



Fraunhofer Institut
Toxikologie und
Experimentelle Medizin

Director
Prof. Dr. Uwe Heinrich

Nikolai-Fuchs-Straße 1
D-30625 Hannover

Phone +49 (0) 5 11/53 50-0
Fax +49 (0) 5 11/53 50-155

Dr. Bernd Bellmann
Phone: +49 (0) 511/53 50-452
Email: bellmann@item.fraunhofer.de

Certificate

Hannover,
February 18, 2004

The biopersistence of the fibre type Superwool 607 HT was investigated after intratracheal installation within the following study:

Fraunhofer ITEM study no.: 02G03012

Test substance: Superwool 607 HT

Sponsor: Thermal Ceramics Europe

This animal study was conducted in compliance with the Principles of Good Laboratory Practice (German Chemicals Law § 19a Appendix 1 pp. 2119-2129, June 28, 2002). 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 June 2003 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:

Long fibres fraction (length > 20 µm, L/D>3/1): **< 40 days**

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

WHO fibre fraction (L>5 µm, D<3µm, L/D>3/1): **< 65 days**

In Germany, Man-Made Vitreous (Silicate) Fibres for high temperature applications (classification temperature > 1000°C) with more than 18% of sodium, potassium, calcium, magnesium and barium oxides do not fall under the production and use ban regulation (Appendix IV n° 22 of the German Dangerous Substances Act and Appendix to § 1 section 23 of the German Chemical Ban Regulation) if their WHO fibres half-time is less or equal to 65 days.

Prof. Dr. Uwe Heinrich
Managing director of Fraunhofer ITEM

Dr. Bernd Bellmann
Study director