

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/20/2016

Reviewed on 10/20/2016

1 Identification

- **Product identifier**
- **Trade name:** Liquichek™ Immunoassay Plus Control, Level 1
- **Catalog or product number:** 361, 267, 12004319
- **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.

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· Listing of dangerous and non-hazardous components:

CAS: 57-13-6 EINECS: 200-315-5	urea		0.01-0.1%
CAS: 56-75-7 EINECS: 200-287-4	chloramphenicol	Carc. 1B, H350	.001-.01%
EINECS: 268-338-3	Human Source Material		50-100%
	Proprietary Reagent KK		1.0-2.5%
	Proprietary Component C		1.0-2.5%
CAS: 9048-46-8	Bovine Serum Albumin		1.0-2.5%

· 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.
- **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

26628-22-8 sodium azide

REL (United States) Ceiling limit value: 0.3** mg/m³, 0.1* ppm
*as HN₃; **as NaN₃; Skin

TLV (United States) Ceiling limit value: 0.29** mg/m³, 0.11* ppm
*as HN₃ vapor **as NaN₃

Proprietary Reagent BS 10

PEL (United States) Long-term value: 15* 5** mg/m³
*total dust **respirable fraction

REL (United States) Long-term value: 10* 5** mg/m³
*total dust **respirable fraction

TLV (United States) Long-term value: 10 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**
Follow the usual biosafety practices for handling potentially infectious materials.
The usual precautionary measures for handling chemicals should be followed.
- **Breathing equipment:** Not required.
- **Protection of hands:** Protective gloves.

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· **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.

9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

Form:	Liquid
Color:	Light yellow
Odor:	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: 7.3 %

· **Other information** No further relevant information available.

10 Stability and reactivity

· **Reactivity** No further relevant information available.

· **Chemical stability**

· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

· **Possibility of hazardous reactions**

This product contains sodium azide. Sodium azide can react with copper, brass, lead, and solder in piping systems to form explosive compounds of lead azide and copper azide.

· **Conditions to avoid** No further relevant information available.

· **Incompatible materials:** No further relevant information available.

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· **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.

· **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)**

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

· **NTP (National Toxicology Program)**

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

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· **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.
Flush pipes with water frequently if discarding solutions containing sodium azide into metal piping systems.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **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:** Not applicable.
- **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

9048-46-8 | Bovine Serum Albumin

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7647-14-5	sodium chloride
	Proprietary Reagent KG
	Proprietary Reagent KJ
7447-40-7	potassium chloride
57-13-6	urea
7558-79-4	disodium hydrogenorthophosphate
	Proprietary Reagent SS
69-93-2	uric acid
554-13-2	lithium carbonate
20830-75-5	digoxin
15687-27-1	ibuprofen
113-52-0	imipramine hydrochloride
9034-40-6	Luteinizing hormone-releasing hormone
50-23-7	hydrocortisone
630-93-3	Phenytoin Sodium
549-18-8	amitriptyline hydrochloride
614-39-1	Procainamide hydrochloride
57-83-0	progesterone
56-54-2	quinidine
103-90-2	paracetamol
58-08-2	caffeine
52-39-1	aldosterone
58-22-0	testosterone
58-55-9	theophylline
60-27-5	Creatinine
56-75-7	chloramphenicol

· California Proposition 65:

· Chemicals known to cause cancer:

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

· Developmental Toxicity

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

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· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

57-13-6 urea

II

· **TLV (Threshold Limit Value established by ACGIH)**

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A4

26628-22-8 sodium azide

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** 10/20/2016 / -

· **Abbreviations and acronyms:**

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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

Carc. 1B: Carcinogenicity – Category 1B