



## KIT COMPONENTS

Product name: Genscreen™ HIV-1 Ag Confirmatory Assay, 25 T. Product code: 71121

Article number	Description	Quantity	Symbols
7123D	RA - HIV-1 Ag Confirmatory Reagent, 1.3 ml	1	GHS07
7123E	C0 - Negative Control, 12 ml	1	GHS07





Printing date 08/04/2015

Reviewed on 07/31/2015

#### 1 Identification

- · Product identifier
  - · Trade name: RA HIV-1 Ag Confirmatory Reagent, 1.3 ml
    - · Article number: 7123D
  - · 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 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



GHS07

Skin Sens. 1 H317 May cause an allergic skin reaction.

- · Label elements
  - · GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms** GHS07
- · Signal word Warning
- · Hazard-determining components of labeling:

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

· Hazard statements

May cause an allergic skin reaction.

· Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection.

If skin irritation or rash occurs: Get medical advice/attention.

If on skin: Wash with plenty of water.

Dispose of contents/container in accordance with local/regional/national/international regulations.

- · Classification system:
  - NFPA ratings (scale 0 4)

Health = 0Fire = 0

Reactivity = 0

(Contd. on page 2)





Printing date 08/04/2015 Reviewed on 07/31/2015

Trade name: RA - HIV-1 Ag Confirmatory Reagent, 1.3 ml

(Contd. of page 1)

· HMIS-ratings (scale 0 - 4)

Health = 0 Fire = 0Reactivity = 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 hazardous components.
  - · Dangerous components:

55965-84-9 reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331

Skin Corr. 1B, H314

Aquatic Acute 1, H400; Aquatic Chronic 1, H410

Skin Sens. 1, H317

#### 4 First-aid measures

- · Description of first aid measures
  - · After inhalation: Supply fresh air and to be sure call for a doctor.
  - · 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: Immediately call a doctor.
  - · 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 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 protective clothing.

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Printing date 08/04/2015 Reviewed on 07/31/2015

Trade name: RA - HIV-1 Ag Confirmatory Reagent, 1.3 ml

(Contd. of page 2)

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:

Absorb liquid components with liquid-binding material.

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 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.
- · Exposure controls
  - · Personal protective equipment:
  - General protective and hygienic measures:

Immediately remove all soiled and contaminated clothing.

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

#### 9 Physical and chemical properties

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

· Form: Fluid · Color: Pale

· Odor: Weak, characteristic

(Contd. on page 4)





Printing date 08/04/2015 Reviewed on 07/31/2015

Trade name: RA - HIV-1 Ag Confirmatory Reagent, 1.3 ml

(Contd. of page 3)

· pH-value: Neutral

· Change in condition

· Melting point/Melting range: Undetermined. · Boiling point/Boiling range: Undetermined.

· Flash point: Not applicable.

• **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.

## 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:
    - · Sensitization: Sensitization possible through skin contact.
  - · Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

- · 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.

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Printing date 08/04/2015 Reviewed on 07/31/2015

Trade name: RA - HIV-1 Ag Confirmatory Reagent, 1.3 ml

(Contd. of page 4)

- · 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: Avoid transfer into the environment.
- · 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.

UN-Number		
· DOT, ADR, ADN, IMDG, IATA	Void	
UN proper shipping name		
· DOT, ADR, ADN, IMDG, IATA	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	ː II of	
MARPOL73/78 and the IBC Code	Not applicable.	

# 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.

(Contd. on page 6)





Printing date 08/04/2015 Reviewed on 07/31/2015

Trade name: RA - HIV-1 Ag Confirmatory Reagent, 1.3 ml

(Contd. of page 5)

· 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.

· 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:

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

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# Safety Data Sheet 29 CFR Part 1910.1200

Printing date 08/04/2015 Reviewed on 07/31/2015

## Trade name: RA - HIV-1 Ag Confirmatory Reagent, 1.3 ml

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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)
Acute Tox. 3: Acute toxicity, Hazard Category 3 Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1

USA





Printing date 08/04/2015

Reviewed on 07/31/2015

#### 1 Identification

- · Product identifier
  - · Trade name: C0 Negative Control, 12 ml
    - · Article number: 7123E
  - · 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



GHS07

Skin Sens. 1 H317 May cause an allergic skin reaction.

- · Label elements
  - · GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms** GHS07
- · Signal word Warning
- · Hazard-determining components of labeling:

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

· Hazard statements

May cause an allergic skin reaction.

· Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection.

If skin irritation or rash occurs: Get medical advice/attention.

If on skin: Wash with plenty of water.

Dispose of contents/container in accordance with local/regional/national/international regulations.

- · Classification system:
  - NFPA ratings (scale 0 4)

Health = 0

Fire = 0

Reactivity = 0

(Contd. on page 2)





Printing date 08/04/2015 Reviewed on 07/31/2015

Trade name: C0 - Negative Control, 12 ml

(Contd. of page 1)

· HMIS-ratings (scale 0 - 4)

Health = 0Fire = 0Reactivity = 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 hazardous components.
  - · Dangerous components:

55965-84-9 reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-0.01-0.1% 7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331

A Skin Corr. 1B, H314

Aquatic Acute 1, H400; Aquatic Chronic 1, H410

Skin Sens. 1, H317

#### 4 First-aid measures

- Description of first aid measures
  - · After inhalation: Supply fresh air and to be sure call for a doctor.
  - · 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: Immediately call a doctor.
  - · 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 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 protective clothing.

(Contd. on page 3)





Printing date 08/04/2015 Reviewed on 07/31/2015

Trade name: C0 - Negative Control, 12 ml

(Contd. of page 2)

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:

Absorb liquid components with liquid-binding material.

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 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.
- · Exposure controls
  - · Personal protective equipment:
    - General protective and hygienic measures:

Immediately remove all soiled and contaminated clothing.

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

#### 9 Physical and chemical properties

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

· Form: Fluid · Color: Pale

· Odor: Weak, characteristic

(Contd. on page 4)





Printing date 08/04/2015 Reviewed on 07/31/2015

Trade name: C0 - Negative Control, 12 ml

(Contd. of page 3)

· pH-value: Neutral

· Change in condition

Melting point/Melting range: Undetermined.
 Boiling point/Boiling range: Undetermined.

· Flash point: Not applicable.

• **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.

## 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:
    - · Sensitization: Sensitization possible through skin contact.
  - · Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

- · 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.

(Contd. on page 5)





Printing date 08/04/2015 Reviewed on 07/31/2015

Trade name: C0 - Negative Control, 12 ml

(Contd. of page 4)

- · 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: Avoid transfer into the environment.
- · 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.

UN-Number · DOT, ADR, ADN, IMDG, IATA	Void	
UN proper shipping name · DOT, ADR, ADN, IMDG, IATA	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	v II of Not applicable.	
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.

(Contd. on page 6)





Printing date 08/04/2015 Reviewed on 07/31/2015

Trade name: C0 - Negative Control, 12 ml

(Contd. of page 5)

· 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.

· 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:

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

(Contd. on page 7)



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## Safety Data Sheet 29 CFR Part 1910.1200

Printing date 08/04/2015 Reviewed on 07/31/2015

Trade name: C0 - Negative Control, 12 ml

(Contd. of page 6)

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)
Acute Tox. 3: Acute toxicity, Hazard Category 3
Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1

USA