KIT SAFETY DATA SHEET



Variant II Hemoglobin A1c Reorder Pack 1000 Tests 2702101NU 2702101NUCN **Kit Product Name**

Kit Catalogue Number(s)

Revision date 14-Apr-2022

Kit Contents

Catalogue Number(s)	Product Name
2700351, 2700352, 2700350	Whole Blood Primer
2702112NU	Variant II Hemoglobin A1c Wash/Diluent Sol.
2200119	Calibrator Diluent
2702110NU	Variant II Hemoglobin A1c Elution Buffer A
	Variant II Level 1, 2 Calibr.
2702108NU	Variant II Hemoglobin A1c Calibrator 2
2702107NU	Variant II Hemoglobin A1c Calibrator 1
2702113NU	Variant II Hb A1c Analytical Cartridge
2702111NU	Variant II Hemoglobin A1c Elution Buffer B

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SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: GB/T 16483-2008, GB/T 17519-2013

Product Name Whole Blood Primer Revision date 27-Aug-2021 Revision Number 1.2

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

Product identifier

Product Name Whole Blood Primer

Catalogue Number(s) 2700351, 2700352, 2700350

Other means of identification

Pure substance/mixture Mixture

Details of the supplier of the safety data sheet

Corporate Headquarters

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

USA

Manufacturer

Bio-Rad Laboratories, Diagnostic Group

4000 Alfred Nobel Drive Hercules, California 94547

USA

Legal Entity / Contact Address

Pathumwan, Bangkok 10330

Bio-Rad Laboratories Ltd. 1st and 2nd Floor, Lumpini 1 Building 239/2, Rajdamri Road, Lumpini,

Thailand

Technical Service +66 2 652 8313

ctsthailand@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Hong Kong: 800-968-793

Recommended use of the chemical and restrictions on use

Recommended use In-vitro laboratory reagent or component

SECTION 2: Hazards identification

Emergency Overview

No significant adverse health effects

Appearance solid Physical state Solid Odour Odourless

Classification of the substance or mixture

Not classified

Label elements

Hazard statements

Not classified

Physical and chemical hazards

Not applicable.

Health hazards

Immediate Health Effects: Not applicable.

Chronic effects: Not applicable.

Environmental hazards

Not applicable

Other hazards which do not result in classification

Not applicable

Contains human source material and / or potentially infectious components.

SECTION 3: Composition/information on ingredients

Substance

Not applicable.

Mixture

Not classified.

Chemical name	Weight-%	CAS No
Human Whole Blood	50 - 100	NO-CAS-22
DL-Threonine	20 - 35	80-68-2
Water	1 - 2.5	7732-18-5
Sodium chloride	0.3 - 0.999	7647-14-5
Tobramycin	0.01 - 0.099	32986-56-4
Gentamicin, sulfate (salt)	0.001 - 0.01	1405-41-0
Glycine, N,N-1,2-ethanediylbis[N-(carboxymethyl)-,	< 0.001	6381-92-6
disodium salt, dihydrate		

SECTION 4: First aid measures

Description of necessary first aid measures

General advice No hazards which require special first aid measures.

Inhalation Remove to fresh air.

Eye contact Contains human source material and / or potentially infectious components. Call a doctor.

Skin contact Wash skin with soap and water.

Ingestion Call a doctor. Contains human source material and / or potentially infectious components.

Most important symptoms and effects, both acute and delayed

No information available.

For emergency responders No information available.

Note to doctors Contains human source material and / or potentially infectious components.

SECTION 5: Firefighting measures

Extinguishing media

surrounding environment.

Revision date 27-Aug-2021

Unsuitable extinguishing media No information available.

Specific hazards arising from the

chemical

No information available.

Special protective actions for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout

gear. Use personal protection equipment.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions See section 8 for more information.

For emergency responders Use personal protection recommended in Section 8.

Environmental precautions See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Do not allow into any sewer, on the ground or into any body of water. Clean contaminated

surface thoroughly. Use:. Disinfectant.

Precautions to prevent secondary

hazards

Clean contaminated objects and areas thoroughly observing environmental regulations.

SECTION 7: Handling and storage

<u>Precautions for safe handling</u> Handle in accordance with good industrial hygiene and safety practice. Follow universal

and standard precautions for handling potentially infectious materials. See Section 8 for

information on appropriate personal protective equipment.

Conditions for safe storage, including any incompatibilities

Store according to product and label instructions.

Incompatible materialsNone known based on information supplied.

SECTION 8: Exposure controls/personal protection

Occupational exposure limits

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

Note See section 16 for terms and abbreviations

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Monitoring and observation processes

No applicable information was found.

Engineering controls Showers

Eyewash stations Ventilation systems.

Individual protection measures, such as personal protective equipment

Revision date 27-Aug-2021

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

Skin and body protection Wear suitable protective clothing.

Hand protection Wear suitable gloves.

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.

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

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

solid **Appearance** Colour red **Physical state** Solid Odourless Odour

Odour threshold No information available

Remarks • Method Property Values

pН 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

No data available Upper flammability or explosive

limits

Lower flammability or explosive No data available

limits

Vapour pressure No data available None known No data available Vapour density None known Relative density No data available None known

Water solubility Soluble in water Solubility(ies) No data available

None known Partition coefficient No data available None known **Autoignition temperature** No data available None known **Decomposition temperature** No data available None known Kinematic viscosity No data available None known **Dynamic viscosity** No data available None known

Additional information

Explosive properties Not applicable **Oxidising properties** Not applicable

SECTION 10: Stability and reactivity

Stability Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Sensitivity to mechanical impact None. Sensitivity to static discharge None.

None known based on information supplied. Conditions to avoid

None known based on information supplied. Incompatible materials

Hazardous decomposition products None known based on information supplied.

Product Name Whole Blood Primer Revision date 27-Aug-2021

SECTION 11: Toxicological information

Acute toxicity

Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
Sodium chloride	= 3 g/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat)1 h
Tobramycin	> 7500 mg/kg (Rat)	-	-
Gentamicin, sulfate (salt)	> 5 g/kg (Rat)	-	-

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 sensitisation 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.

Specific target organ toxicity — single exposure

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

Specific target organ toxicity —

repeated exposure

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

Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

Ecotoxicity

Unknown aquatic toxicity 0 % of the mixture consists of component(s) of unknown hazards to the aquatic environment

Chemical name	Algae/aquatic plants	Fish	Crustacea
Sodium chloride	-	LC50: 4747 - 7824mg/L (96h,	EC50: 340.7 - 469.2mg/L (48h,
		Oncorhynchus mykiss)	Daphnia magna)
		LC50: 5560 - 6080mg/L (96h,	EC50: =1000mg/L (48h,
		Lepomis macrochirus)	Daphnia magna)
		LC50: 6020 - 7070mg/L (96h,	-
		Pimephales promelas)	
		LC50: 6420 - 6700mg/L (96h,	
		Pimephales promelas)	
		LC50: =12946mg/L (96h,	
		Lepomis macrochirus)	
		LC50: =7050mg/L (96h,	
		Pimephales promelas)	

Product Name Whole Blood Primer

Revision date 27-Aug-2021

No information available. Persistence and degradability

Bioaccumulative potential No information available.

