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Certificate

The biopersistence of the fibre type HPC1 was investigated after intratracheal installation within the following study:

Fraunhofer ITA study no.: 02G01013
Test substance: HPC1
Sponsor: PAROC Oy Ab, 21600 Pargas, FINLAND
Title: Biopersistence of the Man-Made Vitreous Fibre HPC1 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, 12001). 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 which are stipulated in the EC protocol were used for analysis.

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

WHO fibre fraction ($L > 5 \mu\text{m}$, $D < 3 \mu\text{m}$, $L/D > 3/1$): 40 Days (95% Confidence limit 35 - 45 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 $> 20 \mu\text{m}$, $L/D > 3/1$): 25 days (95% confidence limit 23 - 27 days)

According to Guideline 67/548/EWG (revised by guideline 97/69/EG of the Commission dated 5. December. 1997) Appendix Q the classification as carcinogenic material is not applicable for mineral wools if the halftime for fibres longer than $20 \mu\text{m}$ is less than 40 days in the biopersistence test by Intratracheal instillation.


Prof. Dr. Uwe Heinrich

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Dr. Bernd Bellmann

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