

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

Product Name: PP RIA

Catalog #: RB316 – RB316RUO

Kit Components: Anti-serum
¹²⁵I-labelled antigen (Tracer)
Double antibody-PEG
Assay buffer
Calibrator
Controls

1.2 Intended Use

In vitro diagnostic or Research use only

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**

Product definition: kits consisting of different reagents.
Tracer contains radioactive IOD-125.

2.1.1 Classification according to Regulation (EC) no 1272/2008 (CLP)

Components not classified as dangerous.
Tracer is covered by Council Directive 96/29 Euratom.

2.2 Label elements**Components:****Tube** : each tube can only be used once

2.3 Other hazards

Other hazards which do not result in classification	None
Substance meets the criteria for PBT under Regulation EC No. 1907/2006, appendix XIII	PBT: No (refers to substances containing)
Substance meets the criteria for vPvB under Regulation EC No. 1907/2006, appendix XIII	vPvB: No (refers to substances containing)

3 COMPOSITION/INFORMATION ON INGREDIENTS

No	Product/ingredient name	EC-number	CAS-number	REACH registration number	Conc. (weight-%)	Classification Regulation (EC) No. 1272/2008 [CLP]
Reagent Anti-serum, 125I-labelled antigen, Double antibody-PEG, Assay buffer, Calibrator, Controls						
	Sodium azide	247-852-1	26628-22-8	--	0,01-0,09	Acute Tox. 2; H300 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032

4 FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation:	Remove to fresh air, rest. Call a physician if the complaints persist.
Skin contact:	Remove contaminated clothing and footwear. Wash the skin properly with soap and water.
Eye contact:	Keep eyelids well apart. Rinse with water for a couple of minutes. Call a physician if the complaints persist.
Ingestion	Wash mouth properly with water. If victim is conscious and alert, give 2-4 cupfuls of milk/water to dilute the substance in stomach. Call a physician if the complaints persist.

4.2 Most important symptoms and effects, both acute and delayed

Inhalation:	Exposure to high airborne concentrations of the reagents in this kit may cause irritation in the respiratory tract, dizziness and sickness.
Skin contact:	Not relevant.
Eye contact:	Not relevant.
Ingestion:	Ingestion of larger amounts may cause sickness and vomiting.

4.3 Indication of any immediate medical attention and special treatment needed

Ingestion:	Treat symptomatically.
Specific treatments:	No specific treatment.

If you suspect exposure to radiation above the applicable dose limits and limit values, contact Office for Nuclear Regulation or your local Health Protection Agency.

5 FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media	Dry chemical, foam, water spray or carbon dioxide.
Unsuitable extinguishing media	Waterjet

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture	None
Hazardous thermal decomposition products	Decomposition products may include the following materials: carbon monoxide, carbon dioxide and nitrous gases.

5.3 Advice for firefighters

Special protective actions for fire-fighters	Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
Special protective equipment for fire-fighters	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.
Further information	Not applicable

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Put on appropriate personal protective equipment.
For emergency responders	If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also Section 8 for additional information on hygiene measures. Contact Office for Nuclear Regulation for further information on guidelines for safety precautions, protective equipment and safety measures during use of radioactive sources.

6.2 Environmental precautions

Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Methods and materials for containment and cleaning up

Small spill	Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
Large spill	Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with noncombustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via a licensed waste disposal contractor.

Contact Office for Nuclear Regulation for further information on guidelines for containment and cleaning up of radioactive sources.

6.4 Reference to other sections

Reference to other sections	See Section 8 for information on appropriate personal protective equipment. See Section 13 for additional waste treatment information.
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7 HANDLING AND STORAGE

7.1 Handling

Protective measures	Put on appropriate personal protective equipment (see Section 8). Contact Office for Nuclear Regulation for further information on guidelines for safe handling of radioactive sources.
Advice on general occupational hygiene	Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Storage

Storage:	Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10), food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage.
Further information:	Follow national guidelines for safe storage of radioactive sources. Contact Office for Nuclear Regulation for further information on guidelines for safe storage of radioactive sources.

7.3 Specific Use(s)

See § 1.2.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION
8.1 Exposure limit values
Occupational exposure limits

Chemical name	European Union	United Kingdom	France	Spain	Germany
Sodium azide (CAS No. 26628-22-8)	TWA: 0.1 mg/m ³ STEL 0.3 mg/m ³	STEL: 0.3 mg/m ³ TWA: 0.1 mg/m ³ Skin	VME: 0.1 mg/m ³ VLCT: 0.3 mg/m ³	VLA-EC: 0.3 mg/m ³ VLA-ED: 0.1 mg/m ³	MAK: 0.2 mg/m ³ Ceiling/Peak: 0.4 mg/m ³ TWA: 0.2 mg/m ³
Chemical name	Italy	Portugal	Netherlands	Finland	Denmark
Sodium azide (CAS No. 26628-22-8)	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Skin	Ceiling: 0.29 mg/m ³ Ceiling: 0.11 ppm	STEL: 0.3 mg/m ³ TWA: 0.1 mg/m ³ Skin	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Skin	TWA: 0.1 mg/m ³ Skin
Chemical name	Austria	Switzerland	Poland	Norway	Ireland
Sodium azide (CAS No. 26628-22-8)	STEL: 0.3 mg/m ³ MAK: 0.1 mg/m ³ Skin	STEL: 0.4 mg/m ³ MAK: 0.2 mg/m ³	NDSch: 0.3 mg/m ³ NDS: 0.1 mg/m ³ Skin	Ceiling: 0.3 mg/m ³ Skin	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Skin

