

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY**1.1 Product identifier**

Product Name: dsDNA-Ab RIA

Catalog #: KIPB19011

Kit Components: 125I-tracer
Calibrators
Controls
Specimen Diluent
Ammonium Sulfate

1.2 Intended Use

Laboratory reagent / Immunoassay.
The product is intended for professional use.

The MSDS is related to the tracer

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-Poisons (BE) 070 245 245
Please refer to your local Anti-Poison Center!

2 HAZARDS IDENTIFICATION**2.1 Classification of the substance or mixture**

The product is not classified according to the Globally Harmonised System (GHS).

2.1.1 Classification according to Directive 1999/45/EC

Not applicable

2.1.2 Additional Information

Results of PBT and vPvB assessment

- PBT: Not applicable.
- vPvB: Not applicable.

2.2 Label elements

Tube : each tube can only be used once














2.3 Other hazards

Radioactive material.

No special remarkable hazards. Please observe the informations given in this safety data sheet.

3 COMPOSITION/INFORMATION ON INGREDIENTS

Dangerous components: 125-Iodine Radionuclide (activity: < 37 kBq)

| | | | |
|-----------|--------------|---|---------|
| 77-86-1 | trometamol |  Xi R36/38 | < 1,0% |
| | |  Skin Irrit. 2, H315; Eye Irrit. 2A, H319 | |
| 60-00-4 | Edetic acid |  Xi R36/38 | <0,1% |
| | |  Eye Irrit. 2A, H319 ; Acute Tox. 5, H303 | |
| 9002-93-1 | Triton X-100 |  Xn R22  Xi R41 | < 0,05% |
| | |  Acute Tox. 3, H301;  Eye Dam. 1, H318 | |
| 54-64-8 | Thiomersal |  T+ R26/27/28 R33 | < 0,01% |
| | |  Acute Tox. 1, H300; Acute Tox. 1, H310; Acute Tox.1, H330;  STOT RE 2, H373 | |

Additional information

The reagents can contain material of human origin which has been tested and confirmed negative for HBsAg and antibodies directed against HIV. Since no test method offers complete assurance that infectious agents are absent, these reagents should be treated as potentially infectious.

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.

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

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.

Information for doctor

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.

5 FIRE FIGHTING MEASURES

Extinguishing media

- **Suitable extinguishing agents :** CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture:** No further relevant information available.

Advice for firefighters

- **Protective equipment:** No special measures required.

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:**
 - o No dangerous substances are released.
 - o See Section 7 for information on safe handling
 - o See Section 8 for information on personal protection equipment.
 - o See Section 13 for disposal information.

7 HANDLING AND STORAGE

7.1 Handling

- **Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.

7.2 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:** None.

7.3 Specific Use(s)

No further relevant information available.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

Additional information about design of technical facilities: No further data; see item 7.

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.

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.

- Protection of hands:

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 protection:** Goggles recommended during refilling.

- **Body protection:** lab coat

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 General information

- **Form:** liquid
- **Colour:** According to product specification
- **Odour:** Odourless
- **Odour threshold:** Not determined

9.2 Important health, safety and environmental information

- **pH-value:** Not determined
- **Change in condition:**
 - **Melting point/Melting range:** undetermined
 - **Boiling point/Boiling range:** undetermined
- **Flash point:** Not applicable
- **Flammability (solid, gaseous):** Not determined.
- **Ignition temperature:**
 - **Decomposition temperature:** Not determined.
- **Self-igniting:** Product is not selfigniting.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Explosion limits:**
 - **Lower:** Not determined.
 - **Upper:** Not determined.
- **Vapour pressure:** Not determined.
- **Density:** Not determined
- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** Not determined.

- **Solubility in / Miscibility with**
 - o *Water: Fully miscible*
- **Segregation coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
 - o *dynamic: Not determined.*
 - o *kinematic: Not determined.*

9.3 Other information

No further relevant information available.

10 STABILITY AND REACTIVITY

- **Reactivity**
- **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

11 TOXICOLOGICAL INFORMATION

Acute toxicity:

Primary irritant effect:

- **on the skin:** No irritant effect known.
- **on the eye:** No irritant effect known.
- **Sensitization:** No sensitizing effects known.

Additional toxicological information:

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12 ECOLOGICAL INFORMATION

Toxicity:

- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability:** No further relevant information available.

Behaviour in environmental systems:

- **Bioaccumulative potential:** No further relevant information available.
- **Mobility in soil:** No further relevant information available.

Additional ecological information:

- **General notes:** Do not allow product to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment:**
 - o **PBT:** Not applicable.
 - o **vPvB:** Not applicable.
- **Other adverse effects:** No further relevant information available.

13 DISPOSAL CONSIDERATIONS**Waste treatment methods:**

Recommendation: Must be specially treated adhering to official regulations.

Uncleaned packaging:**Recommendation:**

Packaging that may not be cleansed are to be disposed of in the same manner as the product.

Dispose of packaging according to applicable local, state, and federal regulations.

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:

| | |
|---|--|
| UN-Number ADR, IMDG, IATA | - |
| UN proper shipping name | - |
| Transport hazard class(es) <i>ADR</i> | |
| Class | 7.1 Radioactive material. |
| Packing group | - |
| Environmental hazards | |
| Marine pollutant: | No |
| Special precautions for user | Not applicable |
| Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code | Not applicable |
| Transport/Additional information | Not dangerous according to the above specifications. This product is part of a kit. Information in this section refers to the kit as a whole. |

15 REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture:**

- **GHS label elements:** Void
- **Hazard pictograms:** Void
- **Signal word:** Void
- **Hazard statements:** Void
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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.
H301 Toxic if swallowed.
H303 May be harmful if swallowed.
H310 Fatal in contact with skin.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H330 Fatal if inhaled.
H373 May cause damage to organs through prolonged or repeated exposure.

R22 Harmful if swallowed.
R26/27/28 Very toxic by inhalation, in contact with skin and if swallowed.
R33 Danger of cumulative effects.
R36 Irritating to eyes.
R36/38 Irritating to eyes and skin.
R41 Risk of serious damage to eyes.

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)

ADR: Accord européen sur le transport 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

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)

Acute Tox. 1: Acute toxicity, Hazard Category 1

Acute Tox. 3: Acute toxicity, Hazard Category 3

Acute Tox. 5: Acute toxicity, Hazard Category 5

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1

Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A

STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2

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 : 2