

# SAFETY DATA SHEET



Revision date 12-Apr-2021

Revision Number 1

## 1. Identification

### Product identifier

**Product Name** Lyphocheck Hemoglobin A1C Linearity Set

### Other means of identification

**Catalog Number(s)** 12000070

### Recommended use of the chemical and restrictions on use

**Recommended use** In vitro diagnostic

### Details of the supplier of the safety data sheet

#### Corporate Headquarters

Bio-Rad Laboratories Inc.  
1000 Alfred Nobel Drive  
Hercules, CA 94547  
USA

#### Manufacturer Address

Bio-Rad Laboratories Inc.  
9500 Jeronimo Road  
Irvine, California 92618  
USA

#### Legal Entity / Contact Address

Bio-Rad Laboratories Inc.  
9500 Jeronimo Road  
Irvine, California 92618  
USA

#### **Technical Service**

1(800) 854-6737  
qsd.techservice@bio-rad.com

### Emergency telephone number

**24 Hour Emergency Phone Number**

CHEMTREC USA: 1 (800) 424-9300

## 2. Hazard(s) identification

### Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

#### Hazard statements

Not a hazardous substance or mixture according to the Globally Harmonized System (GHS)

The product contains no substances which at their given concentration, are considered to be hazardous to health.

**Appearance** powder or cake, lyophilized

**Physical state** Solid

**Odor** Odorless

**Other information**

Contains human source material and / or potentially infectious components.

**3. Composition/information on ingredients****Substance**

Not applicable.

**Mixture**

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

**4. First-aid measures****Description of first aid measures**

<b>General advice</b>	No hazards which require special first aid measures.
<b>Inhalation</b>	Remove to fresh air.
<b>Eye contact</b>	Contains human source material and / or potentially infectious components. Call a physician.
<b>Skin contact</b>	Wash skin with soap and water.
<b>Ingestion</b>	Call a physician. Contains human source material and / or potentially infectious components.

**Most important symptoms and effects, both acute and delayed**

<b>Symptoms</b>	No information available.
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**Indication of any immediate medical attention and special treatment needed**

<b>Note to physicians</b>	Contains human source material and / or potentially infectious components.
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**5. Fire-fighting measures**

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Unsuitable extinguishing media</b>	No information available.
<b>Specific hazards arising from the chemical</b>	None known.
<b>Explosion data</b>	
<b>Sensitivity to mechanical impact</b>	None.
<b>Sensitivity to static discharge</b>	None.
<b>Special protective equipment for fire-fighters</b>	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

**6. Accidental release measures**

**Personal precautions, protective equipment and emergency procedures**

**Personal precautions** See section 8 for more information.

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

**Methods for containment** Do not allow into any sewer, on the ground or into any body of water.

**Methods for cleaning up** Clean contaminated surface thoroughly. Use: Disinfectant.

**7. Handling and storage****Precautions for safe handling**

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice.

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

**Storage Conditions** Store according to product and label instructions.

**8. Exposure controls/personal protection****Control parameters**

**Exposure Limits** This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

**Appropriate engineering controls**

**Engineering controls** Showers  
Eyewash stations  
Ventilation systems.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection** Wear safety glasses with side shields (or goggles).

**Hand protection** Wear suitable gloves.

**Skin and body protection** Wear suitable protective clothing.

**Respiratory protection** No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

**General hygiene considerations** Follow universal and standard precautions for handling potentially infectious materials.

**9. Physical and chemical properties****Information on basic physical and chemical properties**

<b>Physical state</b>	Solid
<b>Appearance</b>	powder or cake, lyophilized
<b>Color</b>	red
<b>Odor</b>	Odorless
<b>Odor threshold</b>	No information available

<b><u>Property</u></b>	<b><u>Values</u></b>	<b><u>Remarks • Method</u></b>
<b>pH</b>	7.6-8.1	
<b>Melting point / freezing point</b>	No data available	None known

Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Relative density	No data available	None known
Water solubility	Soluble in water	
Solubility in other solvents	No data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
<u>Other information</u>		
Explosive properties	Not applicable	
Oxidizing properties	Not applicable	
Softening point	Not applicable	
Molecular weight	Not applicable	
VOC Content (%)	Not applicable	

## 10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous decomposition products	None known based on information supplied.

