

# KIT SAFETY DATA SHEET



**Kit Product Name** VARIANT II Hemoglobin A1c Program Calibrator/Diluent Set

**Kit Catalog Number(s)** 2702115NU

**Revision date** 08-Sep-2021

## Kit Contents

Catalog Number(s)	Product Name
2200119	Calibrator Diluent
2702108NU	Variant II Hemoglobin A1c Calibrator 2
2702107NU	Variant II Hemoglobin A1c Calibrator 1

# SAFETY DATA SHEET



Revision date 17-Aug-2021

Revision Number 2

## 1. Identification

### Product identifier

**Product Name** Calibrator Diluent

### Other means of identification

**Catalog Number(s)** 2200119

### Recommended use of the chemical and restrictions on use

**Recommended use** In-vitro laboratory reagent or component

### Details of the supplier of the safety data sheet

#### Corporate Headquarters

Bio-Rad Laboratories Inc.  
1000 Alfred Nobel Drive  
Hercules, CA 94547  
USA

#### Manufacturer Address

Bio-Rad Laboratories, Diagnostic Group  
4000 Alfred Nobel Drive  
Hercules, California 94547  
USA

#### Legal Entity / Contact Address

Bio-Rad Laboratories  
Clinical Diagnostics  
4000 Alfred Nobel Drive  
Hercules, California 94547  
USA

#### **Technical Service**

1-800-224-6723  
TechSupport.USSD@bio-rad.com

### Emergency telephone number

**24 Hour Emergency Phone Number**

CHEMTREC USA: 1 (800) 424-9300

## 2. Hazard(s) identification

### Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

#### Hazard statements

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

The product contains no substances which at their given concentration, are considered to be hazardous to health.

**Appearance** aqueous solution

**Physical state** Liquid

**Odor** Odorless

Other information**3. Composition/information on ingredients****Substance**

Not applicable.

**Mixture**

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

**4. First-aid measures****Description of first aid measures**

<b>General advice</b>	No hazards which require special first aid measures.
<b>Inhalation</b>	Remove to fresh air.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Wash skin with soap and water.
<b>Ingestion</b>	Rinse mouth thoroughly with water.

**Most important symptoms and effects, both acute and delayed**

<b>Symptoms</b>	No information available.
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**Indication of any immediate medical attention and special treatment needed**

<b>Note to physicians</b>	Treat symptomatically.
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**5. Fire-fighting measures**

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Unsuitable extinguishing media</b>	No information available.
<b>Specific hazards arising from the chemical</b>	None known.
<b>Explosion data</b>	
<b>Sensitivity to mechanical impact</b>	None.
<b>Sensitivity to static discharge</b>	None.
<b>Special protective equipment for fire-fighters</b>	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

**6. Accidental release measures****Personal precautions, protective equipment and emergency procedures**

<b>Personal precautions</b>	See section 8 for more information.
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**Methods and material for containment and cleaning up**

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Pick up and transfer to properly labeled containers.

**7. Handling and storage****Precautions for safe handling**

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice.

**Conditions for safe storage, including any incompatibilities**

**Storage Conditions** Store according to product and label instructions.

**8. Exposure controls/personal protection****Control parameters**

**Exposure Limits** This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

**Appropriate engineering controls**

**Engineering controls** Showers  
Eyewash stations  
Ventilation systems.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection** Wear safety glasses with side shields (or goggles).

**Hand protection** Wear suitable gloves.

**Skin and body protection** Wear suitable protective clothing.

**Respiratory protection** No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

**9. Physical and chemical properties****Information on basic physical and chemical properties**

**Physical state** Liquid  
**Appearance** aqueous solution  
**Color** colorless  
**Odor** Odorless  
**Odor threshold** No information available

<b><u>Property</u></b>	<b><u>Values</u></b>	<b><u>Remarks • Method</u></b>
pH		None known
Melting point / freezing point	0 °C / 32 °F	
Boiling point / boiling range	100 °C / 212 °F	
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	

