

SAFETY DATA SHEET



Revision date 18-Aug-2021

Revision Number 2

1. Identification

Product identifier

Product Name Variant II Hemoglobin A1c Calibrator 2

Other means of identification

Catalog Number(s) 2702108NU

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic

Details of the supplier of the safety data sheet

Corporate Headquarters

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

Manufacturer Address

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

Legal Entity / Contact Address

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

Technical Service

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

Emergency telephone number

24 Hour Emergency Phone Number

CHEMTREC USA: 1 (800) 424-9300

2. Hazard(s) identification

Classification

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

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Hazard statements

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

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

Appearance solid

Physical state Solid

Odor Odorless

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

Not applicable.

Mixture

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

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

4. First-aid measuresDescription of first aid measures

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

Most important symptoms and effects, both acute and delayed

| | |
|----------|---------------------------|
| Symptoms | No information available. |
|----------|---------------------------|

Indication of any immediate medical attention and special treatment needed

| | |
|--------------------|--|
| Note to physicians | Contains human source material and / or potentially infectious components. |
|--------------------|--|

5. Fire-fighting measures

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

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions See section 8 for more information.

Methods and material for containment and cleaning up

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

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

7. Handling and storage

Precautions for safe handling

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

Conditions for safe storage, including any incompatibilities

Storage Conditions Store according to product and label instructions.

8. Exposure controls/personal protection

Control parameters

Exposure Limits

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

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

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

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective clothing.

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

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

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid

| | |
|----------------|--------------------------|
| Appearance | solid |
| Color | Varies |
| Odor | Odorless |
| Odor threshold | No information available |

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

10. Stability and reactivity

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

11. Toxicological information

Information on likely routes of exposure

Product Information

| | |
|-------------|---|
| Inhalation | Specific test data for the substance or mixture is not available. |
| Eye contact | Specific test data for the substance or mixture is not available. |

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

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

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Acute toxicity

Numerical measures of toxicity

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

Component Information

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

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

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

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

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

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

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

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

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

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

Target organ effects Respiratory system, Eyes.

Aspiration hazard No information available.

Other adverse effects No information available.

Interactive effects No information available.

12. Ecological information

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

Persistence and degradability No information available.

Bioaccumulation There is no data for this product.

Other adverse effects No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused products

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

Contaminated packaging

Do not reuse empty containers.

14. Transport information

DOT

Not 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 contains the following Proposition 65 chemicals:

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

U.S. State Right-to-Know Regulations

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

US State Regulations

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

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

| | | | | |
|-------------|-------------------------|-----------------------|---------------------------|------------------------------|
| NFPA | Health hazards 0 | Flammability 0 | Instability 0 | Special hazards - |
| HMIS | Health hazards 0 | Flammability 0 | Physical hazards 0 | Personal protection X |

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

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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

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

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

Prepared By Bio-Rad Laboratories, Environmental Health and Safety

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

Disclaimer

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

End of Safety Data Sheet