Recommended monitoring procedures	Not relevant
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Derived effect levels

Product/ingredient name	Type	Exposure	Value	Population	Effects
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Predicted effect concentrations	Not available
PNEC Summary	Not available

8.2 Exposure controls

Appropriate engineering controls	Good general ventilation should be sufficient to control worker exposure to airborne contaminants. Otherwise, use local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits. Contact Office for Nuclear Regulation for further information on guidelines for personal protective equipment and safe use of radioactive sources.
Hygiene measures	Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
Respiratory protection	Not relevant during normal condition.
Eye/face protection	Safety glasses or face shield shall be worn.
Hand protection	Chemical-resistant, impervious gloves in butyl rubber or nitril rubber complying with an approved standard shall be worn.
Body protection	Wear suitable protective clothing.
Environmental exposure controls	Not applicable

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 General information

	Reagent A	Reagent B	Reagent C	Reagent D	Reagent E	Reagent F	Reagent G	Reagent H	Reagent I
Physical state	Lyophilized	Lyophilized	Liquid	Liquid	Lyophilized	Lyophilized or liquid	Lyophilized	Lyophilized	Liquid
Colour	Yellow	Blue	Red or colourless	Colourless	Colourless	Colourless	Colourless	Colourless	Colourless
Odour	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless
Odour threshold	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Solubility(ies)	Soluble in water	Soluble in water	Soluble in water	Soluble in water	Soluble in water	Soluble in water	Soluble in water	Soluble in water	Soluble in water
pH (product)	7,3-7,5	7,3-7,5	7,3-7,3	7,3-7,5	7,3-7,5	7,3-7,5	7,3-7,5	7,3-7,5	7,3-7,5
Melting point/freezing point	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d
Initial boiling point and boiling range	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d
Flash point	> 100°C	> 100°C	> 100°C	> 100°C	> 100°C	> 100°C	> 100°C	> 100°C	> 100°C
Evaporation rate (butyl acetate = 1)	< 1	< 1	< 1	< 1	< 1	< 1	< 1	< 1	< 1
Flammability (solid, gas)	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Upper/lower flammability or explosive limits	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Combustion rate	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Upper/lower flammability or explosive limits	Upper: n.a Lower: n.a	Upper: n.a Lower: n.a	Upper: n.a Lower: n.a	Upper: n.a Lower: n.a	Upper: n.a Lower: n.a	Upper: n.a Lower: n.a	Upper: n.a Lower: n.a	Upper: n.a Lower: n.a	Upper: n.a Lower: n.a
Vapour pressure (at 20°C)	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d
Vapour density	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Relative density (Water = 1)	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d
Partition coefficient: n-octanol/water	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Autoignition temperature	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d
Decomposition temperature	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d
Viscosity	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d	n.d
Explosive properties	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Oxidising properties	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a

n.a = not applicable. n.d = not determined

9.2 Other information

Tracer : Emits gamma radiation with 28-66 KBq

10 STABILITY AND REACTIVITY

Reactivity	Non-reactive
Chemical stability	Stable under normal conditions of use and storage.
Possibility of hazardous reactions	Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid	Avoid direct sunlight.
Incompatible materials	None
Hazardous decomposition products	Carbon monoxide, carbon dioxide and nitrous gases.

11 TOXICOLOGICAL INFORMATION

Acute toxicity

Assessment of acute toxicity for the different reagents:
 Not harmful if inhaled. Not harmful in contact with skin. Not harmful if swallowed.

Calculated data:

LD50 oral, rat: > 2000 mg/kg
 LD50 dermal, rat: > 2000 mg/kg

Irritation/Corrosion

Assessment of irritating effect for the different reagents
 Experimental/calculated data:
 Corrosive or irritating to the skin, rabbit: Not irritating.
 Serious eye damage/eye irritation, rabbit: Not irritating

Sensitization by inhalation/skin contact

Assessment of sensibility for the different reagents:
 May not cause any sensitizing effects.

Germ cell mutagenicity

Assessment of mutagenicity for the different reagents:
 The chemical structure of the different reagents don't indicate any mutagenic effects.

Carcinogenicity

Assessment of carcinogenicity for the different reagents:
 The chemical structure of the different reagents don't indicate any carcinogenic effects.

Reproduction toxicity

Assessment of reproduction toxicity for the different reagents:
 The chemical structure of the different reagents don't indicate any reproduction toxic effects.

