



10/26/2020

KIT COMPONENTS

Product name: **RDТ Dengue NS1 Ag, 25 Tests**

Product code: **70702**

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

Safety Data Sheet

according to HPR, Schedule 1

Printing date 10/26/2020

Reviewed on 10/26/2020

1 Identification

- **Product identifier**

- **Trade name:** Device

- **Article number:** 7073A

- **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
92430 Marnes-la-Coquette
Phone: +33 (0)1 47 95 60 00
Fax: +33 (0)1 47 41 91 33
e-mail: fds-msds.fr@bio-rad.com

Bio-Rad laboratories (Canada) Ltd.
2403 Guénette Montreal,
Montréal (Québec) H4R 2E9
Phone: (800) 361-1808
Fax: (514) 334-0872

- **Information department:** Customer support.
 - **Emergency telephone number:** See item 16

2 Hazard identification

- **Classification of the substance or mixture**



Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.

- **Label elements**

- **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms** GHS07

- **Signal word** Warning

- **Hazard-determining components of labeling:**

Gold (III) chloride trihydrate

- **Hazard statements**

May cause an allergic skin reaction.

- **Precautionary statements**

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

Contaminated work clothing should not be allowed out of the workplace.

Wear protective gloves.

If on skin: Wash with plenty of soap and water.

Take off contaminated clothing and wash it before reuse.

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

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Specific treatment (see on this label).

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

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**

Health = 0

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

Health = 0

Fire = 0

Reactivity = 0

3 Composition/Information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** Mixture containing components at a non hazardous concentration.

· **Dangerous components:**

57-50-1	sucrose, pure	10-30% w/w *
16961-25-4	Gold (III) chloride trihydrate	0.1-1% w/w *
	<div> <div></div> <div>Skin Corrosion - Category 1B, H314; Serious Eye Damage - Category 1, H318</div> </div>	
	<div> <div></div> <div>Skin Sensitizer - Category 1, H317</div> </div>	

* Actual concentration ranges are withheld as a trade secret.

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, extinguishing powder or water spray. Fight larger fires with water spray.

Use fire fighting measures that suit the environment.

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- **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 protection against explosions and fires:** 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/ Personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

57-50-1 sucrose, pure

EL	TWA: 10* 3** mg/m ³ *total dust; **respirable fraction
EV	TWA: 10 mg/m ³ total dust

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Personal protective equipment:**
 - **General protective and hygienic measures:**
 - The usual precautionary measures for handling chemicals should be followed.
 - **Breathing equipment:** Suitable respiratory protective device recommended.

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- **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 forms
- **Color:** Various colors
- **Odor:** Odorless

- **pH-value:** Not applicable.

· Change in condition

- **Melting point/Melting range:** Undetermined.

- **Flash point:** Not applicable.

- **Auto igniting:** Product is not selfigniting.

- **Danger of explosion:** Product does not present an explosion hazard.

· Solubility in / Miscibility with

- **Water:** Insoluble.
- **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 internally approved calculation methods for preparations:

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

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Trade name: Device

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· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

9003-39-8 Polyvinylpyrrolidone

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· NTP (National Toxicology Program)

None of the ingredients is listed.

12 Ecological information

· Toxicity

· **Aquatic toxicity:** No further relevant information available.

· **Persistence and degradability** No further relevant information available.

· Behavior 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.

· Uncleaned packagings:

· **Recommendation:** Disposal must be made according to official regulations.

· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

· UN-Number

· DOT/TDG, ADR, ADN, IMDG, IATA Void

· UN proper shipping name

· DOT/TDG, ADR, ADN, IMDG, IATA Void

· Transport hazard class(es)

· DOT, ADR, ADN, IMDG, IATA

· Class

Void

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· Packing group	
· DOT/TDG, ADR, IMDG, IATA	Void
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL73/78 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**
- Sara

· Section 355 (extremely hazardous substances):

None of the ingredient is listed.

· Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

· TSCA (Toxic Substances Control Act):

57-50-1	sucrose, pure	ACTIVE
9003-39-8	Polyvinylpyrrolidone	ACTIVE
7558-80-7	Sodium dihydrogen phosphate	ACTIVE
	Tris(hydroxymethyl)-aminomethane	ACTIVE
7647-14-5	sodium chloride	ACTIVE
7758-11-4	dipotassium hydrogenorthophosphate	ACTIVE
7778-77-0	potassium dihydrogenorthophosphate	ACTIVE

· Canadian substance listings:

· Canadian Domestic Substances List (DSL)

57-50-1	sucrose, pure
9003-39-8	Polyvinylpyrrolidone
7558-80-7	Sodium dihydrogen phosphate
	Tris(hydroxymethyl)-aminomethane
7647-14-5	sodium chloride
7758-11-4	dipotassium hydrogenorthophosphate
7778-77-0	potassium dihydrogenorthophosphate

· Canadian Ingredient Disclosure list (limit 0.1%)

None of the ingredients is listed.

