

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

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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

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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.

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

SECTION 5: Firefighting measures

Extinguishing media

surrounding environment.

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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.

Use personal protection recommended in Section 8. For emergency responders

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 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.

Engineering controls Revision date 18-Aug-2021 **Showers**

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Product Name

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.

None known

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

Property Values Remarks • Method

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

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

No data available Vapour pressure Vapour density No data available Relative density No data available

Water solubility

Soluble in water No data available Solubility(ies) No data available Partition coefficient No data available Autoignition temperature No data available **Decomposition temperature** Kinematic viscosity No data available **Dynamic viscosity** No data available

Additional information

Explosive properties Not applicable Oxidising properties Not applicable

SECTION 10: Stability and reactivity

Stable under normal conditions. Stability

None under normal processing. Possibility of hazardous reactions

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

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

Incompatible materialsNone known based on information supplied.

Hazardous decomposition products 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 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.

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.

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Mobility in soil No information available.

SECTION 13: Disposal considerations

Waste chemicals 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

<u>IATA</u> 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

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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

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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

Australian 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)

Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme

Organisation 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

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