

MATERIAL SAFETY DATA SHEET
According to 1907/2006/EG

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

- 1.1 Product name / Code: TechnoLEIA D-Dimer Latex Kit, 150 T. REF 4847200
 TechnoLEIA D-Dimer Latex Kit, 50 T. REF 4847210
 TechnoLEIA D-Dimer Latex Reagent (2x12 ml) REF 4847220
 TechnoLEIA D-Dimer Reaction buffer (2x21 mL) REF 4847222
 TechnoLEIA D-Dimer High Control (5x1 mL) REF 4847230
 TechnoLEIA D-Dimer Low Control (5x1 mL) REF 4847232
 TechnoLEIA D-Dimer Calibrator, ~ 3000 ng/mL (2x1 mL) REF 4847234
 TechnoLEIA D-Dimer Calibrator, 0 ng/mL (2x1 mL) REF 4847236
- 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 Email: sales@technoclone.com
- 1.5 Emergency Phone: +43 1 86373 -10 (08:00 – 16:00 h)

2. HAZARDS IDENTIFICATION

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

3. COMPOSITION, INFORMATION ON INGREDIENTS

- 3.1 Articles contain:
- REF 4847200 and REF 4847210 contain:
- D-Dimer Calibrator (2 mL and 1 mL, resp.) human serum or plasma with 0,09 % sodium azide (CAS-Nr. 26628-22-B; T+; R: 28-32)
- D-Dimer Calibrator (2 mL and 1mL resp.) human serum or plasma with 0,09 % sodium azide (CAS-Nr. 26628-22-B; T+; R: 28-32)
- D-Dimer Latex-Reagenz (12 mL) murine immunoglobulins coupled to polystyrol-beads, with 0,05% Proclin 300
- D-Dimer buffer (21 mL) buffer with 0,05 % Proclin 300 (bactericidal)
- Diluent (8 mL) 0.9 % sodium chloride
- REF 4847230, REF 4847232, REF 4847234 and REF 4847236 contain: human serum or human plasma and 0.09 % sodium azide (CAS-No. 26628-22-B; T+; R: 28-32)
- REF 4847220 contains: murine immunoglobulins coupled to polystyrol-beads, with 0,05% Proclin 300

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REF 4847222 contains: buffer with 0,05 % Proclin 300 (bactericidal)

Sodium azide is dangerous substance according to EG-rule 88/379/EWG, but in this case there is no duty of declaration, as the used concentration is below the limit for formulations.

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

- | | | |
|-----|-----------------------|-----------------|
| 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

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

8. EXPOSURE CONTROLS, PERSONAL PROTECTION

- | | | |
|-----|---|---|
| 8.1 | General protective and hygienic measures: | The usual precautionary measures are to be adhered to when handling biological material. |
| 8.2 | Eye protection: | Eye protection is recommended. |
| 8.3 | 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. |

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- 8.4 Ventilation: No particular ventilation requirements.
8.5 Protective clothing: Protective clothing is not necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES

- 9.1 Appearance: Solid
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

- 10.1 Hazardous reactions: None known if handled correctly
10.2 Hazardous decomposition products: None

11. TOXICOLOGICAL INFORMATION

- 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.

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

- 12.1 Summary: This product is readily miscible with water, rapidly degraded and biodegradable.

13. DISPOSAL CONSIDERATIONS

- 13.1 General information: Disposal should be made in accordance with existing local disposal practices for biological material.

14. TRANSPORT INFORMATION

- 14.1 General information: Not subject to transport regulations
Fragile containers, handle with care.

15. REGULATORY INFORMATION

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

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16. OTHER INFORMATION

This Safety Data Sheet complies with the European Community Directive 1907/2006/EG.

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.