Date of Issue: 11-03-2013 ***Updated: 03-06-2022***

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

Product name:	CA72-4 IRMA kit, coated tube
Product code:	DE51100
Product formal name:	Diagnostic reagent
Application of the substance/preparation:	For In-vitro diagnostic test kit
Manufacturer/Supplier:	Demeditec Diagnostics GmbH Lise-Meitner-Str. 2 24145 Kiel, Germany Phone number: +49 (0) 431 / 71922 - 0 Fax number: +49 (0) 431 / 71922 - 55
Further information available from:	www.demeditec.de
Email address of the competent person:	info@demeditec.de
Information in case of emergency:	call your local emergency centre

2. Hazards identification:

2.1 Classification of the substance or mixture of the kit
Classification according to Regulation (EC) No 1272/2008 [CLP]
Not classified as hazardous per EC 1272/2008 [CLP].

2.2 Label elements
Labelling according to Regulation (EC) No 1272/2008 [CLP]
Not classified as hazardous per EC 1272/2008 [CLP].

2.3 Other hazards
Additional information:
1. ***Sodium azide*** is a toxic substance. Avoid contact with components, which contain sodium azide and do not ingest.
2. ***Biologically derived materials***: All components may contain human or animal biologically derived materials.
3. ***Radioactive component - Iodine 125:*** This is a radioactive tracer element with 60.2 day radioactive half-life. Emits gamma rays. It is the responsibility of the user to ensure that local regulations or code of practice related to the handling of radioactive materials are satisfied.
4. ***Triton-X 100***: Non-ionic surfactant mixtures varying in the number of repeating ethoxy (oxy-1,2-ethanediyl) groups. They are used as detergents in in vitro diagnostic reagents as buffer solutions. The kit components may contain < 0.1 % Triton-X 100.

3. Composition / Information on ingredients:

Component No.	Component Name	Description
1	TRACER	1 bottle (21 mL), ^{125}I-antibody in buffer solution
2	STANDARDS	4 vials (4 x 1 mL), containing human serum
3	CONTROL SERUM	2 vials (2 x 1 mL), containing human serum
4	COATED TUBES	Protein coated polystyrene test tubes, 2 packs, 50 tubes/pack
5	WASH BUFFER CONCENTRATE	1 bottle (40 mL), containing detergent in buffer
6	ANTISERUM	1 bottle (11 mL), containing antibody in buffer
7	DILUENT	1 bottle (5 mL), containing animal serum

Component No.	Hazard description
1	Contains radioactive material (< 980 kBq). Contains animal origin, biologically derived material and sodium azide (NaN_3) as preservative (< 0.1%). Contains Triton-X 100 as detergent (< 0.1%)
2 3	Contains human origin, biologically derived material and NaN_3 as preservative (< 0.1%)
4	Contains animal origin, biologically derived material
5	Contains detergent and sodium azide as preservative (< 0.1%)
6	Contains animal origin, biologically derived material and sodium azide (NaN_3) . Contains Triton-X 100 as detergent (< 0.1%)
7	Contains animal origin, biologically derived material and sodium azide (NaN_3) as preservative (< 0.1%)

Dangerous component(s):

International chemical identification	**CAS #**		**EC no**		
Sodium azide	26628-22-8		247-852-1		
	Classification		**Labelling**		
	Hazard class and Category Code(s)	*Hazard statement Code(s)*	*Supplementary hazard statement Code(s)*	*Pictogram(s), signal word Code(s)*	
	Acute tox. 2	H300	EUH 032	GHS05 GHS06 GHS09 Dgr	
	Aquatic Acute 1	H400			
	Aquatic Chronic 1	H410			
	Signal words		**Pictogram(s)**		
	Danger		 **Skull and crossbones**	 **Environment**	 **Corrosive to metals**

Hazard statements:

H300	Fatal if swallowed
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life
EUH032	Contact with acids liberates very toxic gas

Precautionary statements:

P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301 + P310 + P330	If swallowed immediately called a POISON CENTER or doctor/physician. Rinse mouth.
P302 + P352 + P310	If on skin gently wash with plenty of soap and water. Immediately called a POISON CENTER or doctor/physician.
P391	Collect spillage.
P501	Dispose of contents/container as waste: in an approved waste.

International chemical identification	**CAS #**		**EC no**	
Octylphenyl Polyethylene Glycol (Triton-X 100)	9002-93-1		-	
	Classification		**Labelling**	
	Hazard class and Category Code(s)	*Hazard statement Code(s)*	*Supplemental hazard statement Code(s)*	*Pictogram(s), signal word Code(s)*
	Acute tox. 4	H302	none	GHS05 GHS07 GHS09
	Aquatic Acute 1	H400		
	Aquatic Chronic 2	H410		
	Skin irritation 2	H315		
	Serious eye damage 1	H318		
	Signal words		**Pictogram(s)**	
	Danger		 **Irritant**	 **Environment**  **Corrosive**

Hazard Statements:

H302	Harmful if swallowed
H315	Causes skin irritation
H318	Causes serious eye damage
H410	Very toxic to aquatic life with long lasting effects

Precautionary statements:

P264	Wash skin thoroughly after handling.
P273	Avoid release to the environment.
P280	Wear protective gloves/ eye protection/ face protection.
P301 + P312	Call a POISON CENTER/ doctor if you feel unwell.
P302 + P352	IF ON SKIN: Wash with plenty of water.

4. First Aid:

After inhalation: Remove victim to fresh air. If breath laboured, 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 (2, 3, 6, 7): 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 bottles/vials (1): 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	6	7
Physical state	liquid	liquid	solid	liquid	liquid	liquid
Colour	red	yellow	clear	clear	blue	yellow
Odour	odourless	modest	odourless	odourless	odourless	odourless
pH	7.3 - 7.5	6.0 – 8.0	N/A	6.5-7.0	7.3 - 7.5	6.0 - 8.0
Solubility in water	complete	complete	N/A	complete	complete	complete
Melting point	0 °C	0 °C	ca. 240 °C	0 °C	0 °C	0 °C
Boiling point	100 °C	100 °C	N/A	100 °C	100 °C	100 °C
Flammability	N/A	N/A	N/A	N/A	N/A	N/A
Auto flammability	Will not occur	Will not occur	Will not occur	Will not occur	Will not occur	Will not occur
Vapour pressure	N/A	N/A	N/A	N/A	N/A	N/A
Relative Density	1-2	1-2	N/A	1-2	1-2	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:

Toxicity data for hazardous ingredients:

Sodium azide (CAS # 26628-22-8): Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 mg/kg

Triton-X 100 (CAS # 9002-93-1): Oral LD50 in Rat 1800 mg/kg

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 may cause cancer and reproductive harm.

This product contains materials of human and animal origins and should be considered as potentially infectious materials.

12. Ecological information:

Ecotoxical effects: Sodium Azide and Triton-X 100 are 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 sodium-azide build-up.

14. Transport information:

RID/ADR/IATA **7**

UN Number: 2910

Proper shipping name: UN 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.

Hazard-determining components of labelling: * NaN_3 and Triton-X 100

** But as mentioned in the REGULATION (EC) No 1272/2008 under point 1.5(a) there is no hazard labelling necessary as the total volume of the components of the KIT is under 125 ml.*

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, 2 and Treponema Antibody. 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) as 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 end-user'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 radio safety 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.