

Trade name: CA 19-9 IRMA
Product number: DE50100

Date of Issue: 24-09-2012

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

Product name: CA19-9-IRMA Kit, coated tube
Product code: DE50100
Product formal name: Diagnostic reagent
Application of the substance/preparation: 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: +49 (0) 431 / 71922 - 0

2. Hazards identification:

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]

Acute toxicity, Oral (Category 2)
Acute aquatic toxicity (Category 1)
Chronic aquatic toxicity (Category 1)

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Harmful if swallowed. Contact with acids liberates very toxic gas. Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]



Pictogram(s):

Signal word: Danger

Hazard statement(s):

H300 Fatal if swallowed.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statement(s):

P264 Wash hands thoroughly after handling.
P273 Avoid release to the environment.
P273 If swallowed: immediately call a poison center or doctor/physician.
P501 Dispose of contents/ containers to an approved waste disposal plant.

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.

According to European Directive 67/548/EEC as amended



Hazard symbol(s):

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R-phrase(s):

- R28 Toxic if swallowed
- R32 Contact with acids liberates very toxic gas
- R34 Causes burns
- R43 May cause sensitization by skin contact
- R50/53 Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment.

S-phrase(s):

- S28 After contact with skin, wash immediately with plenty of soap and water
- S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label if possible)
- S61 Avoid release to the environment. Refer to special instructions/ Safety data sheets

2.3 Other hazards

Contains radioactive component

Additional information:

1. **Kathon CG**: is a mixture in the ratio 3:1 of 5-chloro-2methyl-4-isothiazolin-3-one (Methylchloroisothiazolinone; CMI) and 2-methyl-4-isothiazolin-3-one (Methylisothiazolinone; MI).
2. **Kathon CG** is a toxic substance. Avoid contact with components, which contain Kathon CG, and do not ingest. All components may contain human or animal biologically derived materials.
3. **Iodine 125** is a radioactive tracer element with 60.2 day radioactive half-life. Emits gamma rays.

3. Composition / Information on ingredients:

Component No.	Component Name	Description
1	Tracer	1 bottle, ¹²⁵ I-antibody in buffer < 980 kBq
2	Antiserum	1 bottle, containing antibody in buffer
3	Dilution serum	2 bottles, containing animal serum
4	Standards	5 vials, containing human serum
5	Serum Control	2 vials, containing human serum
6	Coated Tubes	Protein coated polystyrene test tubes, 2 packs, 50 tubes/pack
7	Washing Buffer Concentrate	1 vial, containing detergent in buffer

Component No.	Hazard description
1	Contains radioactive material and Kathon CG as preservative (< 0.1%) Contains animal origin, biologically derived material
2	Contains animal origin, biologically derived material and Kathon CG as preservative (< 0.1 %)
3 4 5	Contains human and/or animal origin, biologically derived material and Kathon CG as preservative (< 0.1%)
6	Contains animal origin, biologically derived material
7	Contains detergent and Kathon CG as preservative (< 0.1%)

Dangerous component(s):

	Symbols	R-phrases	CAS #	EC no
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: N Dangerous for the environment
C Corrosive

R-phrases: 34 Causes burns.
43 May cause sensitization by skin contact.
50 Very toxic to aquatic organism, may cause long-term adverse effects in the aquatic environment.

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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: 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.

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9. Physical and chemical properties:

Component No.	1	2	3,4,5	6	7
Physical state	liquid	liquid	liquid	solid	liquid
Colour	red	blue	yellow	clear	clear
Odour	odourless	odourless	modest	odourless	odourless
pH	2.5 – 3.5	2.5 – 3.5	6.0 – 8.0	N/A	2.5 - 3.5
Solubility in water	complete	complete	complete	N/A	complete
Melting point	0 °C	0 °C	0 °C	ca. 240 °C	0 °C
Boiling point	100 °C	100 °C	100 °C	N/A	100 °C
Flammability	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
Vapour pressure	N/A	N/A	N/A	N/A	N/A
Relative Density	1-2	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.

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:

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.

14. Transport information:

RID/ADR/IATA 7

UN Number:

2910

Proper shipping name:

UN 2910 Radioactive material excepted package - limited quantity of materials

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15. Regulatory information:

Labelling according to EU guidelines:

The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials.

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 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.