

02/24/2012

Kit Components

Product code	Description		
270-2455 270-2455EX	Variant II Turbo HbA1c Kit 2.0 kit		
Components:			
270-2456	Variant II Turbo HbA1c Kit 2.0 Elution Buffer A		
270-2457	Variant II Turbo HbA1c Kit 2.0 Elution Buffer B		
270-2459	Variant II Turbo HbA1c Kit 2.0 Calibrator 1		
270-2460	Variant II Turbo HbA1c Kit 2.0 Calibrator 2		
270-2462	Variant II Turbo HbA1c Kit 2.0 Analytical Cartridge		



Printing date 02/24/2012 Reviewed on 12/06/2011

1 Identification of the substance/mixture and of the company/undertaking

- · Product identifier
- · Trade name: Variant II Turbo HbA1c Kit 2.0 Elution Buffer A
- · Catalog or product number: 270-2456
- · Application of the substance / the preparation 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 Composition/information on ingredients

- · Chemical characterization: Substances
- · Identification number(s):
- **EC** number: 231-791-2
- · Additional information: For the wording of the listed risk phrases refer to section 15.

 Listing of dangerous and non-hazardous compound 	nonents.
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· Listing of dangerous and non-nazardous components.		
7732-18-5 water	50-100%	
7601-89-0 sodium perchlorate	Xn R22 0.1-1.0% O R9	

3 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC Void
- · Information concerning particular hazards for human and environment: not applicable
- · Classification system:

The classification was made according to OSHA 29CFR 1910.1200 and 1910.1030, and is expanded upon from company and/or literature information.

- · Label elements
- · Labelling according to EU guidelines:

Observe the general safety regulations when handling chemicals

The substance is not subject to classification according to EU lists and other sources of literature known to us.

The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (GefStoffV).

4 First aid measures

- · General information No special measures required.
- · After inhalation Supply fresh air; consult doctor in case of complaints.

(Contd. on page 2)



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Trade name: Variant II Turbo HbA1c Kit 2.0 Elution Buffer A

(Contd. of page 1)

- · 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.

5 Firefighting measures

· 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.
- · Protective equipment: No special measures required.

6 Accidental release measures

 \cdot Personal precautions, protective equipment and emergency procedures

Wear protective equipment (See section 8). Keep unprotected persons away.

· Environmental precautions:

Do not allow to penetrate the ground/soil.

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

See Section 13 for disposal information.

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.
- 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.

8 Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · 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.

- \cdot **Additional information:** The lists that were valid during the creation were used as basis.
- · Personal protective equipment
- · General protective and hygienic measures The usual precautionary measures for handling chemicals should be followed.
- · Breathing equipment: Not required.
- · Protection of hands: Protective gloves.
- · Material of gloves Synthetic gloves

(Contd. on page 3)



Printing date 02/24/2012 Reviewed on 12/06/2011

Trade name: Variant II Turbo HbA1c Kit 2.0 Elution Buffer A

(Contd. of page 2)

· 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
- · Body protection: Protective work clothing.

9 Physical and chemical properties

· General Information

· Appearance:

Form: Liquid
Color: Colorless
Odor: Odorless

• **pH-value at 20°C:** 6-7

· 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

- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known

11 Toxicological information

- · 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:

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.

The substance is not subject to classification according to the latest version of the EU lists.

· Target organs: Not applicable.

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(Contd. on page 4)



Printing date 02/24/2012 Reviewed on 12/06/2011

Trade name: Variant II Turbo HbA1c Kit 2.0 Elution Buffer A

(Contd. of page 3)

12 Ecological information

- · 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.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

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

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

Flush pipes with water frequently if discarding solutions containing sodium azide into metal piping systems.

Perchlorate material - special handling may apply. See www.dtsc.ca.gov/hazardouswaste/perchlorate

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

4 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.
· 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

- · SARA (Superfund Amendents and Reauthorization Act of 1986 USA)
- Section 302/304 (40CFR355.30 / 40CFR355.40):

All ingredients are listed.

