

KIT COMPONENTSProduct name: **RDТ Dengue NS1 Ag, 25 Tests**Product code: **70702**

Article number	Description	Quantity	Symbols
7073A	Device	25	
7073B	Migration buffer (2.0 ml)	1	GHS07

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 26.10.2020

Version number 1

Revision: 26.10.2020

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
 - **Trade name:** Device
 - **Article number:** 7073A
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**

No further relevant information available.

 - **Application of the substance / the mixture** In vitro diagnostic medical device or component.
- **1.3 Details of the supplier of the safety data sheet**
 - **Manufacturer/Supplier:**

Bio-Rad
3, Boulevard Raymond Poincaré
F-92430 Marnes-la-Coquette
Tel.: +33 (0)1 47 95 60 00
Fax: +33 (0)1 47 41 91 33
e-mail: fds-msds.fr@bio-rad.com
 - **Further information obtainable from:** Customer Support.
- **1.4 Emergency telephone number:** See item 16

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
 - **Classification according to Regulation (EC) No 1272/2008**

The product is not classified, according to the CLP regulation.
- **2.2 Label elements**
 - **Labelling according to Regulation (EC) No 1272/2008** Void
 - **Hazard pictograms** Void
 - **Signal word** Void
 - **Hazard statements** Void
- **2.3 Other hazards**
 - **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
 - **Description:** Mixture containing components at a non hazardous concentration.

- **Dangerous components:**

CAS: 57-50-1	sucrose, pure	substance with a Community workplace exposure limit	10-25%
EINECS: 200-334-9			

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 26.10.2020

Version number 1

Revision: 26.10.2020

Trade name: Device

(Contd. of page 1)

SECTION 4: First aid measures

· 4.1 Description of first aid measures

- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** Consult a doctor, if necessary.

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

No further relevant information available.

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

No further relevant information available.

SECTION 5: Firefighting measures

· 5.1 Extinguishing media

· **Suitable extinguishing agents:**

CO₂, powder or water spray. Fight larger fires with water spray.
Use fire extinguishing methods suitable to surrounding conditions.

· 5.2 Special hazards arising from the substance or mixture

No further relevant information available.

· 5.3 Advice for firefighters

- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Wear disposable gloves.

· 6.2 Environmental precautions:

Do not allow product to reach sewage system or any water course.

· 6.3 Methods and material for containment and cleaning up:

Pick up mechanically.

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Avoid all contact with reagents, even those considered to be non-hazardous.

Follow good laboratory practices.

- **Information about fire - and explosion protection:** No special measures required.

· 7.2 Conditions for safe storage, including any incompatibilities

· **Storage:**

- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.

(Contd. on page 3)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 26.10.2020

Version number 1

Revision: 26.10.2020

Trade name: Device

(Contd. of page 2)

- **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
 - **Ingredients with limit values that require monitoring at the workplace:**

57-50-1 sucrose, pure	
WEL	Short-term value: 20 mg/m ³ Long-term value: 10 mg/m ³
 - **Additional information:** The lists valid during the making were used as basis.
 - **Personal protective equipment:**
 - **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
 - **Respiratory protection:** Suitable respiratory protective device recommended.
 - **Protection of hands:** Protective gloves
 - **Eye protection:** Safety glasses

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
 - **General Information**
 - **Appearance:**
 - **Form:** Solid in various forms
 - **Colour:** Various colours
 - **Odour:** Odourless
 - **pH-value:** Not applicable.
 - **Change in condition**
 - **Melting point/freezing point:** Undetermined.
 - **Flash point:** Not applicable.
 - **Auto-ignition temperature:** Product is not selfigniting.
 - **Explosive properties:** Product does not present an explosion hazard.
 - **Solubility in / Miscibility with**
 - **water:** Insoluble.
 - **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 26.10.2020

Version number 1

Revision: 26.10.2020

Trade name: Device

(Contd. of page 3)

- **10.2 Chemical stability**
 - **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
 - **Acute toxicity** Based on available data, the classification criteria are not met.
 - **Primary irritant effect:**
 - **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
 - **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
 - **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
 - **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
 - **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
 - **Carcinogenicity** Based on available data, the classification criteria are not met.
 - **Reproductive toxicity** Based on available data, the classification criteria are not met.
 - **STOT-single exposure** Based on available data, the classification criteria are not met.
 - **STOT-repeated exposure** Based on available data, the classification criteria are not met.
 - **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
 - **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
 - **Additional ecological information:**
 - **General notes:** Avoid transfer into the environment.
- **12.5 Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
 - **Recommendation** Must be specially treated adhering to official regulations.

