STUDY REPORT

Study Title
ASTM E1052
Standard Test Method to Assess the Activity of Microbicides against Viruses in Suspension

Product Identity
FemiClear for Genital Herpes Symptoms (Multisymptom)
Lot #052820

Test Microorganism
Herpes Simplex Virus 1, Strain HF, ATCC VR-260
Herpes Simplex Virus 2, Strain G, ATCC VR-734

Study Identification Number
NG15494

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Study Completion Date
11JUN2020

Testing Facility
Microchem Laboratory
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RESULTS

Table 1: FemiClear for Genital Herpes Symptoms (Multisymptom) Lot #052820 Test Results – Herpes Simplex Virus 1

Dilution	Test Results Replicate #1	Test Results Replicate #2	Test Results Replicate #3
Cell Control	0 0 0 0	0 0 0 0	0 0 0 0
10^{-2}	+ 0 0 0	0 0 + 0	+ 0 0 0
10^{-3}	0 0 0 0	0 0 0 0	0 0 0 0
10^{-4}	0 0 0 0	0 0 0 0	0 0 0 0
10^{-5}	0 0 0 0	0 0 0 0	0 0 0 0
10^{-6}	0 0 0 0	0 0 0 0	0 0 0 0
10^{-7}	0 0 0 0	0 0 0 0	0 0 0 0
10^{-8}	0 0 0 0	0 0 0 0	0 0 0 0
$TCID_{50}$ per 0.1 ml	1.75 Log_{10}	1.75 Log_{10}	1.75 Log_{10}
Average $TCID_{50}$ per 0.1 ml	1.75 Log_{10}		
Log Reduction Per Carrier	3.92 Log_{10}		
Percent Reduction	99.98%		

Key: + = Virus recovered; 0 = Virus not recovered and/or no cytotoxicity observed; T = Cytotoxicity observed

Table 2: FemiClear for Genital Herpes Symptoms (Multisymptom) Lot #052820 Test Results – Herpes Simplex Virus 2

Dilution	Test Results Replicate #1	Test Results Replicate #2	Test Results Replicate #3
Cell Control	0 0 0 0	0 0 0 0	0 0 0 0
10^{-2}	0 0 0 0	+ 0 0 0	0 0 + 0
10^{-3}	0 0 0 0	0 0 0 0	0 0 0 0
10^{-4}	0 0 0 0	0 0 0 0	0 0 0 0
10^{-5}	0 0 0 0	0 0 0 0	0 0 0 0
10^{-6}	0 0 0 0	0 0 0 0	0 0 0 0
10^{-7}	0 0 0 0	0 0 0 0	0 0 0 0
$TCID_{50}$ per 0.1 ml	$\leq$1.50 Log_{10}	1.75 Log_{10}	1.75 Log_{10}
Average $TCID_{50}$ per 0.1 ml	1.67 Log_{10}		
Log Reduction Per Carrier	4.00 Log_{10}		
Percent Reduction	99.990%		

Key: + = Virus recovered; 0 = Virus not recovered and/or no cytotoxicity observed; T = Cytotoxicity observed

STUDY CONCLUSION

The purpose of the study was to determine the virucidal efficacy of FemiClear for Genital Herpes Symptoms (Multisymptom) Lot: 052820 against Herpes Simplex Virus 1 (HSV1), Strain HF, and Herpes Simplex Virus 2 (HSV2), Strain G at a contact time of 4 hours and an exposure temperature of room temperature (23.6-24.5°C and 42-43% Relative Humidity (RH))

The HSV1 Virus Recovery Control demonstrated an average viral titer of 5.67 $\log_{10}$ $TCID_{50}$ per 0.1 ml.
The HSV2 Virus Recovery Control demonstrated an average viral titer of 5.67 $\log_{10}$ $TCID_{50}$ per 0.1 ml.

Taking the cytotoxicity and neutralization control results into consideration, the evaluated test substance demonstrated an average 3.92 Log10 reduction (99.98%) in the viral titer of HSV1 for the lot assayed.
Taking the cytotoxicity and neutralization control results into consideration, the evaluated test substance demonstrated an average 4.00 Log10 reduction (99.990%) in the viral titer of HSV2 Virus for the lot assayed.

No test substance cytotoxicity was detected for the lot of test substance assayed ($\leq$1.50 Log_{10}) for both HSV1 and HSV2.

The Test Substance Neutralization Control demonstrated that the test substance was neutralized at $\leq$1.50 Log_{10} for the lot assayed for both HSV1 and HSV2.

The test substance will be disposed of 30 days after the completion of this study, unless otherwise requested by the Study Sponsor.

The results of this study apply to the tested substances(s) only. Extrapolation of findings to related materials is the responsibility of the Sponsor.