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"The Biopersistence of Man-Made Vitreous Fibre (MMVF) Alkaline Earth Silicate Fibre

Fraunhofer ITEM study no.: 02G14022

Test substance:

Certificate

FIBRANgeo

FIBRANgeo in Rats after Intratracheal Instillation" within the following study:

FIBRAN S.A.

6th klm. Thessaloniki - Oreokastro

GR-56410 THESSALONIKI

Title: The Biopersistence of Man-Made Vitreous Fibre (MMVFs) FIBRANgeo 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, August 28, 2013). 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 October, 2014 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

For the Man-Made Vitreous Fibre FIBRANgeo, the half-time of the WHO fibre fraction meets the limit of ≤ 40 days given in Annex II No. 5 of the German Gefahrstoffverordnung (Hazardous Substances Ordinance, 2013) which was set for using MMVF for heat and sound insulation in building construction in Germany.

Long fibres fraction (length $> 20 \mu m$):

< 40 days

According to Directive 67/548/EEC (revised by guideline 97/69/EG of the Commission dated December 5th, 1997) Note Q, the classification as a carcinogen need not apply if the halftime for fibres longer than 20 µm/is/les/s than 40 days in the biopersistence test by intratracheal instillation.

Dr. Dr. Uwe Heinrich

Executive director of Fraunhofer ITEM

Dr. Roman Halter

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