

Material Safety Data Sheet

Printing date 03/17/2010

Reviewed on 03/11/2010

1 Identification of substance:

- **Product details:**
- **Trade name:** Lyphochek® Tumor Marker Control
- **Catalog or product number:** 580, 580X
- **Application of the substance / the preparation** In-vitro laboratory reagent or component
- **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 information:**
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 components:

- **Chemical characterization**
- **Description:** Mixture of the substances listed below with non-hazardous additions.

- **Listing of dangerous and non-hazardous components:**

Human Source Material	50-100%
Proprietary Reagent BS 10	10-20%
Proprietary Component C	10-20%
Proprietary Reagent KK	10-20%

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

3 Hazards identification

- **Emergency overview:** not applicable
- **Routes of exposure:**
Ingestion
Inhalation
Skin
- **Information pertaining to particular dangers for man 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.
- **NFPA ratings (scale 0-4)**
Health = 0
Fire = 0
Reactivity = 0
- **Special Hazards** Contains human sourced and/or potentially infectious components.

4 First aid measures

- **General information** No special measures required.
- **After inhalation** Supply fresh air; consult doctor in case of complaints.

(Contd. on page 2)

-QUS-

Material Safety Data Sheet

Printing date 03/17/2010

Reviewed on 03/11/2010

Trade name: **Lyphochek® Tumor Marker Control**

(Contd. of page 1)

- **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**
- **The following symptoms may occur:**
Skin irritation
Eye irritation

5 Fire fighting measures

- **Suitable extinguishing agents**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Person-related safety precautions:** Handle as potentially infectious.
- **Measures for environmental protection:**
Do not allow product to reach sewage system or any water course.
Keep contaminated washing water and dispose of appropriately.
- **Measures for cleaning/collecting:**
Absorb liquid components with liquid-binding material.
Pick up mechanically.
Clean the affected area carefully; suitable cleaners are:
Disinfectant
Dispose contaminated material as waste according to item 13.

7 Handling and storage

- **Handling**
- **Information for safe handling:** No special precautions are necessary if used correctly.
- **Information about protection against explosions and fires:** The product is not flammable
- **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.

8 Exposure controls and personal protection

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

(Contd. on page 3)

QUS

Material Safety Data Sheet

Printing date 03/17/2010

Reviewed on 03/11/2010

Trade name: Lyphochek® Tumor Marker Control

(Contd. of page 2)

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

Proprietary Reagent BS 10

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

· 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.
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:

· General Information

Form:	Solid.
Color:	Light yellow
Odor:	Light

· 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

· pH-value at 20°C: 6-8

· Solvent content:

Organic solvents: 0.0 %

(Contd. on page 4)

Material Safety Data Sheet

Printing date 03/17/2010

Reviewed on 03/11/2010

Trade name: Lyphochek® Tumor Marker Control

(Contd. of page 3)

Solids content: 100 %

10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Materials to be avoided:**
- **Dangerous reactions** No dangerous reactions known
- **Dangerous products of decomposition:** No dangerous decomposition products known

11 Toxicological information

- **Acute toxicity:**
- **LD/LC50 values for hazardous components per OSHA criteria:**

Proprietary Component C

Oral	LD50	15900 mg/kg (rat)
------	------	-------------------

- **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.

12 Ecological information:

- **Additional ecological information:**
- **General notes:** Generally not hazardous for water.

13 Disposal considerations

- **Product:**
- **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

- **DOT regulations:**
- **Hazard class:** -

(Contd. on page 5)

Material Safety Data Sheet

Printing date 03/17/2010

Reviewed on 03/11/2010

Trade name: Lyphochek® Tumor Marker Control

(Contd. of page 4)

· **Land transport ADR/RID (cross-border)**

· **ADR/RID class:** -

· **Maritime transport IMDG:**

· **IMDG Class:** -

· **Marine pollutant:** No

· **Air transport ICAO-TI and IATA-DGR:**

· **ICAO/IATA Class:** -

· **Transport/Additional information:** Not dangerous according to the above specifications.

15 Regulations

· **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):**

Proprietary Reagent BS 10

Proprietary Component C

Proprietary Reagent KK

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

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

Proprietary Reagent BS 10

A4

· **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.

· **Markings 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).

(Contd. on page 6)

Material Safety Data Sheet

Printing date 03/17/2010

Reviewed on 03/11/2010

Trade name: Lyphochek® Tumor Marker Control

(Contd. of page 5)

- **Safety phrases:**
35 This material and its container must be disposed of in a safe way.
- **National regulations**
- **Water hazard class:** Generally not hazardous for water.

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.**

QUS