

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

- 1.1 Productname: TECHNOCHROM® F VIII:C (40 T.) REF 5344101
 TECHNOCHROM® F VIII:C f. Ceveron® (80 T.) REF 5344103
- 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: Liquid solution. Presents little hazard if spilled or in fire.
- 2.2 Health Hazard: Powder regarded as having very low health hazard.

3. COMPOSITION, INFORMATION ON INGREDIENTS

3.1 Article contents:

REF 5344101:

- | | | |
|-------|---------------------------------|--|
| 2 Fl. | F Xa-Substrat 2 mL, lyophilized | chromogenes Substrat with α -NAPAP |
| 2 Fl. | Reagent A 2 mL, lyophilized | Phospholipid, Albumin |
| 2 Fl. | Reagent B 2 mL, lyophilized | FIXa β , FX, Ca ⁺⁺ , Albumine, Thrombine |
| 4 Fl. | Referenzstandard 1mL, lyoph. | human plasma |
| 2 Fl. | F VIII-Dilution buffer 50 mL | NaCl (5,85g/l), Imidazol (3,4 g/l), 0,2 % Albumine, pH 7,4 |
| 2 Fl. | F VIII-Reaction buffer 8 mL | Tris (6,06 g/l), Na ₂ -EDTA (3,03 g/l), NaCl (25 g/l), pH 8,3 |

REF 5344103:

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|-------|---|--|
| 2 Fl. | F Xa-Substrat 2 mL, lyophilized | chromogenes Substrat with α -NAPAP |
| 2 Fl. | Reagent A 2 mL, lyophilized | Phospholipid, Albumin |
| 2 Fl. | Reagent B 2 mL, lyophilized | FIXa β , FX, Ca ⁺⁺ , Albumine, Thrombine |
| 4 Fl. | Referenzstandard 1mL, lyoph. | Human plasma |
| 2 Fl. | F VIII-Dilution buffer
Ceveron 25 mL | NaCl (5,85g/l), Imidazol (3,4 g/l), 0,2 % Albumine, pH 7,4 |
| 2 Fl. | F VIII-Reaction buffer
Ceveron 8 mL | Tris (6,06 g/l), Na ₂ -EDTA (3,03 g/l), NaCl (25 g/l), pH 8,3 |

Hazard classification: None (HCl and NaF concentrations are below the declaration limit)

4. FIRST-AID MEASURES

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| 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. |
| 4.4 | Ingestion: | Wash mouth thoroughly with water and drink water. If substance has been swallowed, drink large quantities of water. |
| 4.5 | Inhalation: | Not applicable. |

5. FIRE-FIGHTING MEASURES

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| 5.1 | Extinguishing media: | Use extinguishing media appropriate for surrounding fire. |
| 5.2 | Flammable properties: | Not flammable. This product does not present any fire or explosion hazard. |

6. ACCIDENTAL RELEASE MEASURES

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|-----|-----------------------|---|
| 6.1 | Personal precautions: | Wear gloves, other protection is not necessary. |
| 6.2 | Cleanup procedures: | Immediately clean up any spillage of specimens with a 1:10 dilution of 5% sodium hypochlorite or with a similar solution. |

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 | 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.
8.5	Protective clothing:	Protective clothing is not necessary.
8.6	Ventilation:	No particular ventilation requirements.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1	Appearance:	Liquid, Powder
9.2	Color:	Colorless
9.3	Solubility:	Miscible with water.
9.4	Specific gravity:	Not applicable
9.5	pH-value:	6-8

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 controls and standards 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 and rated not toxic. Not known potential for bioaccumulation.
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13. DISPOSAL CONSIDERATION

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

14.1	General Information:	Transportation of the product is not regulated by ADR. Fragile containers, handle with care.
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15. REGULATORY INFORMATION

- 15.1 EU regulations: This product is not in accordance with danger Material regulation and the appropriate European Union guidelines marking requiring

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 a 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.