



07/22/2015

Kit Components

Product code	Description
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2700091	Variant Hb A1c Calibrator/Diluent Set
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Components:

35169	Variant/Variant II A1c/GHb Program Calibrator
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2700093	Variant Hb A1c Program Calibrator Diluent
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Safety Data Sheet
acc. to OSHA HCS

Printing date 07/22/2015

Reviewed on 07/22/2015

1 Identification

- **Product identifier**
- **Trade name:** Variant/Variant II A1c/GHb Program Calibrator
- **Catalog or product number:** 35169, 2700332
- **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* laboratory reagent or component
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
Hercules, California 94547 1(510)724-7000
- **Information department:**
Technical services, customer support
TechsupportUSSD@bio-rad.com
- **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

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
- **Special Hazards** *Contains human sourced and/or potentially infectious components.*
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

3 Composition/information on ingredients

- **Chemical characterization:** *Mixtures*
- **Description:** *Mixture of the substances listed below with non-hazardous additions.*

· **Listing of dangerous and non-hazardous components:**

	Human Red Cells	50-100%
57-50-1	sucrose, pure	10-20%
6381-92-6	Ethylenediaminetetraacetic acid disodium salt dihydrate	1.0-2.5%
151-50-8	potassium cyanide	.001-.01%

(Contd. on page 2)

Safety Data Sheet

acc. to OSHA HCS

Printing date 07/22/2015

Reviewed on 07/22/2015

Trade name: Variant/Variant II A1c/GHb Program Calibrator

(Contd. of page 1)

· **Additional information**

Contains human sourced and/or potentially infectious components.
For the wording of the listed risk phrases refer to section 15.

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** Induce vomiting and call for medical help.

· **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 or alcohol resistant foam.

· **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** Handle as potentially infectious.

· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

· **Methods and material for containment and cleaning up:** Disinfectant

· **Reference to other sections** No dangerous substances are released.

7 Handling and storage

· **Handling**

· **Precautions for safe handling** No special measures required.

· **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:** According to product specification

· **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.

DUS

(Contd. on page 3)

Safety Data Sheet
acc. to OSHA HCS

Printing date 07/22/2015

Reviewed on 07/22/2015

Trade name: Variant/Variant II A1c/GHb Program Calibrator

(Contd. of page 2)

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:**

57-50-1 sucrose, pure

PEL (United States)	15* 5** mg/m ³ *total dust **respirable fraction
REL (United States)	10* 5** mg/m ³ *total dust **respirable fraction
TLV (United States)	10 mg/m ³

151-50-8 potassium cyanide

PEL (United States)	5 mg/m ³ Skin
REL (United States)	Short-term value: C 5* mg/m ³ , C 4.7* ppm *10-min
TLV (United States)	Short-term value: C 5 mg/m ³ as CN; Skin

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment**
- **General protective and hygienic measures**
Follow the usual biosafety practices for handling potentially infectious materials.
- **Protection of hands:** Protective gloves.
- **Material of gloves** Synthetic gloves
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Safety glasses

9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

Form:	Solid
Color:	Red
Odor:	Odorless

· **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.

(Contd. on page 4)

Safety Data Sheet
acc. to OSHA HCS

Printing date 07/22/2015

Reviewed on 07/22/2015

Trade name: Variant/Variant II A1c/GHb Program Calibrator

(Contd. of page 3)

- **Density:** Not determined
- **Solubility in / Miscibility with Water:** Fully miscible
- **Solvent content:**
 - Organic solvents:** 0.0 %
 - Water:** 1.0 %
- **Solids content:** 100.0 %
- **Other information** No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known

11 Toxicological information

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

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
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.
- **Target organs:** Not applicable.

Safety Data Sheet
acc. to OSHA HCS

Printing date 07/22/2015

Reviewed on 07/22/2015

Trade name: Variant/Variant II A1c/GHb Program Calibrator

(Contd. of page 4)

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:**
Water hazard class 1 (German Regulation) (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**
Can be disposed of with household garbage with prior chemical-physical or biological treatment following consultation with the waste disposal facility operator and the pertinent authorities and adhering to the necessary technical regulations.
Hand over to hazardous waste disposers.
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.

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) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT, ADR, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |

(Contd. on page 6)

DUS

Safety Data Sheet
acc. to OSHA HCS

Printing date 07/22/2015

Reviewed on 07/22/2015

Trade name: Variant/Variant II A1c/GHb Program Calibrator

(Contd. of page 5)

- **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.

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **SARA (Superfund Amendants and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**

None of the ingredients is listed.

· **Section 313 (40CFR372.65):**

None of the ingredients is listed.

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

57-50-1 sucrose, pure

7732-18-5 water

151-50-8 potassium cyanide

· **California Proposition 65:**

· **Developmental Toxicity**

32986-56-4 tobramycin

1405-41-0 Gentamicin Sulfate

· **National regulations**

- **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
- **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:** Environmental Health and Safety.