<b>Lower flammability or explosive limits</b>	No data available	
<b>Vapor pressure</b>	No data available	None known
<b>Vapor density</b>	No data available	None known
<b>Relative density</b>	No data available	None known
<b>Water solubility</b>	Miscible in water	
<b>Solubility in other solvents</b>	No data available	None known
<b>Partition coefficient</b>	No data available	None known
<b>Autoignition temperature</b>	No data available	None known
<b>Decomposition temperature</b>		None known
<b>Kinematic viscosity</b>	No data available	None known
<b>Dynamic viscosity</b>	No data available	None known
<b><u>Other information</u></b>		
<b>Explosive properties</b>	Not applicable	
<b>Oxidizing properties</b>	Not applicable	
<b>Softening point</b>	Not applicable	
<b>Molecular weight</b>	Not applicable	
<b>VOC Content (%)</b>	Not applicable	

## 10. Stability and reactivity

<b>Reactivity</b>	No information available.
<b>Chemical stability</b>	Stable under normal conditions.
<b>Possibility of hazardous reactions</b>	Avoid contact with metals. This product contains sodium azide. Sodium azide can react with copper, brass, lead, and solder in piping systems to form explosive compounds and toxic gases.
<b>Conditions to avoid</b>	None known based on information supplied.
<b>Incompatible materials</b>	Metals.
<b>Hazardous decomposition products</b>	None known based on information supplied.

## 11. Toxicological information

### Information on likely routes of exposure

#### Product Information

<b>Inhalation</b>	Specific test data for the substance or mixture is not available.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available.
<b>Skin contact</b>	Specific test data for the substance or mixture is not available.
<b>Ingestion</b>	Specific test data for the substance or mixture is not available.

### Symptoms related to the physical, chemical and toxicological characteristics

<b>Symptoms</b>	No information available.
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### Acute toxicity

#### Numerical measures of toxicity

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
<b>Serious eye damage/eye irritation</b>	Based on available data, the classification criteria are not met.
<b>Respiratory or skin sensitization</b>	Based on available data, the classification criteria are not met.
<b>Germ cell mutagenicity</b>	Based on available data, the classification criteria are not met.
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met.
<b>Reproductive toxicity</b>	Based on available data, the classification criteria are not met.
<b>STOT - single exposure</b>	Based on available data, the classification criteria are not met.
<b>STOT - repeated exposure</b>	Based on available data, the classification criteria are not met.
<b>Aspiration hazard</b>	No information available.
<b>Other adverse effects</b>	No information available.
<b>Interactive effects</b>	No information available.

**12. Ecological information****Ecotoxicity**

<b>Persistence and degradability</b>	No information available.
<b>Bioaccumulation</b>	There is no data for this product.
<b>Other adverse effects</b>	No information available.

**13. Disposal considerations****Waste treatment methods**

<b>Waste from residues/unused products</b>	Flush pipes with water frequently if discarding solutions containing sodium azide into metal piping systems. Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
<b>Contaminated packaging</b>	Do not reuse empty containers.
<b>US EPA Waste Number</b>	P105

**14. Transport information**

<b><u>DOT</u></b>	Not regulated
<b><u>TDG</u></b>	Not regulated

MEX Not regulated

IATA Not regulated

IMDG Not regulated

## 15. Regulatory information

### International Inventories

Contact supplier for inventory compliance status

### US Federal Regulations

#### SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

#### SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications. Under the amended regulations at 40 CFR 370, EPCRA 311/312 Tier II reporting for the 2017 calendar year will need to be consistent with updated hazard classifications.

#### CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

#### CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

### US State Regulations

#### California Proposition 65

This product does not contain any Proposition 65 chemicals.

### U.S. State Right-to-Know Regulations

**US State Regulations** This product does not contain any substances regulated by state right-to-know regulations

**US State Regulations**

### U.S. EPA Label Information

**EPA Pesticide Registration Number** Not applicable

## 16. Other information

<u>NFPA</u>	Health hazards 0	Flammability 0	Instability 0	Special hazards -
<u>HMIS</u>	Health hazards 0	Flammability 0	Physical hazards 0	Personal protection X

Key or legend to abbreviations and acronyms used in the safety data sheet

**Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

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TWA Ceiling	TWA (time-weighted average) Maximum limit value	STEL *	STEL (Short Term Exposure Limit) Skin designation
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**Key literature references and sources for data used to compile the SDS**

