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## Confirmation

"The Biopersistence of Man-Made Vitreous Fibre (MMVF) CCEWOOL in Rats after Intratracheal Instillation" within the following study:

Fraunhofer ITEM study no.: 02G16014

Test substance: **CCEWOOL**

Zibo Double Egret Thermal Insulation Co.,Ltd.  
1007 Tower C International Trade Building  
No.105 Liuquan Rd, Zibo  
Shandong 255000, PR China

Title: The Biopersistence of Man-Made Vitreous Fibre (MMVFs) CCEWOOL 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 May, 2017 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 ( $L > 5 \mu\text{m}$ ,  $D < 3 \mu\text{m}$ ,  $L/D > 3/1$ ):  $\leq 40$  days**

For the Man-Made Vitreous Fibre CCEWOOL, the half-time of the WHO fibre fraction meets the limit of  $\leq 40$  days given in Annex II No. 5 of the German Gefahrstoffverordnung (Hazardous Substances Ordinance, 2010) which was set for using MMVF for heat and sound insulation in building construction in Germany.

**Long fibres fraction (length  $> 20 \mu\text{m}$ ):  $< 40$  days**

According to REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of December 16, 2008, § 1.1.3, Table 3.1, INDEX-no. 650-016-00-2 and Note Q, the classification as a carcinogen need not apply if the half-time for fibres longer than  $20 \mu\text{m}$  is less than 40 days in the biopersistence test by intratracheal instillation.

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