

KIT COMPONENTSProduct name: **Genie™ Fast HIV 1/2, 50 Tests**Product code: **72330**

| Article number | Description | Quantity | Symbols |
|----------------|--|----------|---------|
| 764081 | Device | 50 | |
| 7230T | Diluent (for the whole blood protocol), 5 ml | 1 | |

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

Printing date 20.10.2020

Version number 2

Revision: 02.07.2015

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

- **1.1 Product identifier**
 - **Trade name:** Device
 - **Article number:** 764081
- **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 without a chemical hazard.
 - **Dangerous components:** Void
 - **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**
 - **General information:** No special measures required.

(Contd. on page 2)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 20.10.2020

Version number 2

Revision: 02.07.2015

Trade name: Device

(Contd. of page 1)

- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **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:**
Use fire extinguishing methods suitable to surrounding conditions.
CO₂, powder or water spray. Fight larger fires with water spray.
- **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** No dangerous substances are released.

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.
 - **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.

(Contd. on page 3)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 20.10.2020

Version number 2

Revision: 02.07.2015

Trade name: Device

(Contd. of page 2)

· 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:**

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: | Web |
| · Colour: | White |
| · Odour: | Odourless |

· **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:** Insoluble.

· **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.

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 20.10.2020

Version number 2

Revision: 02.07.2015

Trade name: Device

(Contd. of page 3)

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

GB

(Contd. on page 5)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 20.10.2020

Version number 2

Revision: 02.07.2015

Trade name: Device

(Contd. of page 4)

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

- **15.2 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.

- **Department issuing SDS:**
MSDS / FDS Administr.
Bio-Rad
Marnes-la-Coquette, France
- **Contact:**
Customer Support
Phone : +33 (0)1 47 95 62 77

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(Contd. on page 6)

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

Printing date 20.10.2020

Version number 2

Revision: 02.07.2015

Trade name: Device

Fax : +44-20-8328-2550

(Contd. of page 5)

Abbreviations and acronyms:

ICAO: International Civil Aviation Organisation

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

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

GB

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Version number 2

Revision: 02.07.2015

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

- **1.1 Product identifier**
 - **Trade name:** Diluent (for the whole blood protocol), 5 ml
 - **Article number:** 7230T
- **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:** Void
 - **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**
 - **General information:** No special measures required.

(Contd. on page 2)

GB

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Version number 2

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Trade name: Diluent (for the whole blood protocol), 5 ml

(Contd. of page 1)

- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **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:**
Use fire extinguishing methods suitable to surrounding conditions.
CO₂, powder or water spray. Fight larger fires with water spray.
- **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:**
Absorb liquid components with liquid-binding material.
- **6.4 Reference to other sections** No dangerous substances are released.

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

GB

(Contd. on page 3)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 20.10.2020

Version number 2

Revision: 02.07.2015

Trade name: Diluent (for the whole blood protocol), 5 ml

(Contd. of page 2)

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:**
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:** Fluid
 - **Colour:** Colourless
 - **Odour:** Weak, characteristic
 - **Change in condition**
 - **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.

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 20.10.2020

Version number 2

Revision: 02.07.2015

Trade name: Diluent (for the whole blood protocol), 5 ml

(Contd. of page 3)

- **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.

· **LD/LC50 values relevant for classification:**

26628-22-8 Sodium Azide

| | | |
|--------|------|-------------------|
| Oral | LD50 | 27 mg/kg (rat) |
| Dermal | LD50 | 20 mg/kg (rabbit) |

· **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.

· **Uncleaned packaging:**

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

(Contd. on page 5)

Safety data sheet

according to 1907/2006/EC, Article 31

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Version number 2

Revision: 02.07.2015

Trade name: Diluent (for the whole blood protocol), 5 ml

(Contd. of page 4)

· **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

· **15.2 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.

· **Department issuing SDS:**

MSDS / FDS Administr.

Bio-Rad

Marnes-la-Coquette, France

· **Contact:**

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(Contd. on page 6)

GB

Safety data sheet
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Printing date 20.10.2020

Version number 2

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Trade name: Diluent (for the whole blood protocol), 5 ml

(Contd. of page 5)

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· Abbreviations and acronyms:

ICAO: International Civil Aviation Organisation

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

GB