# 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).

## 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:

<table>
<thead>
<tr>
<th>EINECS: 268-338-3 Human Source Material</th>
<th>35-50%</th>
</tr>
</thead>
</table>

(Contd. on page 2)
Trade name: Lyphochek® Unassayed Chemistry Control (Human)

<table>
<thead>
<tr>
<th>Proprietary Reagent KA</th>
<th>20-35%</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS: 56-87-1</td>
<td>Lysine 10-20%</td>
</tr>
<tr>
<td>CAS: 7647-14-5</td>
<td>sodium chloride 2.5-5%</td>
</tr>
<tr>
<td>EINECS: 231-598-3</td>
<td></td>
</tr>
<tr>
<td>Proprietary Reagent MS 1</td>
<td>2.5-5%</td>
</tr>
<tr>
<td>CAS: 6131-90-4</td>
<td>Sodium Acetate 3-Hydrate 2.5-5%</td>
</tr>
<tr>
<td>CAS: 50-99-7</td>
<td>glucose 1.0-2.5%</td>
</tr>
<tr>
<td>EINECS: 200-075-1</td>
<td></td>
</tr>
<tr>
<td>CAS: 57-88-5</td>
<td>cholesterol 1.0-2.5%</td>
</tr>
<tr>
<td>EINECS: 200-353-2</td>
<td></td>
</tr>
<tr>
<td>CAS: 57-13-6</td>
<td>Triglycerides 1.0-2.5%</td>
</tr>
<tr>
<td>EINECS: 200-315-5</td>
<td></td>
</tr>
<tr>
<td>CAS: 57-88-5</td>
<td>urea 0.1-1.0%</td>
</tr>
</tbody>
</table>

· 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.

(Contd. on page 3)
40.1.5

- 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**

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>57-13-6 urea</td>
<td>Long-term value: 10 mg/m³</td>
</tr>
<tr>
<td>WEEL (United States)</td>
<td></td>
</tr>
<tr>
<td>7647-01-0 hydrochloric acid</td>
<td>Ceiling limit value: 7 mg/m³, 5 ppm</td>
</tr>
<tr>
<td>PEL (United States)</td>
<td>Ceiling limit value: 7 mg/m³, 5 ppm</td>
</tr>
<tr>
<td>REL (United States)</td>
<td>Ceiling limit value: 7 mg/m³, 5 ppm</td>
</tr>
<tr>
<td>TLV (United States)</td>
<td>Ceiling limit value: 2.98 mg/m³, 2 ppm</td>
</tr>
</tbody>
</table>

- **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

**General Information**

- **Appearance**:
  - **Form**: Solid
  - **Color**: Light yellow
  - **Odor**: 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.

(Contd. on page 5)
· 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

<table>
<thead>
<tr>
<th>IARC (International Agency for Research on Cancer)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>57-88-5 cholesterol</td>
<td>3</td>
</tr>
<tr>
<td>103-90-2 paracetamol</td>
<td>3</td>
</tr>
<tr>
<td>Proprietary Reagent KB</td>
<td>2A</td>
</tr>
<tr>
<td>50-06-6 phenobarbital</td>
<td>2B</td>
</tr>
<tr>
<td>57-41-0 phenytoin</td>
<td>2B</td>
</tr>
<tr>
<td>58-55-9 theophylline</td>
<td>3</td>
</tr>
<tr>
<td>7647-01-0 hydrochloric acid</td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NTP (National Toxicology Program)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Proprietary Reagent KB</td>
<td>R</td>
</tr>
<tr>
<td>57-41-0 phenytoin</td>
<td>R</td>
</tr>
</tbody>
</table>

· 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.
### 14 Transport information

- **UN-Number**
  - DOT, ADR, ADN, IMDG, IATA: Void

- **UN proper shipping name**
  - DOT, ADR, ADN, IMDG, IATA: Void

- **Transport hazard class(es)**
  - ADR, ADN, IMDG, IATA: 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.

- **UN "Model Regulation"**: -

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### 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 Carbamazepine
- 1405-41-0 Gentamicin Sulfate
- 32986-56-4 tobramycin

Carcinogenic categories
- EPA (Environmental Protection Agency)
  57-13-6 urea I
- TLV (Threshold Limit Value established by ACGIH)
  7647-01-0 hydrochloric acid 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.

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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Trade name: Lyphochek® Unassayed Chemistry Control (Human)

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.