

Printing date 02/27/2013 Reviewed on 02/27/2013

#### 1 Identification of the substance/mixture and of the company/undertaking

- · Product identifier
- Trade name: Lyphochek Hemoglobin A1c Linearity Set
- · Catalog or product number: 120
- · Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

- · Application of the substance / the preparation Laboratory chemicals
- · 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 Hazards 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.

- · 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).

· Safety phrases:

35 This material and its container must be disposed of in a safe way.

- · Classification system
- NFPA ratings (scale 0-4)

Health = 0

Fire = 0

Reactivity = 0

- · 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.

(Contd. on page 2)



Printing date 02/27/2013 Reviewed on 02/27/2013

Trade name: Lyphochek Hemoglobin A1c Linearity Set

(Contd. of page 1)

· Listing of dangerous and non-hazardous components:			
	Human Red Cells		50-100%
CAS: 80-68-2 EINECS: 201-300-6	DL-threonine		35-50%
CAS: 151-50-8 EINECS: 205-792-3	potassium cyanide	T+ R26/27/28 N R50/53 R32	0.01-0.1%

#### · Additional information

Contains human sourced and/or potentially infectious components.

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 Eye irritation

Skin irritation

- · Indication of any immediate medical attention and special treatment needed No further relevant information available.
- · Medical conditions aggravated by exposure: None expected.

#### 5 Firefighting 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.

Avoid formation of dust.

· 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:

Clean the affected area carefully; suitable cleaners are:

Disinfectant

Dispose contaminated material as waste according to item 13.

(Contd. on page 3)



Printing date 02/27/2013 Reviewed on 02/27/2013

Trade name: Lyphochek Hemoglobin A1c Linearity Set

(Contd. of page 2)

· Reference to other sections

See Section 8 for information on personal protection equipment.

No dangerous substances are released.

### 7 Handling and storage

- · Handling
- · Precautions for safe handling

No special measures required.

No special precautions are necessary if used correctly.

- · Information about protection against explosions and fires: The product is not flammable
- · 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.

### 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:

#### 151-50-8 potassium cyanide

PEL () 5 mg/m³

as CN; Skin

REL () Short-term value: C 5\* mg/m³, C 4.7\* ppm

as CN; \*10-min

TLV () Short-term value: C 5 mg/m<sup>3</sup>

as CN: Skin

- · 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.

- · Eve protection: Safety glasses
- · Body protection: Protective work clothing.

QUS



Printing date 02/27/2013 Reviewed on 02/27/2013

Trade name: Lyphochek Hemoglobin A1c Linearity Set

(Contd. of page 3)

#### 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: 7.7

· Change in condition

Melting point/Melting range: undetermined Boiling point/Boiling range: undetermined

· Flash point: Not applicable

· Auto igniting: Product is not selfigniting.

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

· **Density:** Not determined

· Solubility in / Miscibility with

Water: Fully miscible

· Solvent content:

Organic solvents: 0.0 %

Solids content: 88.2 %

· 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: 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:

(Contd. on page 5)



Printing date 02/27/2013 Reviewed on 02/27/2013

Trade name: Lyphochek Hemoglobin A1c Linearity Set

(Contd. of page 4)

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.

### 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

Must be specially treated adhering to official regulations.

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.

- 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

(Contd. on page 6)



Printing date 02/27/2013 Reviewed on 02/27/2013

Trade name: Lyphochek Hemoglobin A1c Linearity Set

(Contd. of page 5)

- · 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.

# 15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · 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):

80-68-2 DL-threonine

- · California Proposition 65:
- · Developmental Toxicity

1405-41-0 Gentamicin Sulfate

32986-56-4 tobramycin

- · 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.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

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

(Contd. on page 7)



Printing date 02/27/2013 Reviewed on 02/27/2013

Trade name: Lyphochek Hemoglobin A1c Linearity Set

(Contd. of page 6)

· 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 MSDS: 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.

OUS