

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: IAA RIA
Catalog #: KIPM2035
Kit Components: Tracer
Reconstitution buffer
Precipitation buffer
Protein A (lyophilized)
Calibrators (1 – 4)
Control sera (CI, CII)

1.2 Intended Use

Radioligand assay for the determination of autoantibodies to insulin (IAA) in human serum.

1.3 Company

DIAsource ImmunoAssays S.A.
Rue du Bosquet, 2
B-1348 Louvain-la-Neuve
Belgium
Tel. Nr. +32 (0)10/84.99.11
E-mail: tech.support@diasource.be

1.4 Emergency telephone

DIAsource (only office hours): +32 (0)10/84.99.23
Centre Anti-Poison (BE) 070 245 245
Please refer to your local Anti-Poison Center!

2 HAZARDS IDENTIFICATION

2.1 Hazard identification (reagents)

The product / product components are, in accordance to EU Regulation (EG) No. 1272/2008 classified as **non-hazardous**.

Radioactive nuclide 125-Iodine in solid form.
Limited quantity of substance of hazard class 7, page 1 GGVS/ADR

2.2 Identification elements

According to 1272/2008/EG: none

2.3 Other hazards

The product/product components contain preservatives, which in the present concentrations can cause skin sensitization and weak water pollution. As there are always certain dangers associated with chemicals, the product/product component should only be handled by appropriately trained persons, using proper chemical safety precautions.

Results of the PBT/vPvB evaluation: not applicable

3 COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Description of ingredients

Component	Ingredients	Preservative
Tracer	125-I-Insulin (human)	0.09% Sodium azide
Reconstitution buffer	TRIS, NaCl, BSA	0.09% Sodium azide
Precipitation buffer	TRIS, NaCl, BSA	0.09% Sodium azide
Protein A (lyophilized)	TRIS, NaCl	0.09% Sodium azide
Negative control serum	human serum	0.09% Sodium azide
Calibrators (1 – 4)	human serum	0.09% Sodium azide
Control sera (CI, CII)	human serum	0.09% Sodium azide

3.2 Hazardous Components and their concentrations

CAS No.	EINECS No.	Ingredient	Procent	Classification (in conc. form) in 1272/2008/EG
26628-22-8	247-852-1	Sodium azide	< 0.01	Acute tox. 2, H300 EUH032 Aquatic acute 1, H400 Aquat. Chronic 1, H410

The full wording of the listed hazard warnings is given in section 16

4 FIRST AID MEASURES

4.1 Description of first aid measures

Due to the very low concentrations of the hazardous ingredients in the product/components, consultation of a doctor is not necessary.

Eye or skin contact: Wash with copious amounts of water. Rinse out for several minutes with water, with eyelids open

Ingestion: Rinse out and drink copious amounts of water.

4.2 Important Symptoms and Effects

There are no known acute or delayed onset symptoms and effects.

5 FIRE FIGHTING MEASURES

5.1 Extinguishers

Extinguishers indicated: Water spray, foam, powder.

5.2 Special hazards arising from the contents

With fire, sodium azide can release poisonous fumes.

5.3 Notes on firefighting

Surround the fire with appropriate extinguishing material.

If necessary use breathing apparatus and protective clothing for firefighting.

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions

Observe the safety regulations of the laboratory.

To minimize the risk of contact with the skin and eyes, wear appropriate protective clothing. Do not swallow, do not pipette by mouth.

6.2 Environmental precautions

Do not release into drains/surface water/ground water.

6.3 Methods and materials for containment and cleaning

Contain spills with absorbent material, and dispose of appropriately. Following complete removal of the material, clean the affected area thoroughly.

6.4 Reference to other sections

Information on appropriate protective clothing can be found in section 8.2.

For disposal, consult section 13.

7 HANDLING AND STORAGE

7.1 Protective measures for safe handling

Apart from the usual laboratory safety regulations, no particular protective measures are required.

Information on required protective clothing can be found in section 8.2.

7.2 Conditions for safe storage, including any incompatibilities

When well sealed according to instructions on the product components, storage at 2 - 8°C.

7.3 Specific End Uses

No further relevant information available

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Parameters/exposure values to be observed

CAS No.	Ingredient	MAK or AGW (from TRGS 900)
26628-22-8	Sodium azide	0.2 mg/m ³

With appropriate use of the pack/pack contents, no air pollution is expected.

8.2 Limitations and monitoring of exposure

Respiratory protection: Not required
Gloves: Nitrile or natural latex laboratory gloves
Eye protection: Safety goggles
Bodily protection: Appropriate laboratory wear

The handling of all components must be made according to Good Laboratory Practice (GLP) regulations

The handling of radioactive material is subject to the protection and control requirements of the currently valid Radiation Protection Ordinance. There is a licensing requirement according to § 7 StrlSchV. The handling radioactive material may only take place when the receiver is in possession of an official handling permit (§ 69 StrlSchV). Radioactive material is to be disposed of in special waste containers suited to this purpose.

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Form: liquid (tracer, buffers, standards, controls) solid/ lyophilized (protein A)
Color: clear
Odor: odorless
pH value: 8.0
Melting point / melting range / boiling point / boiling range / density : not determined
Flash point: not applicable
Risk of explosion: no risk of explosion

9.2 Other properties

Solubility in / miscibility with water: complete

10 STABILITY AND REACTIVITY

10.1 Reactivity

There are no chemical reactive properties of the product / product components

10.2 Chemical stability

Within the stated storage temperatures and expiry dates, the product / components are chemically stable.