No information available. Mobility in soil

SECTION 13: Disposal considerations

Dispose of in accordance with local regulations. Dispose of waste in accordance with Waste chemicals

environmental legislation.

Do not reuse empty containers. Contaminated packaging

SECTION 14: Transport information

Not regulated

No information available Transport in bulk according to

Annex II of MARPOL and the IBC

Code

IATA Not regulated

China Not regulated

Special precautions for user

Please refer to the applicable dangerous goods regulations for additional information

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations

Law of the People's Republic of China on Prevention and Control of Occupational Diseases

Catalogue of occupational hazard factors: Not applicable. Catalogue of occupational diseases: Not applicable.

Regulations on the Control over Safety of Hazardous Chemicals

Inventory of hazardous chemicals Not applicable.

GB 18218-2009 Identification of major hazard installations for dangerous chemicals Not applicable

List of hazardous chemicals under priority management Not applicable

Regulations on Labour Protection in Workplaces Where Toxic Substances Are Used

Inventory of highly toxic goods Not applicable

Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

List of toxic chemicals severely restricted for import and export in China Not applicable

Measures for the Environmental Management of New Chemical Substances

IECSC - China Inventory of Existing Chemical SubstancesContact supplier for inventory compliance status.

International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

Revision date 27-Aug-2021

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

SECTION 16: Other information

Prepared By Bio-Rad Laboratories, Environmental Health and Safety

Revision date 27-Aug-2021

Revision Note SDS sections updated. 1. 2.

Abbreviations and acronyms

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value * Skin designation

C Carcinogen

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

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

This safety data sheet was created pursuant to the requirements of: GB/T 16483-2008, GB/T 17519-2013

Product Name Variant II Hemoglobin A1c Wash/Diluent Sol.

Revision date 17-Aug-2021 **Revision Number** 1.1

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

Product identifier

Product Name Variant II Hemoglobin A1c Wash/Diluent Sol.

Catalogue Number(s) 2702112NU

Other means of identification

CAS No 7732-18-5

Pure substance/mixture Mixture

Details of the supplier of the safety data sheet

Corporate Headquarters Manufacturer

Bio-Rad Laboratories Inc.

1000 Alfred Nobel Drive

Bio-Rad Labora
4000 Alfred No

Hercules, CA 94547

USA

Bio-Rad Laboratories, Diagnostic Group

4000 Alfred Nobel Drive Hercules, California 94547

USA

Legal Entity / Contact Address

Bio-Rad Laboratories Ltd. 1st and 2nd Floor, Lumpini 1 Building 239/2, Rajdamri Road, Lumpini, Pathumwan, Bangkok 10330

Thailand

Technical Service +66 2 652 8313

ctsthailand@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Hong Kong: 800-968-793

Recommended use of the chemical and restrictions on use

Recommended use In-vitro laboratory reagent or component

SECTION 2: Hazards identification

Emergency Overview

No significant adverse health effects

Appearance aqueous solution Physical state Liquid Odour Odourless

Classification of the substance or mixture

Not classified

Label elements

Hazard statements

Not classified

Product Name Variant II Hemoglobin A1c Wash/Diluent

Sol

Revision date 17-Aug-2021

Physical and chemical hazards

Not applicable.

Health hazards

Immediate Health Effects: Not applicable.

Chronic effects: Not applicable.

Environmental hazards

Not applicable

Other hazards which do not result in classification

Not applicable

SECTION 3: Composition/information on ingredients

Substance

Not applicable.

CAS No 7732-18-5

Mixture

Not classified.

SECTION 4: First aid measures

Description of necessary 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 doctor.

Skin contact Wash skin with soap and water.

Ingestion Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed

No information available.

For emergency responders No information available.

Note to doctors Treat symptomatically.

SECTION 5: Firefighting measures

Extinguishing media

surrounding environment.

Unsuitable extinguishing media No information available.

Specific hazards arising from the No information available.

Product Name Variant II Hemoglobin A1c Wash/Diluent

chemical

Special protective actions for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout

Revision date 17-Aug-2021

gear. Use personal protection equipment.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions See section 8 for more information.

Use personal protection recommended in Section 8. For emergency responders

See Section 12 for additional Ecological Information. **Environmental precautions**

Methods and material for containment and cleaning up Prevent further leakage or spillage if safe to do so. Pick up and transfer to properly

labelled containers.

<u>hazards</u>

<u>Precautions to prevent secondary</u> Clean contaminated objects and areas thoroughly observing environmental regulations.

SECTION 7: Handling and storage

Precautions for safe handling Handle in accordance with good industrial hygiene and safety practice. See Section 8 for

information on appropriate personal protective equipment.

Conditions for safe storage, including any incompatibilities Store according to product and label instructions.

Metals. Incompatible materials

SECTION 8: Exposure controls/personal protection

Occupational exposure limits

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

Note See section 16 for terms and abbreviations

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Monitoring and observation processes

No applicable information was found.

Showers Engineering controls

> Eyewash stations Ventilation systems.

Individual protection measures, such as personal protective equipment

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

Skin and body protection Wear suitable protective clothing. Product Name Variant II Hemoglobin A1c Wash/Diluent

Sol

Hand protection Wear suitable gloves.

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.

Revision date 17-Aug-2021

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

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Appearance aqueous solution

Colour colourless
Physical state Liquid
Odour Odourless

Odour threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

pH None known

Melting point / freezing point 0 °C
Boiling point / boiling range 100 °C

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 No data available

limits

Lower flammability or explosive No data available

limits

Vapour pressureNo data availableNone knownVapour densityNo data availableNone knownRelative densityNo data availableNone knownWater solubilityMiscible in water

Miscible in water Water solubility Solubility(ies) No data available None known None known **Partition coefficient** No data available None known No data available **Autoignition temperature** No data available **Decomposition temperature** None known No data available None known Kinematic viscosity Dynamic viscosity No data available None known

Additional information

Explosive properties Not applicable
Oxidising properties Not applicable

SECTION 10: Stability and reactivity

<u>Stability</u> Stable under normal conditions.

Possibility of hazardous reactions
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.

Sensitivity to mechanical impact None. Sensitivity to static discharge None.

