

**KIT COMPONENTS**Product name: **Genie™ III HIV-1/HIV-2, 50 Tests**Product code: **72328**

<b>Article number</b>	<b>Description</b>	<b>Quantity</b>	<b>Symbols</b>
1.850	Genie™ III HIV-1/HIV-2 Test Device	50	
1.851	Genie™ III HIV-1/HIV-2 Wash Reagent, 10 ml	1	

**Safety Data Sheet**  
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/01/2015

**1 Identification**

- **Product identifier**
  - **Trade name: Genie™ III HIV-1/HIV-2 Test Device**
  - **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.
  - **Dangerous components:** Void

**Safety Data Sheet**  
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/01/2015

**Trade name: Genie™ III HIV-1/HIV-2 Test Device**

(Contd. of page 1)

**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.
- **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.
  - **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.

USA

(Contd. on page 3)

**Safety Data Sheet**  
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/01/2015

**Trade name: Genie™ III HIV-1/HIV-2 Test Device**

(Contd. of page 2)

**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:** Solid
      - **Color:** According to product specification
    - **Odor:** 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:** Insoluble.
  - **Other information** No further relevant information available.

**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.

(Contd. on page 4)

**Safety Data Sheet**  
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/01/2015

**Trade name: Genie™ III HIV-1/HIV-2 Test Device**

(Contd. of page 3)

- **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:** Generally not hazardous for water

**· 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.

USA

(Contd. on page 5)

**Safety Data Sheet**  
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/01/2015

**Trade name: Genie™ III HIV-1/HIV-2 Test Device**

(Contd. of page 4)

**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):
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.
· 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.

(Contd. on page 6)

**Safety Data Sheet**  
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/01/2015

**Trade name: Genie™ III HIV-1/HIV-2 Test Device**

(Contd. of page 5)

**· 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 / 1

**· Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

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)

USA

**Safety Data Sheet**  
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/01/2015

**1 Identification**· **Product identifier**

- **Trade name: Genie™ III HIV-1/HIV-2 Wash Reagent, 10 ml**
- **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 07/01/2015

**Trade name: Genie™ III HIV-1/HIV-2 Wash Reagent, 10 ml**

(Contd. of page 1)

**· Dangerous components:**

25322-68-3 Polyethylene glycol

0.1-2.5%

**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:**

CO<sub>2</sub>, 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**

In case of fire, the following can be released:

Nitrogen oxides (NO<sub>x</sub>)

Carbon monoxide (CO)

**· Advice for firefighters****· Protective equipment:**

Wear fully protective suit.  
Wear self-contained respiratory protective device.

**6 Accidental release measures****· Personal precautions, protective equipment and emergency procedures**

Wear disposable gloves.

**· Environmental precautions:**

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

**· Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Dispose contaminated material as waste according to item 13.

**· 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.

USA

(Contd. on page 3)

**Safety Data Sheet**  
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/01/2015

**Trade name: Genie™ III HIV-1/HIV-2 Wash Reagent, 10 ml**

(Contd. of page 2)

**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:**

**25322-68-3 Polyethylene glycol**

WEEL	10 mg/m <sup>3</sup> aerosol
------	---------------------------------

· **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.  
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
    - **Body protection:** Protective work clothing

**9 Physical and chemical properties**

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· <b>Form:</b>	Fluid
· <b>Color:</b>	Colorless
· <b>Odor:</b>	Odorless

· **pH-value at 20 °C (68 °F):** 8.3

· **Change in condition**

· <b>Melting point/Melting range:</b>	Undetermined.
· <b>Boiling point/Boiling range:</b>	100 °C (212 °F)

(Contd. on page 4)

**Safety Data Sheet**  
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/01/2015

**Trade name: Genie™ III HIV-1/HIV-2 Wash Reagent, 10 ml**

(Contd. of page 3)

· <b>Flash point:</b>	Not applicable.
· <b>Auto igniting:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Vapor pressure at 20 °C (68 °F):</b>	23 hPa (17 mm Hg)
· <b>Density at 20 °C (68 °F):</b>	1.01 g/cm <sup>3</sup> (8.428 lbs/gal)
· <b>Solubility in / Miscibility with</b>	
· <b>Water:</b>	Fully miscible.
· <b>Other information</b>	No further relevant information available.

**10 Stability and reactivity**

- **Reactivity**
  - **Chemical stability**
    - **Thermal decomposition / conditions to be avoided:**  
No decomposition if used according to specifications.
- **Possibility of hazardous reactions**  
Reacts with heavy metals.  
Contact with acids releases toxic gases.
- **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.

(Contd. on page 5)

**Safety Data Sheet**  
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/01/2015

**Trade name: Genie™ III HIV-1/HIV-2 Wash Reagent, 10 ml**

(Contd. of page 4)

· **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** biodegradable
- **Behavior in environmental systems:**
  - **Bioaccumulative potential** Does not accumulate in organisms
  - **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
  - **General notes:**  
Water hazard class 1 (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **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**

- |                                     |      |
|-------------------------------------|------|
| · <b>UN-Number</b>                  |      |
| · DOT, ADR, ADN, IMDG, IATA         | Void |
| · <b>UN proper shipping name</b>    |      |
| · DOT, ADN, IMDG, IATA              | Void |
| · ADR                               | Void |
| · <b>Transport hazard class(es)</b> |      |
| · DOT, ADR, ADN, IMDG, IATA         |      |
| · Class                             | Void |
| · <b>Packing group</b>              |      |
| · DOT, ADR, IMDG, IATA              | Void |
| · <b>Environmental hazards:</b>     |      |
| · <b>Marine pollutant:</b>          | No   |

(Contd. on page 6)

**Safety Data Sheet**  
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/01/2015

**Trade name: Genie™ III HIV-1/HIV-2 Wash Reagent, 10 ml**

(Contd. of page 5)

· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	Not dangerous according to the above specifications.
· <b>UN "Model Regulation":</b>	-

**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
------------	--------------

· **Section 313 (Specific toxic chemical listings):**

26628-22-8	Sodium Azide
------------	--------------

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

25322-68-3	Polyethylene glycol
------------	---------------------

64-02-8	tetrasodium ethylenediaminetetraacetate
---------	---

7447-40-7	potassium chloride
-----------	--------------------

77-86-1	trometamol
---------	------------

1185-53-1	2-amino-2-(hydroxymethyl)propane-1,3-diolhydrochloride
-----------	--

26628-22-8	Sodium Azide
------------	--------------

137-16-6	Sarkosyl
----------	----------

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.

· **Carcinogeny 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.

(Contd. on page 7)

**Safety Data Sheet**  
29 CFR Part 1910.1200

Printing date 08/04/2015

Reviewed on 07/01/2015

**Trade name: Genie™ III HIV-1/HIV-2 Wash Reagent, 10 ml**

(Contd. of page 6)

· **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 / 1

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

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