

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).

- **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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	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

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· **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/m³

56-75-7 chloramphenicol

WEEL (United States) Long-term value: 0.5 mg/m³

· **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.

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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.

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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.

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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

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· **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)

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LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

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

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