Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2015 Reviewed on 05/26/2015

1 Identification

· **Product identifier**

· **Trade name:** **in2it HbA1c Control 2, 0.5 ml**

· **Catalog or product number:** 402166W
· **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.

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2 Composition/information on ingredients

· **Chemical characterization: Substances**
· **CAS No. Description:**
Human Blood - Lyophilized
· **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:**

1403-66-3	Gentamicin	0.01-0.1%
32986-56-4	tobramycin	0.01-0.1%

· **Additional information** For the wording of the listed risk phrases refer to section 15.

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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
· **Classification system**
· **Special Hazards** Contains human sourced and/or potentially infectious components.

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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.

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· **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.

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.

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6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
· **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.

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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:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· **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.
· **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.

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· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing.

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9 Physical and chemical properties

· **General Information**	
· **Appearance:**	
Form:	Solid
Color:	Red
· **Odor:**	Odorless
· **Odour threshold:**	Not determined.
· **pH-value at 20 °C:**	6-9
· **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.
· **Density:**	Not determined
· **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 %
Solids content:	100.0 %
· **Other information**	No further relevant information available.

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* 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.

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.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

* 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.

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· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

* 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)** · **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.
· **UN "Model Regulation":**	-

* 15 Regulatory information

· **SARA (Superfund Amendents 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):**

60-00-4	ethylenediaminetetraacetic acid

· **California Proposition 65:**

· **Developmental Toxicity**

32986-56-4	tobramycin

· **National regulations**

· **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.

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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.***