

MATERIAL SAFETY DATA SHEET
 According to 91/155 EEC

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

- 1.1. Product name / Code: TECHNOCHROM® Protein C (30 T) REF 5341013
- 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 Kit contents:
- | | |
|----------------------------------|------------------------|
| Substrat PCa-2, 3 x 1mL | chromogenic substrate |
| Protac, 3 x 1mL | extract of snake venom |
| Referenz Standards PC 1-3, 1x1mL | human plasma |
| PC Puffer, 60ml | Tris (6,1g/l) |
| | NaCl (12,7g/l) |
| | Albumin (0,1%) |
| | pH 8,4 |

3. HAZARDS IDENTIFICATION

Reference Standards PC:

Reagents and Control solutions containing human plasma* or human plasma derived material. They should be handled with care, observing the precautions recommended for bio-hazardous material.

* The human plasma is tested on antibodies against HIV Typ 1 and 2, Hepatitis C-virus, Treponema pallidum and Hepatitis B surface antigen. Hepatitis C was tested by PCR screen. The plasma was found to be negative. As complete absence of infectious agents can never be assured, all materials derived from human or bovine tissue or body fluids should always be handled with care, observing the precautions recommended for bio-hazardous material.

- 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

4. FIRST AID MEASURES

- 4.1. Skin Contact: Rinse with water, and wipe with skin disinfectant.
- 4.2. Eye Contact: Flush eyes immediately with water, if persistent irritation occurs, seek medical advice.
- 4.3. Inhalation: Seek medical advice immediately.
- 4.4. Ingestion: Wash out mouth with water, seek medical advice immediately.
- 4.5 Other first aid information: In case of injury and contamination with human plasma material it is strongly recommended to consult a physician.

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5. FIRE FIGHTING MEASURES

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| 5.1 | Extinguishing media: | No limitation |
| 5.2 | Flammable properties: | None |

6. ACCIDENTAL RELEASE MEASURES

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| 6.1 | Personal precautions: | Wear gloves, avoid substance contact |
| 6.2 | Cleanup procedures: | Take up dry, discard according to local practices |

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 AND 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. |

9. PHYSICAL AND CHEMICAL PROPERTIES

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| 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: | pH 7,4 – pH 8,3 |

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10. STABILITY AND REACTIVITY

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|-------|--------------------------|---------------------------------|
| 10.2. | Materials to avoid: | None known |
| 10.2. | Hazardous reactions: | None known if handled correctly |
| 10.3. | Hazardous decomposition: | Toxic gases |

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. Human Plasma used for production of reference standards is derived exclusively from donors who have been tested negative for antibodies against HIV 1/2, 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. | Ecotoxicity: | No information available |
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13. DISPOSAL CONSIDERATIONS

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| 13.1. | Product disposal: | Incineration according to local and national legislation. |
| 13.2. | Packaging disposal: | Dispose of in a manner in accordance with local and national regulations. |

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

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| 15.1. | Not classified as dangerous acc. to European Community Directive 93/21/EEC |
| 15.2. | National legislation: For further product information, we recommend consideration of the corresponding appropriate National Legislation. |

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.