<u>Conditions to avoid</u> None known based on information supplied.

Incompatible materials Metals.

<u>Hazardous decomposition products</u> None known based on information supplied.

SECTION 11: Toxicological information

Sol.

Acute toxicity

Numerical measures of toxicity

Skin corrosion/irritationBased 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 sensitisation 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.

Specific target organ toxicity —

single exposure

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

Specific target organ toxicity —

repeated exposure

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

Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

Ecotoxicity

Unknown aquatic toxicity 0 % of the mixture consists of component(s) of unknown hazards to the aquatic

environment

Persistence and degradability No information available.

<u>Bioaccumulative potential</u> No information available.

<u>Mobility in soil</u> No information available.

SECTION 13: Disposal considerations

<u>Waste chemicals</u> 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.

<u>Contaminated packaging</u> Do not reuse empty containers.

SECTION 14: Transport information

IMDG Not regulated

Transport in bulk according to No information available

Annex II of MARPOL and the IBC

Code

Product Name Variant II Hemoglobin A1c Wash/Diluent

Sol.

Revision date 17-Aug-2021

IATA Not regulated

<u>China</u> Not regulated

Special precautions for user

Please refer to the applicable dangerous goods regulations for additional information

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations

Law of the People's Republic of China on Prevention and Control of Occupational Diseases

Catalogue of occupational hazard factors:

Catalogue of occupational diseases:

Not applicable.

Not applicable.

Regulations on the Control over Safety of Hazardous Chemicals

Inventory of hazardous chemicals Not applicable.

GB 18218-2009 Identification of major hazard installations for dangerous chemicals

Not applicable

List of hazardous chemicals under priority management Not applicable

Regulations on Labour Protection in Workplaces Where Toxic Substances Are Used

Inventory of highly toxic goods

Not applicable

Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

List of toxic chemicals severely restricted for import and export in China Not applicable

Measures for the Environmental Management of New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances Contact supplier for inventory compliance status.

International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

SECTION 16: Other information

Prepared By Bio-Rad Laboratories, Environmental Health and Safety

Revision date 17-Aug-2021

Revision Note SDS sections updated. 1. 2.

Abbreviations and acronyms

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value * Skin designation

C Carcinogen

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

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

Legal Entity / Contact Address

239/2, Rajdamri Road, Lumpini,

Pathumwan, Bangkok 10330

Thailand

1st and 2nd Floor, Lumpini 1 Building

Bio-Rad Laboratories Ltd.

This safety data sheet was created pursuant to the requirements of: GB/T 16483-2008, GB/T 17519-2013

Product Name Calibrator Diluent Revision date 17-Aug-2021 Revision Number 2

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

Product identifier

Product Name Calibrator Diluent

Catalogue Number(s) 2200119

Other means of identification

CAS No 7732-18-5

Pure substance/mixture Mixture

Details of the supplier of the safety data sheet

Corporate Headquarters Manufacturer

Bio-Rad Laboratories Inc.

Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
4000 Alfred Nobel Drive

1000 Alfred Nobel Drive 4000 Alfred Nobel Drive Hercules, CA 94547 Hercules, California 94547

USA USA

Technical Service +66 2 652 8313

ctsthailand@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Hong Kong: 800-968-793

Recommended use of the chemical and restrictions on use

Recommended use In-vitro laboratory reagent or component

SECTION 2: Hazards identification

Emergency Overview

No significant adverse health effects

Appearance aqueous solution Physical state Liquid Odour Odourless

Classification of the substance or mixture

Not classified

Label elements

Hazard statements

Not classified

Physical and chemical hazards

Not applicable.

Health hazards

Immediate Health Effects: Not applicable.

Chronic effects: Not applicable.

Environmental hazards

Not applicable

Other hazards which do not result in classification

Not applicable

SECTION 3: Composition/information on ingredients

Substance

Not applicable.

CAS No 7732-18-5

Mixture

Not classified.

SECTION 4: First aid measures

Description of necessary 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 doctor.

Skin contact Wash skin with soap and water.

Ingestion Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed

No information available.

For emergency responders No information available.

<u>Note to doctors</u> Treat symptomatically.

SECTION 5: Firefighting measures

Extinguishing media

surrounding environment.

Unsuitable extinguishing media No information available.

Specific hazards arising from the

chemical

No information available.

Special protective actions for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout

gear. Use personal protection equipment.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions See section 8 for more information.

Environmental precautions See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Prevent further leakage or spillage if safe to do so. Pick up and transfer to properly

labelled containers.

Precautions to prevent secondary

hazards

Clean contaminated objects and areas thoroughly observing environmental regulations.

SECTION 7: Handling and storage

Precautions for safe handling Handle in accordance with good industrial hygiene and safety practice. See Section 8 for

information on appropriate personal protective equipment.

Conditions for safe storage, including any incompatibilities

Store according to product and label instructions.

Incompatible materials Metals.

SECTION 8: Exposure controls/personal protection

Occupational exposure limits

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

Note See section 16 for terms and abbreviations

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Monitoring and observation processes

No applicable information was found.

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).

Skin and body protectionWear suitable protective clothing.

Hand protection Wear suitable gloves.

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.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Appearance aqueous solution
Colour colourless
Physical state Liquid

Odour Odourless

Odour threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

pH None known

Melting point / freezing point 0 °C

Boiling point / boiling range 100 °C

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 No data available

limits

Lower flammability or explosive No data available

limits

Vapour pressureNo data availableNone knownVapour densityNo data availableNone knownRelative densityNo data availableNone known

Water solubility Miscible in water Solubility(ies) No data available None known No data available None known Partition coefficient No data available None known **Autoignition temperature** No data available None known **Decomposition temperature** No data available None known Kinematic viscosity Dynamic viscosity No data available None known

Additional information

Explosive properties Not applicable
Oxidising properties Not applicable

SECTION 10: Stability and reactivity

<u>Stability</u> Stable under normal conditions.

Possibility of hazardous reactions
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.

Sensitivity to mechanical impact None. **Sensitivity to static discharge** None.

Conditions to avoid None known based on information supplied.

Incompatible materials Metals.

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

Acute toxicity

Numerical measures of toxicity

Skin corrosion/irritationBased 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 sensitisation 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 toxicityBased on available data, the classification criteria are not met.

Specific target organ toxicity —

single exposure

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

Specific target organ toxicity —

repeated exposure

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

Aspiration hazardBased on available data, the classification criteria are not met.

SECTION 12: Ecological information

Ecotoxicity

Unknown aquatic toxicity 0 % of the mixture consists of component(s) of unknown hazards to the aquatic

environment

Persistence and degradability No information available.

Bioaccumulative potential No information available.

Mobility in soil No information available.

SECTION 13: Disposal considerations

<u>Waste chemicals</u> 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.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

IMDG Not regulated

Transport in bulk according to No information available

Annex II of MARPOL and the IBC

Code

IATA Not regulated

<u>China</u> Not regulated

Special precautions for user

Please refer to the applicable dangerous goods regulations for additional information

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations

Law of the People's Republic of China on Prevention and Control of Occupational Diseases

Catalogue of occupational hazard factors:

Catalogue of occupational diseases:

Not applicable.

Not applicable.

Regulations on the Control over Safety of Hazardous Chemicals

Inventory of hazardous chemicals Not applicable.

GB 18218-2009 Identification of major hazard installations for dangerous chemicals

Not applicable

List of hazardous chemicals under priority management Not applicable

Regulations on Labour Protection in Workplaces Where Toxic Substances Are Used

Inventory of highly toxic goods

Not applicable

Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

List of toxic chemicals severely restricted for import and export in China Not applicable

Measures for the Environmental Management of New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances Contact supplier for inventory compliance status.

International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

SECTION 16: Other information

Prepared By Bio-Rad Laboratories, Environmental Health and Safety

Revision date 17-Aug-2021

Revision Note SDS sections updated. 1. 2.

Abbreviations and acronyms

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value * Skin designation

C Carcinogen

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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End of Safety Data Sheet



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: GB/T 16483-2008, GB/T 17519-2013

Product Name Variant II Hemoglobin A1c Elution Buffer A

Revision date 26-Aug-2021 **Revision Number** 1.1

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

Product identifier

Product Name Variant II Hemoglobin A1c Elution Buffer A

Catalogue Number(s) 2702110NU

Other means of identification

Pure substance/mixture Mixture

Details of the supplier of the safety data sheet

Corporate Headquarters

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

USA

Manufacturer

Bio-Rad Laboratories, Diagnostic Group

4000 Alfred Nobel Drive Hercules, California 94547

USA

Legal Entity / Contact Address

Bio-Rad Laboratories Ltd. 1st and 2nd Floor, Lumpini 1 Building 239/2, Rajdamri Road, Lumpini, Pathumwan, Bangkok 10330

Thailand

Technical Service +66 2 652 8313

ctsthailand@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Hong Kong: 800-968-793

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic

SECTION 2: Hazards identification

Emergency Overview

No significant adverse health effects

Appearance clear liquid Physical state Liquid Odour Odourless

Classification of the substance or mixture

Not classified

Label elements

Hazard statements

Not classified

Physical and chemical hazards

Not applicable.

Product Name Variant II Hemoglobin A1c Elution Buffer

Buffer Revision date 26-Aug-2021

F

Health hazards

Immediate Health Effects: Not applicable.

Chronic effects: Not applicable.

Environmental hazards

Not applicable

Other hazards which do not result in classification

Not applicable

SECTION 3: Composition/information on ingredients

Substance

Not applicable.

Mixture

Not classified.

SECTION 4: First aid measures

Description of necessary 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 doctor.

Skin contact Wash skin with soap and water.

Ingestion Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed

No information available.

For emergency responders No information available.

Note to doctors Treat symptomatically.

SECTION 5: Firefighting measures

Extinguishing media

surrounding environment.

Unsuitable extinguishing media No information available.

Specific hazards arising from the

chemical

No information available.

Special protective actions for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout

gear. Use personal protection equipment.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions See section 8 for more information.

For emergency responders

Use personal protection recommended in Section 8.

Environmental precautions See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Prevent further leakage or spillage if safe to do so. Pick up and transfer to properly

Revision date 26-Aug-2021

labelled containers.

Precautions to prevent secondary

hazards

Clean contaminated objects and areas thoroughly observing environmental regulations.

SECTION 7: Handling and storage

Precautions for safe handling Handle in accordance with good industrial hygiene and safety practice. See Section 8 for

information on appropriate personal protective equipment.

Conditions for safe storage, including any incompatibilities

Store according to product and label instructions.

Incompatible materials Metals.

SECTION 8: Exposure controls/personal protection

Occupational exposure limits

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

Note See section 16 for terms and abbreviations

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Monitoring and observation processes

No applicable information was found.

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).

Skin and body protection Wear suitable protective clothing.

Hand protection Wear suitable gloves.

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.

Α

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

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Appearance clear liquid
Colour colourless
Physical state Liquid
Odour Odourless

Odour threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

pH 5.8-6.2

Melting point / freezing point 0 °C

Boiling point / boiling range 100 °C

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 No data available

limits

Lower flammability or explosive No data available

limits

Vapour pressure None known No data available Vapour density No data available None known Relative density No data available None known Water solubility Miscible in water Solubility(ies) No data available None known Partition coefficient No data available None known Autoignition temperature No data available None known **Decomposition temperature** No data available None known Kinematic viscosity No data available None known No data available Dynamic viscosity None known

Additional information

Explosive properties Not applicable Oxidising properties Not applicable

SECTION 10: Stability and reactivity

Stability Stable under normal conditions.

<u>Possibility of hazardous reactions</u> 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.

Sensitivity to mechanical impact None. **Sensitivity to static discharge** None.

Conditions to avoidNone known based on information supplied.

Incompatible materials Metals.

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

Acute toxicity

Numerical measures of toxicity

Revision date 26-Aug-2021

Skin corrosion/irritationBased 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 sensitisation Based on available data, the classification criteria are not met.

Germ cell mutagenicityBased on available data, the classification criteria are not met.

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

Reproductive toxicityBased on available data, the classification criteria are not met.

Specific target organ toxicity —

single exposure

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

Specific target organ toxicity —

repeated exposure

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

Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

Ecotoxicity

Unknown aquatic toxicity 0 % of the mixture consists of component(s) of unknown hazards to the aquatic

environment

Persistence and degradability No information available.

Bioaccumulative potential No information available.

Mobility in soil No information available.

SECTION 13: Disposal considerations

Waste chemicals 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.

<u>Contaminated packaging</u> Do not reuse empty containers.

SECTION 14: Transport information

MDG Not regulated

Transport in bulk according to No information available

Annex II of MARPOL and the IBC

Code

IATA Not regulated

<u>China</u> Not regulated

Revision date 26-Aug-2021

Special precautions for user

Please refer to the applicable dangerous goods regulations for additional information

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations

Law of the People's Republic of China on Prevention and Control of Occupational Diseases

Catalogue of occupational hazard factors: Not applicable. Catalogue of occupational diseases: Not applicable.

Regulations on the Control over Safety of Hazardous Chemicals

Inventory of hazardous chemicals Not applicable.

GB 18218-2009 Identification of major hazard installations for dangerous chemicals Not applicable

List of hazardous chemicals under priority management Not applicable

Regulations on Labour Protection in Workplaces Where Toxic Substances Are Used

Not applicable Inventory of highly toxic goods

Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

List of toxic chemicals severely restricted for import and export in China Not applicable

Measures for the Environmental Management of New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances Contact supplier for inventory compliance status.

International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

SECTION 16: Other information

Prepared By Bio-Rad Laboratories, Environmental Health and Safety

Revision date 26-Aug-2021

Revision Note SDS sections updated. 1.

Abbreviations and acronyms

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA (time-weighted average) STEL STEL (Short Term Exposure Limit) TWA

Ceiling Maximum limit value Skin designation

Carcinogen С

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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End of Safety Data Sheet



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: GB/T 16483-2008, GB/T 17519-2013

Product Name Variant II Hemoglobin A1c Calibrator 2

Revision date 18-Aug-2021

Revision Number 2

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

Product identifier

Product Name Variant II Hemoglobin A1c Calibrator 2

Catalogue Number(s) 2702108NU

Other means of identification

Pure substance/mixture Mixture

Details of the supplier of the safety data sheet

Corporate Headquarters

Bio-Rad Laboratories Inc. 1000 Alfred Nobel Drive

Hercules, CA 94547

USA

Manufacturer

Bio-Rad Laboratories, Diagnostic Group

4000 Alfred Nobel Drive Hercules, California 94547

USA

Legal Entity / Contact Address

Bio-Rad Laboratories Ltd. 1st and 2nd Floor, Lumpini 1 Building

239/2, Rajdamri Road, Lumpini, Pathumwan, Bangkok 10330

Thailand

Technical Service +66 2 652 8313

ctsthailand@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Hong Kong: 800-968-793

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic

SECTION 2: Hazards identification

Emergency Overview

No significant adverse health effects

Appearance solid Physical state Solid Odour Odourless

Classification of the substance or mixture

Not classified

Label elements

Hazard statements

Not classified

Physical and chemical hazards

Not applicable.

Health hazards

Immediate Health Effects: Not applicable.

Chronic effects: Not applicable.

Environmental hazards

Not applicable

Other hazards which do not result in classification

Not applicable

SECTION 3: Composition/information on ingredients

Substance

Not applicable.

Mixture

Not classified.

SECTION 4: First aid measures

Description of necessary 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 doctor.

Skin contact Wash skin with soap and water.

Ingestion Call a doctor. Contains human source material and / or potentially infectious components.

Most important symptoms and effects, both acute and delayed

No information available.

For emergency responders No information available.

Note to doctors Contains human source material and / or potentially infectious components.

SECTION 5: Firefighting measures

Extinguishing media

surrounding environment.

Unsuitable extinguishing media No information available.

Specific hazards arising from the

chemical

No information available.

Special protective actions for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout

gear. Use personal protection equipment.

Product Name Variant II Hemoglobin A1c Calibrator 2

Revision date 18-Aug-2021

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

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

For emergency responders Use personal protection recommended in Section 8.

See Section 12 for additional Ecological Information. **Environmental precautions**

Methods and material for containment and cleaning up Do not allow into any sewer, on the ground or into any body of water. Clean contaminated

surface thoroughly. Use:. Disinfectant.

hazards

Precautions to prevent secondary Clean contaminated objects and areas thoroughly observing environmental regulations.

SECTION 7: Handling and storage

Precautions for safe handling Handle in accordance with good industrial hygiene and safety practice. Follow universal

and standard precautions for handling potentially infectious materials. See Section 8 for

information on appropriate personal protective equipment.

Conditions for safe storage, including any incompatibilities Store according to product and label instructions.

Incompatible materials None known based on information supplied.

SECTION 8: Exposure controls/personal protection

Occupational exposure limits

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

Note See section 16 for terms and abbreviations

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Monitoring and observation processes

No applicable information was found.

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).

Skin and body protection Wear suitable protective clothing.

Hand protection Wear suitable gloves.

No protective equipment is needed under normal use conditions. If exposure limits are Respiratory protection

exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations

Follow universal and standard precautions for handling potentially infectious materials.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Appearance solid
Colour Varies
Physical state Solid
Odour Odourless

Odour threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

рΗ 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 No data available

limits

Lower flammability or explosive No data available

limits

Vapour pressureNo data availableNone knownVapour densityNo data availableNone knownRelative densityNo data availableNone known

Water solubility Miscible in water Solubility(ies) No data available None known Partition coefficient No data available None known **Autoignition temperature** No data available None known **Decomposition temperature** No data available None known Kinematic viscosity No data available None known Dynamic viscosity No data available None known

Additional information

Explosive properties Not applicable Oxidising properties Not applicable

SECTION 10: Stability and reactivity

<u>Stability</u> Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Sensitivity to mechanical impact None. Sensitivity to static discharge None.

<u>Conditions to avoid</u> None known based on information supplied.

<u>Incompatible materials</u>

None known based on information supplied.

<u>Hazardous decomposition products</u> None known based on information supplied.

SECTION 11: Toxicological information

Acute toxicity

Numerical measures of toxicity

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

Component Information

Skin corrosion/irritationBased 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 sensitisation Based on available data, the classification criteria are not met.

Germ cell mutagenicityBased on available data, the classification criteria are not met.

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

Reproductive toxicityBased on available data, the classification criteria are not met.

Specific target organ toxicity —

single exposure

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

Specific target organ toxicity —

repeated exposure

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

Target organ effects Respiratory system. Eyes.

Aspiration hazardBased on available data, the classification criteria are not met.

SECTION 12: Ecological information

EcotoxicityThe environmental impact of this product has not been fully investigated.

Unknown aquatic toxicity 0 % of the mixture consists of component(s) of unknown hazards to the aquatic

environment

Persistence and degradability No information available.

<u>Bioaccumulative potential</u> No information available.

Mobility in soil No information available.

SECTION 13: Disposal considerations

<u>Waste chemicals</u> Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

<u>IMDG</u> Not regulated

Transport in bulk according to No information available

Annex II of MARPOL and the IBC

Code

IATA Not regulated

China Not regulated

Special precautions for user

Please refer to the applicable dangerous goods regulations for additional information

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations

Law of the People's Republic of China on Prevention and Control of Occupational Diseases

Catalogue of occupational hazard factors:

Catalogue of occupational diseases:

Not applicable.

Not applicable.

Regulations on the Control over Safety of Hazardous Chemicals

Inventory of hazardous chemicals

Not applicable.

GB 18218-2009 Identification of major hazard installations for dangerous chemicals

Not applicable

List of hazardous chemicals under priority management Not applicable

Regulations on Labour Protection in Workplaces Where Toxic Substances Are Used

Inventory of highly toxic goods

Not applicable

Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

List of toxic chemicals severely restricted for import and export in China Not applicable

Measures for the Environmental Management of New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances
Contact supplier for inventory compliance status.

International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

SECTION 16: Other information

Prepared By Bio-Rad Laboratories, Environmental Health and Safety

Revision date 18-Aug-2021

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

Abbreviations and acronyms

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value * Skin designation

C Carcinogen

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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End of Safety Data Sheet



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: GB/T 16483-2008, GB/T 17519-2013

Product Name Variant II Hemoglobin A1c Calibrator 1

Revision date 18-Aug-2021

Revision Number 2

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

Product identifier

Product Name Variant II Hemoglobin A1c Calibrator 1

Catalogue Number(s) 2702107NU

Other means of identification

Pure substance/mixture Mixture

Details of the supplier of the safety data sheet

Corporate Headquarters

Bio-Rad Laboratories Inc. 1000 Alfred Nobel Drive

Hercules, CA 94547

USA

Manufacturer

Bio-Rad Laboratories, Diagnostic Group

4000 Alfred Nobel Drive Hercules, California 94547

USA

Legal Entity / Contact Address

Bio-Rad Laboratories Ltd. 1st and 2nd Floor, Lumpini 1 Building

239/2, Rajdamri Road, Lumpini, Pathumwan, Bangkok 10330

Thailand

Technical Service +66 2 652 8313

ctsthailand@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Hong Kong: 800-968-793

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic

SECTION 2: Hazards identification

Emergency Overview

No significant adverse health effects

Appearance solid Physical state Solid Odour Odourless

Classification of the substance or mixture

Not classified

Label elements

Hazard statements

Not classified

Physical and chemical hazards

Not applicable.

Health hazards

Immediate Health Effects: Not applicable.

Chronic effects: Not applicable.

Environmental hazards

Not applicable

Other hazards which do not result in classification

Not applicable

SECTION 3: Composition/information on ingredients

Substance

Not applicable.

Mixture

Not classified.

SECTION 4: First aid measures

Description of necessary 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 doctor.

Skin contact Wash skin with soap and water.

Ingestion Call a doctor. Contains human source material and / or potentially infectious components.

Most important symptoms and effects, both acute and delayed

No information available.

For emergency responders No information available.

Note to doctors Contains human source material and / or potentially infectious components.

SECTION 5: Firefighting measures

Extinguishing media

surrounding environment.

Unsuitable extinguishing media No information available.

Specific hazards arising from the

chemical

No information available.

Special protective actions for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout

gear. Use personal protection equipment.

Product Name Variant II Hemoglobin A1c Calibrator 1

Revision date 18-Aug-2021

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

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

For emergency responders Use personal protection recommended in Section 8.

See Section 12 for additional Ecological Information. **Environmental precautions**

Methods and material for containment and cleaning up Do not allow into any sewer, on the ground or into any body of water. Clean contaminated

surface thoroughly. Use:. Disinfectant.

hazards

Precautions to prevent secondary Clean contaminated objects and areas thoroughly observing environmental regulations.

SECTION 7: Handling and storage

Precautions for safe handling Handle in accordance with good industrial hygiene and safety practice. Follow universal

and standard precautions for handling potentially infectious materials. See Section 8 for

information on appropriate personal protective equipment.

Conditions for safe storage, including any incompatibilities Store according to product and label instructions.

Incompatible materials None known based on information supplied.

SECTION 8: Exposure controls/personal protection

Occupational exposure limits

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

Note See section 16 for terms and abbreviations

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Monitoring and observation processes

No applicable information was found.

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).

Skin and body protection Wear suitable protective clothing.

Hand protection Wear suitable gloves.

No protective equipment is needed under normal use conditions. If exposure limits are Respiratory protection

exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations

Follow universal and standard precautions for handling potentially infectious materials.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Appearance solid
Colour Varies
Physical state Solid
Odour Odourless

Odour threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

рΗ 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 No data available

limits

Lower flammability or explosive No data available

limits

Vapour pressureNo data availableNone knownVapour densityNo data availableNone knownRelative densityNo data availableNone known

Water solubility Soluble in water Solubility(ies) No data available None known Partition coefficient No data available None known **Autoignition temperature** No data available None known **Decomposition temperature** No data available None known Kinematic viscosity No data available None known Dynamic viscosity No data available None known

Additional information

Explosive properties Not applicable Oxidising properties Not applicable

SECTION 10: Stability and reactivity

<u>Stability</u> Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Sensitivity to mechanical impact None. Sensitivity to static discharge None.

<u>Conditions to avoid</u> None known based on information supplied.

<u>Incompatible materials</u>

None known based on information supplied.

<u>Hazardous decomposition products</u> None known based on information supplied.

SECTION 11: Toxicological information

Acute toxicity

Numerical measures of toxicity

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

Component Information

Skin corrosion/irritationBased 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 sensitisation Based on available data, the classification criteria are not met.

Germ cell mutagenicityBased on available data, the classification criteria are not met.

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

Reproductive toxicityBased on available data, the classification criteria are not met.

Specific target organ toxicity —

single exposure

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

Specific target organ toxicity —

repeated exposure

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

Target organ effects Respiratory system. Eyes.

Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

EcotoxicityThe environmental impact of this product has not been fully investigated.

Unknown aquatic toxicity 0 % of the mixture consists of component(s) of unknown hazards to the aquatic

environment

Persistence and degradability No information available.

<u>Bioaccumulative potential</u> No information available.

Mobility in soil No information available.

SECTION 13: Disposal considerations

<u>Waste chemicals</u> Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

<u>Contaminated packaging</u> Do not reuse empty containers.

SECTION 14: Transport information

<u>IMDG</u> Not regulated

Transport in bulk according to No information available

Annex II of MARPOL and the IBC

Code

IATA Not regulated

China Not regulated

Special precautions for user

Please refer to the applicable dangerous goods regulations for additional information

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations

Law of the People's Republic of China on Prevention and Control of Occupational Diseases

Catalogue of occupational hazard factors:

Catalogue of occupational diseases:

Not applicable.

Not applicable.

Regulations on the Control over Safety of Hazardous Chemicals

Inventory of hazardous chemicals

Not applicable.

GB 18218-2009 Identification of major hazard installations for dangerous chemicals Not applicable

List of hazardous chemicals under priority management Not applicable

Regulations on Labour Protection in Workplaces Where Toxic Substances Are Used

Inventory of highly toxic goods Not applicable

Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

List of toxic chemicals severely restricted for import and export in China Not applicable

Measures for the Environmental Management of New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances
Contact supplier for inventory compliance status.

International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

SECTION 16: Other information

Prepared By Bio-Rad Laboratories, Environmental Health and Safety

Revision date 18-Aug-2021

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

Abbreviations and acronyms

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value * Skin designation

C Carcinogen

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

Disclaimer

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End of Safety Data Sheet



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: GB/T 16483-2008, GB/T 17519-2013

Product Name Variant II Hb A1c Analytical Cartridge

Revision date 12-Aug-2021 **Revision Number** 1.1

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

Product identifier

Product Name Variant II Hb A1c Analytical Cartridge

Catalogue Number(s) 2702113NU

Other means of identification

Pure substance/mixture Mixture

Details of the supplier of the safety data sheet

Corporate Headquarters

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

USA

Manufacturer

Bio-Rad Laboratories, Diagnostic Group

4000 Alfred Nobel Drive Hercules, California 94547

USA

Legal Entity / Contact Address

Bio-Rad Laboratories Ltd. 1st and 2nd Floor, Lumpini 1 Building 239/2, Rajdamri Road, Lumpini,

Pathumwan, Bangkok 10330 Thailand

Technical Service +66 2 652 8313

ctsthailand@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Hong Kong: 800-968-793

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic

SECTION 2: Hazards identification

Emergency Overview

No significant adverse health effects

Appearance granules Physical state Solid Odour Slight

Classification of the substance or mixture

Not classified

Label elements

Hazard statements

Not classified

Physical and chemical hazards

Not applicable.

Health hazards

Immediate Health Effects: Not applicable.

Chronic effects: Not applicable.

Environmental hazards

Not applicable

Other hazards which do not result in classification

Not applicable

SECTION 3: Composition/information on ingredients

Substance

Not applicable.

Mixture

Not classified.

SECTION 4: First aid measures

Description of necessary 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 doctor.

Skin contact Wash skin with soap and water.

Ingestion Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed

No information available.

<u>For emergency responders</u> No information available.

Note to doctors Treat symptomatically.

SECTION 5: Firefighting measures

Extinguishing media

surrounding environment.

Unsuitable extinguishing media No information available.

Specific hazards arising from the

chemical

No information available.

Special protective actions for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout

gear. Use personal protection equipment.

Product Name Variant II Hb A1c Analytical Cartridge

Revision date 12-Aug-2021

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

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

For emergency responders Use personal protection recommended in Section 8.

See Section 12 for additional Ecological Information. **Environmental precautions**

Methods and material for containment and cleaning up Prevent further leakage or spillage if safe to do so. Pick up and transfer to properly

labelled containers.

hazards

Precautions to prevent secondary Clean contaminated objects and areas thoroughly observing environmental regulations.

SECTION 7: Handling and storage

Precautions for safe handling Handle in accordance with good industrial hygiene and safety practice. See Section 8 for

information on appropriate personal protective equipment.

Conditions for safe storage, including any incompatibilities Store according to product and label instructions.

Incompatible materials None known based on information supplied.

SECTION 8: Exposure controls/personal protection

Occupational exposure limits

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

See section 16 for terms and abbreviations Note

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Monitoring and observation processes

No applicable information was found.

Showers Engineering controls

Eyewash stations Ventilation systems.

Individual protection measures, such as personal protective equipment

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

Skin and body protection Wear suitable protective clothing.

Hand protection Wear suitable gloves.

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.

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

Revision date 12-Aug-2021

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Appearance granules
Colour white
Physical state Solid
Odour Slight

Odour threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

рΗ None known Melting point / freezing point No data available Not applicable 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 No data available

limits

Lower flammability or explosive No data available

limits

Vapour pressureNo data availableNone knownVapour densityNo data availableNone knownRelative densityNo data availableNone knownWater solubilityInsoluble in waterSolubility(ies)No data availableNone knownNo tata availableNone known

Partition coefficient
No data available
None known
Autoignition temperature
No data available
None known
Decomposition temperature
No data available
None known
Kinematic viscosity
No data available
None known

Additional information

Explosive propertiesOxidising properties
Not applicable
Not applicable

SECTION 10: Stability and reactivity

Stability Stable under normal conditions.

<u>Possibility of hazardous reactions</u> None under normal processing.

Sensitivity to mechanical impact None. **Sensitivity to static discharge** None.

Conditions to avoidNone known based on information supplied.

<u>Incompatible materials</u> None known based on information supplied.

<u>Hazardous decomposition products</u> None known based on information supplied.

SECTION 11: Toxicological information

Acute toxicity

Numerical measures of toxicity

Skin corrosion/irritationBased 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 sensitisation 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.

Specific target organ toxicity —

single exposure

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

Specific target organ toxicity —

repeated exposure

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

Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

EcotoxicityThe environmental impact of this product has not been fully investigated.

Unknown aquatic toxicity 0 % of the mixture consists of component(s) of unknown hazards to the aquatic

environment

Persistence and degradability No information available.

Bioaccumulative potential No information available.

Mobility in soil No information available.

SECTION 13: Disposal considerations

<u>Waste chemicals</u> Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

IMDG Not regulated

Transport in bulk according to No information available

Annex II of MARPOL and the IBC

Code

IATA Not regulatedChina Not regulated

Special precautions for user

Please refer to the applicable dangerous goods regulations for additional information

SECTION 15: Regulatory information

Revision date 12-Aug-2021

Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations

Law of the People's Republic of China on Prevention and Control of Occupational Diseases

Catalogue of occupational hazard factors: Not applicable. Catalogue of occupational diseases: Not applicable.

Regulations on the Control over Safety of Hazardous Chemicals

Inventory of hazardous chemicals Not applicable.

GB 18218-2009 Identification of major hazard installations for dangerous chemicals Not applicable

List of hazardous chemicals under priority management Not applicable

Regulations on Labour Protection in Workplaces Where Toxic Substances Are Used

Inventory of highly toxic goods Not applicable

Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

List of toxic chemicals severely restricted for import and export in China Not applicable

Measures for the Environmental Management of New Chemical Substances

IECSC - China Inventory of Existing Chemical SubstancesContact supplier for inventory compliance status.

International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

SECTION 16: Other information

Prepared By Bio-Rad Laboratories. Environmental Health and Safety

12-Aug-2021 **Revision date**

Revision Note Significant changes throughout SDS. Review all sections.

