

KIT COMPONENTS

Product name: **RDT Dengue NS1 Ag, 25 Tests** Product code: **70702**

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



according to WHS Regulations

Version number 1 Revision: 26.10.2020 Printing date 26.10.2020

Not classified as hazardous according to criteria of Safe Work Australia.

1 Identification

· Article number: 7073A

· 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.

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.

· Emergency telephone number: See item 16

2 Hazard(s) Identification

· Classification of the substance or mixture

The product is not classified, according to the Globally Harmonised System (GHS).

- · Label elements
 - · GHS label elements Void
 - · Hazard pictograms Void
 - · Signal word Void
 - · Hazard statements Void
- · Other hazards
 - Results of PBT and vPvB assessment
 - · **PBT:** Not applicable.
 - · vPvB: Not applicable.

3 Composition and Information on Ingredients

- · Chemical characterisation: Mixtures
 - Description: Mixture containing components at a non hazardous concentration.
 - Dangerous components:

57-50-1 sucrose, pure

10-25%

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· Product identifier

· Trade name: Device





according to WHS Regulations

Printing date 26.10.2020 Version number 1 Revision: 26.10.2020

Trade name: Device

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

4 First Aid Measures

- 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.
 - · Information for doctor:
 - · Most important symptoms and effects, both acute and delayed No further relevant information available.
 - · Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Fire Fighting Measures

- · Extinguishing media
 - Suitable extinguishing agents:

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

- · Special hazards arising from the substance or mixture No further relevant information available.
- Advice for firefighters
 - · Protective equipment: No special measures required.

6 Accidental Release Measures

- · Personal precautions, protective equipment and emergency procedures Wear disposable gloves.
- Environmental precautions: Do not allow product to reach sewage system or any water course.
- · Methods and material for containment and cleaning up: Pick up mechanically.
- 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.

7 Handling and Storage

- · Handling:
 - 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.

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Trade name: Device

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- · 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.
- · Specific end use(s) No further relevant information available.

8 Exposure controls and personal protection

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

57-50-1 sucrose, pure

WES Long-term value: 10 mg/m³

- · 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

9 Physical and Chemical Properties

- · Information on basic physical and chemical properties
 - · General Information
 - · Appearance:

Form: Solid in various formsColour: Various colours

· 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.

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Trade name: Device

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· Other information

No further relevant information available.

10 Stability and Reactivity

- · Reactivity No further relevant information available.
 - Chemical stability
 - Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological Information

- Information on toxicological effects
 - · Additional toxicological information:

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12 Ecological Information

- · Toxicity
 - Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
 - · Bioaccumulative potential No further relevant information available.
 - · Mobility in soil No further relevant information available.
- · Additional ecological information:
 - · General notes: Avoid transfer into the environment.
- · Results of PBT and vPvB assessment
 - · **PBT**: Not applicable.
 - · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

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

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Trade name: Device

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

4 Transport information	
· UN-Number · ADG, ADN, IMDG, IATA	Void
· UN proper shipping name · ADG, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
ADG, ADN, IMDG, IATA Class	Void
· Packing group · ADG, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.
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

15 Regulatory information

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

· <i>p</i>	· Australian Inventory of Industrial Chemicals		
57-50-1	sucrose, pure		
9003-39-8	Polyvinylpyrrolidone		
6131-90-4	sodium acetate trihydrate		
6138-23-4	D(+) Trehalose		
7558-80-7	Sodium dihydrogen phosphate		
	Tris(hydroxymethyl)-aminomethane		
7647-14-5	sodium chloride		
6132-04-3	Trisodium citrate dihydrate		
7758-11-4	dipotassium hydrogenorthophosphate		
7778-77-0	potassium dihydrogenorthophosphate		
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Safety Data Sheet

according to WHS Regulations

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Trade name: Device

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· Standard for the Uniform Scheduling of Medicines and Poisons

Tris(hydroxymethyl)-aminomethane

S4

· Australia: Priority Existing Chemicals

None of the ingredients is listed.

· Directive 2012/18/EU

- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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

AUSTRALIA

Bio-Rad Laboratories Pty. Ldt. Level 5, 446 Vistoria Road Gladesville NSW 2111 Phone: +61-2-9914-2800

Fax: +61-2-9914-2888

· 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

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

AUS





according to WHS Regulations

Printing date 26.10.2020 Version number 1 Revision: 26.10.2020

Hazardous according to criteria of Safe Work Australia.

1 Identification

· Product identifier

· Trade name: Migration buffer (2.0 ml)

· Article number: 7073B

· 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.

