



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

according to HPR, Schedule 1

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
92430 Marnes-la-Coquette
Phone: +33 (0)1 47 95 60 00
Fax: +33 (0)1 47 41 91 33
e-mail: fds-msds.fr@bio-rad.com

Bio-Rad laboratories (Canada) Ltd.
2403 Guénette Montreal,
Montréal (Québec) H4R 2E9
Phone: (800) 361-1808
Fax: (514) 334-0872

- **Information department:** Customer support.

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

2 Hazard 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

3 Composition/Information on ingredients

- **Chemical characterization: Mixtures**

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

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Safety Data Sheet

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

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· **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.
- **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.

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

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- **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.
- **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** No further relevant information available.

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

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- **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.

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

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:** Must be specially treated adhering to official regulations.

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

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- **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/TDG, ADR, ADN, IMDG, IATA

Void

- **UN proper shipping name**

- DOT/TDG, ADN, IMDG, IATA

Void

- ADR

Void

- **Transport hazard class(es)**

- DOT, ADR, ADN, IMDG, IATA

- Class

Void

- **Packing group**

- DOT/TDG, 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.

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

None of the ingredients is listed.

- **Canadian substance listings:**

- **Canadian Domestic Substances List (DSL)**

None of the ingredients is listed.

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

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· Canadian Ingredient Disclosure list (limit 0.1%)

None of the ingredients is listed.

· Canadian Ingredient Disclosure list (limit 1%)

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

CANADA

Bio-Rad laboratories (Canada) Ltd.,

2403 Guénette Montreal,

Montreal (Québec) H4R 2E9

Phone : (800) 361-1808

Fax : (514) 334-0872

· Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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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
92430 Marnes-la-Coquette
Phone: +33 (0)1 47 95 60 00
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Phone: (800) 361-1808
Fax: (514) 334-0872

- **Information department:** Customer support.

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

2 Hazard 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

3 Composition/Information on ingredients

- **Chemical characterization: Mixtures**

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

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

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

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 protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
 - **Storage:**
 - **Requirements to be met by storerooms and receptacles:** No special requirements.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/ Personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
 - **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
 - **Additional information:** The lists that were valid during the creation were used as basis.
- **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:**
 - **Form:** Fluid
 - **Color:** Colorless
 - **Odor:** Odorless
 - **pH-value at 20 °C:** 8.3

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Reviewed on 07/01/2015

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

(Contd. of page 3)

- **Change in condition**

- **Melting point/Melting range:** Undetermined.

- **Boiling point/Boiling range:** 100 °C

- **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:** 23 hPa

- **Density at 20 °C:** 1.01 g/cm³

- **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 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.

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

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· 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.

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

· UN-Number

· **DOT/TDG, ADR, ADN, IMDG, IATA** Void

· UN proper shipping name

· **DOT/TDG, ADN, IMDG, IATA** Void

· **ADR** Void

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

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· Transport hazard class(es)	
· DOT, ADR, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· DOT/TDG, 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

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

· Canadian substance listings:

· Canadian Domestic Substances List (DSL)

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

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CDN

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

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26628-22-8	Sodium Azide
137-16-6	Sarkosyl
7732-18-5	water, distilled, conductivity or of similar purity

· **Canadian Ingredient Disclosure list (limit 0.1%)**

None of the ingredients is listed.

· **Canadian Ingredient Disclosure list (limit 1%)**

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

CANADA

Bio-Rad laboratories (Canada) Ltd.,

2403 Guénette Montreal,

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· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

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)

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