SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

ACHRAB® Assay RIA (RiaRSR™ AChRAb)
Catalogue no: RA001/25 & RA001/25/S (REF RB/25)
RA105/100 & RA105/100/S (REF RB/100)

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

Quantitative determination tion of autoantibodies to acetylcholine receptor (AChR) in human 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:

+49(0)40-5558710 (Mon – Fri, except public holidays, 8.00 – 15.30)

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*
Precipitation Enhancer (optional)	Specific target organ toxicity – repeated exposure, Category 2	H373

*See section 16 for full text

2.2 Label elements

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

PRECIPITATION ENHANCER (Optional)	
Hazard pictogram	 **Signal word:** Warning
Hazard statement(s)	
H373	May cause damage to organs through prolonged or repeated exposure.
Precautionary statement(s)	
P260	Do not breathe dust/fume/gas/mist/vapours/spray
P314	Get medical advice/attention if you feel unwell.

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.

This kit contains ^{125}Iodine, 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.

ACHRAB® Assay RIA kit components ingredients listed in 3.2 have not been identified as having endocrine disrupting properties according to Regulation (EU) 2017/2100 and does not meet the criteria for vPvB and PBT according to Regulation (EC) No. 1907/2006 Annex XIII.

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)

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

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

PRECIPITATION ENHANCER (Optional)					
Ingredient(s)	**CAS No.**	**EC No.**	**Classification (GHS)**	**Conc. (v/v)**	**Conc. Limits**
Silica (silicon dioxide)	14808-60-7	238-878-4	STOT RE 1; H372	1 – 10%	STOT RE 1 C≥10% STOT RE 2 1≤C<10%

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.

Component(s)	Ingredient	Number	Classification (GHS)	Conc. (v/v)	Conc. Limits (v/v)
Reconstitution Buffer Precipitation Enhancer (optional) Anti Human IgG Normal Human Serum Wash Solution Calibrators (optional) Controls	Sodium Azide	CAS No. 26628-22-8 EC No. 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*	<0.1%	Acute Tox. 2 (Oral & Inhalation) C≥0.1% Acute Tox. 1 (Dermal) C≥0.1% STOT RE 2 C≥10% Aquatic Acute 1 C≥0.1% Aquatic Chronic 1 C≥0.1%

^{125}I-labelled AChR tracer, anti-human IgG, normal human serum, calibrators (optional) and positive and negative controls contain animal proteins and/or human proteins and should be treated as potential biohazards.

^{125}I-labelled AChR is radioactive, ~70 kBq per vial (~1.89 µCi).

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)
Silica	None
Sodium Azide	Nitrogen oxides (NOx)

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

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 ^{125}Iodine 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.

SECTION 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 2 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 ACHRAB® 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.

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
Silica		
TWA	0.1 mg/m^3	UK: EH40 Workplace Exposure Limits (WEL)
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

*See section 16 for full text

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: >= 0.4 mm thickness
Permeation Time: >= 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.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Kit component	Appearance	Odour	pH	Solubility
^{125}I-labelled AChR Tracer	Cream solid	None	N/A	In water
Reconstitution Buffer	Colourless liquid	None	~7.6	N/A
Precipitation Enhancer (optional)	White suspension	None	N/A	N/A
Anti Human IgG	Yellow/brown liquid	None	N/A	N/A
Wash Solution	Colourless liquid	None	~7.6	N/A
Normal Human Serum	Yellow/brown liquid	None	N/A	N/A
Positive and Negative Controls	Yellow/brown liquid	None	N/A	N/A
Calibrators (optional)	Yellow/brown 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, relative vapour density, relative density, particle characteristics, partition coefficient, autoignition temperature, decomposition temperature, kinematic 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.

10.2 Chemical stability

All components of the ACHRAB® 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 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.

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 ingredients listed in subsection 3.2:

Ingredient	Incompatible materials
Silica	Reacts with hydrogen fluoride.
Sodium Azide	Aluminium and heavy metals.

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

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
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

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

No data available for other ingredients listed in subsection 3.2.

(c) Serious eye damage/irritation

Ingredient	Test/Result
Sodium Azide	Bovine cornea, exposure time 4 hours – No 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

No data available for other ingredients listed in subsection 3.2.

(e) Germ cell mutagenicity

Ingredient	Test/Result
Sodium Azide	Chromosome aberration: Chinese hamster ovary cells – Negative Unscheduled DNA Synthesis assay: Chinese hamster lung cells – Negative Sister Chromatid exchange assay: Chinese hamster ovary cells – Negative

No data available for other ingredients listed in subsection 3.2.

(f) Carcinogenicity

No data available for ingredients listed in subsection 3.2.

(g) Reproductive toxicity

No data available for ingredients listed in subsection 3.2.

(h) STOT-single exposure

No data available for ingredients listed in subsection 3.2.

(i) STOT-repeated exposure

Ingredient	Exposure/Result/Target Organ
Sodium Azide	Oral – may cause damage to organs through repeated exposure - Brain

No data available for other ingredients listed in subsection 3.2.

(j) Aspiration hazard

No data available for ingredients listed in subsection 3.2.

11.2 Information on other hazards

(a) Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to Commision Regulations (EU) 2017/2100 and (EU) 2018/605.

(b) Other information

As the kit components have not been tested for their toxicological effects, other hazardous properties cannot be excluded but are unlikely when the product is handled appropriately.

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
Sodium Azide	Fish (*Oncorhynchus mykiss* (rainbow trout)	LC_{50}	2.75 mg/L (96h)
	Algae (*Psuedokirchneriella subcapita*)	ErC_{50}	0.35 mg/L (96h)

No data available for other ingredients listed in subsection 3.2.

12.2 Persistence and degradability

No data available for ingredients listed in subsection 3.2.

12.3 Bioaccumulative potential

No data available for ingredients listed in subsection 3.2.

12.4 Mobility in soil

No data available for ingredients listed in subsection 3.2

12.5 Results of PBT and vPvB assessment

Ingredient	Test/Result
Sodium Azide	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%.

No data available for other ingredients listed in subsection 3.2.

12.6 Endocrine disrupting properties

The ingredients listed in subsection 3.2 do not have endocrine disrupting properties with respect to non-target organisms as it does not meet the criteria set out in section B of Regulation (EU) No 2017/2100.

12.7 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 or ID numbrt

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 Maritime transport in bulk according to IMO instruments

Not applicable.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture.

Not applicable.

15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for the ACHRAB® Assay RIA kit by the manufacturer.

SECTION 16: Other information

This SDS has been compiled in accordance with Commission Regulation (EC) No. 1907/2006 as amended by Commission Regulation (EU) 2020/878.
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.
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.
H372: Causes damage to organs (lungs) through prolonged or repeated exposure 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:
LC50 = The lethal concentration of a substance that kills 50% of the test population within a designated period.
ErC50 = The effective concentration of a substance that causes 50% reduction in growth rate of the test population 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.

REVISION INFORMATION

Revision Number	Effective Date	Description of Changes
11	22nd May 2023	Revision of SDS to meet (EU) 2020/878 – changes throughout.