

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

LEMS® Assay RIA
Catalogue no: RA117/25

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

Quantitative Determination of Antibodies to the Voltage-gated P/Q-Calcium Channel (VGCC) in 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:

+49405558710

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

The LEMS® Assay RIA 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 + P331, 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

¹²⁵I-labelled VGCC tracer, anti-human IgG, negative and positive controls contain animal and/or human proteins and should be treated as potential biohazards.

¹²⁵I-labelled VGCC tracer is 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	Ingredient(s)	Concentration
¹²⁵ I VGCC (LT/NS tracers)	Digitonin	0.036%
	Sodium azide	0.011%
Dilution Buffer	Digitonin	0.1% w/v
	Sodium azide	0.05% w/v
Anti-human IgG	Digitonin	0.067% w/v
	Sodium azide	0.033% w/v
Wash Solution	Sodium azide	0.05% w/v
	Tergitol™	0.02% w/v
Negative Control	Sodium azide	0.05% w/v
Positive Control	Digitonin	0.09% w/v
	Sodium azide	0.05% w/v

Ingredient	CAS No.	EC No.	Classification GHS/CLP
Digitonin	11024-24-1	234-255-6	Acute Tox 3 (oral), STOT RE 2; H301, H373
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; H300, H310, H330, H373, H400, H410, EUH032
Tergitol™	84133-50-6	617-534-0	Acute Tox. 4 (Oral & Inhalation), Skin Irrit. 2, Eye Dam. 1; H302, H315, H318, H332

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)
Digitonin	Carbon oxides
Sodium Azide	Nitrogen oxides (NOx)
Tergitol™	Nature of decomposition products not known

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 ¹²⁵Iodine 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.

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.

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.

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 LEMS® Assay RIA 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 (see subsection 3.2 for components containing these substances):

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

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.

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

Kit component	Appearance	Odour	pH	Solubility
LT and NS Tracer	White solid	None	N/A	In water
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 is not available on the reactivity of individual kit components but is given, where available, on ingredients listed in subsection 3.2.

10.2 Chemical stability

All components of the LEMS® Assay RIA 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 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.

10.4 Conditions to avoid

Proteins, sodium azide and Tergitol™ 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
Digitonin	Strong oxidising agents, strong alkalis and strong acids.
Sodium Azide	Aluminium and heavy metals
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
Digitonin	LD ₅₀ (Oral)	>50 mg/kg	Rat
Sodium Azide	LD ₅₀ (Oral)	27 mg/kg	Rat
	LD ₅₀ (Inhalation)	0.054 – 0.52 mg/L (4h)	Rat
	LD ₅₀ (Dermal)	20 mg/kg	Rabbit

No data available for other ingredients listed in subsection 3.2.

(b) Skin corrosion/irritation

Ingredient	Test/Result
Sodium Azide	In vitro study, human skin model test – No skin irritation
Tergitol™	Irritating to skin

No data available for other ingredients listed in subsection 3.2.

(c) Serious eye damage/irritation

Ingredient	Test/Result
Sodium Azide	In vitro study, exposure time 4 hours – No eye irritation
Tergitol™	Causes severe eye irritation

No data available for other ingredients listed in subsection 3.2.

(d) Respiratory or skin sensitisation

Ingredient	Test/Result
Sodium Azide	Sensitisation test, Mouse – Negative
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

No data available.

(f) Carcinogenicity

Ingredient	Test/Result
Digitonin	IARC: No component of this product present at levels ≥0.1% is identified as probable, possible or confirmed human carcinogen by IARC
Tergitol™	

No data available for other ingredients listed in subsection 3.2.

(g) Reproductive toxicity

No data available.

(h) STOT-single exposure

No data available.

(i) STOT-repeated exposure

Digitonin may cause damage through prolonged or repeated exposure.

(j) Aspiration hazard

No data available.

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

Ingredient	Toxicity to	Measurement*	Value
Sodium Azide	Fish (Lepomis macrochirus (bluegill sunfish))	LD ₅₀	0.70 mg/L (96h)
	Daphnia (Daphnia pulex (water flea))	LD ₅₀	4.2 mg/L (48h)
	Algae (mixed culture of green algae)	LD ₅₀	272 mg/L
	Microorganisms (Photobacterium phosphoreum)	LD ₅₀	38.5 mg/L

No data available for other ingredients listed in subsection 3.2.

12.2 Persistence and degradability

Ingredient	Test/Result
Tergitol™	Result: >60% - Readily biodegradable

No data available for other ingredients listed in subsection 3.2.

12.3 Bioaccumulative potential

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

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
Digitonin	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 $\geq 0.1\%$.
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 – 8°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 (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 phrases (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.

H300: Fatal if swallowed.

H301: Toxic if swallowed.

H302: Harmful if swallowed.

H310: Fatal in contact with skin.

H315: Causes skin irritation.

H318: Causes serious eye damage.

H330: Fatal if inhaled.

H332: Harmful if inhaled.

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:

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

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

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

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.

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.