

MATERIAL SAFETY DATA SHEET
According to 1272/2008/EG

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

- 1.1 Product name / Code: TECHNOVIEW Rivaroxaban CAL (1 x 1 mL) REF 5090169
 TECHNOVIEW Rivaroxaban CAL Set (5 x 1 mL) REF 5090170
 TECHNOVIEW Rivaroxaban CAL Set High (5 x 1 mL) REF 5090171
 TECHNOVIEW Rivaroxaban Control Low (5 x 1 mL) REF 5090172
 TECHNOVIEW Rivaroxaban Control Medium (5 x 1 mL) REF 5090173
 TECHNOVIEW Rivaroxaban Control High (5 x 1 mL) REF 5090174
- 1.2. Recommended use: For research use only
- 1.3. Manufacturer: Technoclone GmbH
 Brunner Str. 67
 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: No hazardous product according to 1272/2008/EG

3. COMPOSITION, INFORMATION ON INGREDIENTS

TECHNOVIEW Rivaroxaban Calibrator 1x1 mL REF 5090169 contains:

mL	Reagent
1	Calibrator human plasma, freeze dried, supplemented with Rivaroxaban (CAL at 450 ng/mL)

TECHNOVIEW Rivaroxaban Calibrator Set 5x1 mL REF 5090170 contains:

mL	Reagent
1	Calibrator 1 human plasma, freeze dried, without any additive of Rivaroxaban (CAL 1 at 0 ng/mL)
1	Calibrator 2 human plasma, freeze dried, supplemented with Rivaroxaban (CAL 2 at ~ 15 ng/mL)
1	Calibrator 3 human plasma, freeze dried, supplemented with Rivaroxaban (CAL 3 at ~ 60 ng/mL)
1	Calibrator 4 human plasma, freeze dried, supplemented with Rivaroxaban (CAL 4 at ~ 100 ng/mL)
1	Calibrator 5 human plasma, freeze dried, supplemented with Rivaroxaban (CAL 5 at ~ 150 ng/mL)

TECHNOVIEW Rivaroxaban Calibrator Set High 5x1 mL REF 5090171 contains:

mL	Reagent
1	Calibrator 1 High human plasma, freeze dried, without any additive of Rivaroxaban (CAL 1 at 0 ng/mL)
1	Calibrator 2 High human plasma, freeze dried, supplemented with Rivaroxaban (CAL 2 at ~50 ng/mL)
1	Calibrator 3 High human plasma, freeze dried, supplemented with Rivaroxaban (CAL 3 at ~ 100 ng/mL)
1	Calibrator 4 High human plasma, freeze dried, supplemented with Rivaroxaban (CAL 4 ~ 200 ng/mL)
1	Calibrator 5 High human plasma, freeze dried, supplemented with Rivaroxaban (CAL 5 ~ 500 ng/mL)

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TECHNOVIEW Rivaroxaban Control Low 5x1 mL [REF] 5090172 containing 5 vials:

mL	Reagent
1	Control Low human plasma, freeze dried, supplemented with Rivaroxaban (CONT L at ~ 60 ng/mL)

TECHNOVIEW Rivaroxaban Control Medium 5x1 mL [REF] 5090173 containing 5 vials:

mL	Reagent
1	Control Medium human plasma, freeze dried, supplemented with Rivaroxaban (CONT M at ~ 150 ng/mL)

TECHNOVIEW Rivaroxaban Control High 5x1 mL [REF] 5090174 containing 5 vials:

mL	Reagent
1	Control High human plasma, freeze dried, supplemented with Rivaroxaban (CONT H at ~ 300 ng/mL)

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, 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

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

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Material of gloves:	glove material can be given for the product/the preparation/the chemical mixture 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.
8.4 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:	Oodourless
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.
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13. DISPOSAL CONSIDERATIONS

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

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

15. REGULATORY INFORMATION

15.1 Safety rules: Not subject to regulation under the European
community Directive 93/21/EEC about
transport and labeling dangerous substances.

16. OTHER INFORMATION

This Safety Data Sheet complies with the European Community Directive 1272/2008/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.