10.3 Possible hazardous reactions

In high concentrations sodium azide and heavy metals, such as copper and lead, can form explosive complexes.

10.4 Conditions to be avoided

None

10.5 Incompatible materials

Acids, alkalis and solvents can negatively influence the functional ability of the product / components.

10.6 Hazardous decomposition products

Within the stated storage and handling conditions, the product / components product no known hazardous decomposition products. Use of radioactive material is in accordance with local and government regulations.

11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute Toxicity

Ingredient	Administration	Value	Species
Sodium azide	LD50 (oral)	27 mg/kg	Rat

Other health effects

Ingredient	Irritation and Corrosion	Sensitization	CMR Effect
Sodium azide	No data available	No data available	No data available

12 ECOLOGICAL INFORMATION

12.1 Toxicity

Ingredient	Administration	Value	Species
Sodium azide	LC50	0.68 mg/l	Sun perch
Sodium azide	EC50	4.2 mg/l	Invertebrate (Daphnia pulex)

12.2 Persistence and biodegradability

Ingredient	Administration	Value	Remarks
Sodium azide	No data available		

12.3 Bioaccumulation potential

No data available

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB analyses

No data available.

12.6 Other harmful effects

Ingredient	Type of effect
Sodium azide	very poisonous to water organisms

Due to the very low concentration of hazardous ingredients in the product / components, no ecological problems are expected arising from their use.

13 DISPOSAL CONSIDERATIONS

13.1 Disposal methods

Product components

May not be disposed of with household waste.

Residues of chemical preparations are usually classed as waste which must be disposed of according to the rules issued by the country and government. Information on the disposal of hazardous waste can be given by the local authorities (agency or authorized waste disposal contractor).

Radioactive material is to be disposed of in special waste containers suited to this purpose.

Packaging

Disposal according to official regulations.

Contaminated packaging should be treated as per the product.

Non-contaminated packaging can be handled as household waste and be recycled, when regulations do not state otherwise.

14 TRANSPORT INFORMATION

According to ADR and IATA (Chapter 10.3.1) regulations, shipment below the exemption quantity (1 MBq for Iodine 125) are considered as not dangerous goods. If the shipment exceed this quantity, please refer to the information given below:

This product has no transport regulations

14.1 UN number

UN 2910

14.2 Proper UN shipping designation

UN 2910

14.3 Transport hazard class

Limited amount of substance of hazard class 7, page 1 GGVS/ADR.

14.4 Packaging group

Not applicable

14.5 Environmental hazard

Not applicable

14.6 Special precautions for users

Use of radioactive material is in accordance with local and government regulations.

14.7 Mass transport in accordance with appendix II MARPOL agreements 73/78 and IBC code

Not applicable.

15 REGULATORY INFORMATION

This safety data sheet fulfils the requirements of regulation 1907/2006/EG on the registration, evaluation, authorization and restriction of chemicals, (REACH), and the regulation 1272/2008/EG on the classification, labeling and packaging of chemicals and mixtures, as well as the regulation 830/2015/EG on the production of safety data sheets.

15.1 Safety, health and environmental regulations/ regulations specific to this substance or mixture

When handling the product, the current regulations for handling potentially infectious human sample material should be observed.

Product classification to 1272/2008/EG: none

Water pollution class: WPC 1 (self-assessment), weakly water polluting

Use of radioactive material is in accordance with local and government regulations.

15.2 Chemical safety assessment

A chemical safety assessment has not been performed.

16 OTHER INFORMATION

Full text of section 3.2., listed risk phrases

EUH032	Produces very poisonous gases on contact with acids
H 300	Life-threatening if swallowed
H400	Very toxic to aquatic life
H 410	Very poisonous for water organisms with long-term effect

Abbreviations and Acronyms

AGW	Arbeitsplatzgrenzwert (workplace limit)
CAS	Chemical Abstract Service (division of American Chemical Society)
CLP	Regulation of Classification, Labelling, and Packaging of Substances and Mixtures
CMR	Carcinogenic, mutagenic or reprotoxic
EC50	Effective concentration for 50% of subjects
EINECS	European Inventory of Existing Commercial Chemical Substances
GHS	Globally Harmonized System of Classification and Labelling of Substances
IBC-Code	International Code for the Construction and Equipment of Ships carrying dangerous Chemicals in Bulk
IARC	International Agency for Research on Cancer
LD50	Lethal dose for 50% of subjects
LC50	Lethal concentration for 50% of subjects
MAK	Maximale Arbeitsplatzkonzentration (maximum workplace concentration)
MARPOL	International Convention for the Prevention of Pollution from Ships
OEDC	Organisation for Economic Co-operation and Development
PBT/vPvB	Persistent, bioaccumulative, and toxic substances / very persistent and very bioaccumulative substances
REACH	Registration, Evaluation, and Authorisation of Chemicals
TGRS	Technische Regeln für Gefahrstoffe (technical regulations for hazardous chemicals)
USDA	US Department of Agriculture

The information given is based on our most current knowledge. It is intended to describe our products in terms of safety requirements, and should be seen by users as a guide. It does not form a guarantee of any specific product features, and does not constitute a legal relationship or state liability for damages which may arise from handling or having contact with this product/product components.

Notification:

English is acceptable for our MSDS as the following conditions are met:

- Medical specialists (users) are well educated in the English language

MSDS established : 2019-10-31

Revision number : 1