

Acetylcholine Receptor Autoantibodies (ARAb) RRA

REF **KIPIB21021**

Single components with dangerous ingredients:

KRAR013 ARAb ¹²⁵I-Tracer lyophilized

Not listed single components contains no hazardous substances in concentrations to be declared, a labelling is not required.



IBL International GmbH
Flughafenstrasse 52a
22335 Hamburg, Germany

Tel. +49 (0) 40 53 28 91-0
Fax +49 (0) 40 53 28 91-11
IBL@tecan.com
www.tecan.com/ibl



DIAsource ImmunoAssays S.A.
Rue du Bosquet, 2
1348 Louvain-la-Neuve, Belgium

Tel: +32 (0) 10 84 99-11
Fax: +32 (0) 10 84 99-91
customer.service@diasource.be
www.diasource-diagnostics.com

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Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 08.08.2023

Version number 12

Revision: 08.08.2023

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

- **Product identifier**

- **Trade name:** RIA 125I-Tracer (LYO)

- **Article number:** Valid for products listed in the table on the first page.

- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

- **Application of the substance / the preparation:**

laboratory reagent / Immunoassay

The product is intended for professional use.

- **Details of the supplier of the safety data sheet**

- **Manufacturer:**

IBL International GmbH

Flughafenstr. 52 a

22335 Hamburg

Germany

Tel.: ++49-40-53 28 91-0

Fax.: ++49-40-53 28 91-11

E-Mail: IBL@tecan.com

http: //www.tecan.com/ibl

- **Further information obtainable from:** Safety Representative

- **Emergency telephone number:** ++49-40-53 28 91 - 0

SECTION 2: Hazards identification

- **Classification of the substance or mixture**

- **Classification according to Regulation (EC) No 1272/2008**

The product is not classified, according to the GB CLP regulation.

- **Label elements**

- **Labelling according to Regulation (EC) No 1272/2008** Void

- **Hazard pictograms** Void

- **Signal word** Void

- **Hazard statements** Void

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **Mixtures Preparation**

- **Description:** Lyophilized powder

- **Dangerous components:**

125-Iodine Radionuclide

Activity: < 125 kBq

- **Components**

CAS: 77-86-1	trometamol	<1%
EINECS: 201-064-4	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	
CAS: 26628-22-8	sodium azide	≥0.025-<0.25%
EINECS: 247-852-1	⚠ Acute Tox. 2, H300; ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410, EUH032	

- **Additional information**

The regulation (EC) No. 1907/2006 does not cover radioactive material. Its receipt, acquisition, possession use and/or transfer are subject to the regulations and a specific license issued by the Nuclear Regulatory Commission or issued by a state with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority.

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For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- **Description of first aid measures**
- **General information** No special measures required.
- **After inhalation** Call a doctor immediately.
- **After skin contact** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact** Rinse opened eye for several minutes under running water.
- **After swallowing** Do not induce vomiting; call for medical help immediately.
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents** Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to item 13.
- **Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities -**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Store in separated, identified rooms.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
The kit is shipped at ambient temperature and should be stored at 2-8°C. Keep away from heat or direct sun light. The storage and stability of prepared reagents is stated in the corresponding chapters of the instruction for use.
- **Specific end use(s)** No further relevant information available.

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SECTION 8: Exposure controls/personal protection

- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
This product contains radioactive material.
- **Additional information:** *The lists valid during the making were used as basis.*
- **Exposure controls**
- **Appropriate engineering controls** *No further data; see item 7.*
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures**
The usual precautionary measures are to be adhered to when handling chemicals and radioactive material.
- **Respiratory protection:** *Not required.*
- **Hand protection**
*The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation*
- **Material of gloves**
*The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
The quality of the protective gloves must be chosen as a function of the specific working place concentration and quantity of hazardous substances.
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.*
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye/face protection** *Not required.*
- **Body protection:** *lab coat*

SECTION 9: Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Physical state** *Solid.*
- **Colour:** *Various colours*
- **Odour:** *Nearly odourless*
- **Odour threshold:** *Not determined.*
- **Melting point/freezing point:** *undetermined*
- **Boiling point or initial boiling point and boiling range** *undetermined*
- **Flammability** *Not determined.*
- **Lower and upper explosion limit**
- **Lower:** *Not determined.*
- **Upper:** *Not determined.*
- **Flash point:** *Not applicable*
- **Decomposition temperature:** *Not determined.*
- **pH** *Not applicable.*
- **Viscosity:**
- **Kinematic viscosity** *Not applicable.*

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· dynamic:	Not applicable.
· Solubility	
· Water:	Soluble
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not applicable.
· Density and/or relative density	
· Density:	Not determined
· Relative density	Not determined.
· Vapour density	Not applicable.

