RSR Limited

SAFETY DATA SHEET

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

RiaRSR™ VGCC Ab Catalogue no: LEM/25 (25 tube)

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

Detection of autoantibodies to P-type voltage-gated calcium channels (VGCC) 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 RiaRSR[™] VGCC 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.

This kit contains ¹²⁵Iodine, a radioisotope with a half-life of approximately 60 days which emits gamma radiation with a maximum energy of 35 keV. Evidence exists of mutagenic, teratogenic and carcinogenic effects by ionising radiation.

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

All kit components contain animal proteins and/or human proteins and should be treated as potential biohazards.

¹²⁵I-labelled VGCC tracers are radioactive, ~6 kBq per vial (~0.162µCi).

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		Ingredien	t(s)	Concentration	
¹²⁵ I VGCC (LT/NS tracers)		ω-Conotoxin MVIIC		<1.0%	
, , ,		Digitonin		0.036%	
		Sodium az	zide	0.011%	
Dilution Buffer		Digitonin		0.1% w/v	
		Sodium az	zide	0.013% w/v	
Anti-human IgG		Digitonin		0.067% w/v	
3		Sodium az	zide	0.025% w/v	
Wash Solution		Sodium az	zide	0.5% w/v	
		Triton™ X	-100	0.01% w/v	
Negative Control		Sodium azide		0.05% w/v	
Positive Control		Digitonin		0.09% w/v	
		Sodium azide		0.016% w/v	
Ingredient	CAS No.	EC No.	Classification GHS/CLP		
ω-Conotoxin			Acute Tox. 4	4, Eye Irrit. 2, Skin Irrit. 2,	
MVIIC	147794-23-8	N/A		STOT SE 3;	
MIVIIC			H302, H312,	H315, H319, H332, H335	
Digitonin	11024-24-1	234-255-6	Acute 7	Tox. 2, Acute Tox 3;	
Digitoriin			H3	01, H311, H330	
				x. 2, Aquatic Acute 1,	
Sodium Azide	26628-22-8	247-852-1		uatic Chronic 1;	
				1400, H410, EUH032	
				Tox. 4, Eye Irrit. 2,	
Triton™ X-100	9002-93-1	N/A		uatic Chronic 2;	
			H3	02, H319, H411	

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

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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:

Hazardous combustion product(s)
Carbon oxide, carbon dioxide, nitrogen oxides and sulphur
oxides
Carbon oxides
Sodium oxides
Carbon oxides

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

Radioactive spills should be dealt with immediately in accordance with the current local and national regulations and guidelines.

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 and decontaminate with a suitable disinfectant solution. Any surfaces contaminated with ¹²⁵lodine should be washed with a suitable detergent to remove all traces of radioactivity. Dispose of radioactive waste via an authorised route.

6.4 Reference to other sections

See sections 8 and 13.

7. Handling and storage

7.1 Precautions for safe handling

Users should make themselves aware of, and observe any national and local legislation and codes of practice governing the use, storage, transportation and disposal of radioactive materials. 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.

Radioactive materials should only be used by authorised personnel and in designated areas. Wash hands thoroughly after handling. Monitor hands and clothing before leaving the designated area. Report contamination to the responsible person and take remedial action.

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 RiaRSR[™] VGCC 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.

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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 (see subsection 3.2 for components containing these substances):

Value	Control	Basis
	Parameters	
Sodium Az	zide	
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	USA: NIOSH Recommended Exposure Limits (REL)
	0.1 ppm	
TLV	0.29 mg/m ³	USA: ACGIH Threshold Limit Values (TLV)
	0.11 ppm	

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	рН	Solubility
LT and NS Tracer	White solid	None	N/A	In water

Kit component	Appearance	Odour	рН	Solubility
Dilution Buffer	Colourless liquid	None	~7.4	N/A
Anti-Human IgG	Pale brown liquid	None	N/A	N/A
Wash Solution	Colourless liquid	None	~7.6	N/A
Negative Control	Pale brown liquid	None	N/A	N/A
Positive Control	Pale yellow to colourless 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 not available.

10.2 Chemical stability

All components of the RiaRSR[™] VGCC 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.

10.4 Conditions to avoid

Proteins and sodium azide 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
ω-Conotoxin MVIIC	Reacts with strong oxidising agents.
Digitonin	Reacts with strong oxidising agents and strong acids.
Triton™ X-100	Reacts with strong acids, strong bases and strong oxidising agents.

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Ingredient	Incompatible materials
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.
10.6 Hazardous deco	omposition products
specified storage May evolve toxic for the kit compo	on products are formed if kit is stored and used under the and handling conditions. fumes in fire. Thermal decomposition products are not known onents but hazardous combustion products of the ingredients on 3.2 can be found in subsection 5.2
11. Toxicological info	ormation
concentrations of	oxicological effects information is known regarding the kit components. The ingredients listed in subsection 3.2 are below the acceptable s substances; the toxicological risk is minimal.
12. Ecological inform	nation
12.1 Toxicity No data available	9.
12.2 Persistence and No data available	
12.3 Bioaccumulative No data available	
12.4 Mobility in soil No data available	a.
12.5 Results of PBT a No data available	and vPvB assessment
ingredients listed substances; the	ffects formation exists for kit components. The concentrations of in subsection 3.2 are below the acceptable limit for hazardous ecological risk is minimal. However, it is recommended that enter drains in large quantities.
13. Disposal conside	erations
are covered by re	at methods ological residues are classified as special waste and as such, egulations which may vary according to location. cal waste disposal authority for advice or pass to a licensed

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 $2 - 8^{\circ}$ C with all reagents contained within the packaging provided.

14.1 UN number

UN2910 for excepted quantity of radioactive materials

- **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: H300: Fatal if swallowed.
- H301: Toxic if swallowed.
- H302: Harmful if swallowed.
- H311: Toxic in contact with skin.
- H312: Harmful in contact with skin.
- H315: Causes skin irritation.
- H319: Causes serious eye irritation.
- H330: Fatal if inhaled.
- H332: Harmful if inhaled.
- H335: May cause respiratory irritation.
- H400: Very toxic to aquatic life.
- H410: Very toxic to aquatic life with long lasting effects.
- H411: Toxic to aquatic life with long lasting effects.
- EUH032: Contact with acids liberates toxic gas.

The above information is believed to be correct but does not purport to be allinclusive 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.