

**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 1
- **Catalog or product number:** 2702512
- **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.*

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- **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: 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.*

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

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**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/m <sup>3</sup> *total dust **respirable fraction
REL (United States)	Long-term value: 10* 5** mg/m <sup>3</sup> *total dust **respirable fraction
TLV (United States)	Long-term value: 10 mg/m <sup>3</sup>

- **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:** Protective gloves.
- **Material of gloves** 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.
- **Eye protection:** Safety glasses

**9 Physical and chemical properties**

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

· **General Information**

· **Appearance:**

<b>Form:</b>	Granulate
<b>Color:</b>	White
<b>Odor:</b>	Odorless
<b>Odor threshold:</b>	Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

<b>Melting point/Melting range:</b>	undetermined
<b>Boiling point/Boiling range:</b>	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.

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· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapor pressure:</b>	Not applicable.
· <b>Density at 20 °C:</b>	0.94 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapor density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with Water:</b>	Insoluble
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>dynamic:</b>	Not applicable.
<b>kinematic:</b>	Not applicable.
· <b>Solvent content:</b>	
<b>Water:</b>	0.0 %
<b>Solids content:</b>	99.7 %
· <b>Other information</b>	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.
- **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.

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**· 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**

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

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- **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%
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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
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· **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.

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· **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.**

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