

## Fraunhofer

## Institut Toxikologie und Aerosolforschung

Pharmaforschung und Klinische Inhalation

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## Certificate

The biopersistence of the fibre type HPE5 was investigated after intratracheal installation within the following study:

Fraunhofer ITA study no.:

02G01019

Test substance:

HPE5

Sponsor:

PAROC Oy Ab, 21600 Pargas, FINLAND

Title:

Biopersistence of the Man-Made Vitreous Fibre HPE5 in Rats after

Intratracheal Instillation

This animal study was conducted in compliance with the Principles of Good Laboratory Practice (German Chemicals Law § 19a Appendix 1 pp. 1724-1732, July 25, 1994, amended on May 14, 2001). The protocol of the European Commission (ECB/TM 27 Rev. 7, 1998) with slight changes according study protocol was followed.

The treatment of rats was performed in May 2001 by intratracheal instillation of a total dose of 2 mg per rat. The fibre retention data of sacrifice dates up to 3 months after instillation were used for analysis.

Following halftimes were calculated by the method according to the protocol of the European Commission:

WHO fibre fraction (L>5 μm, D<3μm, L/D>3/1): 40 Days (95% Confidence limit 31 - 50 days)

According to Appendix V Nr.7.1 Abs. 1 Satz 2 Kriterium 2 of the German Gefahrstoffverordnung (Revision date 12. June 1998) the halftime for WHO fibres should be less or equal to 40 days.

Long fibres fraction (length > 20 µm, L/D>3/1): 28 days (95% confidence limit 22 - 35 days)

According to Guideline 67/548/EWG (revised by guideline 97/69/EG of the Commission dated 5. December. 1997) Note Q the classification as carcinogenic material is not applicable for mineral wools if the halftime for fibres longer than 20 µm is less than 40 days in the biopersistence test by

Intratrachea/ins/illation.

Prof. Dr. Uwe Hemrich

Managing director of Fraunhofer ITA

Dr. Bernd Bellmann

Study director