

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

Printing date 05/26/2015

Reviewed on 05/22/2015

**1 Identification**

- **Product identifier**
- **Trade name:** Liquichek™ Immunoassay Plus Control, Level 2
- **Catalog or product number:** 362, 268
- **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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|                                   |                           |           |
|-----------------------------------|---------------------------|-----------|
|                                   | Proprietary Reagent KK    | 1.0-2.5%  |
|                                   | Proprietary Component C   | 1.0-2.5%  |
|                                   | Proprietary Reagent BS 10 | 1.0-2.5%  |
| CAS: 57-13-6<br>EINECS: 200-315-5 | urea                      | 0.01-0.1% |
| CAS: 56-75-7<br>EINECS: 200-287-4 | chloramphenicol           | .001-.01% |

**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.
- **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:**

**Proprietary Reagent BS 10**

|                     |   |
|---------------------|---|
| PEL (United States) | Long-term value: 15* 5** mg/m <sup>3</sup><br>*total dust **respirable fraction |
| REL (United States) | Long-term value: 10* 5** mg/m <sup>3</sup><br>*total dust **respirable fraction |
| TLV (United States) | Long-term value: 10 mg/m <sup>3</sup>   |

**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 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.

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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>  | Liquid       |
| <b>Color:</b> | Light yellow |
| <b>Odor:</b>  | Light        |

· **pH-value at 20 °C:** 7.2-7.4

· **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:** Fully miscible

· **Solvent content:**

**Organic solvents:** 0.0 %

**Solids content:** 5.8 %

· **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:** 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)**

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

**NTP (National Toxicology Program)**

|          |                  |   |
|----------|------------------|---|
| 56-75-7  | chloramphenicol  | R |
| 630-93-3 | Phenytoin Sodium | 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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· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

**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          |
|            | Proprietary Component C         |
|            | Proprietary Reagent BS 10       |
| 7647-14-5  | sodium chloride                 |
|            | Proprietary Reagent KG          |
| 69-72-7    | Salicylic acid                  |
| 7447-40-7  | potassium chloride              |
| 57-13-6    | urea                            |
| 7558-79-4  | disodium hydrogenorthophosphate |
| 554-13-2   | lithium carbonate               |
| 15687-27-1 | ibuprofen                       |
| 69-93-2    | uric acid                       |

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|          |                  |
|----------|------------------|
| 58-08-2  | caffeine         |
| 56-75-7  | chloramphenicol  |
| 630-93-3 | Phenytoin Sodium |

**· 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  |
| 32986-56-4 | tobramycin         |
| 298-46-4   | Carbamazepin       |
| 1405-41-0  | Gentamicin Sulfate |

**· Carcinogenic categories**

**· EPA (Environmental Protection Agency)**

|         |      |    |
|---------|------|----|
| 57-13-6 | urea | II |
|---------|------|----|

**· 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.

**· 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

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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)

QUS