(Contd. on page 5)



Printing date 02/24/2012 Reviewed on 12/06/2011

Trade name: Variant II Turbo HbA1c Kit 2.0 Elution Buffer A

(Contd. of page 4)

· Section 313 (40CFR372.65):

All ingredients are listed.

· TSCA (Toxic Substances Control Act):

All ingredients are listed.

- · California Proposition 65:
- Chemicals known to cause cancer:
- · Developmental Toxicity
- · 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)

All ingredients are listed.

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 MSDS: 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

· * Data compared to the previous version altered.

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Printing date 02/24/2012 Reviewed on 12/06/2011

1 Identification of the substance/mixture and of the company/undertaking

- · Product identifier
- · Trade name: Variant II Turbo HbA1c Kit 2.0 Elution Buffer B
- · Catalog or product number: 270-2457
- · Application of the substance / the preparation 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 Composition/information on ingredients

- · Chemical characterization: Substances
- · Identification number(s):
- **EC number:** 231-791-2
- · Additional information: For the wording of the listed risk phrases refer to section 15.

· I isting of dangero	us and non-hazardou	is components:
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Listing of dangerous and non-nazardous components.			
7732-18-5	water		50-100%
7601-89-0	sodium perchlorate	Xn R22 O R9	1.0-2.5%

3 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC Void
- · Information concerning particular hazards for human and environment: not applicable
- · Classification system:

The classification was made according to OSHA 29CFR 1910.1200 and 1910.1030, and is expanded upon from company and/or literature information.

- · Label elements
- · Labelling according to EU guidelines:

Observe the general safety regulations when handling chemicals

The substance is not subject to classification according to EU lists and other sources of literature known to us.

The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (GefStoffV).

4 First aid measures

- · General information No special measures required.
- After inhalation Supply fresh air; consult doctor in case of complaints.

(Contd. on page 2)



Printing date 02/24/2012 Reviewed on 12/06/2011

Trade name: Variant II Turbo HbA1c Kit 2.0 Elution Buffer B

(Contd. of page 1)

- · 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.

5 Firefighting measures

· 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.
- · Protective equipment: No special measures required.

6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

Wear protective equipment (See section 8). Keep unprotected persons away.

· Environmental precautions:

Do not allow to penetrate the ground/soil.

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

See Section 13 for disposal information.

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.
- 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.

8 Exposure controls/personal protection

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

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

- · Additional information: The lists that were valid during the creation were used as basis.
- · Personal protective equipment
- · General protective and hygienic measures The usual precautionary measures for handling chemicals should be followed.
- · Breathing equipment: Not required.
- · Protection of hands: Protective gloves.
- · Material of gloves Synthetic gloves

(Contd. on page 3)



Printing date 02/24/2012 Reviewed on 12/06/2011

Trade name: Variant II Turbo HbA1c Kit 2.0 Elution Buffer B

(Contd. of page 2)

· 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
- · Body protection: Protective work clothing.

9 Physical and chemical properties

· General Information

· Appearance:

Form: Liquid
Color: Colorless
Odor: Odorless

• **pH-value at 20°C:** 6-7

· 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

- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known

11 Toxicological information

- · 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:

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.

The substance is not subject to classification according to the latest version of the EU lists.

· Target organs: Not applicable.

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Printing date 02/24/2012 Reviewed on 12/06/2011

Trade name: Variant II Turbo HbA1c Kit 2.0 Elution Buffer B

(Contd. of page 3)

12 Ecological information

- · 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.
- · Additional ecological information:
- · General notes: Generally not hazardous for water.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

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

Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Flush pipes with water frequently if discarding solutions containing sodium azide into metal piping systems. Perchlorate material - special handling may apply. See www.dtsc.ca.gov/hazardouswaste/perchlorate

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

Transport information	
UN-Number ADR, ADN, IMDG, IATA	Void
UN proper shipping name ADR, ADN, IMDG, IATA	Void
Transport hazard class(es)	
ADR, ADN, IMDG, IATA Class	Void
Packing group ADR, IMDG, IATA	Void
Environmental hazards: Marine pollutant:	No
Special precautions for user	Not applicable.
Transport in bulk according to Annex II of MA and the IBC Code	RPOL73/78 Not applicable.
Transport/Additional information:	Not dangerous according to the above specifications.