Agency for Toxic Substances and Disease Registry (ATSDR)  
U.S. Environmental Protection Agency ChemView Database  
European Food Safety Authority (EFSA)  
EPA (Environmental Protection Agency)  
Acute Exposure Guideline Level(s) (AEGL(s))  
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act  
U.S. Environmental Protection Agency High Production Volume Chemicals  
Food Research Journal  
Hazardous Substance Database  
International Uniform Chemical Information Database (IUCLID)  
Japan GHS Classification  
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)  
NIOSH (National Institute for Occupational Safety and Health)  
National Library of Medicine's ChemID Plus (NLM CIP)  
National Library of Medicine's PubMed database (NLM PUBMED)  
National Toxicology Program (NTP)  
New Zealand's Chemical Classification and Information Database (CCID)  
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications  
Organization for Economic Co-operation and Development High Production Volume Chemicals Program  
Organization for Economic Co-operation and Development Screening Information Data Set  
RTECS (Registry of Toxic Effects of Chemical Substances)  
World Health Organization

**Prepared By** Bio-Rad Laboratories, Environmental Health and Safety

**Revision date** 17-Aug-2021

**Revision Note** SDS sections updated. 1. 2. 3.

**Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet**



# SAFETY DATA SHEET



Revision date 18-Aug-2021

Revision Number 2

## 1. Identification

### Product identifier

**Product Name** Variant II Hemoglobin A1c Calibrator 2

### Other means of identification

**Catalog Number(s)** 2702108NU

### Recommended use of the chemical and restrictions on use

**Recommended use** In vitro diagnostic

### Details of the supplier of the safety data sheet

#### Corporate Headquarters

Bio-Rad Laboratories Inc.  
1000 Alfred Nobel Drive  
Hercules, CA 94547  
USA

#### Manufacturer Address

Bio-Rad Laboratories, Diagnostic Group  
4000 Alfred Nobel Drive  
Hercules, California 94547  
USA

#### Legal Entity / Contact Address

Bio-Rad Laboratories  
Clinical Diagnostics  
4000 Alfred Nobel Drive  
Hercules, California 94547  
USA

#### **Technical Service**

1-800-224-6723  
TechSupport.USSD@bio-rad.com

### Emergency telephone number

**24 Hour Emergency Phone Number**

CHEMTREC USA: 1 (800) 424-9300

## 2. Hazard(s) identification

### Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

#### Hazard statements

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

The product contains no substances which at their given concentration, are considered to be hazardous to health.

**Appearance** solid

**Physical state** Solid

**Odor** Odorless

Other information**3. Composition/information on ingredients**Substance

Not applicable.

Mixture

Chemical name	CAS No	Weight-%	Trade secret
Sucrose	57-50-1	10 - 20	*

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

**4. First-aid measures**Description of first aid measures

General advice	No hazards which require special first aid measures.
Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash skin with soap and water.
Ingestion	Call a physician. Contains human source material and / or potentially infectious components.

Most important symptoms and effects, both acute and delayed

Symptoms	No information available.
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Indication of any immediate medical attention and special treatment needed

Note to physicians	Contains human source material and / or potentially infectious components.
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**5. Fire-fighting measures**

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	No information available.
Specific hazards arising from the chemical	None known.
Explosion data	
Sensitivity to mechanical impact	None.
Sensitivity to static discharge	None.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

**6. Accidental release measures**Personal precautions, protective equipment and emergency procedures

**Personal precautions** See section 8 for more information.

#### **Methods and material for containment and cleaning up**

**Methods for containment** Do not allow into any sewer, on the ground or into any body of water.

**Methods for cleaning up** Clean contaminated surface thoroughly. Use: Disinfectant.

### **7. Handling and storage**

#### **Precautions for safe handling**

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice.

#### **Conditions for safe storage, including any incompatibilities**

**Storage Conditions** Store according to product and label instructions.

### **8. Exposure controls/personal protection**

#### **Control parameters**

##### **Exposure Limits**

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Sucrose 57-50-1	TWA: 10 mg/m <sup>3</sup>	TWA: 15 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable fraction (vacated) TWA: 15 mg/m <sup>3</sup> total dust (vacated) TWA: 5 mg/m <sup>3</sup> respirable fraction	TWA: 10 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable dust

#### **Appropriate engineering controls**

**Engineering controls** Showers  
Eyewash stations  
Ventilation systems.

#### **Individual protection measures, such as personal protective equipment**

**Eye/face protection** Wear safety glasses with side shields (or goggles).

**Hand protection** Wear suitable gloves.

**Skin and body protection** Wear suitable protective clothing.

**Respiratory protection** No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

**General hygiene considerations** Follow universal and standard precautions for handling potentially infectious materials.

### **9. Physical and chemical properties**

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

**Physical state** Solid  
**Appearance** solid  
**Color** Varies  
**Odor** Odorless  
**Odor threshold** No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH		None known
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Relative density	No data available	None known
Water solubility	Miscible in water	
Solubility in other solvents	No data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
<u>Other information</u>		
Explosive properties	Not applicable	
Oxidizing properties	Not applicable	
Softening point	Not applicable	
Molecular weight	Not applicable	
VOC Content (%)	Not applicable	

## 10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous decomposition products	None known based on information supplied.

## 11. Toxicological information

### Information on likely routes of exposure

#### Product Information

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

### Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	No information available.
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**Acute toxicity****Numerical measures of toxicity**

The following values are calculated based on chapter 3.1 of the GHS document

**Component Information**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sucrose 57-50-1	= 29700 mg/kg ( Rat )	-	-

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
<b>Serious eye damage/eye irritation</b>	Based on available data, the classification criteria are not met.
<b>Respiratory or skin sensitization</b>	Based on available data, the classification criteria are not met.
<b>Germ cell mutagenicity</b>	Based on available data, the classification criteria are not met.
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met.
<b>Reproductive toxicity</b>	Based on available data, the classification criteria are not met.
<b>STOT - single exposure</b>	Based on available data, the classification criteria are not met.
<b>STOT - repeated exposure</b>	Based on available data, the classification criteria are not met.
<b>Target organ effects</b>	Respiratory system, Eyes.
<b>Aspiration hazard</b>	No information available.
<b>Other adverse effects</b>	No information available.
<b>Interactive effects</b>	No information available.

**12. Ecological information**

<b>Ecotoxicity</b>	The environmental impact of this product has not been fully investigated.
<b>Persistence and degradability</b>	No information available.
<b>Bioaccumulation</b>	There is no data for this product.
<b>Other adverse effects</b>	No information available.

**13. Disposal considerations****Waste treatment methods**

<b>Waste from residues/unused products</b>	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
<b>Contaminated packaging</b>	Do not reuse empty containers.

**14. Transport information**

<u>DOT</u>	Not regulated
<u>TDG</u>	Not regulated
<u>MEX</u>	Not regulated
<u>IATA</u>	Not regulated
<u>IMDG</u>	Not regulated

**15. Regulatory information****International Inventories**

Contact supplier for inventory compliance status

**US Federal Regulations****SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

**SARA 311/312 Hazard Categories**

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications. Under the amended regulations at 40 CFR 370, EPCRA 311/312 Tier II reporting for the 2017 calendar year will need to be consistent with updated hazard classifications.

**CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

**CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

**US State Regulations****California Proposition 65**

This product contains the following Proposition 65 chemicals:.

Chemical name	California Proposition 65
Tobramycin - 32986-56-4	Developmental
Gentamicin, sulfate (salt) - 1405-41-0	Developmental

**U.S. State Right-to-Know Regulations**

**US State Regulations** This product does not contain any substances regulated by state right-to-know regulations

**US State Regulations**

Chemical name	New Jersey	Massachusetts	Pennsylvania
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Sucrose 57-50-1	-	X	X
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**U.S. EPA Label Information**

EPA Pesticide Registration Number Not applicable

**16. Other information**

<b>NFPA</b>	Health hazards 0	Flammability 0	Instability 0	Special hazards -
<b>HMIS</b>	Health hazards 0	Flammability 0	Physical hazards 0	Personal protection X

**Key or legend to abbreviations and acronyms used in the safety data sheet****Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

**Key literature references and sources for data used to compile the SDS**

Agency for Toxic Substances and Disease Registry (ATSDR)  
 U.S. Environmental Protection Agency ChemView Database  
 European Food Safety Authority (EFSA)  
 EPA (Environmental Protection Agency)  
 Acute Exposure Guideline Level(s) (AELG(s))  
 U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act  
 U.S. Environmental Protection Agency High Production Volume Chemicals  
 Food Research Journal  
 Hazardous Substance Database  
 International Uniform Chemical Information Database (IUCLID)  
 Japan GHS Classification  
 Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)  
 NIOSH (National Institute for Occupational Safety and Health)  
 National Library of Medicine's ChemID Plus (NLM CIP)  
 National Library of Medicine's PubMed database (NLM PUBMED)  
 National Toxicology Program (NTP)  
 New Zealand's Chemical Classification and Information Database (CCID)  
 Organization for Economic Co-operation and Development Environment, Health, and Safety Publications  
 Organization for Economic Co-operation and Development High Production Volume Chemicals Program  
 Organization for Economic Co-operation and Development Screening Information Data Set  
 RTECS (Registry of Toxic Effects of Chemical Substances)  
 World Health Organization

