

# Safety Data Sheet

acc. to OSHA HCS

Printing date 06/03/2015

Reviewed on 05/28/2015

## 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:**  
Technical services, customer support  
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 Composition/information on ingredients

- **Chemical characterization: Substances**
- **CAS No. Description:**  
57-50-1 sucrose, pure
- **Identification number(s):**
- **EC number:** 200-334-9
- **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:** *Void*
- **Additional information** *For the wording of the listed risk phrases refer to section 15.*

## 3 Hazard(s) identification

- **Classification of the substance or mixture**  
*The product is not classified according to the Globally Harmonized System (GHS).*
- **Label elements**
- **GHS label elements** *Void*
- **Hazard pictograms** *Void*
- **Signal word** *Void*
- **Hazard statements** *Void*

## 4 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.*

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

**5 Fire-fighting measures**

- **Suitable extinguishing agents**  
CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **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.
- **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.

**8 Exposure controls/personal protection**

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

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

**57-50-1 sucrose, pure**

PEL (United States)	15* 5** mg/m <sup>3</sup> *total dust **respirable fraction
REL (United States)	10* 5** mg/m <sup>3</sup> *total dust **respirable fraction
TLV (United States)	10 mg/m <sup>3</sup>

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

· **Personal protective equipment**

· **General protective and hygienic measures**

Follow the usual biosafety practices for handling potentially infectious materials.

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**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

**Body protection:** Protective work clothing.

**9 Physical and chemical properties**

**General Information**

**Appearance:**

**Form:** Granulate

**Color:** White

**Odor:** Odorless

**Odour threshold:** Not determined.

**pH-value:** Not applicable.

**Change in condition**

**Melting point/Melting range:** undetermined

**Boiling point/Boiling range:** undetermined

**Flash point:** Not applicable

**Flammability (solid, gaseous)** Not determined.

**Ignition temperature:**

**Decomposition temperature:** Not determined.

**Auto igniting:** Product is not selfigniting.

**Danger of explosion:** Product does not present an explosion hazard.

**Explosion limits:**

**Lower:** Not determined.

**Upper:** Not determined.

**Vapor pressure:** Not applicable.

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- **Density at 20 °C:** 0.94 g/cm<sup>3</sup>
- **Relative density** Not determined.
- **Vapour density** Not applicable.
- **Evaporation rate** Not applicable.
- **Solubility in / Miscibility with Water:** Fully miscible
- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
  - dynamic:** Not applicable.
  - kinematic:** Not applicable.
- **Solvent content:**
  - Organic solvents:** 0.0 %
  - Other information** No further relevant information available.

**10 Stability and reactivity**

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known

**11 Toxicological information**

- **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.

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**12 Ecological information**

- **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.

**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.  
Hand over to hazardous waste disposers.  
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**

- |  |  |
|--|--|
| · <b>UN-Number</b>   |  |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>   | Void   |
| · <b>UN proper shipping name</b>   |  |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>   | Void   |
| · <b>Transport hazard class(es)</b>  |  |
| · <b>ADR, ADN, IMDG, IATA</b>  |  |
| · <b>Class</b>   | Void   |
| · <b>Packing group</b>   |  |
| · <b>DOT, ADR, IMDG, IATA</b>  | Void   |
| · <b>Environmental hazards:</b>  |  |
| · <b>Marine pollutant:</b>   | No   |
| · <b>Special precautions for user</b>  | Not applicable.                                      |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable.                                      |
| · <b>Transport/Additional information:</b>                                       | Not dangerous according to the above specifications. |
| · <b>UN "Model Regulation":</b>  | -  |

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**15 Regulatory information**

· **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:**

· **Developmental Toxicity**

32986-56-4 tobramycin

1405-41-0 Gentamicin Sulfate

**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

· **Date of preparation / last revision** 06/03/2015 / -

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

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