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(Contd. on page 5)



Printing date 02/24/2012 Reviewed on 12/06/2011

Trade name: Variant II Turbo HbA1c Kit 2.0 Elution Buffer B

(Contd. of page 4)

15 Regulatory information

- · SARA (Superfund Amendents and Reauthorization Act of 1986 USA)
- Section 302/304 (40CFR355.30 / 40CFR355.40):

All ingredients are listed.

Section 313 (40CFR372.65):

All ingredients are listed.

TSCA (Toxic Substances Control Act):

All ingredients are listed.

- · California Proposition 65:
- · Chemicals known to cause cancer:
- · Developmental Toxicity
- · 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)

All ingredients are listed.

- · National regulations
- · Water hazard class: Generally not hazardous for water.

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 MSDS: 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

· * Data compared to the previous version altered.



Printing date 02/24/2012 Reviewed on 12/06/2011

1 Identification of the substance/mixture and of the company/undertaking

- · Product identifier
- · Trade name: Variant II Turbo HbA1c Kit 2.0 Calibrator 1
- · Catalog or product number: 270-2459
- · Application of the substance / the preparation 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 Composition/information on ingredients

· Description: Mixture of the substances listed below with non-hazardous additions.

· Listing of	· Listing of dangerous and non-hazardous components:		
	Human Whole Blood	50-100%	
57-50-1	sucrose, pure	10-20%	
7732-18-5	water	1.0-2.5%	

[·] Additional information For the wording of the listed risk phrases refer to section 15.

3 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC Void
- · Information concerning particular hazards for human and environment:

The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

· Classification system:

The classification was made according to the latest editions of the EU-lists, and expanded upon from company and literature data.

The classification was made according to OSHA 29CFR 1910.1200 and 1910.1030, and is expanded upon from company and/or literature information.

- · Label elements
- · Labelling according to EU guidelines:

Observe the general safety regulations when handling chemicals

The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (GefStoffV).

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

Health = 0

Fire = 0

Reactivity = 0

(Contd. on page 2)



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Trade name: Variant II Turbo HbA1c Kit 2.0 Calibrator 1

· Special Hazards Contains human sourced and/or potentially infectious components.

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4 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.

5 Firefighting measures

- · 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.
- · 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: Pick up mechanically.
- · 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.
- · 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.

8 Exposure controls/personal protection

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

57-50-1 sucrose, pure

PEL (United States) 15* 5** mg/m³

*total dust **respirable fraction

REL (United States) 10* 5** mg/m³

*total dust **respirable fraction

TLV (United States) 10 mg/m³

· Additional information: The lists that were valid during the creation were used as basis.

(Contd. on page 3)



Printing date 02/24/2012 Reviewed on 12/06/2011

Trade name: Variant II Turbo HbA1c Kit 2.0 Calibrator 1

(Contd. of page 2)

- · 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.

For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:

Synthetic gloves

- · For the permanent contact gloves made of the following materials are suitable: Synthetic gloves
- · For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable: Synthetic gloves
- · As protection from splashes gloves made of the following materials are suitable: Synthetic gloves
- · Eye protection: Safety glasses
- · Body protection: Protective work clothing.

9 Physical and chemical p	roperties
· General Information · Appearance: Form: Color: · Odor:	Solid. Red Odorless
· Change in condition Melting point/Melting range: Boiling point/Boiling range:	
· 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
· Solvent content: Organic solvents: Water:	0.0 % 1.0 %
Solids content: · Other information	99.0 % No further relevant information available.

10 Stability and reactivity

- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Incompatible materials: No further relevant information available.

(Contd. on page 4)



Printing date 02/24/2012 Reviewed on 12/06/2011

Trade name: Variant II Turbo HbA1c Kit 2.0 Calibrator 1

(Contd. of page 3)

· Hazardous decomposition products: No dangerous decomposition products known

11 Toxicological information

- · 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.

Target organs: Not applicable.