Prepared By Bio-Rad Laboratories, Environmental Health and Safety

Revision date 18-Aug-2021

Revision Note SDS sections updated. 1. 2. 3.

**Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet**

# SAFETY DATA SHEET



Revision date 18-Aug-2021

Revision Number 2

## 1. Identification

### Product identifier

**Product Name** Variant II Hemoglobin A1c Calibrator 1

### Other means of identification

**Catalog Number(s)** 2702107NU

### Recommended use of the chemical and restrictions on use

**Recommended use** In vitro diagnostic

### Details of the supplier of the safety data sheet

#### Corporate Headquarters

Bio-Rad Laboratories Inc.  
1000 Alfred Nobel Drive  
Hercules, CA 94547  
USA

#### Manufacturer Address

Bio-Rad Laboratories, Diagnostic Group  
4000 Alfred Nobel Drive  
Hercules, California 94547  
USA

#### Legal Entity / Contact Address

Bio-Rad Laboratories  
Clinical Diagnostics  
4000 Alfred Nobel Drive  
Hercules, California 94547  
USA

#### **Technical Service**

1-800-224-6723  
TechSupport.USSD@bio-rad.com

### Emergency telephone number

**24 Hour Emergency Phone Number**

CHEMTREC USA: 1 (800) 424-9300

## 2. Hazard(s) identification

### Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

#### Hazard statements

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

The product contains no substances which at their given concentration, are considered to be hazardous to health.

**Appearance** solid

**Physical state** Solid

**Odor** Odorless



Other information**3. Composition/information on ingredients**Substance

Not applicable.

Mixture

Chemical name	CAS No	Weight-%	Trade secret
Sucrose	57-50-1	10 - 20	*

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

**4. First-aid measures**Description of first aid measures

General advice	No hazards which require special first aid measures.
Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash skin with soap and water.
Ingestion	Call a physician. Contains human source material and / or potentially infectious components.

Most important symptoms and effects, both acute and delayed

Symptoms	No information available.
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Indication of any immediate medical attention and special treatment needed

Note to physicians	Contains human source material and / or potentially infectious components.
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**5. Fire-fighting measures**

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	No information available.
Specific hazards arising from the chemical	None known.
Explosion data	
Sensitivity to mechanical impact	None.
Sensitivity to static discharge	None.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

**6. Accidental release measures**

**Personal precautions, protective equipment and emergency procedures**

**Personal precautions** See section 8 for more information.

**Methods and material for containment and cleaning up**

**Methods for containment** Do not allow into any sewer, on the ground or into any body of water.

**Methods for cleaning up** Clean contaminated surface thoroughly. Use: Disinfectant.

**7. Handling and storage****Precautions for safe handling**

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice.

**Conditions for safe storage, including any incompatibilities**

**Storage Conditions** Store according to product and label instructions.

**8. Exposure controls/personal protection****Control parameters****Exposure Limits**

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Sucrose 57-50-1	TWA: 10 mg/m <sup>3</sup>	TWA: 15 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable fraction (vacated) TWA: 15 mg/m <sup>3</sup> total dust (vacated) TWA: 5 mg/m <sup>3</sup> respirable fraction	TWA: 10 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable dust

**Appropriate engineering controls**

**Engineering controls** Showers  
Eyewash stations  
Ventilation systems.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection** Wear safety glasses with side shields (or goggles).

**Hand protection** Wear suitable gloves.

**Skin and body protection** Wear suitable protective clothing.

**Respiratory protection** No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

**General hygiene considerations** Follow universal and standard precautions for handling potentially infectious materials.

