805-45-9	N/A	Skin Corr. 1B; <i>H314</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:

Ingredient	Hazardous combustion product(s)
2-Chloroacetamide	Carbon oxides, nitrogen oxides and hydrogen chloride gas
MIT	Carbon oxides, nitrogen oxides and sulphur oxides
Oxypyrrion	No data available
Sodium Azide	Sodium oxides
Sulphuric Acid	Sulphur oxides
TCEP.HCl	Carbon dioxide, carbon monoxide, phosphorus oxides and halogenated compounds

5.3 Advice for fire-fighters

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

6. Accidental release measures

6.1 Personal precautions

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 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™ 21-OH Ab 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, the following limits apply to component ingredients: sodium azide and sulphuric acid

Value	Control parameters	Basis
Sodium Azide		
STEL	0.3 mg/m ³	UK: EH40/2005 Workplace Exposure Limits (WEL) Europe: Commission Directive 2000/39/EC
TWA	0.1 mg/m ³	UK: EH40/2005 Workplace Exposure Limits (WEL) Europe: Commission Directive 2000/39/EC
REL	0.3 mg/m ³ 0.1 ppm	USA: NIOSH Recommended Exposure Limits (REL)
TLV	0.29 mg/m ³ 0.11 ppm	USA: ACGIH Threshold Limit Values (TLV)

Value	Control parameters	Basis
Sulphuric Acid		
TWA	0.05 mg/m ³	UK: EH40/2005 Workplace Exposure Limits (WEL) Europe: Commission Directive 2009/161/EU
TWA	1.0 mg/m ³	USA: NIOSH Recommended Exposure Limits (REL) USA: ACGIH Threshold Limit Values (TLV)

8.2 Exposure controls

The following controls should be followed as appropriate to the situation and the quantities handled.

General protective measures

Avoid contact with skin or eyes. Wash hands after use.

Hygiene measures

General laboratory practice (see section 7).

Respiratory protection

Local exhaust.

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.

Other equipment

Eye bath and safety shower

9. Physical and chemical properties**9.1 Information on the basic physical and chemical properties**

Kit component	Appearance	Odour	pH	Solubility
21-OH Coated Wells	Colourless polystyrene microplate	None	N/A	N/A
21-OH-Biotin	White solid	None	N/A	In water
Reconstitution Buffer for 21-OH-Biotin	Colourless liquid	None	~8.3	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

Kit component	Appearance	Odour	pH	Solubility
Peroxidase Substrate (TMB)	Colourless to slight blue liquid	None	N/A	N/A
Reaction Enhancer	Pink liquid	None	~7.3	N/A
Stop Solution (0.25M sulphuric acid)	Colourless liquid	May be slightly sulphurous	<1.0	N/A
Concentrated Wash Solution	Colourless liquid	None	~7.7	N/A
Reference Preparation, Calibrators (if applicable) 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.

10. Stability and reactivity**10.1 Reactivity**

Data is not available on the reactivity of individual kit components but is given, where available, on substances 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 substances.

10.2 Chemical stability

All components of the ElisaRSR™ 21-OH Ab 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:

Ingredient	Hazardous reaction
Sodium Azide	Risk of explosion with acids, heavy metals and metallic salts which may result in the formation of toxic vapours.
Sulphuric Acid	Violent reactions possible with acetonitrile, organic nitro compounds, potassium permanganate, metal halogenates perchlorates and alkali metals. Contact with metals liberates toxic gas.

Ingredient	Hazardous reaction
TCEP.HCl	Fine dust may form explosive mixtures with air.
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, 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:	
Ingredient	Incompatible materials
2-Chloroacetamide	Reacts with strong oxidising agents, strong acids, strong bases and reducing agents.
MIT	Reacts with strong oxidising agents.
Oxypyron	No data available.
Sodium Azide	Forms toxic vapours with water/carbon dioxide and with acids. Sodium azide forms explosive mixtures with heavy metals and metallic salts. Prolonged contact with copper or lead in the drainage system can result in the formation of explosive azides.
Sulphuric Acid	Reacts with acetonitrile, organic nitro compounds, potassium permanganate, metal halogenates, perchlorates and alkali metals. Other incompatible materials include animal and vegetable tissues.
TCEP.HCl	Reacts with 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	
No toxicological information is known regarding the kit components. The concentrations of ingredients listed in subsection 3.2 are below the acceptable limit for hazardous substances; the toxicological risk is minimal.	
12. Ecological information	
12.1 Toxicity	
No data available.	
12.2 Persistence and degradability	
No data available.	

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

No data available.

12.6 Other adverse effects

No ecological information exists for kit components. 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 – 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.

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 (EU) No. 453/2010.

Full text of precautionary phrases (listed in subsection 2.3) 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: IF SWALLOWED rinse mouth.

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.

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

H290: May be corrosive to metals.

H300: Fatal if swallowed.

H301: Toxic if swallowed.

H302: Harmful if swallowed.

H314: Causes severe skin burns and eye damage.

H317: May cause an allergic skin reaction.

H318: Causes serious eye damage.

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

H335: May cause respiratory irritation.

H361f: Suspected of damaging fertility.

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting effects.

EUH032: Contact with acids liberates very toxic gas.

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.