12 Ecological information

- · 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.
- · 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.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

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

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	Irar	ispo	rt in	TOTII	lation

- · 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

(Contd. on page 5)



Printing date 02/24/2012 Reviewed on 12/06/2011

Trade name: Variant II Turbo HbA1c Kit 2.0 Calibrator 1

(Contd. of page 4)

· 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

- · SARA (Superfund Amendents 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

- · California Proposition 65:
- · Developmental Toxicity

32986-56-4 tobramycin

1405-41-0 Gentamicin Sulfate

- · 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.

- · National regulations
- · Water hazard class: Water hazard class 1 (Self-assessment): slightly hazardous for water.

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 MSDS: Environmental Health and Safety.
- · Contact:

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(Contd. of page 5)

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Printing date 02/24/2012 Reviewed on 12/06/2011

1 Identification of the substance/mixture and of the company/undertaking

- · Product identifier
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- · Catalog or product number: 270-2460
- · Application of the substance / the preparation 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:

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2 Composition/information on ingredients

· Description: Mixture of the substances listed below with non-hazardous additions.

· Listing of dangerous and non-hazardous components:		
	Human Whole Blood	50-100%
57-50-1	sucrose, pure	10-20%
7732-18-5	water	1.0-2.5%

[·] Additional information For the wording of the listed risk phrases refer to section 15.

3 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC Void
- · Information concerning particular hazards for human and environment:

The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

· Classification system:

The classification was made according to the latest editions of the EU-lists, and expanded upon from company and literature data.

The classification was made according to OSHA 29CFR 1910.1200 and 1910.1030, and is expanded upon from company and/or literature information.

- · Label elements
- · Labelling according to EU guidelines:

Observe the general safety regulations when handling chemicals

The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (GefStoffV).

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

Health = 0

Fire = 0

Reactivity = 0

(Contd. on page 2)



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Trade name: Variant II Turbo HbA1c Kit 2.0 Calibrator 2

· Special Hazards Contains human sourced and/or potentially infectious components.

(Contd. of page 1)

4 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.

5 Firefighting measures

- · 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.
- · 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: Pick up mechanically.
- · 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.
- · 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.

8 Exposure controls/personal protection

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

57-50-1 sucrose, pure

PEL (United States) | 15* 5** mg/m³ | *total dust **respirable fraction | REL (United States) | 10* 5** mg/m³ | *total dust **respirable fraction

TLV (United States) 10 mg/m³

· Additional information: The lists that were valid during the creation were used as basis.

(Contd. on page 3)



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Trade name: Variant II Turbo HbA1c Kit 2.0 Calibrator 2

(Contd. of page 2)

- · 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.

For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:

Synthetic gloves

- · For the permanent contact gloves made of the following materials are suitable: Synthetic gloves
- · For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable: Synthetic gloves
- · As protection from splashes gloves made of the following materials are suitable: Synthetic gloves
- · Eye protection: Safety glasses
- · Body protection: Protective work clothing.

9 Physical and chemical properties		
 General Information Appearance: Form: Color: Odor: 	Solid. Red Odorless	
· Change in condition Melting point/Melting range: Boiling point/Boiling range:		
· 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	
· Solvent content: Organic solvents: Water:	0.0 % 1.0 %	
Solids content: Other information	99.0 % No further relevant information available.	

10 Stability and reactivity

- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Incompatible materials: No further relevant information available.

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Trade name: Variant II Turbo HbA1c Kit 2.0 Calibrator 2

(Contd. of page 3)

· Hazardous decomposition products: No dangerous decomposition products known

11 Toxicological information

- · 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.

· Target organs: Not applicable.

12 Ecological information

- · 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.
- · 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.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

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

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.

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- · 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

(Contd. on page 5)



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Trade name: Variant II Turbo HbA1c Kit 2.0 Calibrator 2

(Contd. of page 4)

· Packing	group
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· 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

- · SARA (Superfund Amendents 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

- · California Proposition 65:
- · Developmental Toxicity

32986-56-4 tobramycin

1405-41-0 Gentamicin Sulfate

- · 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.

