

Safety Data Sheet
acc. to OSHA HCS

Printing date 10/26/2018

Reviewed on 10/25/2018

1 Identification

- **Product identifier**
- **Trade name:** Variant II Dual HbA1c Calibrator Level 2
- **Catalog or product number:** 2702513
- **Application of the substance / the mixture** *In-vitro laboratory reagent or component*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
*Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
Hercules, California 94547* 1(510)724-7000
- **Information department:** *TechsupportUSSD@bio-rad.com*
- **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

2 Hazard(s) identification

- **Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** *not applicable*
- **Information concerning particular hazards for human and environment:**
The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system:**
The classification was made according to the latest editions of the EU-lists, and expanded upon from company and literature data.
The classification was made according to OSHA 29CFR 1910.1200 and 1910.1030, and is expanded upon from company and/or literature information.

- **Label elements**
- **Labelling according to EU guidelines:**
Observe the general safety regulations when handling chemicals
The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (GefStoffV).
- **Classification system**
- **Special Hazards** *Contains human sourced and/or potentially infectious components.*
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

3 Composition/information on ingredients

- **Chemical characterization: Substances**
- **Additional information:** *Contains human sourced and/or potentially infectious components.*
- **Chemical characterization: Mixtures**
- **Description:** *Mixture of the substances listed below with non-hazardous additions.*

Listing of dangerous and non-hazardous components:

57-50-1	sucrose, pure	50-100%
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· **Additional information**

Contains human sourced and/or potentially infectious components.
For the wording of the listed risk phrases refer to section 15.

4 First-aid measures

· **Description of first aid measures**

· **General information** No special measures required.

· **After inhalation** Supply fresh air; consult doctor in case of complaints.

· **After skin contact** Generally the product does not irritate the skin.

· **After eye contact** Rinse opened eye for several minutes under running water.

· **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.

· **Information for doctor**

· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**

· **Suitable extinguishing agents** Use fire fighting measures that suit the environment.

· **Special hazards arising from the substance or mixture** No further relevant information available.

· **Advice for firefighters**

· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.

· **Environmental precautions:** No special measures required.

· **Methods and material for containment and cleaning up:** Pick up mechanically.

· **Reference to other sections**

No dangerous substances are released.

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

· **Handling**

· **Precautions for safe handling** No special measures required.

· **Information about protection against explosions and fires:** No special measures required.

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

· **Storage**

· **Requirements to be met by storerooms and receptacles:** According to product specification

· **Information about storage in one common storage facility:** Not required.

· **Further information about storage conditions:** None.

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· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

57-50-1 sucrose, pure

PEL (United States) Long-term value: 15* 5** mg/m³
*total dust **respirable fraction

REL (United States) Long-term value: 10* 5** mg/m³
*total dust **respirable fraction

TLV (United States) Long-term value: 10 mg/m³

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**

· **Personal protective equipment**

· **General protective and hygienic measures**

Follow the usual biosafety practices for handling potentially infectious materials.

· **Protection of hands:**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Protective gloves.

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Synthetic gloves

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:**

Synthetic gloves

· **For the permanent contact gloves made of the following materials are suitable:** Synthetic gloves

· **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**

Synthetic gloves

· **As protection from splashes gloves made of the following materials are suitable:** Synthetic gloves

· **Eye protection:** Safety glasses

9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

Form: Granulate

Color: White

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· Odor:	Odorless
· Odor threshold:	Not determined.
· pH-value:	Not applicable.
· Change in condition	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	undetermined
· Flash point:	Not applicable Not determined.
· Flammability (solid, gaseous)	Not determined. Not applicable.
· Decomposition temperature:	Not determined.
· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard. Not determined.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not applicable.
· Density at 20 °C:	0.94 g/cm ³
· Relative density	Not determined.
· Vapor density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with Water:	Insoluble
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
dynamic:	Not applicable.
kinematic:	Not applicable.
· Solvent content:	
Water:	0.0 %
Solids content:	99.7 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.

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· **Hazardous decomposition products:** No dangerous decomposition products known

11 Toxicological information

· **Information on toxicological effects**

· **Acute toxicity:**

· **Primary irritant effect:**

· **on the skin:** No irritant effect.

· **on the eye:** No irritant effect.

· **Sensitization:** No sensitizing effects known.

· **Additional toxicological information:**

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

· **Target organs:** Not applicable.

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:** No further relevant information available.

· **Persistence and degradability** No further relevant information available.

· **Behavior in environmental systems:**

· **Bioaccumulative potential** No further relevant information available.

· **Mobility in soil** No further relevant information available.

· **Additional ecological information:**

· **General notes:** Generally not hazardous for water.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**

· **Recommendation**

Can be disposed of with household garbage with prior chemical-physical or biological treatment following consultation with the waste disposal facility operator and the pertinent authorities and adhering to the necessary technical regulations.

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

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Dispose of waste in accordance to applicable national, regional, or local regulations.

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· **UN-Number**

· DOT, ADR, ADN, IMDG, IATA Void

· **UN proper shipping name**

· DOT, ADR, ADN, IMDG, IATA Void

· **Transport hazard class(es)**

· DOT, ADR, ADN, IMDG, IATA

· Class Void

· **Packing group**

· DOT, ADR, IMDG, IATA Void

· **Environmental hazards:**

· **Marine pollutant:** No

· **Special precautions for user**

Not applicable.

· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Not applicable.

· **Transport/Additional information:**

Not dangerous according to the above specifications.

15 Regulatory information

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

· **SARA (Superfund Amendments and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**

None of the ingredients is listed.

· **Section 313 (40CFR372.65):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

57-50-1 sucrose, pure

7732-18-5 water

· **California Proposition 65:**

None of the ingredients is listed.

· **Chemicals known to cause cancer:**

The product does not contain listed components.

· **Developmental Toxicity**

32986-56-4 tobramycin

* 0.0600%

1405-41-0 Gentamicin Sulfate

* 0.0500%

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· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

57-50-1 sucrose, pure

A4

· **National regulations**

· **Water hazard class:** Generally not hazardous for water.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.

· **Contact:**

Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000

· *** Data compared to the previous version altered.**