Abbreviations and acronyms

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA (time-weighted average) STEL (Short Term Exposure Limit) TWA STEL

Ceiling Maximum limit value Skin designation

С Carcinogen

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)

Revision date 12-Aug-2021

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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End of Safety Data Sheet



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: GB/T 16483-2008, GB/T 17519-2013

Product Name Variant II Hemoglobin A1c Elution Buffer B

Revision date 27-Aug-2021 Revision Number 2.1

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

Product identifier

Product Name Variant II Hemoglobin A1c Elution Buffer B

Catalogue Number(s) 2702111NU

Other means of identification

Pure substance/mixture Mixture

Details of the supplier of the safety data sheet

Corporate Headquarters
Bio-Rad Laboratories Inc.

1000 Alfred Nobel Drive Hercules, CA 94547

USA

Manufacturer

Bio-Rad Laboratories, Diagnostic Group

4000 Alfred Nobel Drive Hercules, California 94547

USA

Legal Entity / Contact Address

Pathumwan, Bangkok 10330

Bio-Rad Laboratories Ltd. 1st and 2nd Floor, Lumpini 1 Building 239/2, Rajdamri Road, Lumpini,

Thailand

Technical Service +66 2 652 8313

ctsthailand@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Hong Kong: 800-968-793

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic

SECTION 2: Hazards identification

Emergency Overview

No significant adverse health effects

Appearance aqueous solution Physical state Liquid Odour Odourless

Classification of the substance or mixture

Not classified

Label elements

Hazard statements

Not classified

Review Date 27-Aug-2021

Buffer E

Revision date 27-Aug-2021

Physical and chemical hazards

Not applicable.

Health hazards

Immediate Health Effects: Not applicable.

Chronic effects: Not applicable.

Environmental hazards

Not applicable

Other hazards which do not result in classification

Contains animal source material (Cattle)

SECTION 3: Composition/information on ingredients

Substance

Not applicable.

Mixture

Not classified.

SECTION 4: First aid measures

Description of necessary 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 doctor.

Skin contact Wash skin with soap and water.

Ingestion Call a doctor. Contains human source material and / or potentially infectious components.

Most important symptoms and effects, both acute and delayed

No information available.

For emergency responders No information available.

Note to doctors Contains human source material and / or potentially infectious components.

SECTION 5: Firefighting measures

Extinguishing media

surrounding environment.

Unsuitable extinguishing media No information available.

Specific hazards arising from the

No information available.

chemical

Buffer B

Special protective actions for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout

Revision date 27-Aug-2021

gear. Use personal protection equipment.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions See section 8 for more information.

For emergency responders

Use personal protection recommended in Section 8.

Environmental precautions See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Do not allow into any sewer, on the ground or into any body of water. Clean contaminated

surface thoroughly. Use:. Disinfectant.

Precautions to prevent secondary

hazards

Clean contaminated objects and areas thoroughly observing environmental regulations.

SECTION 7: Handling and storage

Precautions for safe handling Handle in accordance with good industrial hygiene and safety practice. Follow universal

and standard precautions for handling potentially infectious materials. See Section 8 for

information on appropriate personal protective equipment.

Conditions for safe storage, including any incompatibilities

Store according to product and label instructions.

Incompatible materials Metals.

SECTION 8: Exposure controls/personal protection

Occupational exposure limits

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

Note See section 16 for terms and abbreviations

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Monitoring and observation processes

No applicable information was found.

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).

Skin and body protectionWear suitable protective clothing.

Buffer E

Hand protection Wear suitable gloves.

exceeded or irritation is experienced, ventilation and evacuation may be required.

Revision date 27-Aug-2021

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

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties
Appearance aqueous solution

Colour yellow
Physical state Liquid
Odour Odourless

Odour threshold No information available

Property Values Remarks • Method

oH =

Melting point / freezing point = $0 \, ^{\circ}$ C

Boiling point / boiling range= 100 °CFlash pointNo data availableNone knownEvaporation rateNo data availableNone knownFlammability (solid, gas)No data availableNone known

Flammability Limit in Air

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Vapour pressureNo data availableNone knownVapour densityNo data availableNone knownRelative densityNo data availableNone known

Miscible in water Water solubility Solubility(ies) No data available None known None known **Partition coefficient** No data available None known No data available **Autoignition temperature** None known **Decomposition temperature** No data available No data available None known Kinematic viscosity Dynamic viscosity No data available None known

Additional information

Explosive propertiesNot applicable
Not applicable

SECTION 10: Stability and reactivity

<u>Stability</u> Stable under normal conditions.

Possibility of hazardous reactions
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

None known

toxic gases.

Sensitivity to mechanical impact None. Sensitivity to static discharge None.

<u>Conditions to avoid</u> None known based on information supplied.

Incompatible materials Metals.

<u>Hazardous decomposition products</u> None known based on information supplied.

SECTION 11: Toxicological information

Buffer B

Revision date 27-Aug-2021

Acute toxicity

Numerical measures of toxicity

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

ATEmix (oral) 26,930.70 mg/kg ATEmix (dermal) 41,337.30 mg/kg

Skin corrosion/irritationBased 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 sensitisation 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.

Specific target organ toxicity —

single exposure

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

Specific target organ toxicity —

repeated exposure

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

Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

Ecotoxicity

Unknown aquatic toxicity 0 % of the mixture consists of component(s) of unknown hazards to the aquatic

environment

Persistence and degradability No information available.

Bioaccumulative potential No information available.

Mobility in soil No information available.

SECTION 13: Disposal considerations

Waste chemicals 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.

<u>Contaminated packaging</u> Do not reuse empty containers.

SECTION 14: Transport information

IMDG Not regulated

Buffer B

Revision date 27-Aug-2021

Transport in bulk according to No information available Annex II of MARPOL and the IBC

Code

IATA Not regulated

China Not regulated

Special precautions for user

Please refer to the applicable dangerous goods regulations for additional information

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations

Law of the People's Republic of China on Prevention and Control of Occupational Diseases

Catalogue of occupational hazard factors:

Catalogue of occupational diseases:

Not applicable.

Not applicable.

Regulations on the Control over Safety of Hazardous Chemicals

Inventory of hazardous chemicals

Not applicable.

GB 18218-2009 Identification of major hazard installations for dangerous chemicals Not applicable

List of hazardous chemicals under priority management Not applicable

Regulations on Labour Protection in Workplaces Where Toxic Substances Are Used

Inventory of highly toxic goods Not applicable

Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

List of toxic chemicals severely restricted for import and export in China Not applicable

Measures for the Environmental Management of New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances Contact supplier for inventory compliance status.

International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

SECTION 16: Other information

Prepared By Bio-Rad Laboratories, Environmental Health and Safety

Revision date 27-Aug-2021

Revision Note Significant changes throughout SDS. Review all sections.

Abbreviations and acronyms

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value * Skin designation

C Carcinogen

Revision date 27-Aug-2021

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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End of Safety Data Sheet