

Fraunhofer Institute for Toxicology
and Experimental Medicine ITEM

Institute directors
Prof. Dr. med. Norbert Krug (Executive Director)
Prof. Dr. Dr. med. Thomas Thum

Nikolai-Fuchs-Straße 1
30625 Hannover
Germany
Phone +49 (0) 5 11/53 50-0
Fax +49 (0) 5 11/53 50-155
Internet <http://www.item.fraunhofer.de>

Dr. Florian Schulz
Phone: +49 (0) 511/53 50-318
Email: florian.schulz@item.fraunhofer.de

Hannover, June 07, 2021

Confirmation

“The biopersistence of Man-Made Vitreous Fibre (MMVF) BSMW2.2 in Rats after Intratracheal Instillation” within the following study:

Fraunhofer ITEM study no.: 02G20014
Test substance: BSMW2.2
Sponsor: Volcalis Isolamentos Minerais
Zona Industrial de Bustos, Azurveira
3770-011 Bustos
Portugal

Title: The biopersistence of Man-Made Vitreous Fibre (MMVF) BSMW2.2 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 January, 2021 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 halftime was 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

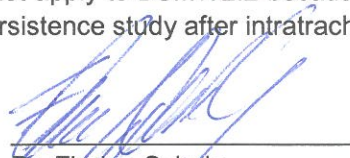
For the Man-Made Vitreous Fibre BSMW2.2 the half-time of the WHO fibre fraction meets the limit of ≤40 days given in Annex II No. 5 of the German Gefahrstoffverordnung (Hazardous Substances Ordinance) which was set for the use of MMVF for heat and sound insulation in building construction in Germany.

Long fibres fraction (length > 20 µm): <40 days

According to REGULATION (EC) No 1272/2008 (CLP regulation), annex VI, table 3.1, INDEX-no. 650-016-00-2, Note Q, the classification as carcinogen does not apply to BSMW2.2 because the half-time for fibres longer than 20 µm is below 40 days in this biopersistence study after intratracheal instillation.



Prof. Dr. med. Norbert Krug
Executive director of Fraunhofer ITEM



Dr. Florian Schulz
Study director