· **Contact:**

Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000

· **Date of preparation / last revision** 07/22/2015 / -

· **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

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)

(Contd. on page 7)



Safety Data Sheet
acc. to OSHA HCS

Printing date 07/22/2015

Reviewed on 07/22/2015

Trade name: Variant/Variant II A1c/GHb Program Calibrator

(Contd. of page 6)

PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

*** Data compared to the previous version altered.**

DUS

Safety Data Sheet
acc. to OSHA HCS

Printing date 07/22/2015

Reviewed on 05/28/2015

1 Identification

- **Product identifier**
- **Trade name:** Variant Hb A1c Program Calibrator Diluent
- **Catalog or product number:** 2700093
- **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* laboratory reagent or component
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
Hercules, California 94547 1(510)724-7000
- **Information department:**
Technical services, customer support
TechsupportUSSD@bio-rad.com
- **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

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

3 Composition/information on ingredients

- **Chemical characterization: Substances**
- **CAS No. Description:**
7732-18-5 water
- **Identification number(s):**
- **EC number:** 231-791-2
- **Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with non-hazardous additions.

· **Listing of dangerous and non-hazardous components:**

10043-35-3	boric acid	0.01-0.1%
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- **Additional information** For the wording of the listed risk phrases refer to section 15.

Safety Data Sheet

acc. to OSHA HCS

Printing date 07/22/2015

Reviewed on 05/28/2015

Trade name: Variant Hb A1c Program Calibrator Diluent

(Contd. of page 1)

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** Rinse mouth with water. Seek medical attention and appropriate follow-up.
- **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 or alcohol resistant foam.
- **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.
- **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).
- **Reference to other sections**
No dangerous substances are released.
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** No special measures required.
- **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:** According to product specification
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.

(Contd. on page 3)

DUS

Safety Data Sheet
acc. to OSHA HCS

Printing date 07/22/2015

Reviewed on 05/28/2015

Trade name: Variant Hb A1c Program Calibrator Diluent

(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:**

10043-35-3 boric acid

TLV (United States)	Short-term value: 6* mg/m ³ Long-term value: 2* mg/m ³ *as inhalable fraction
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· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**

· **Personal protective equipment**

· **General protective and hygienic measures** The usual precautionary measures for handling chemicals should be followed.

· **Breathing equipment:** Not required.

· **Protection of hands:** Protective gloves.

· **Material of gloves** Synthetic gloves

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:** Safety glasses

9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

Form:	Liquid
Color:	Colorless
Odor:	Odorless
Odour threshold:	Not determined.

· **pH-value at 20 °C:** 7.8

· **Change in condition**

Melting point/Melting range:	0 °C
Boiling point/Boiling range:	100 °C

· **Flash point:** Not applicable

· **Flammability (solid, gaseous)** Not applicable.

· **Ignition temperature:**

Decomposition temperature: Not determined.

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

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

(Contd. on page 4)

Safety Data Sheet
acc. to OSHA HCS

Printing date 07/22/2015

Reviewed on 05/28/2015

Trade name: Variant Hb A1c Program Calibrator Diluent

(Contd. of page 3)

· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure at 20 °C:	23 hPa
· Density:	Not determined
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water:	Fully miscible
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
dynamic:	Not determined.
kinematic:	Not determined.
· Solvent content:	
Organic solvents:	0.0 %
Water:	99.9 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritant effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
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.

(Contd. on page 5)

Safety Data Sheet
acc. to OSHA HCS

Printing date 07/22/2015

Reviewed on 05/28/2015

Trade name: Variant Hb A1c Program Calibrator Diluent

(Contd. of page 4)

· **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.

· **Target organs:** Not applicable.

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:**

Water hazard class 1 (German Regulation) (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**

Hand over to hazardous waste disposers.

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

Dispose of waste in accordance to applicable national, regional, or local regulations.

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

· **UN-Number**

· **DOT, ADR, ADN, IMDG, IATA**

Void

· **UN proper shipping name**

· **DOT, ADR, ADN, IMDG, IATA**

Void

(Contd. on page 6)

Safety Data Sheet
acc. to OSHA HCS

Printing date 07/22/2015

Reviewed on 05/28/2015

Trade name: Variant Hb A1c Program Calibrator Diluent

(Contd. of page 5)

· Transport hazard class(es)	
· 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.

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- SARA (Superfund Amendments and Reauthorization Act of 1986 - USA)

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**

151-50-8 | potassium cyanide

· **Section 313 (40CFR372.65):**

151-50-8 | potassium cyanide

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

10043-35-3 | boric acid

151-50-8 | potassium cyanide

7732-18-5 | water

· **California Proposition 65:**

· **Developmental Toxicity**

1405-41-0 | Gentamicin Sulfate

32986-56-4 | tobramycin

· **National regulations**

- **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
- **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:** Environmental Health and Safety.
- **Contact:**

(Contd. on page 7)

Safety Data Sheet
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Trade name: Variant Hb A1c Program Calibrator Diluent

(Contd. of page 6)

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· **Date of preparation / last revision** 07/22/2015 / -

· **Abbreviations and acronyms:**

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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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

· * **Data compared to the previous version altered.**