



10/20/2020

KIT COMPONENTS

Product 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

29 CFR Part 1910.1200

Printing date 10/20/2020

Reviewed on 07/02/2015

1 Identification

- **Product identifier**

- **Trade name:** Device

- **Article number:** 764081

- **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

- **Information department:** Customer support.

- **Emergency telephone number:**

- See item 16

- This SDS is listed with CHEMTREC 1800-424-9300 / 1-510-741-1000.

- Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION or ACCIDENT with this product.

2 Hazard(s) identification

- **Classification of the substance or mixture**

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

- **Label elements**

- **GHS label elements** Void

- **Hazard pictograms** Void

- **Signal word** Void

- **Hazard statements** Void

- **Classification system:**

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

- Health = 0

- Fire = 0

- Reactivity = 0

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

- Health = 0

- Fire = 0

- Reactivity = 0

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

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Trade name: Device

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3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
 - **Description:** Mixture without a chemical hazard.
 - **Dangerous components:** Void

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:** 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.
- **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:**
Use fire fighting measures that suit the environment.
CO₂, extinguishing powder or water spray. Fight larger fires with water spray.
- **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** No dangerous substances are released.

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.

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- **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:**
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.
- **Exposure controls**
 - **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.
 - **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: | Web |
| · Color: | White |
| · Odor: | Odorless |

- **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**

- | | |
|---|------------|
| <ul style="list-style-type: none"> · Water: | Insoluble. |
|---|------------|

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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 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.

- **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.

- **OSHA-Ca (Occupational Safety & Health Administration)**

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.

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· **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, ADR, ADN, IMDG, IATA	Void
· UN proper shipping name	
· DOT, ADN, IMDG, IATA	Void
· ADR	Void
· Transport hazard class(es)	
· DOT, ADR, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· DOT, 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.

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· **TSCA (Toxic Substances Control Act):**

None of the ingredients is listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenicity categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

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:**

SDS / FDS Administr.

Bio-Rad

Marnes-la-Coquette, France

· **Contact:**

Customer Support

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

USA

Bio-Rad Laboratories

6565 185th Avenue NE

Redmond, WA 98052-5039

Phone Number: 1-800-2BIORAD (1-800-224-6723) or (425) 881-8300 (daytime PST)

· **Date of preparation / last revision** 10/20/2020 / 1

· **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)

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IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
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
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit

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1 Identification

- **Product identifier**

- **Trade name:** Diluent (for the whole blood protocol), 5 ml
 - **Article number:** 7230T
 - **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

- **Information department:** Customer support.

- **Emergency telephone number:**

See item 16

This SDS is listed with CHEMTREC 1800-424-9300 / 1-510-741-1000.

Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION or ACCIDENT with this product.

2 Hazard(s) identification

- **Classification of the substance or mixture**

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

- **Label elements**

- **GHS label elements** Void
 - **Hazard pictograms** Void
 - **Signal word** Void
 - **Hazard statements** Void

- **Classification system:**

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

Health = 0

Fire = 0

Reactivity = 0

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

Health = 0

Fire = 0

Reactivity = 0

- **Other hazards**

- **Results of PBT and vPvB assessment**

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

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

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3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
 - **Description:** Mixture containing components at a non hazardous concentration.
 - **Dangerous components:** Void

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:** 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.
 - **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:**
Use fire fighting measures that suit the environment.
CO₂, extinguishing powder or water spray. Fight larger fires with water spray.
- **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:**
Absorb liquid components with liquid-binding material.
- **Reference to other sections** No dangerous substances are released.

7 Handling and storage

- **Handling:**
 - **Precautions for safe handling**
Avoid all contact with reagents, even those considered to be non-hazardous.

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

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- 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:**
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.
- **Exposure controls**
 - **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.
 - **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:** Fluid
- **Color:** Colorless
- **Odor:** Weak, characteristic

· Change in condition

- **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.

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

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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**

· **Acute toxicity:**

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

26628-22-8 Sodium Azide

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

· **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.

· **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.

· **OSHA-Ca (Occupational Safety & Health Administration)**

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.

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

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- **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, ADR, ADN, IMDG, IATA	Void
· UN proper shipping name	
· DOT, ADN, IMDG, IATA	Void
· ADR	Void
· Transport hazard class(es)	
· DOT, ADR, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· DOT, 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

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

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15 Regulatory information

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

- **Section 355 (extremely hazardous substances):**

26628-22-8	Sodium Azide
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- **Section 313 (Specific toxic chemical listings):**

26628-22-8	Sodium Azide
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- **TSCA (Toxic Substances Control Act):**

7647-14-5	sodium chloride
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26628-22-8	Sodium Azide
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7732-18-5	water, distilled, conductivity or of similar purity
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- **Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients is listed.	
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- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.	
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- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.	
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- **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.	
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- **Carcinogen categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.	
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- **TLV (Threshold Limit Value established by ACGIH)**

26628-22-8	Sodium Azide
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- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.	
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- **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:**
SDS / FDS Administr.
Bio-Rad
Marnes-la-Coquette, France

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

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· Contact:

Customer Support
Phone : +33 (0)1 47 95 62 77
USA
Bio-Rad Laboratories
6565 185th Avenue NE
Redmond, WA 98052-5039

Phone Number: 1-800-2BIORAD (1-800-224-6723) or (425) 881-8300 (daytime PST)

· Date of preparation / last revision 10/20/2020 / 1**· 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
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit

— USA —