

**Safety Data Sheet**  
acc. to OSHA HCS

Printing date 05/26/2015

Reviewed on 05/13/2015

**1 Identification**

- **Product identifier**
- **Trade name:** *Lyphochek® Immunoassay Plus Control*
- **Catalog or product number:** 370, 371, 372, 373, 370X
- **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).*

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- **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:**

EINECS: 268-338-3 Human Source Material	50-100%
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(Contd. on page 2)

**Safety Data Sheet**  
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Reviewed on 05/13/2015

**Trade name: Lyphochek® Immunoassay Plus Control**

(Contd. of page 1)

	Proprietary Reagent KK	0-20%
	Proprietary Reagent RF I	0-20%
	Proprietary Reagent KF	0-20%
CAS: 6131-90-4	Sodium Acetate 3-Hydrate	2.5-5%
CAS: 57-13-6 EINECS: 200-315-5	urea	0.1-1.0%
CAS: 56-75-7 EINECS: 200-287-4	chloramphenicol	0.01-0.1%

**Additional information**

- Contains human sourced and/or potentially infectious components.
- Contains added constituents of animal origin.

**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**  
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:**  
Do not allow to enter sewers/ surface or ground water.  
Keep contaminated washing water and dispose of appropriately.
- 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

(Contd. on page 3)

**Safety Data Sheet**  
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Reviewed on 05/13/2015

**Trade name: Lyphochek® Immunoassay Plus Control**

(Contd. of page 2)

· **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.
- **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:**

**57-13-6 urea**

WEEL (United States) Long-term value: 10 mg/m<sup>3</sup>

**56-75-7 chloramphenicol**

WEEL (United States) Long-term value: 0.5 mg/m<sup>3</sup>

· **Additional information:** The lists that were valid during the creation were used as basis.

- **Exposure controls**
- **Personal protective equipment**
- **General protective and hygienic measures**  
The usual precautionary measures for handling chemicals should be followed.  
Follow the usual biosafety practices for handling potentially infectious materials.
- **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.

QUS

(Contd. on page 4)

**Safety Data Sheet**  
acc. to OSHA HCS

Printing date 05/26/2015

Reviewed on 05/13/2015

Trade name: **Lyphochek® Immunoassay Plus Control**

(Contd. of page 3)

**9 Physical and chemical properties**

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

· **General Information**

· **Appearance:**

Form:	Solid
Color:	Amber
Odor:	Light

· **pH-value at 20 °C:** 7.40 - 7.90

· **Change in condition**

Melting point/Melting range: undetermined  
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:**

· **LD/LC50 values for hazardous components per OSHA criteria:**

**Proprietary Reagent KF**

Oral	LD50	15900 mg/kg (rat)
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· **Primary irritant effect:**

· **on the eye:** Irritant effect.

· **Sensitization:** No sensitizing effects known.

(Contd. on page 5)

**Safety Data Sheet**  
acc. to OSHA HCS

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Reviewed on 05/13/2015

**Trade name: Lyphochek® Immunoassay Plus Control**

(Contd. of page 4)

**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)**

103-90-2	paracetamol	3
50-06-6	phenobarbital	2B
58-55-9	theophylline	3
56-75-7	chloramphenicol	2A
58-08-2	caffeine	3

**NTP (National Toxicology Program)**

630-93-3	Phenytoin Sodium	R
56-75-7	chloramphenicol	R
57-83-0	progesterone	R

**OSHA-Ca (Occupational Safety & Health Administration)**

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

**Uncleaned packagings:**

**Recommendation:** Disposal must be made according to official regulations.

QUS

(Contd. on page 6)

**Safety Data Sheet**  
acc. to OSHA HCS

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Reviewed on 05/13/2015

Trade name: **Lyphochek® Immunoassay Plus Control**

(Contd. of page 5)

**14 Transport information**

· UN-Number	
· ADR, ADN, IMDG, IATA	Void
· UN proper shipping name	
· ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· 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.

**15 Regulatory information**

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

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

20830-75-5 digoxin

· Section 313 (40CFR372.65):

554-13-2 lithium carbonate

· TSCA (Toxic Substances Control Act):

	Proprietary Reagent KK
614-39-1	Procainamide hydrochloride
	Proprietary Reagent KF
69-72-7	Salicylic acid
7647-14-5	sodium chloride
57-13-6	urea
7447-40-7	potassium chloride
7558-79-4	disodium hydrogenorthophosphate
103-90-2	paracetamol
554-13-2	lithium carbonate
69-93-2	uric acid
58-55-9	theophylline
630-93-3	Phenytoin Sodium
56-75-7	chloramphenicol
58-08-2	caffeine

(Contd. on page 7)

**Safety Data Sheet**  
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**Trade name: Lyphochek® Immunoassay Plus Control**

(Contd. of page 6)

· **California Proposition 65:**

· **Chemicals known to cause cancer:**

50-06-6	phenobarbital
630-93-3	Phenytoin Sodium
50-28-2	estradiol
57-83-0	progesterone
58-22-0	testosterone

· **Developmental Toxicity**

554-13-2	lithium carbonate
298-46-4	Carbamazepin
1405-41-0	Gentamicin Sulfate
32986-56-4	tobramycin

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

57-13-6	urea	II
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· **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

· **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
- 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)

(Contd. on page 8)



**Safety Data Sheet**  
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Reviewed on 05/13/2015

**Trade name: Lyphochek® Immunoassay Plus Control**

(Contd. of page 7)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

· \* **Data compared to the previous version altered.**

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