

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

Printing date 05/26/2015

Reviewed on 05/26/2015

**1 Identification**

- **Product identifier**
- **Trade name:** Lyphochek® Unassayed Chemistry Control (Human)
- **Catalog or product number:** 731, 732, 730X, C-320-10, C-325-10, 323X
- **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	35-50%
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	Proprietary Reagent KA	20-35%
CAS: 56-87-1	Lysine	10-20%
CAS: 7647-14-5 EINECS: 231-598-3	sodium chloride	2.5-5%
	Proprietary Reagent MS 1	2.5-5%
CAS: 6131-90-4	Sodium Acetate 3-Hydrate	2.5-5%
CAS: 50-99-7 EINECS: 200-075-1	glucose	1.0-2.5%
CAS: 57-88-5 EINECS: 200-353-2	cholesterol	1.0-2.5%
	Triglycerides	1.0-2.5%
CAS: 57-13-6 EINECS: 200-315-5	urea	0.1-1.0%

**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**

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

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- **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
- **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>
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**7647-01-0 hydrochloric acid**

PEL (United States)	Ceiling limit value: 7 mg/m <sup>3</sup> , 5 ppm
REL (United States)	Ceiling limit value: 7 mg/m <sup>3</sup> , 5 ppm
TLV (United States)	Ceiling limit value: 2.98 mg/m <sup>3</sup> , 2 ppm

- **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 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.

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- **Eye protection:** Safety glasses
- **Body protection:** Protective work clothing.

**9 Physical and chemical properties**

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

· **General Information**

· **Appearance:**

<b>Form:</b>	Solid
<b>Color:</b>	Light yellow
<b>Odor:</b>	Light

· **pH-value at 20 °C:** 7.5-8.4

· **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:** 54.7 %

· **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.

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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)**

57-88-5	cholesterol	3
103-90-2	paracetamol	3
	Proprietary Reagent KB	2A
50-06-6	phenobarbital	2B
57-41-0	phenytoin	2B
58-55-9	theophylline	3
7647-01-0	hydrochloric acid	3

**NTP (National Toxicology Program)**

	Proprietary Reagent KB	R
57-41-0	phenytoin	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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· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

**14 Transport information**

· <b>UN-Number</b>	
· <b>DOT, ADR, ADN, IMDG, IATA</b>	Void
· <b>UN proper shipping name</b>	
· <b>DOT, ADR, ADN, IMDG, IATA</b>	Void
· <b>Transport hazard class(es)</b>	
· <b>ADR, ADN, IMDG, IATA</b>	
· <b>Class</b>	Void
· <b>Packing group</b>	
· <b>DOT, ADR, IMDG, IATA</b>	Void
· <b>Environmental hazards:</b>	
· <b>Marine pollutant:</b>	No
· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>UN "Model Regulation":</b>	-

**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):**

57-41-0 | phenytoin

· **TSCA (Toxic Substances Control Act):**

56-87-1 | Lysine

7647-14-5 | sodium chloride

Proprietary Reagent MS 1

50-99-7 | glucose

57-88-5 | cholesterol

57-13-6 | urea

7447-40-7 | potassium chloride

69-72-7 | Salicylic acid

69-93-2 | uric acid

79-33-4 | l-(+)-lactic acid

103-90-2 | paracetamol

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7447-41-8	lithium chloride
635-65-4	bilirubin
60-27-5	Creatinine
	Proprietary Reagent KB

**· California Proposition 65:**

**· Chemicals known to cause cancer:**

50-06-6	phenobarbital
57-41-0	phenytoin

**· Developmental Toxicity**

57-41-0	phenytoin
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)**

7647-01-0	hydrochloric acid	A4
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**· 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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

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ELINCS: European List of Notified Chemical Substances  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
NFPA: National Fire Protection Association (USA)

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

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