## 11. Toxicological information

### Information on likely routes of exposure

#### Product Information

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

### Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	No information available.
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### Acute toxicity

**Numerical measures of toxicity****Delayed and immediate effects as well as chronic effects from short and long-term exposure**

<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
<b>Serious eye damage/eye irritation</b>	Based on available data, the classification criteria are not met.
<b>Respiratory or skin sensitization</b>	Based on available data, the classification criteria are not met.
<b>Germ cell mutagenicity</b>	Based on available data, the classification criteria are not met.
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met.
<b>Reproductive toxicity</b>	Based on available data, the classification criteria are not met.
<b>STOT - single exposure</b>	Based on available data, the classification criteria are not met.
<b>STOT - repeated exposure</b>	Based on available data, the classification criteria are not met.
<b>Aspiration hazard</b>	No information available.
<b>Other adverse effects</b>	No information available.
<b>Interactive effects</b>	No information available.

**12. Ecological information**

<b>Ecotoxicity</b>	.
<b>Persistence and degradability</b>	No information available.
<b>Bioaccumulation</b>	There is no data for this product.
<b>Other adverse effects</b>	No information available.

**13. Disposal considerations****Waste treatment methods**

<b>Waste from residues/unused products</b>	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
<b>Contaminated packaging</b>	Do not reuse empty containers.

**14. Transport information**

<u>DOT</u>	Not regulated
UN proper shipping name	
<u>TDG</u>	Not regulated
<u>MEX</u>	Not regulated
<u>IATA</u>	Not regulated
<u>IMDG</u>	Not regulated

**15. Regulatory information****International Inventories**

Contact supplier for inventory compliance status

**US Federal Regulations****SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

**SARA 311/312 Hazard Categories**

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications. Under the amended regulations at 40 CFR 370, EPCRA 311/312 Tier II reporting for the 2017 calendar year will need to be consistent with updated hazard classifications.

**CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

**CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

**US State Regulations****California Proposition 65**

This product contains the following Proposition 65 chemicals:.

Chemical name	California Proposition 65
Trade secret -	Developmental
Trade secret -	Developmental
Trade secret -	Male Reproductive

**U.S. State Right-to-Know Regulations**

**US State Regulations** This product does not contain any substances regulated by state right-to-know regulations

**US State Regulations**

**U.S. EPA Label Information**

EPA Pesticide Registration Number Not applicable

**16. Other information**

<b>NFPA</b>	Health hazards 0	Flammability 0	Instability 0	Physical and chemical properties -
<b>HMIS</b>	Health hazards 0	Flammability 0	Physical hazards 0	Personal protection X

**Key or legend to abbreviations and acronyms used in the safety data sheet****Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

**Key literature references and sources for data used to compile the SDS**

Agency for Toxic Substances and Disease Registry (ATSDR)  
 U.S. Environmental Protection Agency ChemView Database  
 European Food Safety Authority (EFSA)  
 EPA (Environmental Protection Agency)  
 Acute Exposure Guideline Level(s) (AELG(s))  
 U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act  
 U.S. Environmental Protection Agency High Production Volume Chemicals  
 Food Research Journal  
 Hazardous Substance Database  
 International Uniform Chemical Information Database (IUCLID)  
 Japan GHS Classification  
 Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)  
 NIOSH (National Institute for Occupational Safety and Health)  
 National Library of Medicine's ChemID Plus (NLM CIP)  
 National Library of Medicine's PubMed database (NLM PUBMED)  
 National Toxicology Program (NTP)  
 New Zealand's Chemical Classification and Information Database (CCID)  
 Organization for Economic Co-operation and Development Environment, Health, and Safety Publications  
 Organization for Economic Co-operation and Development High Production Volume Chemicals Program  
 Organization for Economic Co-operation and Development Screening Information Data Set  
 RTECS (Registry of Toxic Effects of Chemical Substances)  
 World Health Organization

Prepared By Bio-Rad Laboratories, Environmental Health and Safety

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Revision Note \*\*\* Indicates this information has changed since the previous revision.

**Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet**