

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

Article number	Description	Quantity	Symbols
764081	Test device Genie™ Fast HIV 1/2	50	
7230T	Diluant (for the whole blood protocol), 5 ml	1	

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/02/2015

1 Identification· **Product identifier**

-
- Trade name: Test device Genie™ Fast HIV 1/2**

· **Article number:** 764081

-
- 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

-
- Information department:**
- Customer support.

-
- Emergency telephone number:**

See item 16

+33 (0)1 47 95 62 77

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.**3 Composition/information on ingredients**· **Chemical characterization: Mixtures**

-
- Description:**
- Mixture without a chemical hazard.

(Contd. on page 2)

USA

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/02/2015

Trade name: Test device Genie™ Fast HIV 1/2

(Contd. of page 1)

- **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:**
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**
Prevent formation of dust.
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.

(Contd. on page 3)

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/02/2015

Trade name: Test device Genie™ Fast HIV 1/2

(Contd. of page 2)

- **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:** Not required.
 - **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
 - **Eye protection:** Not required.

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.
 - **Auto igniting:** Product is not selfigniting.
 - **Danger of explosion:** Product does not present an explosion hazard.
 - **Density:** Not determined.
 - **Solubility in / Miscibility with**
 - **Water:** Insoluble.
 - **Other information** No further relevant information available.

USA

(Contd. on page 4)

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/02/2015

Trade name: Test device Genie™ Fast HIV 1/2

(Contd. of page 3)

10 Stability and reactivity

- **Reactivity**
 - **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:**
 - **Primary irritant effect:**
 - **on the skin:** No irritant effect.
 - **on the eye:** No irritating effect.
 - **Sensitization:** No sensitizing effects known.
 - **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:** Generally not hazardous for water
- **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

(Contd. on page 5)

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/02/2015

Trade name: Test device Genie™ Fast HIV 1/2

· **Other adverse effects** No further relevant information available.

(Contd. of page 4)

13 Disposal considerations

· **Waste treatment methods**

· **Recommendation:**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **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 Void

· Class

· **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":**

-

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):**

None of the ingredients is listed.

(Contd. on page 6)

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/02/2015

Trade name: Test device Genie™ Fast HIV 1/2

(Contd. of page 5)

· 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.

· Cancerogenity 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 08/04/2015 / -

· 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)

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/02/2015

1 Identification

- **Product identifier**
 - **Trade name: Diluant (for the whole blood protocol), 5 ml**
 - **Article number:** 7230T
 - **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
 - **Information department:** Customer support.
 - **Emergency telephone number:**
See item 16
+33 (0)1 47 95 62 77

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.

3 Composition/information on ingredients

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

(Contd. on page 2)

USA

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/02/2015

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

(Contd. of page 1)

- **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:**
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:** Dilute with plenty of water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **Reference to other sections** No dangerous substances are released.

7 Handling and storage

- **Handling:**
 - **Precautions for safe handling**
Keep receptacles tightly sealed.
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.

(Contd. on page 3)

USA

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/02/2015

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

(Contd. of page 2)

- **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:** Not required.
 - **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
 - **Eye protection:** Goggles recommended during refilling.

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**
 - **Melting point/Melting range:** Undetermined.
 - **Boiling point/Boiling range:** Undetermined.
 - **Flash point:** Not applicable.
 - **Auto igniting:** Product is not selfigniting.
 - **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.

USA

(Contd. on page 4)

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/02/2015

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

(Contd. of page 3)

10 Stability and reactivity

- **Reactivity**
 - **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)

- **Primary irritant effect:**
 - **on the skin:** No irritant effect.
 - **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.

- **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:** Generally not hazardous for water

(Contd. on page 5)

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/02/2015

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

(Contd. of page 4)

- **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 not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **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":	-

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

(Contd. on page 6)

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/02/2015

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

(Contd. of page 5)

· Section 313 (Specific toxic chemical listings):		
26628-22-8	Sodium Azide	
· TSCA (Toxic Substances Control Act):		
7647-14-5	sodium chloride	
26628-22-8	Sodium Azide	
7732-18-5	water, distilled, conductivity or of similar purity	
· 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.		
· Cancerogenity categories		
· EPA (Environmental Protection Agency)		
None of the ingredients is listed.		
· TLV (Threshold Limit Value established by ACGIH)		
26628-22-8	Sodium Azide	A4
· 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 08/04/2015 / -

· 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)

(Contd. on page 7)

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/02/2015

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

(Contd. of page 6)

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

USA