(Contd. on page 5)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 26.10.2020

Version number 1

Revision: 26.10.2020

Trade name: Device

(Contd. of page 4)

- **Uncleaned packaging:**
 - **Recommendation:** Disposal must be made according to official regulations.
 - **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

· 14.1 UN-Number	
· ADR, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name	
· ADR, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	Void
· 14.4 Packing group	
· ADR, IMDG, IATA	Void
· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	Not dangerous according to the above specifications.
· UN "Model Regulation":	Void

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
 - **Directive 2012/18/EU**
 - **Named dangerous substances - ANNEX I** None of the ingredients is listed.
 - **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**
 - None of the ingredients is listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

GB

(Contd. on page 6)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 26.10.2020

Version number 1

Revision: 26.10.2020

Trade name: Device

(Contd. of page 5)

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Department issuing SDS:

MSDS / FDS Administr.

Bio-Rad

Marnes-la-Coquette, France

· Contact:

Customer Support

Phone : +33 (0)1 47 95 62 77

UNITED KINGDOM

Bio-Rad Laboratories Ltd.

Bio-Rad House, Maxted Road,

Hemel Hempstead , Hertfordshire HP2 7DX

Phone : +44-20-8328-2000

Fax : +44-20-8328-2550

· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 26.10.2020

Version number 1

Revision: 26.10.2020

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
 - **Trade name:** Migration buffer (2.0 ml)
 - **Article number:** 7073B
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**


No further relevant information available.

 - **Application of the substance / the mixture** In vitro diagnostic medical device or component.
- **1.3 Details of the supplier of the safety data sheet**
 - **Manufacturer/Supplier:**

Bio-Rad
3, Boulevard Raymond Poincaré
F-92430 Marnes-la-Coquette
Tel.: +33 (0)1 47 95 60 00
Fax: +33 (0)1 47 41 91 33
e-mail: fds-msds.fr@bio-rad.com
 - **Further information obtainable from:** Customer Support.
- **1.4 Emergency telephone number:** See item 16

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
 - **Classification according to Regulation (EC) No 1272/2008**



GHS07

Skin Sens. 1 H317 May cause an allergic skin reaction.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.
- **2.2 Label elements**
 - **Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the CLP regulation.

 - **Hazard pictograms** GHS07
 - **Signal word** Warning
 - **Hazard-determining components of labelling:**

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)
 - **Hazard statements**

H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.
 - **Precautionary statements**

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P273 Avoid release to the environment.
P302+P352 IF ON SKIN: Wash with plenty of water and soap.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P321 Specific treatment (see on this label).

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 26.10.2020

Version number 1

Revision: 26.10.2020

Trade name: Migration buffer (2.0 ml)

P501

Dispose of contents/container in accordance with local/regional/national/international regulations.

(Contd. of page 1)

· 2.3 Other hazards

· Results of PBT and vPvB assessment





- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures

- **Description:** Preparation containing hazardous components.

· Dangerous components:

CAS: 55965-84-9 Index number: 613-167-00-5	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)  Acute Tox. 3, H301; Acute Tox. 2, H310; Acute Tox. 2, H330  Skin Corr. 1C, H314; Eye Dam. 1, H318  Aquatic Acute 1, H400; Aquatic Chronic 1, H410  Skin Sens. 1A, H317	<0.01%
---	--	--------

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

· 4.1 Description of first aid measures

- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** Call for a doctor immediately.

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

No further relevant information available.

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

No further relevant information available.

SECTION 5: Firefighting measures

· 5.1 Extinguishing media

· Suitable extinguishing agents:

CO₂, powder or water spray. Fight larger fires with water spray.
Use fire extinguishing methods suitable to surrounding conditions.

· 5.2 Special hazards arising from the substance or mixture

No further relevant information available.

· 5.3 Advice for firefighters

- **Protective equipment:** No special measures required.

GB

(Contd. on page 3)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 26.10.2020

Version number 1

Revision: 26.10.2020

Trade name: Migration buffer (2.0 ml)

(Contd. of page 2)

SECTION 6: Accidental release measures**· 6.1 Personal precautions, protective equipment and emergency procedures**

Wear protective clothing.