**9. Physical and chemical properties****Information on basic physical and chemical properties**

**Physical state** Solid  
**Appearance** solid  
**Color** Varies  
**Odor** Odorless  
**Odor threshold** No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH		None known
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Relative density	No data available	None known
Water solubility	Soluble in water	
Solubility in other solvents	No data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
<u>Other information</u>		
Explosive properties	Not applicable	
Oxidizing properties	Not applicable	
Softening point	Not applicable	
Molecular weight	Not applicable	
VOC Content (%)	Not applicable	

## 10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous decomposition products	None known based on information supplied.

## 11. Toxicological information

### Information on likely routes of exposure

#### Product Information

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

### Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** No information available.

**Acute toxicity**

**Numerical measures of toxicity**

The following values are calculated based on chapter 3.1 of the GHS document

**Component Information**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sucrose 57-50-1	= 29700 mg/kg ( Rat )	-	-

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**Skin corrosion/irritation** Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation** Based on available data, the classification criteria are not met.

**Respiratory or skin sensitization** Based on available data, the classification criteria are not met.

**Germ cell mutagenicity** Based on available data, the classification criteria are not met.

**Carcinogenicity** Based on available data, the classification criteria are not met.

**Reproductive toxicity** Based on available data, the classification criteria are not met.

**STOT - single exposure** Based on available data, the classification criteria are not met.

**STOT - repeated exposure** Based on available data, the classification criteria are not met.

**Target organ effects** Respiratory system, Eyes.

**Aspiration hazard** No information available.

**Other adverse effects** No information available.

**Interactive effects** No information available.

**12. Ecological information**

**Ecotoxicity** The environmental impact of this product has not been fully investigated.

**Persistence and degradability** No information available.

**Bioaccumulation** There is no data for this product.

**Other adverse effects** No information available.

**13. Disposal considerations**

**Waste treatment methods**

**Waste from residues/unused products** Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging

Do not reuse empty containers.

**14. Transport information**DOT Not regulatedTDG Not regulatedMEX Not regulatedIATA Not regulatedIMDG Not regulated**15. Regulatory information****International Inventories**

Contact supplier for inventory compliance status

**US Federal Regulations****SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

**SARA 311/312 Hazard Categories**

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications. Under the amended regulations at 40 CFR 370, EPCRA 311/312 Tier II reporting for the 2017 calendar year will need to be consistent with updated hazard classifications.

**CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

**CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

**US State Regulations****California Proposition 65**

This product contains the following Proposition 65 chemicals:.

Chemical name	California Proposition 65
Tobramycin - 32986-56-4	Developmental
Gentamicin, sulfate (salt) - 1405-41-0	Developmental

**U.S. State Right-to-Know Regulations****US State Regulations**

This product does not contain any substances regulated by state right-to-know regulations

**US State Regulations**

Chemical name	New Jersey	Massachusetts	Pennsylvania
Sucrose 57-50-1	-	X	X

**U.S. EPA Label Information**

EPA Pesticide Registration Number Not applicable

**16. Other information**

<b>NFPA</b>	<b>Health hazards</b> 0	<b>Flammability</b> 0	<b>Instability</b> 0	<b>Special hazards</b> -
<b>HMIS</b>	<b>Health hazards</b> 0	<b>Flammability</b> 0	<b>Physical hazards</b> 0	<b>Personal protection</b> X

**Key or legend to abbreviations and acronyms used in the safety data sheet****Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

**Key literature references and sources for data used to compile the SDS**

Agency for Toxic Substances and Disease Registry (ATSDR)  
U.S. Environmental Protection Agency ChemView Database  
European Food Safety Authority (EFSA)  
EPA (Environmental Protection Agency)  
Acute Exposure Guideline Level(s) (AEGL(s))  
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act  
U.S. Environmental Protection Agency High Production Volume Chemicals  
Food Research Journal  
Hazardous Substance Database  
International Uniform Chemical Information Database (IUCLID)  
Japan GHS Classification  
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)  
NIOSH (National Institute for Occupational Safety and Health)  
National Library of Medicine's ChemID Plus (NLM CIP)  
National Library of Medicine's PubMed database (NLM PUBMED)  
National Toxicology Program (NTP)  
New Zealand's Chemical Classification and Information Database (CCID)  
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications  
Organization for Economic Co-operation and Development High Production Volume Chemicals Program  
Organization for Economic Co-operation and Development Screening Information Data Set  
RTECS (Registry of Toxic Effects of Chemical Substances)  
World Health Organization

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Revision Note SDS sections updated. 1. 2. 3.

**Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet**