



KIT COMPONENTS

Product name: **Genie™ Fast HIV 1/2, 25 Tests** Product code: **72327**

Article number	Description	Quantity Symbols
764081	Test device Genie™ Fast HIV 1/2	25
7230T	Diluant (for the whole blood protocol), 5 ml	1





Printing date 08/04/2015 Reviewed on 07/02/2015

1 Identification

- · Product identifier
 - · Trade name: Test device Genie™ Fast HIV 1/2
 - · Article number: 764081
 - · Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

- · Application of the substance / the mixture In vitro diagnostic medical device or component.
- · Details of the supplier of the safety data sheet
 - · Manufacturer/Supplier:

Bio-Rad

3, Boulevard Raymond Poincaré

F-92430 Marnes-la-Coquette

Tel.: +33 (0)1 47 95 60 00 Fax: +33 (0)1 47 41 91 33

e-mail: fds-msds.fr@bio-rad.com

- · Information department: Customer support.
- Emergency telephone number:

See item 16

+33 (0)1 47 95 62 77

2 Hazard(s) identification

· Classification of the substance or mixture

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

- · Label elements
 - · GHS label elements Void
 - · Hazard pictograms Void
 - · Signal word Void
 - · Hazard statements Void
- · Classification system:
 - · NFPA ratings (scale 0 4)

Health = 0

Fire = 0

Reactivity = 0

· HMIS-ratings (scale 0 - 4)

Health = 0

Fire = 0

Reactivity = 0

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

3 Composition/information on ingredients

- · Chemical characterization: Mixtures
 - · Description: Mixture without a chemical hazard.

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Printing date 08/04/2015 Reviewed on 07/02/2015

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

(Contd. of page 1)

· Dangerous components: Void

4 First-aid measures

- · Description of first aid measures
 - · General information: No special measures required.
 - · After inhalation: Supply fresh air; consult doctor in case of complaints.
 - · After skin contact: Generally the product does not irritate the skin.
 - · After eye contact: Rinse opened eye for several minutes under running water.
 - · After swallowing: Consult a doctor, if necessary.
 - · Information for doctor:
 - Most important symptoms and effects, both acute and delayed No further relevant information available.
 - · Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Fire-fighting measures

- · Extinguishing media
 - · Suitable extinguishing agents:

CO2, extinguishing powder or water spray. Fight larger fires with water spray.

- · Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters
 - · Protective equipment: No special measures required.

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures
 Wear disposable gloves.
- Environmental precautions: Do not allow product to reach sewage system or any water course.
- · Methods and material for containment and cleaning up: Pick up mechanically.
- · Reference to other sections No dangerous substances are released.

7 Handling and storage

- · Handling:
 - · Precautions for safe handling

Prevent formation of dust.

Avoid all contact with reagents, even those considered to be non-hazardous. Follow good laboratory practices.

- · Information about protection against explosions and fires: No special measures required.
- · Conditions for safe storage, including any incompatibilities
 - Storage:
 - · Requirements to be met by storerooms and receptacles: No special requirements.
 - · Information about storage in one common storage facility: Not required.
 - · Further information about storage conditions: None.

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Printing date 08/04/2015 Reviewed on 07/02/2015

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

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· Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · Control parameters
 - · Components with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · Additional information: The lists that were valid during the creation were used as basis.
- · Exposure controls
 - · Personal protective equipment:
 - · General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed.

- · Breathing equipment: Not required.
- · Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

· Eye protection: Not required.

9 Physical and chemical properties

- · Information on basic physical and chemical properties
 - · General Information
 - · Appearance:

Form: WebColor: WhiteOdorless

- · Change in condition
 - Melting point/Melting range: Undetermined.
 Boiling point/Boiling range: Undetermined.
- · Flash point: Not applicable.

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

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

· **Density:** Not determined.

· Solubility in / Miscibility with

· Water: Insoluble.

• Other information No further relevant information available.

