

MATERIAL SAFETY DATA SHEET

According to EC Directive 1907/2006/EC.

Date of Issue: 28-02-2008

1. Identification of the substance/preparation and of the company

Product name: PAPP-A IRMA Kit, coated tube

Product code: RK-4CT

Product formal name: Diagnostic reagent

Application of the substance/preparation: In-vitro diagnostic test KIT

Manufacturer/Supplier:



Institute of Isotopes Co., Ltd.

Konkoly Thege Miklós út 29-33

H-1121 Budapest, Hungary

Phone number: (36-1) 391-0826

Fax number: (36-1) 392-2575, 395-9247

Further information available from: www.izotop.hu

Email address of the competent person: immuno@izotop.hu

Information in case of emergency: 06-80-201199

Egészségügyi-Toxicológiai szolgálat

2. Hazards identification:

Hazard description: Xn Harmful.

Information concerning particular hazards for human and environment:

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Harmful if swallowed.

3. Composition / Information on ingredients:

Component No.	Component Name	Description
1	Tracer	1 vial, ¹²⁵ I-antibody in buffer < 740 kBq
2	Standards	6 vials, containing animal serum
3	Serum Control	2 vials, containing animal serum
4	Coated Tubes	Protein coated polystyrene test tubes, 2 packs, 50 tubes/pack
5	Washing Buffer Concentrate	1 vial, containing detergent in buffer

Component No.	Hazard description
1	Contains radioactive material and sodium azide (NaN ₃) as preservatives (< 0.1%) Contains animal origin, biologically derived material
2 3	Contain animal origin, biologically derived material and Kathon CG as preservatives (< 0.1%)
4	Contains animal origin, biologically derived material
5	Contains detergent and sodium azide as preservatives (< 0.1%)

Dangerous component(s):

	Symbols	R-phrases	CAS #	EC no
Sodium azide	T+ -N	28-32-50/53	26628-22-8	247-852-1
Kathon CG:	C	34-43	None	None
Methylisothiazolinone	C	34-43	2682-20-4	220-239-6
Methylchloroisothiazolinone	C, N	34-43-50	26172-55-4	None

- Hazard codes:**
- T+ Very toxic
 - N Dangerous for the environment
 - C Corrosive
- R-phrases:**
- 28 Very toxic if swallowed.
 - 32 Contact with acids liberates very toxic gas.
 - 34 Causes burns.
 - 43 May cause sensitization by skin contact.
 - 50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Additional information: Kathon CG: is a mixture in the ratio 3:1 of 5-chloro-2-methyl-4-isothiazolin-3-one (Methylchloroisothiazolinone; CMI) and 2-methyl-4-isothiazolin-3-one (Methylisothiazolinone; MI). Sodium azide, and Kathon CG are toxic substances. Avoid contact with components, which contain sodium azide or Kathon CG, and do not ingest. All components may contain human or animal biologically derived materials.

Iodine 125 is a radioactive tracer element with 60.2 days of radioactive half-life. Emits gamma rays.

4. First Aid:

- After inhalation:** Remove victim to fresh air. If breath labored, administer oxygen as needed. If victim is not breathing, administer artificial respiration or CPR.
- After eye contact:** Flush with copious amount of fresh water for at least 15 minutes.
- After skin contact:** Wash well with mild soap and copious amount of fresh water.
- After swallowing:** Flush mouth with copious water (do not swallow rinse water).
- General information:** If ingested, or in case of feeling unwell, seek medical advice urgently. If possible, save sample of material that caused reaction for use in determination of appropriate treatment.

5. Fire extinguishing measures:

- Suitable extinguishing agents:** Use extinguishing media (dry sand, cement) appropriate to surrounding fire. Dangerous gases, which are damaging to health, do not form in dangerous quantities.
- Extinguishing agents not to be used:** None known.
- Protective equipment:** No special equipment or procedures are required.

6. Accidental release measures:

- Personal precaution:** Ensure adequate ventilation. Use personal protective equipment.
- Environmental precaution:** Prevent further leakage or spillage of safe to do so.
- Methods for cleaning up, after spillage:**
- Biological vials:** Absorb spills of reagents and patient samples with absorbent paper. Clean spill area with a freshly prepared sodium hypochlorite (bleach) solution and absorb it.
 - Radioactive vials:** The radioactive material should be wiped up immediately. Wastes have to be treated according to the country's legislation.

7. Handling and storage:

- Handling:** Wear suitable personal protective equipment. Do not pipette patient samples or reagents by mouth. Avoid splashing. Use all reagents in accordance with relevant package insert. Avoid high temperature and freezing. Do not eat, drink, smoke or apply cosmetics in laboratory areas.
- Storage:** Store kit reagents in accordance with the relevant package insert. Do not store together with ignitable and flammable substances.

8. Exposure controls/personal protection:

- Personal protective equipment:**
- Body and skin protection:** Wear laboratory coat.
 - Respiratory protection:** Under normal and intended conditions of use not required. In case of fire, wear self-contained breathing apparatus.
 - Protection of hands:** Wear non-permeable rubber, neoprene, latex or nitrile disposable gloves. Change gloves when they become contaminated.
 - Skin protection:** Wash hands after working with substance.
 - Eye protection:** Wear safety glasses or goggles when splash hazard exists.
 - Hygienic measures:** Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and immediately after handling the product. Keep away from food and drink.
- Additional information:** Avoid contact with skin and/or mouth. Avoid absorption through non-protected wound. Avoid splashing or aerosol formation. Use all reagents in accordance with the relevant package insert.

