

MATERIAL SAFETY DATA SHEET
According to 91/155 EEC

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

- 1.1 Product name / Code: immunoLEIA[®] Lp(a) Latex Reagenz (2 x 5 mL) REF 4845195
immunoLEIA[®] Lp(a) Latex Reagenz (2 x 20mL) REF 4845205
immunoLEIA[®] CRP Reaction Set (110 T.) REF 4846119
immunoLEIA[®] D-Dimer Latex Kit (115 T.) REF 4847100
immunoLEIA[®] D-Dimer Latex Kit (38 T.) REF 4847101
- 1.2. Recommended use: In-vitro diagnostic
- 1.3. Manufacturer: Technoclone GmbH
Brunner Str. 59/5
1230 Vienna
AUSTRIA
Tel. + 43 1 86373 - 0
Fax + 43 1 86373 - 44
- 1.4. Emergency Phone: +43 1 86373 -10

2. COMPOSITION, INFORMATION ON INGREDIENTS

- 2.1 Article contains:
Immunoglobulins (from goat), coupled to Latex particles, NaN₃
REF 4846119 additionally contains CRP diluent, which is composed as follows:

| | |
|------------------|------------|
| Glycin | 0,17 mol/L |
| NaCl | 1,1 mol/L |
| EDTA2Na | 50 mmol/L |
| NaN ₃ | 0,09% |

REF 4847100 and REF 4847101 additionally contains a reaction buffer with similar composition as CRP diluent, a 0,9% NaCl solution and D-Dimer Control and Calibrator made of human plasma.

Hazard classification: None
CAS No. NaN₃: 26628-22-B;T+;R:28-32

3. HAZARDS IDENTIFICATION

- 3.1 Emergency overview: General rules for handling biological material have to be followed
- 3.2 Health hazard: Health hazard upon ingestion
Presents little hazard if spilled or in fire

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4. FIRST AID MEASURES

- | | | |
|-----|---------------|---|
| 4.1 | General | Miscible with water |
| 4.2 | Eyes: | Flush eyes with water, if persistent irritation occurs, seek medical advice |
| 4.3 | Skin contact: | Wash with water, and wipe with skin disinfectant |
| 4.4 | Ingestion: | Drink water, seek medical advice |

5. FIRE-FIGHTING MEASURES

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|-----|-----------------------|-----------------|
| 5.1 | Extinguishing media: | No limitation |
| 5.2 | Flammable properties: | Not combustible |

6. ACCIDENTAL RELEASE MEASURES

- | | | |
|-----|-----------------------|--|
| 6.1 | Personal precautions: | Wear gloves, avoid substance contact |
| 6.2 | Cleanup procedures: | Take up dry and discard according to the rules for biological material |

7. HANDLING AND STORAGE

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|-----|-----------------------|------------------------|
| 7.1 | Handling precautions: | No special precautions |
| 7.2 | Storage: | Store at +2 – 8°C |

8. EXPOSURE CONTROLS, PERSONAL PROTECTION

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|-----|---|---|
| 8.1 | Ventilation: | No particular ventilation requirements. |
| 8.2 | Protection of hands: | The glove material has to be impermeable and resistant to the product/the substance/the preparation. Due to missing tests no recommendation to the glove material can be given for the product/the preparation/the chemical mixture |
| | 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 |
| | 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. |
| 8.3 | Eye protection: | Eye protection is recommended. |
| 8.4 | Protective clothing: | Protective clothing is not necessary. |
| 8.5 | General protective and hygienic measures: | The usual precautionary measures are to be adhered to when handling biological material. |

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9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|-----|-------------|---------------------|
| 9.1 | Appearance: | Liquid |
| 9.2 | Colour: | Colourless |
| 9.3 | Odour: | Odourless |
| 9.4 | Solubility: | Miscible with water |
| 9.5 | Viscosity: | No data available |
| 9.6 | pH-value: | No data available |

10. STABILITY AND REACTIVITY

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|------|-----------------------------------|--|
| 10.1 | Hazardous reactions: | None known if handled correctly |
| 10.2 | Hazardous decomposition products: | None |
| 10.3 | Hazardous incompatibilities: | Metals and metallic compounds Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. |

11. TOXICOLOGICAL INFORMATION

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|------|------------------------------------|--|
| 11.1 | Acute toxicity: | Not known |
| 11.2 | Skin effects: | Not known |
| 11.3 | Eye effects: | Not known |
| 11.4 | Further toxicological information: | No cases of intoxication known so far. Raw material used for production of this diagnosticum is exclusively derived from healthy animals. Human Plasma used for production of control plasma is derived exclusively from donors who have been tested negative for antibodies against HIV, HCV and HBs antigen using approved test procedures. Nevertheless human plasma should be considered as potentially infectious and handled with care. |

12. ECOLOGICAL INFORMATION

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| 12.1 | Summary: | This product is readily miscible with water, rapidly degraded and biodegradable. |
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13. DISPOSAL CONSIDERATIONS

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| 13.1 | General information: | Disposal should be made in accordance with existing local disposal practices for biological material. |
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14. TRANSPORT INFORMATION

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| 14.1 | General information: | Not subject to transport regulations Fragile containers, handle with care |
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15. REGULATORY INFORMATION

15.1 Safety rules: Not regulated under the European Community Directive 93/21/EEC

16. OTHER INFORMATION

This Safety Data Sheet complies with the European Community Directive 93/112/EC amended 91/155/EC.

All information and instructions provided in this Safety Data Sheet are based on the current state of scientific and technical knowledge at the date indicated on this Safety Data Sheet. Technoclone GmbH shall not be held responsible for any defect in the product covered by this Safety Data Sheet, should the existence of such a defect not be detectable considering the current state of scientific and technical knowledge.

It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.