- · National regulations
- · Water hazard class: Water hazard class 1 (Self-assessment): slightly hazardous for water.

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 MSDS: Environmental Health and Safety.
- · Contact:

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

(Contd. on page 6)



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Trade name: Variant II Turbo HbA1c Kit 2.0 Calibrator 2

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

• * Data compared to the previous version altered.



Printing date 02/24/2012 Reviewed on 12/06/2011

1 Identification of the substance/mixture and of the company/undertaking

- · Product identifier
- · Trade name: Variant II Turbo HbA1c Kit 2.0 Analytical Cartridge
- · Catalog or product number: 270-2462
- · Application of the substance / the preparation 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 Composition/information on ingredients

- · Chemical characterization: Substances
- · CAS No. Description:

72642-12-7 2-Propenoic acid, 2-methyl-, oxiranylmethyl ester, polymer with oxydi-2,1-ethanediyl bis(2-methyl-2-propenoate)

- Additional information: For the wording of the listed risk phrases refer to section 15.
- · Listing of dangerous and non-hazardous components:

7732-18-5 *water* 1.0-2.5%

3 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC Void
- · Information concerning particular hazards for human and environment: not applicable
- · Classification system:

The classification was made according to OSHA 29CFR 1910.1200 and 1910.1030, and is expanded upon from company and/or literature information.

- · Label elements
- · Labelling according to EU guidelines:

Observe the general safety regulations when handling chemicals

The substance is not subject to classification according to EU lists and other sources of literature known to us.

The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (GefStoffV).

4 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.

(Contd. on page 2)



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Trade name: Variant II Turbo HbA1c Kit 2.0 Analytical Cartridge

(Contd. of page 1)

· After swallowing Rinse mouth with water. Seek medical attention and appropriate follow-up.

5 Firefighting measures

- · 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.
- · Protective equipment: No special measures required.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Wear protective equipment (See section 8). Keep unprotected persons away.
- · Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · 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 No special measures required.
- · Information about protection against explosions and fires: No special measures required.
- 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.

8 Exposure controls/personal protection

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

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

- · Additional information: The lists that were valid during the creation were used as basis.
- · Personal protective equipment
- · General protective and hygienic measures The usual precautionary measures for handling chemicals should be followed.
- · 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

- DUS



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Trade name: Variant II Turbo HbA1c Kit 2.0 Analytical Cartridge

(Contd. of page 2)

9 Physical and chemical properties

· General Information

· Appearance:

Form: Granulate
Color: Whitish
Odor: Odorless

· Change in condition

Melting point/Melting range: x °C

Boiling point/Boiling range: undetermined

· Flash point: Not applicable

· Flammability (solid, gaseous) Product is not flammable.

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

• **Density at 20°C:** 1.03 g/cm³

· Solubility in / Miscibility with

Water: Fully miscible

· Solvent content:

Organic solvents: 0.0 % Under: 2.0 %

Solids content: 100.0 %

· Other information No further relevant information available.

10 Stability and reactivity

- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known

11 Toxicological information

- · 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:

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.

The substance is not subject to classification according to the latest version of the EU lists.

· Target organs: Not applicable.

12 Ecological information

- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.

(Contd. on page 4)



Printing date 02/24/2012 Reviewed on 12/06/2011

Trade name: Variant II Turbo HbA1c Kit 2.0 Analytical Cartridge

(Contd. of page 3)

- · Behavior in environmental systems:
- · Bioaccumulative potential 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.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

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

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.
 Transport in bulk according to Annex II of MARPOL7 and the IBC Code 	73/78 Not applicable.
· Transport/Additional information:	Not dangerous according to the above specifications.

15 Regulatory information

- · SARA (Superfund Amendents 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.

(Contd. on page 5)



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Trade name: Variant II Turbo HbA1c Kit 2.0 Analytical Cartridge

(Contd. of page 4)

· TSCA (Toxic Substances Control Act):

7732-18-5 water

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

None of the ingredients is listed.

· NTP (National Toxicology Program)

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· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

- · National regulations
- · Water hazard class: Water hazard class 1 (Self-assessment): slightly hazardous for water.

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DUS