USA -

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Printing date 08/04/2015 Reviewed on 07/02/2015

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

(Contd. of page 3)

10 Stability and reactivity

- · Reactivity
 - · Chemical stability
 - · Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

- · Information on toxicological effects
 - · Acute toxicity:
 - · Primary irritant effect:
 - · on the skin: No irritant effect.
 - · on the eye: No irritating effect.
 - · Sensitization: No sensitizing effects known.
 - · Additional toxicological information:

The product is not subject to classification according to internally approved calculation methods for preparations:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

- · Carcinogenic categories
 - · IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

12 Ecological information

- Toxicity
 - · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
 - · Bioaccumulative potential No further relevant information available.
 - · **Mobility in soil** No further relevant information available.
- · Additional ecological information:
 - · General notes: Generally not hazardous for water
- Results of PBT and vPvB assessment
 - · PBT: Not applicable.
 - · vPvB: Not applicable.

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Printing date 08/04/2015 Reviewed on 07/02/2015

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

(Contd. of page 4)

· Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
 - · Recommendation:

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

- · Uncleaned packagings:
 - · Recommendation: Disposal must be made according to official regulations.
 - · Recommended cleansing agent: Water, if necessary with cleansing agents.

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 specification

15 Regulatory information

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

· Section 35	5 (extremely ha	zardous subs	stances):

None of the ingredient is listed.

· Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

· TSCA (Toxic Substances Control Act):

None of the ingredients is listed.

(Contd. on page 6)





Printing date 08/04/2015 Reviewed on 07/02/2015

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

(Contd. of page 5)

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Cancerogenity categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

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

16 Other information

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

· Department issuing SDS:

SDS / FDS Administr.

Bio-Rad

Marnes-la-Coquette, France

· Contact:

Customer Support

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

USA

Bio-Rad Laboratories 6565 185th Avenue NE Redmond, WA 98052-5039

Phone Number: 1-800-2BIORAD (1-800-224-6723) or (425) 881-8300 (daytime PST)

· Date of preparation / last revision 08/04/2015 / -

· Abbreviations and acronyms:

ICAO: International Civil Aviation Organisation

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

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

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

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

NFPA: National Fire Protection Association (USA) HMIS: Hazardous Materials Identification System (USA)





Printing date 08/04/2015 Reviewed on 07/02/2015

1 Identification

- · Product identifier
 - · Trade name: Diluant (for the whole blood protocol), 5 ml
 - · Article number: 7230T
 - · Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

- · Application of the substance / the mixture In vitro diagnostic medical device or component.
- · Details of the supplier of the safety data sheet
 - · Manufacturer/Supplier:

Bio-Rad

3, Boulevard Raymond Poincaré

F-92430 Marnes-la-Coquette

Tel.: +33 (0)1 47 95 60 00 Fax: +33 (0)1 47 41 91 33

e-mail: fds-msds.fr@bio-rad.com

- · Information department: Customer support.
- · Emergency telephone number:

See item 16

+33 (0)1 47 95 62 77

2 Hazard(s) identification

· Classification of the substance or mixture

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

- · Label elements
 - · GHS label elements Void
 - · Hazard pictograms Void
 - · Signal word Void
 - · Hazard statements Void
- · Classification system:
 - · NFPA ratings (scale 0 4)

Health = 0

Fire = 0

Reactivity = 0

· HMIS-ratings (scale 0 - 4)

Health = 0

Fire = 0

Reactivity = 0

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

3 Composition/information on ingredients

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

(Contd. on page 2)





Printing date 08/04/2015 Reviewed on 07/02/2015

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

(Contd. of page 1)

· Dangerous components: Void

4 First-aid measures

- · Description of first aid measures
 - · General information: No special measures required.
 - · After inhalation: Supply fresh air; consult doctor in case of complaints.
 - · After skin contact: Generally the product does not irritate the skin.
 - · After eye contact: Rinse opened eye for several minutes under running water.
 - · After swallowing: Consult a doctor, if necessary.
 - · Information for doctor:
 - Most important symptoms and effects, both acute and delayed No further relevant information available.
 - · Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Fire-fighting measures

- · Extinguishing media
 - · Suitable extinguishing agents:

CO2, extinguishing powder or water spray. Fight larger fires with water spray.

- · Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters
 - · Protective equipment: No special measures required.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Wear disposable gloves.
- Environmental precautions: Dilute with plenty of water.
- · Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

· Reference to other sections No dangerous substances are released.

7 Handling and storage

- · Handling:
 - · Precautions for safe handling

Keep receptacles tightly sealed.

