

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/26/2015

Reviewed on 05/26/2015

1 Identification

- **Product identifier**
- **Trade name:** Lyphochek® Hemoglobin A1C Linearity Set
- **Catalog or product number:** 12000070
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Sector of Use** SU20 Health services
- **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
9500 Jeronimo Road
Irvine, California 92618-2017 1(949) 598-1200
- **Information department:** Technical services, customer support
- **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**
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
- **Emergency overview:**
- **Routes of exposure:**
Ingestion
Inhalation
Skin
- **Classification system**
- **NFPA ratings (scale 0-4)**
Health = 0
Fire = 0
Reactivity = 0
- **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:

Human Red Cells	50-100%
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Proprietary Reagent FF

35-50%

Proprietary Reagent GG

.001-.01%

· **Additional information** Contains human sourced and/or potentially infectious components.

4 First-aid measures

· **Description of first aid measures**

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

· **After skin contact**

Immediately wash with water and soap and rinse thoroughly.

Generally the product does not irritate the skin.

· **After eye contact** Rinse opened eye for several minutes under running water. Then consult a doctor.

· **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**

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.

· **Advice for firefighters**

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

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Handle as potentially infectious.

· **Environmental precautions:**

Keep contaminated washing water and dispose of appropriately.

Do not allow to enter sewers/ surface or ground water.

· **Methods and material for containment and cleaning up:**

Absorb liquid components with liquid-binding material.

Pick up mechanically.

Clean the affected area carefully; suitable cleaners are:

Disinfectant

· **Reference to other sections** See Section 13 for disposal information.

7 Handling and storage

· **Handling**

· **Precautions for safe handling** No special precautions are necessary if used correctly.

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

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- **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:**
Refer to package insert for additional information regarding storage conditions.
- **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:**

Proprietary Reagent GG

PEL (United States)	Long-term value: 5 mg/m ³ as CN; Skin
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- **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.
The usual precautionary measures for handling chemicals should be followed.
- **Breathing equipment:** Not required.
- **Protection of hands:** 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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
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
- **Body protection:** Protective work clothing.

9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

Form:	Solid
Color:	Red
Odor:	Odorless

· **pH-value at 20 °C:** 7.6-8.1

· **Change in condition**

Melting point/Melting range: undetermined

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Boiling point/Boiling range:	undetermined
Flash point:	Not applicable
Danger of explosion:	Product does not present an explosion hazard.
Density:	Not determined
Solubility in / Miscibility with Water:	Soluble
Solvent content:	
Organic solvents:	0.0 %
Solids content:	100.0 %
Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity**
- **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:** 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.

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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:**
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.
- **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** Dispose of waste in accordance to applicable national, regional, or local regulations.
- **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. |

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· **UN "Model Regulation":** -

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **SARA (Superfund Amendants and Reauthorization Act of 1986 - USA)**

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

Proprietary Reagent GG

· **Section 313 (40CFR372.65):**

None of the ingredients is listed.

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

Proprietary Reagent FF

Proprietary Chemical CP2

Proprietary Reagent GG

· **California Proposition 65:**

· **Developmental Toxicity**

Proprietary Reagent J15

Proprietary Reagent J7

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

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

None of the ingredients is listed.

· **MAK (German Maximum Workplace Concentration)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **National regulations**

· **Water hazard class:** Water hazard class 1 (Self-assessment): slightly 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

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· Date of preparation / last revision 05/26/2015 / -**· 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**ACGIH: American Conference of Governmental Industrial Hygienists**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)**NFPA: National Fire Protection Association (USA)***· * Data compared to the previous version altered.**

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