

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

**Date of Issue:** 24-09-2012

**Updated:** 19-09-2019

## 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:** 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](http://www.demeditec.de)  
**Email address of the competent person:** [info@demeditec.de](mailto: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:

- a. **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). This is a toxic substance. Avoid contact with components, which contain Kathon CG, and do not ingest.
- b. **Sodium azide** is a toxic substance. Avoid contact with components, which contain sodium azide and do not ingest.
- c. **Biologically derived materials**: All components may contain human or animal biologically derived materials.
- d. **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.

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**3. Composition / Information on ingredients:**

| Component No. | Component Name          | Description  |
|---------------|-------------------------|--|
| 1             | TRACER                  | 1 bottle (21 mL), <sup>125</sup> I-antibody in buffer solution   |
| 2             | ANTISERUM               | 1 bottle (11 mL), containing antibody in buffer                  |
| 3             | DILUTION SERUM          | 2 bottles (2 x 2.5 mL), containing animal serum                  |
| 4             | STANDARDS               | 5 vials (5 x 1.0 mL), containing human serum                     |
| 5             | CONTROL SERUM           | 2 vials (2 x 1.0 mL), containing human serum                     |
| 6             | COATED TUBES            | Protein coated polystyrene test tubes,<br>2 packs, 50 tubes/pack |
| 7             | WASH BUFFER CONCENTRATE | 1 bottle (20 mL), containing detergent in buffer                 |

| Component No. | Hazard description  |
|---------------|---|
| 1             | Contains radioactive material (< 980 kBq). Contains animal origin, biologically derived material and Kathon CG as preservative (< 0.1%) |
| 2             | Contains animal origin, biologically derived material and Kathon CG as preservative (< 0.1 %)   |
| 3<br>4<br>5   | Contains human and/or animal origin, biologically derived material, NaN <sub>3</sub> and Kathon CG as preservative (< 0.1%)             |
| 6             | Contains animal origin, biologically derived material   |
| 7             | Contains detergent and Kathon CG as preservative (< 0.1%)   |

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**Dangerous component(s):**

| International chemical identification | CAS #                                    | EC no  |  |   |
|---------------------------------------|--|--|--|---|
| <b>Kathon CG</b>                      | 55965-84-9                               | -  |  |   |
|                                       | Classification                           | Labelling  |  |   |
|                                       | <i>Hazard class and Category Code(s)</i> | <i>Hazard statement Code(s)</i>  | <i>Supplementary hazard statement Code(s)</i>  | <i>Pictogram(s), signal word Code(s)</i>  |
|                                       | Acute tox. 3                             | H301   |  | GHS06<br>GHS09<br>GHS05<br>Dgr  |
|                                       | Acute tox. 3                             | H311   |  |   |
|                                       | Skin Corr. 1B                            | H314   |  |   |
|                                       | Skin Sens. 1                             | H317   |  |   |
|                                       | Acute Tox. 3                             | H331   |  |   |
|                                       | Aquatic Acute 1                          | H400   |  |   |
|                                       | Aquatic Chronic 1                        | H410   |  |   |
|                                       | Signal words                             | Pictogram(s)   |  |   |
|                                       | Danger                                   | <br><b>Skull and crossbones</b> | <br><b>Enviroment</b> | <br><b>Corrosion</b> |

**Hazardous statements:**

H301 Toxic if swallowed.  
H311 Toxic in contact with skin.  
H314 Causes severe skin burns and eye damage.  
H317 May cause an allergic skin reaction.  
H331 Toxic if inhaled.  
H400 Very toxic to aquatic life.  
H410 Very toxic to aquatic life with long lasting effects.

**Precautionary statements:**

P273 Avoid release to the environment.  
P280 Wear protective gloves/protective clothing/eye protection/face protection.  
P305 + P351 + P338 IF IN EYES: rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P310 Immediately call a POISON CENTER or doctor/phisycian.

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

**Hazardous 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/phisycian. Rinse mouth.  
P302 + P352 + P310 If on skin gently wash with plenty of soap and water. Immediately called a POISON CENTER or doctor/phisycian.  
P391 Collect spillage.  
P501 Dispose of contents/container as waste: in an approved waste.

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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 (2, 3, 4, 5):** 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.

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**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         | 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 |
| Vapour pressure     | N/A            | N/A            | N/A            | N/A            | N/A            |
| Relative Density    | 1-2            | 1-2            | 1-2            | N/A            | 1-2            |

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**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:****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

Kathon-CG:

Oral LD50 Rat female 3723 mg/kg, Rat male 3600 mg/kg;

Dermal LD50 Rabbit female 3600 mg/kg, Rabbit male 3500 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.

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**12. Ecological information:****Ecotoxicological effects:** Sodium Azide is toxic for aquatic organisms.

Kathon CG is toxic to aquatic life for long lasting effects.

**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:** \* **Kathon CG and NaN<sub>3</sub>***\* But as mentioned in the REGULATION (EC) No 1272/2008 under point 1.5(a) there is no hazard labeling 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.

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|------------------------|--------------|
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**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.