SAFETY DATA SHEET



Revision date 12-Aug-2021 Revision Number 1.1

1. Identification

Product identifier

Product Name Variant II Hb A1c Analytical Cartridge

Other means of identification

Catalog Number(s) 2702113NU

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic

Details of the supplier of the safety data sheet

Corporate Headquarters Man

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

USA

<u>Manufacturer Address</u> Bio-Rad Laboratories, Diagnostic Group

4000 Alfred Nobel Drive Hercules, California 94547

USA

Legal Entity / Contact Address

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

USA

Technical Service 1-800-224-6723

TechSupport.USSD@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone

Number

CHEMTREC USA: 1 (800) 424-9300

2. Hazard(s) identification

Classification

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

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Hazard statements

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

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

Appearance granules Physical state Solid Odor Slight

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Other information

3. Composition/information on ingredients

Substance

Not applicable.

Mixture

4. First-aid measures

Description of first aid measures

General advice No hazards which require special first aid measures.

Inhalation Remove to fresh air.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a physician.

Skin contact Wash skin with soap and water.

Ingestion Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed

Symptoms No information available.

Indication of any immediate medical attention and special treatment needed

5. Fire-fighting measures

surrounding environment.

Unsuitable extinguishing media No information available.

Specific hazards arising from the

chemical

None known.

Explosion data

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

Special protective equipment for

fire-fighters

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

gear. Use personal protection equipment.

6. Accidental release measures

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

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Personal precautions, protective equipment and emergency procedures

Personal precautions See section 8 for more information.

Methods and material for containment and cleaning up

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

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

7. Handling and storage

Precautions for safe handling

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

Conditions for safe storage, including any incompatibilities

Storage Conditions Store according to product and label instructions.

8. Exposure controls/personal protection

Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational

exposure limits established by the region specific regulatory bodies.

Appropriate engineering controls

Engineering controls Showers

> Eyewash stations Ventilation systems.

Individual protection measures, such as personal protective equipment

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

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective clothing.

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

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

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

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid **Appearance** granules Color white Odor Sliaht

Odor threshold No information available

Property Values Remarks • Method

None known Melting point / freezing point No data available Not applicable No data available None known Boiling point / boiling range

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Flash pointNo data availableNone knownEvaporation rateNo data availableNone knownFlammability (solid, gas)No data availableNone knownFlammability Limit in AirNone known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Vapor pressureNo data availableNone knownVapor densityNo data availableNone knownRelative densityNo data availableNone known

Water solubility Insoluble in water

Solubility in other solventsNo data availableNone knownPartition coefficientNo data availableNone knownAutoignition temperatureNo data availableNone knownDecomposition temperatureNo data availableNone known

Kinematic viscosityNo data availableNone knownDynamic viscosityNo data availableNone known

Other information

Explosive properties
Oxidizing properties
Not applicable
Not applicable
Not applicable
Not applicable
VOC Content (%)
Not applicable

10. Stability and reactivity

Reactivity No information available.

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid None known based on information supplied.

Incompatible materials None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available.

Eve contact Specific test data for the substance or mixture is not available.

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

Ingestion Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Acute toxicity

Numerical measures of toxicity

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

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

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

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

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

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

STOT - repeated exposureBased on available data, the classification criteria are not met.

Aspiration hazard No information available.

Other adverse effects No information available.

Interactive effects No information available.

12. Ecological information

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

Persistence and degradability No information available.

Bioaccumulation There is no data for this product.

Other adverse effects No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused

products

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

environmental legislation.

Contaminated packaging Do not reuse empty containers.

14. Transport information

DOT Not regulated

TDG Not regulated

MEX Not regulated

IATA Not regulated

IMDG Not regulated

15. Regulatory information

International Inventories

Contact supplier for inventory compliance status

US Federal Regulations

SARA 313

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

SARA 311/312 Hazard Categories

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

CWA (Clean Water Act)

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

CERCLA

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

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

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

US State Regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPAHealth hazards0Flammability0Instability0Special hazards-HMISHealth hazards0Flammability0Physical hazards0Personal protectionX

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

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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

Ceiling Maximum limit value * Skin designation

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

Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA) EPA (Environmental Protection Agency) Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

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

Organization for Economic Co-operation and Development Screening Information Data Set

RTECS (Registry of Toxic Effects of Chemical Substances)

World Health Organization

Prepared By Bio-Rad Laboratories, Environmental Health and Safety

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Revision Note Significant changes throughout SDS. Review all sections.

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