



SAFETY DATA SHEET

1. IDENTIFICATION OF THE PRODUCT AND THE COMPANY

- 1.1 Product name and code : **Pefakit® PiCT® Controls LMWH / 505-21**
- 1.2 Recommended use : Diagnostic Control Kit
- 1.3 Manufacturer : **PENTAPHARM LTD.**
 Engelgasse 109
 P.O. Box
 CH-4002 Basel / Switzerland
 Tel. ##41-61-706 48 48
 Fax. ##41-61-319 96 19
- 1.4 Emergency phone number ##41-61-706 48 48

2. COMPOSITION AND INFORMATION ON INGREDIENTS

- 2.1 Chemical characterisation : The kit consists of vials with lyophilized human plasma containing different amounts of Low Molecular Weight Heparin (LMWH) → see attachment
 None of the ingredients are classified as dangerous acc. to EU guidelines
- | <u>Hazardous ingredients</u> | <u>CAS No</u> | <u>Concentration</u> | <u>EU classification</u> |
|------------------------------|---------------|----------------------|--------------------------|
| Controls C1 / C2 | | | |
| Human Plasma (FNP) | --- | --- | --- |

3. HAZARD IDENTIFICATION

Pefakit® PiCT® Controls LMWH is not classified as dangerous acc. to EU guidelines.

The controls contain human derived blood plasma. This material always should be handled with care, observing the precautions recommended for bio-hazardous material *.

*The human plasma used is tested on antibodies against HIV Type 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.

Product Name : Pefakit® PiCT® Controls LMWH
 Issue Date : 17.03.2004
 Version/Ref : 1/rsc

Product Code : 505-21
 Replaces issue of : ---
 Page : 1 of 5

**4. FIRST AID MEASURES**

- | | | | |
|-----|-----------------------------|---|---|
| 4.1 | Skin Contact | : | Rinse with water. |
| 4.2 | Eye Contact | : | Rinse immediately with plenty of water possibly containing a mild detergent. Contact physician in case of irritation. |
| 4.3 | Inhalation | : | Contact physician in case of irritation. |
| 4.4 | Ingestion | : | Wash out mouth with water provided person is conscious. Seek medical advice immediately. |
| 4.5 | Other first aid information | : | None known |

5. FIRE FIGHTING MEASURES

- | | | | |
|-----|---------------------------------|---|--|
| 5.1 | Extinguishing media | : | Carbon dioxide, foam, dry powder, water |
| 5.2 | Unsuitable extinguishing media | : | None known |
| 5.3 | Unusual fire fighting hazards | : | Besides the normally occurring toxic combustion gases no special degradation products are known. |
| 5.4 | Special fire fighting procedure | : | None known |
| 5.5 | Other recommendations | : | No special precautions and measures necessary. |

6. ACCIDENTAL RELEASE MEASURES

- | | | | |
|-----|--|---|---|
| 6.1 | Personal precautions | : | Avoid eye contact. |
| 6.2 | Precautions to protect the environment | : | Keep away from drains and ground water. |
| 6.3 | Cleanup procedures | : | Dam large quantities and pump them into a container. For the remaining amount use inert absorbent material. Small |

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Page : 2 of 5