



10/29/2020

KIT COMPONENTS

Product 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

29 CFR Part 1910.1200

Printing date 10/29/2020

Reviewed on 07/01/2015

1 Identification

- **Product identifier**

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

- **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: **Genie™ III HIV-1/HIV-2 Test 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:** 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.

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- **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:** 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.

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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:** Not hazardous for water.
- **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.

· **Carcinogen 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** 10/29/2020 / 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

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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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Safety Data Sheet

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1 Identification

- **Product identifier**

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

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

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3 Composition/information on ingredients

- **Chemical characterization: Mixtures**

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

- **Dangerous components:**

25322-68-3	Polyethylene glycol	0.1-2.5%
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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, 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_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).

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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.

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 ³ aerosol
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· **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

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

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9 Physical and chemical properties

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

- **General Information**

- **Appearance:**

· Form:	Fluid
· Color:	Colorless
· Odor:	Odorless

- **pH-value at 20 °C (68 °F):** 8.3

- **Change in condition**

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

- **Flash point:** Not applicable.

- **Auto igniting:** Product is not selfigniting.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Vapor pressure at 20 °C (68 °F):** 23 hPa (17.3 mm Hg)

- **Density at 20 °C (68 °F):** 1.01 g/cm³ (8.42845 lbs/gal)

- **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.

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

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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** 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.

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

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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):
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

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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

· 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)

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

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· Date of preparation / last revision 10/29/2020 / 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

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 —