

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/26/2015

Reviewed on 05/26/2015

1 Identification

- **Product identifier**
- **Trade name:** Lyphochek® Assayed Chemistry Control
- **Catalog or product number:** C-310-5, C-315-5, 313X
- **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	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 CS 2	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%
	Proprietary Reagent KB	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**

Skin irritation

Eye irritation

· **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.

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- **Environmental precautions:**
Keep contaminated washing water and dispose of appropriately.
Do not allow to enter sewers/ surface or ground water.
- **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/m³

Proprietary Reagent KB

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

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- **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:	Solid
Color:	Light yellow
Odor:	Light

· **pH-value at 20 °C:** 7.55-7.65

· **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.

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- **on the eye:** No 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)**

57-88-5	cholesterol	3
103-90-2	paracetamol	3
	Proprietary Reagent KB	2A
50-06-6	phenobarbital	2B
58-55-9	theophylline	3

· **NTP (National Toxicology Program)**

Proprietary Reagent KB	R
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· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.	
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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 · DOT, ADR, ADN, IMDG, IATA	Void
· UN proper shipping name · DOT, ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class	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":	-

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):**

None of the ingredients is listed.

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

56-87-1	Lysine
7647-14-5	sodium chloride
	Proprietary Reagent CS 2
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
630-93-3	Phenytoin Sodium

· **Developmental Toxicity**

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

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

57-13-6	urea	//
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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

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

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

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NFPA: National Fire Protection Association (USA)

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

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