9. Physical and chemical properties:

Component No.	1	2, 3	4	5
Physical state	liquid	liquid	solid	liquid
Colour	red	yellow	clear	clear
Odour	odourless	modest	odourless	odourless
pH	7.2 – 7.6	6.0 – 8.0	N/A	6.5-7.5
Solubility in water	complete	complete	N/A	complete
Melting point	0 °C	0 °C	ca. 240 °C	0 °C
Boiling point	100 °C	100 °C	N/A	100 °C
Flammability	N/A	N/A	N/A	N/A
Auto flammability	Will not occur	Will not occur	Will not occur	Will not occur
Vapour pressure	N/A	N/A	N/A	N/A
Relative Density	1-2	1-2	N/A	1-2

10. Stability and reactivity:

Reactivity:	No hazardous reactions when used appropriately.
Stability:	The reagents in the kit are stable under the storage conditions described in the package insert.
Materials to avoid:	Avoid contact with acids, bases, oxidizing agents, reducing agents, explosive, heavy metals and metallic salts (explosive metal azide complex, when azide built up occur).
Hazardous decomposition products:	None known.
Hazardous polymerization:	Will not occur.
Conditions to avoid:	None known.

11. Toxicological information:

Signs and symptoms of exposure:	The chemical, physical, and toxicological properties have not been thoroughly investigated.
Route of exposure:	
Skin contact:	May cause skin irritation.
Skin absorption:	Danger of skin absorption, may be harmful if absorbed through the skin.
Eye contact:	May cause eye irritation.
Inhalation:	May be harmful if inhaled. May cause irritations of mucous membranes and upper respiratory tract.
Ingestion:	Harmful if swallowed. May cause irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract.
Additional information:	This product contains radionuclide, a chemical known to cause cancer and reproductive harm.

12. Ecological information:

Ecotoxicological effects:	Sodium Azide is toxic for aquatic organisms.
Radioactivity:	Dispose of following local regulations and guidelines.

13. Disposal considerations:

Product / packaging: Contact appropriate local authorities, approved waste disposal companies who will advise you on how to dispose of special waste.
If drain disposed, dilute and flush with copious amount of running water to prevent azide build-up.

14. Transport information:

Land transport ADR/RID:

ADR/RID class: 7
UN. -Number: 2910
Packaging group: II
Hazard label: 7
Description of goods: 2910 Radioactive material excepted package limited quantity of materials

Sea transport IMDG:

IMDG class: 7
UN Number: 2910
Label: 7
Packaging group: II
Marine pollutant: No
Proper shipping name: 2910 Radioactive material excepted package limited quantity of materials

Air transport ICAO/IATA:

ICAO/IATA class: 7
UN/ID Number: 2910
Label: 7
Packaging group: II
Proper shipping name: 2910 Radioactive material excepted package limited quantity of materials

15. Regulatory information:

Labelling according to EU guidelines: The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials.

Code letter and hazard designation of product: Xn Harmful

Hazard-determining components of labelling: NaN₃, Kathon CG

R-phrases: 22-52/53 Harmful if swallowed. Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

S phrases: 2-13-28-61 Keep out of the reach of children. Keep away from food, drink and animal feeding stuffs. After contact with skin, wash immediately with plenty of water. Avoid release to the environment. Refer to special instructions/safety data sheets.

Other information: Radioactive material in accordance with "A.R. of 28/02/1963 art. 31" and following, relating to the protection of the population and workers against the danger of ionising radiations.

16. Other information:

The human blood components included in this kit have been tested and found negative for HBsAg, anti-HCV and anti-HIV-1 and 2. No known method can offer complete assurance that human blood derivatives will not transmit hepatitis, AIDS or other infections. Therefore, handling of reagents, serum or plasma specimens should be in accordance with local safety procedures.

All animal products and derivatives are collected in healthy animals without any disease.

The BSA (Bovine Serum Albumin) originates from countries where BSE (Bovine Spongiform Encephalopathy) has not been reported.

The information herein is believed to be correct as of the date hereof but is provided without warranty of any kind. The recipient of our products is responsible for observing any laws and guidelines.

For in vitro diagnostics only.

This radioactive product can be transferred to and used only by authorised persons; purchase, storage, use and exchange of radioactive products are subject to the legislation of the enduser's country.

In no case the product must be administered to humans or animals.

Do not smoke, drink, eat or apply cosmetics in the working area.

Do not pipette by mouth.

Use protective clothing and disposable gloves.

All radioactive handling should be executed in a designated area, away from regular passage.

A logbook for receipt and storage of radioactive materials must be kept in the lab.

Laboratory equipment and glassware, which could be contaminated with radioactive substances, should be segregated to prevent cross contamination of different radioisotopes.

Any radioactive spills must be cleaned immediately in accordance with the radiosafety procedures.

The radioactive waste must be disposed of following the local regulations and guidelines of the notified bodies holding jurisdiction over the laboratory.

Adherence to the basic rules of the radiation safety provides adequate protection.