· 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.
- · Emergency telephone number: See item 16

2 Hazard(s) Identification

· Classification of the substance or mixture



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

- · Label elements
 - · GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

- · 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

May cause an allergic skin reaction.

· Precautionary statements

Avoid breathing dust/fume/gas/mist/vapours/spray.

Wear protective gloves.

IF ON SKIN: Wash with plenty of water and soap.

If skin irritation or rash occurs: Get medical advice/attention.

Specific treatment (see on this label).

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

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Trade name: Migration buffer (2.0 ml)

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- · Other hazards
 - · Results of PBT and vPvB assessment
 - PBT: Not applicable.vPvB: Not applicable.

3 Composition and Information on Ingredients

- · Chemical characterisation: Mixtures
 - · **Description:** Preparation containing hazardous components.
 - · Dangerous components:

55965-84-9 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. 1, H314; Eye Dam. 1, H318

Skin Sens. 1A, H317

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

4 First Aid Measures

- · 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.
 - · Information for doctor:
 - · Most important symptoms and effects, both acute and delayed No further relevant information available.
 - · Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Fire Fighting Measures

- Extinguishing media
 - · Suitable extinguishing agents:

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

- · Special hazards arising from the substance or mixture No further relevant information available.
- Advice for firefighters
 - · Protective equipment: No special measures required.

6 Accidental Release Measures

· Personal precautions, protective equipment and emergency procedures Wear protective clothing.

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Trade name: Migration buffer (2.0 ml)

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Wear disposable gloves.

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

Absorb liquid components with liquid-binding material.

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.

7 Handling and Storage

- · Handling:
 - Precautions for safe handling Follow good laboratory practices.
 - · Information about fire and explosion protection: No special measures required.
- 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.
- · Specific end use(s) No further relevant information available.

8 Exposure controls and personal protection

- Additional information about design of technical facilities: No further data; see item 7.
- · 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
 - · Eve protection: Safety glasses

9 Physical and Chemical Properties

- · Information on basic physical and chemical properties
 - General Information
 - · Appearance:

Form: Solution
Colour: Colourless
Odour: Odourless

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according to WHS Regulations

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Trade name: Migration buffer (2.0 ml)

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· pH-value:	Not determined.	
Change in condition		
Melting point/freezing point:	Undetermined.	
· Initial boiling point and boiling	g range: Undetermined.	
· Flash point:	Not applicable.	
· Explosive properties:	plosive properties: Product does not present an explosion hazard.	
· Density:	sity: Not determined.	
· Solubility in / Miscibility with		
· water:	Fully miscible.	
· Other information	No further relevant information available.	

10 Stability and Reactivity

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

11 Toxicological Information

- · Information on toxicological effects
 - · Acute toxicity
 - Respiratory or skin sensitisation Sensitisation possible through skin contact.

12 **Ecological Information**

- · Toxicity
 - · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
 - · Bioaccumulative potential No further relevant information available.
 - · Mobility in soil No further relevant information available.
- Additional ecological information:
 - · General notes: Avoid transfer into the environment.
- · Results of PBT and vPvB assessment
 - · PBT: Not applicable.
 - · vPvB: Not applicable.

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Trade name: Migration buffer (2.0 ml)

· Other adverse effects No further relevant information available.

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13 Disposal considerations

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

Transport information		
UN-Number · ADG, ADN, IMDG, IATA	Void	
UN proper shipping name ADG, ADN, IMDG, IATA	Void	
Transport hazard class(es)		
· ADG, ADN, IMDG, IATA · Class	Void	
Packing group · ADG, IMDG, IATA	Void	
Environmental hazards: · Marine pollutant:	No	
Special precautions for user	Not applicable.	
Transport in bulk according to Anni Marpol and the IBC Code	ex II of Not applicable.	
UN "Model Regulation":	Void	

15 Regulatory information

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

· Australian Inventory of Industrial Chemicals	
7732-18-5	water, distilled, conductivity or of similar purity
7558-80-7	Sodium dihydrogen phosphate
7558-79-4	disodium hydrogenorthophosphate
9000-71-9	CASEINE
9005-64-5	Polysorbate 20
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Trade name: Migration buffer (2.0 ml)

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· Standard for the Uniform Scheduling of Medicines and Poisons

7558-79-4 disodium hydrogenorthophosphate

S3, S4

· Australia: Priority Existing Chemicals

None of the ingredients is listed.

· Directive 2012/18/EU

- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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.

Department issuing SDS:

MSDS / FDS Administr.

Bio-Rad

Marnes-la-Coquette, France

· Contact:

Customer Support

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

AUSTRALIA

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IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

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. 1: Skin corrosion/irritation - Category 1

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

Skin Sens. 1: Skin sensitisation – Category 1

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