SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
- Trade name: Lyphochek® Immunoassay Plus Control
- Article number: 370, 371, 372, 373, 370X

1.2 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

1.3 Details of the supplier of the safety data sheet
- Manufacturer/Supplier: Bio-Rad Laboratories Pvt. Ltd.
  Bio-Rad House
  86-87, Udyog Vihar Phase IV
  Gurgaon 122005
  Haryana
  phone: 91-124-4029300  Fax: 91-124-2398115

- Information department: Technical services, customer support.
  support.india@bio-rad.com

1.4 Emergency telephone number: 91-124-2398112/113/114

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008: The product is not classified according to the CLP regulation.

2.2 Label elements
- Labelling according to Regulation (EC) No 1272/2008: Void
- Hazard pictograms: Void
- Signal word: Void
- Hazard statements: Void

2.3 Other hazards
- Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures
- Description: Mixture of the substances listed below with nonhazardous additions.

- Dangerous components:
  - 6131-90-4 Sodium Acetate 3-Hydrate: 2,5-5%
  - 57-13-6 urea: substance with a Community workplace exposure limit 0,1-1,0%
  - 56-75-7 chloramphenicol: substance with a Community workplace exposure limit 0,01-0,1%

- Additional information
  Contains human sourced and/or potentially infectious components.
  Contains added constituents of animal origin.

(Contd. on page 2)
SECTION 4: First aid measures

- 4.1 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.

- 4.2 Most important symptoms and effects, both acute and delayed  No further relevant information available.

- 4.3 Indication of any immediate medical attention and special treatment needed  No further relevant information available.

SECTION 5: Firefighting measures

- 5.1 Extinguishing media
  - Suitable extinguishing agents  CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- 5.2 Special hazards arising from the substance or mixture  No further relevant information available.

- 5.3 Advice for firefighters
  - Protective equipment: No special measures required.

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures  Handle as potentially infectious.

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

- 6.3 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

- 6.4 Reference to other sections  See Section 13 for disposal information.

SECTION 7: Handling and storage

- 7.1 Precautions for safe handling  No special precautions are necessary if used correctly.

- 7.2 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.
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- Further information about storage conditions: Refer to package insert for additional information regarding storage conditions.
- 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- Additional information about design of technical systems: No further data; see item 7.
- 8.1 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
  - Additional information: The lists that were valid during the creation were used as basis.
- 8.2 Exposure controls
  - Personal protective equipment
    - General protective and hygienic measures
      - The usual precautionary measures should be adhered to when handling chemicals.
      - 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
      - Penetration time of glove material
        - The exact break trough 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.

SECTION 9: Physical and chemical properties

- 9.1 Information on basic physical and chemical properties
  - General Information
    - Appearance:
      - Form: Solid.
      - Colour: Amber coloured
      - Odour: Light
    - pH-value at 20 °C: 7,40 - 7,90
    - Change in condition
      - Melting point/Melting range: undetermined
      - Boiling point/Boiling range: undetermined
    - Flash point: Not applicable

(Contd. of page 2)
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- **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: 100,0 %
- **9.2 Other information**
  - No further relevant information available.

### SECTION 10: Stability and reactivity

- **10.1 Reactivity**
- **10.2 Chemical stability**
  - **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
  - **10.3 Possibility of hazardous reactions** No dangerous reactions known
  - **10.4 Conditions to avoid** No further relevant information available.
  - **10.5 Incompatible materials:** No further relevant information available.
  - **10.6 Hazardous decomposition products:** No dangerous decomposition products known

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
  - **Acute toxicity:**
    - **LD/LC50 values that are relevant for classification:**
      - **Proprietary Reagent KF**
        - Oral LD50 15900 mg/kg (rat)
  - **Primary irritant effect:**
    - **on the eye:** Irritating effect.
    - **Sensitisation:** No sensitising 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.

### SECTION 12: Ecological information

- **12.1 Toxicity**
  - **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 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.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.
vPvB: Not applicable.

12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation Dispose of waste in accordance to applicable national, regional, or local regulations.

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

Recommended cleansing agent: Water, if necessary with cleansing agents.

SECTION 14: Transport information

14.1 UN-Number

ADR, ADN, IMDG, IATA Void

14.2 UN proper shipping name

ADR, ADN, IMDG, IATA Void

14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA Void

Class

14.4 Packing group

ADR, IMDG, IATA Void

14.5 Environmental hazards:

Marine pollutant: No

14.6 Special precautions for user

Not applicable.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations

Water hazard class: Water hazard class 1 (Self-assessment): slightly hazardous for water.

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.
SECTION 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

- **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
  GHS: Globally Harmonised System of Classification and Labelling of Chemicals
  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)
  LC50: Lethal concentration, 50 percent
  LD50: Lethal dose, 50 percent