Wear disposable gloves.

· 6.2 Environmental precautions: Do not allow product to reach sewage system or any water course.**· 6.3 Methods and material for containment and cleaning up:**

Absorb liquid components with liquid-binding material.

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage**· 7.1 Precautions for safe handling** Follow good laboratory practices.**· Information about fire - and explosion protection:** No special measures required.**· 7.2 Conditions for safe storage, including any incompatibilities****· Storage:****· Requirements to be met by storerooms and receptacles:** No special requirements.**· Information about storage in one common storage facility:** Not required.**· Further information about storage conditions:** None.**· 7.3 Specific end use(s)** No further relevant information available.**SECTION 8: Exposure controls/personal protection****· Additional information about design of technical facilities:** No further data; see item 7.**· 8.1 Control parameters****· Ingredients with limit values that require monitoring at the workplace:**

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

· Additional information: The lists valid during the making were used as basis.**· Personal protective equipment:****· General protective and hygienic measures:** Wash hands before breaks and at the end of work.**· Respiratory protection:** Suitable respiratory protective device recommended.**· Protection of hands:** Protective gloves**· Eye protection:** Safety glasses

GB

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 26.10.2020

Version number 1

Revision: 26.10.2020

Trade name: Migration buffer (2.0 ml)

(Contd. of page 3)

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

· Form:	Solution
· Colour:	Colourless
· Odour:	Odourless

· pH-value: Not determined.

· Change in condition

· Melting point/freezing point: Undetermined.

· Initial boiling point and boiling range: Undetermined.

· Flash point: Not applicable.

· Explosive properties: Product does not present an explosion hazard.

· Density: Not determined.

· Solubility in / Miscibility with

· water: Fully miscible.

· 9.2 Other information No further relevant information available.

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

· 10.2 Chemical stability

· Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

· 10.3 Possibility of hazardous reactions No dangerous reactions known.

· 10.4 Conditions to avoid No further relevant information available.

· 10.5 Incompatible materials: No further relevant information available.

· 10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

· Acute toxicity Based on available data, the classification criteria are not met.

· Primary irritant effect:

· Skin corrosion/irritation Based on available data, the classification criteria are not met.

· Serious eye damage/irritation Based on available data, the classification criteria are not met.

· Respiratory or skin sensitisation

May cause an allergic skin reaction.

· CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

· Germ cell mutagenicity Based on available data, the classification criteria are not met.

· Carcinogenicity Based on available data, the classification criteria are not met.

(Contd. on page 5)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 26.10.2020

Version number 1

Revision: 26.10.2020

Trade name: Migration buffer (2.0 ml)

(Contd. of page 4)

- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
 - **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
 - **Additional ecological information:**
 - **General notes:** Avoid transfer into the environment.
- **12.5 Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
 - **Recommendation** Must be specially treated adhering to official regulations.
- **Uncleaned packaging:**
 - **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|---|------|
| · 14.1 UN-Number
· ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name
· ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es)
· ADR, ADN, IMDG, IATA
· Class | Void |
| · 14.4 Packing group
· ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards:
· Marine pollutant: | No |

(Contd. on page 6)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 26.10.2020

Version number 1

Revision: 26.10.2020

Trade name: Migration buffer (2.0 ml)

(Contd. of page 5)

- | | |
|--|-----------------|
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Void |

SECTION 15: Regulatory information

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

- **Directive 2012/18/EU**

- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

- **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**

H301 Toxic if swallowed.
H310 Fatal in contact with skin.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H330 Fatal if inhaled.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

- **Department issuing SDS:**

MSDS / FDS Administr.
Bio-Rad
Marnes-la-Coquette, France

- **Contact:**

Customer Support
Phone : +33 (0)1 47 95 62 77

UNITED KINGDOM
Bio-Rad Laboratories Ltd.
Bio-Rad House, Maxted Road,
Hemel Hempstead, Hertfordshire HP2 7DX

(Contd. on page 7)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 26.10.2020

Version number 1

Revision: 26.10.2020

Trade name: Migration buffer (2.0 ml)

(Contd. of page 6)

Phone : +44-20-8328-2000

Fax : +44-20-8328-2550

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 3: Acute toxicity - oral – Category 3

Acute Tox. 2: Acute toxicity - dermal – Category 2

Skin Corr. 1C: Skin corrosion/irritation – Category 1C

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1A: Skin sensitisation – Category 1A

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

GB