Avoid all contact with reagents, even those considered to be non-hazardous.

Follow good laboratory practices.

- Information about protection against explosions and fires: No special measures required.
- · Conditions for safe storage, including any incompatibilities
 - · Storage:
 - · Requirements to be met by storerooms and receptacles: No special requirements.
 - · Information about storage in one common storage facility: Not required.
 - · Further information about storage conditions: None.

(Contd. on page 3)





Printing date 08/04/2015 Reviewed on 07/02/2015

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

(Contd. of page 2)

· Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · Control parameters
 - · Components with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · Additional information: The lists that were valid during the creation were used as basis.
- · Exposure controls
 - · Personal protective equipment:
 - · General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed.

- · Breathing equipment: Not required.
- · Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

· Eye protection: Goggles recommended during refilling.

9 Physical and chemical properties

- · Information on basic physical and chemical properties
 - · General Information
 - · Appearance:

Form: FluidColor: Colorless

· Odor: Weak, characteristic

- · Change in condition
 - Melting point/Melting range: Undetermined.
 Boiling point/Boiling range: Undetermined.

· Flash point: Not applicable.

Auto igniting: Product is not selfigniting.

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

· **Density:** Not determined.

· Solubility in / Miscibility with

· Water: Fully miscible.

• Other information No further relevant information available.

USA -

(Contd. on page 4)





Printing date 08/04/2015 Reviewed on 07/02/2015

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

(Contd. of page 3)

10 Stability and reactivity

- · Reactivity
 - · Chemical stability
 - · Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

- · Information on toxicological effects
 - · Acute toxicity:
 - · LD/LC50 values that are relevant for classification:

26628-22-8 Sodium Azide

Oral LD50 27 mg/kg (rat)
Dermal LD50 20 mg/kg (rabbit)

- · Primary irritant effect:
 - · on the skin: No irritant effect.
 - · on the eye: No irritating effect.
- · Sensitization: No sensitizing effects known.
- · Additional toxicological information:

The product is not subject to classification according to internally approved calculation methods for preparations:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

12 Ecological information

- · Toxicity
 - · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
 - · Bioaccumulative potential No further relevant information available.
 - · Mobility in soil No further relevant information available.
- · Additional ecological information:
 - · General notes: Generally not hazardous for water

(Contd. on page 5)





Printing date 08/04/2015 Reviewed on 07/02/2015

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

(Contd. of page 4)

- · Results of PBT and vPvB assessment
 - PBT: Not applicable.vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
 - · Recommendation:

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

- · Uncleaned packagings:
 - · Recommendation: Disposal must be made according to official regulations.
 - · Recommended cleansing agent: Water, if necessary with cleansing agents.

14 Transport information	
· UN-Number · DOT, ADR, ADN, IMDG, IATA	Void
 UN proper shipping name DOT, ADN, IMDG, IATA ADR 	Void 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 MARPOL73/78 and the IBC Code	II of Not applicable.
· Transport/Additional information:	Not dangerous according to the above specifications.
· UN "Model Regulation":	-

15 Regulatory information

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

· Section 355 (extremely hazardous substances):		
26628-22-8 Sodium Azide		
	(Contd. on page 6)	





Printing date 08/04/2015 Reviewed on 07/02/2015

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

(Contd. of page 5)

· Section 313 (Specific toxic chemical listings):

26628-22-8 Sodium Azide

· TSCA (Toxic Substances Control Act):

7647-14-5 sodium chloride

26628-22-8 | Sodium Azide

7732-18-5 water, distilled, conductivity or of similar purity

Proposition 65

· Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Cancerogenity categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

26628-22-8 | Sodium Azide

A4

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

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

16 Other information

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

· Department issuing SDS:

SDS / FDS Administr.

Bio-Rad

Marnes-la-Coquette, France

· Contact:

Customer Support

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

USA

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- · Date of preparation / last revision 08/04/2015 / -
- Abbreviations and acronyms:

ICAO: International Civil Aviation Organisation

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

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Safety Data Sheet 29 CFR Part 1910.1200

Printing date 08/04/2015 Reviewed on 07/02/2015

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

(Contd. of page 6)

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the

International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation
IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

USA