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EXPERT REPORT ON THE STUDY OF THE VIRUCIDAL EFFICACY OF STERILLIUM® AGAINST THE SARS-ASSOCIATED CORONA VIRUS (SARS-CoV)

Sample amount submitted:	500 mL minimum
Sample name:	VP 83/2B
Lot:	1225 227515
Composition:	100 g of solution contain: 45.0 g 2-Propanol 30.0 g 1-Propanol 0.2 g Mecetronium etilsulphate
Start of study:	15.01.2004
Study sponsor:	PD Dr. Günter Kampf BODE Chemie GmbH & C., Scientific Affairs Melanchthonstraße 27, 22525 Hamburg
Contact at BODE Chemie GmbH & Co.:	PD Dr. Günter Kampf
Internal Test Code:	Sterillium 28.7.04.doc
Person doing the experiments:	Ms. G. Bauer (MTA) (Medical Technician)
Investigators:	Prof. Dr. med. H. W. Doerr Prof. Dr. rer. med. H. F. Rabenau Institute for Medical Virology in the Centre for Hygiene of the University Hospitals Frankfurt/Main Paul Ehrlich Str. 40 60596 Frankfurt am Main

Table 4: Results of termination controls of Sterillium® in the suspension test (without addition of protein). Tests performed with single assays (titer of corresponding control titration: 7.68 ± 0.25 $\log_{10}$ $TCID_{50}$/mL – Titer of the "stock virus": 9.0 ± 0.31 $\log_{10}$ $TCID_{50}$/mL)

Test substance	Conc.	Virus titer ($\log_{10}$ $TCID_{50}$/mL ± 2s) (balance run)	($\log_{10}$) Reduction factor (incl. variance)
VP 83/2B	undil.	7.55 ± 0.44	0.13 ± 0.51

s = Standard deviation

Overall evaluation

The studies performed showed that under the specified test conditions SARS-CoV was inactivated quickly and efficiently by Sterillium®, i.e. that the infectious titer decreased below the limit of detection determined by the cytotoxicity of the disinfectant. Accordingly, a ($\log_{10}$) reduction factor ≥ 4.25 ± 0.47 was determined for Sterillium® undiluted in 30 seconds regardless of the chosen test conditions (active concentration, contact time, clean conditions [added protein increase by a factor], with 10 % (FC) serum load, and under dirty conditions).

The parallel controls confirmed the validity of the test assays. For instance the control titrations showed that the titer of the 1:10 dilution was lower than that of the "stock virus" by approx. 1 $\log_{10}$ unit, as would be expected, that the termination controls had about the same values as the control titrations ($\log_{10}$ difference < 0.5), meaning there was no significant "after-effect" of the disinfectant, and that the standard deviations of all titrations were always ≤ 0.5 $\log_{10}$. Due to the high cytotoxicity (up to 1:10,000) only a ($\log_{10}$) reduction factor of ≥ 3.0 ± 0 could be determined for the formalin control.

A virucidal effect against other viruses cannot be derived from this study.

Frankfurt/Main, 28.07.2004

Prof. Dr. rer. med. H. F. Rabenau

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