

Name and version of the MSDS: **NG-Test CARBA 5 - version 3 – Revision 10/2019****SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Product NG-Test CARBA 5 (Ref. NGB-CAR-S23-XXX)

1.2. Relevant identified uses of the substance or mixture and uses advised against

Rapid qualitative immunoassay for the detection of KPC, OXA, VIM, IMP and NDM carbapenemases in bacterial colony from culture. In vitro diagnostic for professional use.

1.3. Details of the supplier of the safety data sheetManufacturer NG Biotech
Z.A. Courbouton Secteur 1,
35480 Guipry, FRANCE
info@ngbiotech.com**1.4. Emergency telephone number**Emergency telephone Phone: +33 (0)2 23 30 17 83 (during normal business hours only)
+33 (0)1 45 42 59 59 (Poisons Information Service in France)
Other countries: Contact local authorities**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture**

The mixture does not meet the criteria for classification in accordance with Regulation (EC) No. 1272/2008 / (EC) No. 1907/2006 / GHS

2.2. Label elements

None according to Regulation (EC) No. 1272/2008 / GHS

2.3. Other hazards

Not applicable.

SECTION 3: Composition/information on ingredients**3.1. Substances**

This product is a mixture.

| Component | No. CAS | No. CE | Percent (by weight) | Classification according to EU regulation 1272/2008 / GHS |
|-----------|---------|--------|---------------------|---|
| N/A | N/A | N/A | N/A | N/A |

3.2. Mixtures

The kit is composed by a test strip (sample pad, nitrocellulose membrane pre-coated with antibodies, polyester release matrix pre-coated with antibodies labelled with colloidal gold and absorbent pad) protected by a plastic housing, one vial of extraction buffer and accessories.

Mixture including substances found in traces listed below, with non-hazardous additions.

| Component | No. CAS | No. CE | Percent (by weight) | Classification according to EU regulation 1272/2008 / GHS |
|------------------------|-------------|-----------|---------------------|--|
| Sodium azide | 26628-22-8 | 247-852-1 | < 0.1% | Acut Tox 2, Acute Tox 1, STOT RE 2, aquatic acute 1, Aquatic Chronic 1 |
| EDTA | 6381-91-6 | 205-358-3 | < 0.1% | Acute Tox. 4, STOT RE 2 |
| N, N-Dimethylformamide | 331717-45-4 | 68-12-2 | < 0.1% | Repr. 1B, Acute Tox. 4 Eye Irrit. 2 |

SECTION 4: First aid measures

The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the strip.

4.1. Description of first aid measures

After skin contact: Wash with soap and plenty of water.

After eye contact: Rinse eyes with water as a precaution.

After ingestion: Rinse mouth with water.

After inhalation: In case of inhalation, remove the person from the contaminated area.

4.2. Most important symptoms and effects, both acute and delayed

Not applicable

4.3. Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Not Applicable, the device is not inflammable

5.2. Special hazards arising from the substance or mixture

No data available

5.3. Advice for firefighters

Not Applicable, the device is not inflammable

SECTION 6: Accidental release measures

Information are pertinent only with an abusive use of the device (opening the device with a direct exposition of chemical products)

6.1. Personal precautions, protective equipment and emergency procedures

Avoid direct contact with skin, eyes, mucous membranes, and clothing with appropriate personal protective equipment (PPE) including gloves and lab coat.

6.2. Environmental precautions

Avoid release in the environment

6.3. Methods and material for containment and cleaning up

Dispose of in a biological and risk of infection bin

6.4. Reference to other sections

Not applicable

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Do not eat, drink or smoke in the zone of manipulation. Wearing individual protective equipment is recommended

7.2. Conditions for safe storage, including any incompatibilities

Store between 4-30°C.

7.3. Specific end use(s)

see section 1.2

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace

8.2. Exposure controls

Not assigned

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Form: Solid

Color : White

Odor: N/A

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known if handled under normal conditions of use

10.2. Chemical stability

Stable under recommended storage temperature

10.3. Possibility of hazardous reactions

None if used for the intended purpose

10.4. Conditions to avoid

None if used for the intended purpose

10.5. Incompatible materials

None known

10.6. Hazardous decomposition products

None known

SECTION 11: Toxicological information

Information are pertinent only with an abusive use of the device (opening the device with a direct exposition of chemical products)

11.1. Information on toxicological effects

No data available

SECTION 12: Ecological information

Information are pertinent only with an abusive use of the device (opening the device with a direct exposition of chemical products)

12.1. Toxicity

No data available

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

No data available

12.6. Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Dispose the device and/or the packing of in a biological and risk of infection bin in compliance with national rules

SECTION 14: Transport information

14.1. UN number

Not applicable

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

See section 12

14.6. Special precautions for user

See section 6

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Delivery will only be made in an approved and regulated packaging

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Not classified as dangerous according to EU regulation

15.2. Chemical safety assessment

The mixture has not been subject to a safety assessment

SECTION 16: Other information

Warranty

The above information is believed to be correct but is all inclusive and should only be used as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not present any guarantee of the properties of the product. NG Biotech shall not be liable for any damage resulting from handling or contact with the above product

Written by: Francius Laura – R&D project Manager

Date: October 21, 2019

Signature:

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Date: October 21, 2019

Signature:

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