Developmental toxicity

Assessment of teratogenicity for the different reagents:
 The chemical structure of the different reagents don't indicate any teratogenic effects.

Specific target organ toxicity (single exposure)

STOT assessment single dos toxicity:
 Based on available information an organ specific toxicity is not expected for the different reagents.

Repeated dose toxicity and specific organ toxicity (repeated exposure)

Based on available information an organ specific toxicity is not expected for the different reagents.

If allowable dose limits and limit values for radioactive (ionizing) radiation is exceeded, it may cause damage.
 Contact Office for Nuclear Regulation for further information.

12 ECOLOGICAL INFORMATION

12.1 Toxicity

12.1.1 Acute toxicity in the aquatic environment for sodium azide

Test	Value/unit (mg/l)	Test method	Exp. time (h)	Species
Fish LC50	0.8-1.6	--	96	Rainbow trout
Daphnia EC50	4.2	--	48	Daphnia pulex
Not readily biodegradable.				

12.1.2 Acute toxicity in the aquatic environment for all reagents (calculated)

Test	Value/unit (mg/l)	Test method	Exp. time (h)	Species
Fish LC50	> 100	--	96	--
Daphnia EC50	> 100	--	48	Daphnia magna
Algae IC50	> 100	--	72	Green algae

12.1.3 Ecotoxicity

Components contains only a low concentration of sodium azide. This concentration is below the lowest concentration limit for classification as harmful to aquatic organisms. Thus, all reagents in the kit are classified as not harmful to aquatic organisms.

12.2 Persistence and degradability

Conclusion/Summary	The reagents will be classified as readily biodegradable.
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12.3 Bioaccumulative potential

Conclusion/Summary	The reagents will not be classified as bioaccumulative.
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12.4 Mobility in soil

Soil/water partition coefficient (KOC)	Not available
Mobility	Not available

12.5 Results of PBT and vPvB assessment

PBT	Not applicable
vPvB	Not applicable

12.6 Summary – ecological information

Conclusion	The reagents will not be classified as dangerous for the environment. The product contains radioactive Iodine (IOD-125) which emits gamma radiation that has a decay time of approximately 60 days.
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13 DISPOSAL CONSIDERATIONS
13.1 Waste treatment methods
Product

Method of disposal	The generation of waste should be avoided or minimized wherever possible. This material and its container must be disposed of in a safe way. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Used kit may be potentially infectious material and shall be disposed as a hazardous waste. Contact Office for Nuclear Regulation for further information on guidelines for classification, signage and requirements for maximal radioactive activity from waste including safe disposal of radioactive sources.
Hazardous waste	Within the present knowledge of the supplier, this product is regarded as hazardous waste, as defined by EU Directive 2008/98/EU.

European Waste Catalogue (EWC)

EWC Waste Code	Type of waste
18 01 06*	Chemicals consisting of or containing dangerous substances
15 01 10*	Packaging containing residues of or contaminated by dangerous substances

Packaging

Method of disposal	Incineration.
Special precautions	None.

14 TRANSPORT INFORMATION

Product classified as dangerous goods: Yes No Not decided

	ADR/RID	ADN/ADNR	IMDG	IATA
UN number	Not regulated	Not regulated	Not regulated	Not regulated
UN proper shipping name	--	--	--	--
Transport hazard class(es)	--	--	--	--
Packing Group	--	--	--	--
Environmental hazards	--	--	--	--
Special precautions for user	Not available	Not available	Not available	Not available
Additional information	Contact Office for Nuclear Regulation for further information about national guidelines for safe transport and handling of radioactive sources. Used kit is dangerous goods by transportation in class 6.2, UN 3291. Contact the manufacturer for further information.			

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

EU Regulation (EC) No. 1907/2006 (REACH)

REACH Status	In compliance. Pre-registration status: All components are listed or exempted.
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Annex XIV - List of substances subject to authorization

Substances of very high concern
 None of the components are listed.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

Not applicable.

The product contains radioactive Iodine (IOD-125) which emits radiation with 28-66 KBq/kit, therefore please consult with the Office for Nuclear Regulation about safe use and handling of radioactive sources.
 Contact Office for Nuclear Regulation for further information on national guidelines for appropriate signage.



15.2 Chemical Safety Assessment

The reagents in this kit contain substances for which Chemical Safety Assessments still are required.

15.3 Other information

Tarif Code – harmonized system	Not applicable
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The EU Seveso Directive	Not applicable
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International regulations

Chemical Weapons Convention List Schedule I Chemicals	Chemical Weapons Convention List Schedule II Chemicals	Chemical Weapons Convention List Schedule III Chemicals
Not regulated	Not regulated	Not regulated

16 OTHER INFORMATION

Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II

Notification:

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

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

Disclaimer: The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties, protections and disposal which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.

LIST OF HAZARD STATEMENTS MENTIONED UNDER SECTION 3

No.	H-Statements
H300	Fatal if swallowed.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
EUH032	Contact with acids liberates very toxic gas.

MSDS established : 2019-03-14

Revision number : 0