

KIT COMPONENTSProduct name: **Access® HCV Ab PLUS CALIBRATORS**Product code: **34335**

Article number	Description	Quantity	Symbols
3435A	Access® HCV Ab PLUS CALIBRATORS - Negative Calibrator C0 (1 ml)	1	
3435B	Access® HCV Ab PLUS CALIBRATORS - Positive Calibrator C1 (1 ml)	1	

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 07/23/2015

Reviewed on 07/22/2015

1 Identification**· Product identifier**

- **Trade name: Access® HCV Ab PLUS CALIBRATORS - Negative Calibrator C0 (1 ml)**
 - **Article number:** 3435A
- **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.
Contains components of human origin.

(Contd. on page 2)

USA

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 07/23/2015

Reviewed on 07/22/2015

Trade name: Access® HCV Ab PLUS CALIBRATORS - Negative Calibrator C0 (1 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:**
Use fire fighting measures that suit the environment.
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:**
Absorb liquid components with liquid-binding material.
Dispose contaminated material as waste according to item 13.
- **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.
 - **Further information about storage conditions:** None.

(Contd. on page 3)

USA

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 07/23/2015

Reviewed on 07/22/2015

Trade name: Access® HCV Ab PLUS CALIBRATORS - Negative Calibrator C0 (1 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:** 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:** Light yellow
 - **Odor:** Odorless
 - **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.

(Contd. on page 4)

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 07/23/2015

Reviewed on 07/22/2015

Trade name: Access® HCV Ab PLUS CALIBRATORS - Negative Calibrator C0 (1 ml)

(Contd. of page 3)

· **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.

· **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:** 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.

(Contd. on page 5)

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 07/23/2015

Reviewed on 07/22/2015

Trade name: Access® HCV Ab PLUS CALIBRATORS - Negative Calibrator C0 (1 ml)

(Contd. of page 4)

· **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, 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 II of MARPOL73/78 and the IBC Code	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

· **Section 313 (Specific toxic chemical listings):**

26628-22-8 | Sodium Azide

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

All ingredients are 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.

(Contd. on page 6)

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 07/23/2015

Reviewed on 07/22/2015

Trade name: Access® HCV Ab PLUS CALIBRATORS - Negative Calibrator C0 (1 ml)

(Contd. of page 5)

· **Carcinogenicity 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)

· **Date of preparation / last revision** 07/23/2015 / 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

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 07/23/2015

Reviewed on 07/22/2015

1 Identification

- **Product identifier**
 - **Trade name: Access® HCV Ab PLUS CALIBRATORS - Positive Calibrator C1 (1 ml)**
 - **Article number:** 3435B
 - **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.
Contains components of human origin.

(Contd. on page 2)

USA

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 07/23/2015

Reviewed on 07/22/2015

Trade name: Access® HCV Ab PLUS CALIBRATORS - Positive Calibrator C1 (1 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:**
Use fire fighting measures that suit the environment.
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:**
Absorb liquid components with liquid-binding material.
Dispose contaminated material as waste according to item 13.
- **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.
 - **Further information about storage conditions:** None.

(Contd. on page 3)

USA

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 07/23/2015

Reviewed on 07/22/2015

Trade name: Access® HCV Ab PLUS CALIBRATORS - Positive Calibrator C1 (1 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:** 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:** Light yellow
 - **Odor:** Odorless
 - **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.

(Contd. on page 4)

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 07/23/2015

Reviewed on 07/22/2015

Trade name: Access® HCV Ab PLUS CALIBRATORS - Positive Calibrator C1 (1 ml)

(Contd. of page 3)

· **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.

· **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.

· **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.

(Contd. on page 5)

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 07/23/2015

Reviewed on 07/22/2015

Trade name: Access® HCV Ab PLUS CALIBRATORS - Positive Calibrator C1 (1 ml)

(Contd. of page 4)

· **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, 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 II of MARPOL73/78 and the IBC Code	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

· **Section 313 (Specific toxic chemical listings):**

26628-22-8 | Sodium Azide

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

All ingredients are 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.

(Contd. on page 6)

Safety Data Sheet
29 CFR Part 1910.1200

Printing date 07/23/2015

Reviewed on 07/22/2015

Trade name: Access® HCV Ab PLUS CALIBRATORS - Positive Calibrator C1 (1 ml)

(Contd. of page 5)

· 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)

- Date of preparation / last revision**
- 07/23/2015 / 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

USA