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Trade name: Device

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· Canadian Ingredient Disclosure list (limit 1%)

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

CANADA

Bio-Rad laboratories (Canada) Ltd.,
2403 Guénette Montreal,
Montreal (Québec) H4R 2E9

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· Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
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)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

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1 Identification

· **Product identifier**

· **Trade name:** Migration buffer (2.0 ml)

· **Article number:** 7073B

· **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
92430 Marnes-la-Coquette
Phone: +33 (0)1 47 95 60 00
Fax: +33 (0)1 47 41 91 33
e-mail: fds-msds.fr@bio-rad.com

Bio-Rad laboratories (Canada) Ltd.
2403 Guénette Montreal,
Montréal (Québec) H4R 2E9
Phone: (800) 361-1808
Fax: (514) 334-0872

· **Information department:** Customer support.

· **Emergency telephone number:** See item 16

2 Hazard identification

· **Classification of the substance or mixture**



Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.

Aquatic Acute 3 H402 Harmful to aquatic life.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· **Label elements**

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms** GHS07

· **Signal word** Warning

· **Hazard-determining components of labeling:**

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.

Harmful to aquatic life.

Harmful to aquatic life with long lasting effects.

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Trade name: Migration buffer (2.0 ml)

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- **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapours/spray.
 Contaminated work clothing should not be allowed out of the workplace.
 Avoid release to the environment.
 Wear protective gloves.
 If on skin: Wash with plenty of soap and water.
 Take off contaminated clothing and wash it before reuse.
 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.

- **Classification system:**

- **NFPA ratings (scale 0 - 4)**

Health = 0
 Fire = 0
 Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**

Health = 0
 Fire = 0
 Reactivity = 0

3 Composition/Information on ingredients

- **Chemical characterization: Mixtures**

- **Description:** Mixture 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)	≤0.1% w/w
	<ul style="list-style-type: none"> ⚠ Acute Toxicity (Oral) - Category 3, H301; Acute Toxicity (Dermal) - Category 2, H310; Acute Toxicity (Inhalation) - Category 2, H330 ⚠ Skin Corrosion - Category 1C, H314; Serious Eye Damage - Category 1, H318 ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410 ⚠ Skin Sensitizer - Category 1A, H317 	

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:** Immediately call a doctor.

- **Information for doctor:**

- **Most important symptoms and effects, both acute and delayed**

No further relevant information available.

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Trade name: Migration buffer (2.0 ml)

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- **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, extinguishing powder or water spray. Fight larger fires with water spray.
Use fire fighting measures that suit the environment.
- **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.
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 protection against explosions and fires:** 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/ Personal protection

- **Additional information about design of technical systems:** No further data; see item 7.

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Trade name: Migration buffer (2.0 ml)

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- **Control parameters**
 - **Components 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 that were valid during the creation were used as basis.
- **Personal protective equipment:**
 - **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
 - **Breathing equipment:** 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:** Solution
 - **Color:** Colorless
 - **Odor:** Odorless
- **pH-value:** Not determined.
- **Change in condition**
 - **Melting point/Melting range:** Undetermined.
 - **Boiling point/Boiling range:** Undetermined.
- **Flash point:** Not applicable.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Density:** 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.

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Trade name: Migration buffer (2.0 ml)

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- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
 - **Acute toxicity:**
 - **Sensitization:** Sensitization possible through skin contact.
 - **Additional toxicological information:**
 - **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
 - **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior 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.
- **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **UN-Number**
- **DOT/TDG, ADR, ADN, IMDG, IATA** Void

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- | | |
|--|-----------------|
| · UN proper shipping name | |
| · DOT/TDG, ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT/TDG, ADR, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Void |

15 Regulatory information

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

· Section 355 (extremely hazardous substances):

None of the ingredient is listed.

· Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

· TSCA (Toxic Substances Control Act):

7732-18-5	water, distilled, conductivity or of similar purity	ACTIVE
7558-80-7	Sodium dihydrogen phosphate	ACTIVE
7558-79-4	disodium hydrogenorthophosphate	ACTIVE
9000-71-9	CASEINE	ACTIVE
9005-64-5	Polysorbate 20	ACTIVE

· Canadian substance listings:

· Canadian Domestic Substances List (DSL)

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
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)

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· Canadian Ingredient Disclosure list (limit 0.1%)

None of the ingredients is listed.

· Canadian Ingredient Disclosure list (limit 1%)

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

CANADA

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2403 Guénette Montreal,

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Phone : (800) 361-1808

Fax : (514) 334-0872

· Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative