

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

Article number	Description	Quantity	Symbols
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

according to WHS Regulations

Printing date 29.10.2020

Version number 2

Revision: 01.07.2015

Not classified as hazardous according to criteria of Safe Work Australia.

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

- **Further information obtainable from:** Customer Support.

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

2 Hazard(s) Identification

- **Classification of the substance or mixture**

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

- **Label elements**

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

- **Other hazards**

- **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

3 Composition and Information on Ingredients

- **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.

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

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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, 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 fire - and explosion protection:** 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.

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8 Exposure controls and personal protection

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

9 Physical and Chemical Properties

- **Information on basic physical and chemical properties**
 - **General Information**
 - **Appearance:**
 - **Form:** Solid
 - **Colour:** According to product specification
 - **Odour:** Characteristic
- **Change in condition**
 - **Melting point/freezing point:** Undetermined.
 - **Initial boiling point and boiling range:** Undetermined.
- **Flash point:** Not applicable.
- **Auto-ignition temperature:** Product is not selfigniting.
- **Explosive properties:** 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** 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.

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- **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 the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12 Ecological Information

- **Toxicity**
 - **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
 - **Bioaccumulative potential** No further relevant information available.
 - **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
 - **General notes:** 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 packaging:**
 - **Recommendation:** Disposal must be made according to official regulations.
 - **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

- | | |
|---|------|
| <ul style="list-style-type: none"> · UN-Number <ul style="list-style-type: none"> · ADG, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · UN proper shipping name <ul style="list-style-type: none"> · ADG, ADN, IMDG, IATA | Void |

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

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· Transport hazard class(es)	
· ADG, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· ADG, IMDG, IATA	Void
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Not applicable.
· 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

15 Regulatory information

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

· **Australian Inventory of Industrial Chemicals**

None of the ingredients is listed.

· **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:**

MSDS / FDS Administr.

Bio-Rad

Marnes-la-Coquette, France

· **Contact:**

Customer Support

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

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Printing date 29.10.2020

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Revision: 01.07.2015

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

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· 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

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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Printing date 29.10.2020

Version number 2

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Not classified as hazardous according to criteria of Safe Work Australia.

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

· **Further information obtainable from:** Customer Support.

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

2 Hazard(s) Identification

· **Classification of the substance or mixture**

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

· **Label elements**

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

· **Other hazards**

- **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

3 Composition and Information on Ingredients

· **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.

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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, powder or water spray. Fight larger fires with water spray.
Use fire extinguishing methods suitable to surrounding conditions.

- **Special hazards arising from the substance or mixture**

In case of fire, the following can be released:

Nitrogen oxides (NO_x)
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.

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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 fire - and explosion protection:** 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 and personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **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.
Wash hands before breaks and at the end of work.
 - **Respiratory protection:** 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:**
 - **Form:** Fluid
 - **Colour:** Colourless
 - **Odour:** Odourless
 - **pH-value at 20 °C:** 8.3
 - **Change in condition**
 - **Melting point/freezing point:** Undetermined.

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

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· Initial boiling point and boiling range: 100 °C	
· Flash point:	Not applicable.
· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Vapour pressure at 20 °C:	23 hPa
· Density at 20 °C:	1.01 g/cm ³
· Solubility in / Miscibility with	
· water:	Fully miscible.
· Other information	No further relevant information available.

10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
 - **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **Possibility of hazardous reactions**
 - 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 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 the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

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

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12 Ecological Information

- **Toxicity**
 - **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** biodegradable
- **Behaviour 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 (German Regulation) (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 packaging:**
 - **Recommendation:** Disposal must be made according to official regulations.
 - **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

· UN-Number	
· ADG, ADN, IMDG, IATA	Void
· UN proper shipping name	
· ADG, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· ADG, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· ADG, IMDG, IATA	Void
· Environmental hazards:	
· Marine pollutant:	No

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

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· Special precautions for user	Not applicable.
· 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

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture

· Australian Inventory of Industrial Chemicals

25322-68-3	Polyethylene glycol
64-02-8	tetrasodium ethylenediaminetetraacetate
7447-40-7	potassium chloride
	Tris(hydroxymethyl)-aminomethane
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

· Standard for the Uniform Scheduling of Medicines and Poisons

7447-40-7	potassium chloride	S4
	Tris(hydroxymethyl)-aminomethane	S4

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Department issuing SDS:

MSDS / FDS Administr.

Bio-Rad

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· Contact:

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

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· 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

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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