· Other information	
· Appearance:	
· Form:	Solid.
· Important information on protection of health and environment, and on safety.	
· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Solvent content:	
· Organic solvents:	0 %
· Change in condition	
· Evaporation rate	Not applicable.

· Information with regard to physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

SECTION 10: Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known

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SECTION 11: Toxicological information

- **Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **Other adverse effects**
- **Additional ecological information:**
- **General notes:** Do not allow product to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

- **Waste treatment methods -**
- **Recommendation** Must be specially treated adhering to official regulations.
- **Uncleaned packaging:**
- **Recommendation:**
Completely emptied packages can be recycled.
Dispose of packaging according to applicable local, state, and federal regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

- | | |
|---------------------------------|--------|
| · UN number or ID number | |
| · ADR, IMDG, IATA | UN2910 |

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<ul style="list-style-type: none"> · <i>UN proper shipping name</i> · ADR · IMDG, IATA 	<p>2910 RADIOACTIVE MATERIAL, EXCEPTED PACKAGE - LIMITED QUANTITY OF MATERIAL</p> <p>RADIOACTIVE MATERIAL, EXCEPTED PACKAGE - LIMITED QUANTITY OF MATERIAL</p>
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<ul style="list-style-type: none"> · <i>Transport hazard class(es)</i> · ADR 	<p>7 7.1 Radioactive material.</p> <p>7.1 Radioactive material.</p>
<ul style="list-style-type: none"> · Class · Label 	<p>7 7.1 Radioactive material.</p> <p>7</p>



<ul style="list-style-type: none"> · IMDG, IATA 	<p>7 7.1 Radioactive material.</p>
<ul style="list-style-type: none"> · Class · Label 	<p>7 7.1 Radioactive material.</p> <p>7</p>



<ul style="list-style-type: none"> · <i>Packing group</i> · ADR, IMDG, IATA 	<p>Void</p>
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<ul style="list-style-type: none"> · <i>Environmental hazards:</i> · <i>Marine pollutant:</i> 	<p>No</p>
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<ul style="list-style-type: none"> · <i>Special precautions for user</i> · <i>Hazard identification number (Kemler code):</i> - · <i>Stowage Category</i> 	<p>Warning: 7.1 Radioactive material.</p> <p>-</p> <p>A</p>
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<ul style="list-style-type: none"> · <i>Maritime transport in bulk according to IMO instruments</i> 	<p>Not applicable.</p>
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<ul style="list-style-type: none"> · <i>Transport/Additional information:</i> · ADR · <i>Limited quantities (LQ)</i> · <i>Transport category</i> · <i>Tunnel restriction code</i> 	<p>0</p> <p>4</p> <p>E</p>
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<ul style="list-style-type: none"> · <i>UN "Model Regulation":</i> 	<p>UN 2910 RADIOACTIVE MATERIAL, EXCEPTED PACKAGE - LIMITED QUANTITY OF MATERIAL, 7</p>
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SECTION 15: Regulatory information

- *Safety, health and environmental regulations/legislation specific for the substance or mixture*
- *Labelling according to Regulation (EC) No 1272/2008* Void
- *Hazard pictograms* Void
- *Signal word* Void
- *Hazard statements* Void

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- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **National regulations**
- **Waterhazard class:** Generally not hazardous for water.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**

- H300 Fatal if swallowed.
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.
- EUH032 Contact with acids liberates very toxic gas.

· **Department issuing SDS:** Safety Representative

· **Contact:** IBL International

· **Abbreviations and acronyms:**

- RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
- ICAO: International Civil Aviation Organisation
- ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
- IMDG: International Maritime Code for Dangerous Goods
- IATA: International Air Transport Association
- GHS: Globally Harmonised System of Classification and Labelling of Chemicals
- EINECS: European Inventory of Existing Commercial Chemical Substances
- ELINCS: European List of Notified Chemical Substances
- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative

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