



EXECUTIVE SUMMARY

This study was designed to evaluate the antiviral properties of one test product when challenged with Influenza A/Swine/Iowa/15/30 (H1N1) (ATCC #VR-333) using a Virucidal Suspension Test (In-Vitro Time-Kill Method). The percent and log₁₀ reductions from the initial population of the viral strain were determined following exposure to the test product for 30 seconds, 1 minute and 2 minutes. The test product was evaluated at a 90% (v/v) concentration.

The test product, GentleCare Non Alcohol Skin Sanitizer formulation reduced the infectivity of Influenza A H1N1 virus strain A/Swine/Iowa/15/30 (ATCC #VR-333) by 4.50 log₁₀ (>99.99% reduction) following 30-second, 1-minute and 2-minute exposures.

All testing was performed in accordance with Good Laboratory Practices as specified in 21 CFR Part 58.

RESULTS – TABLE 1:

Table 1 presents the Cytotoxicity Control, the Neutralization Control, and the Cell Control data as well as the Virus Control ineffectivity (TCID₅₀), and the log₁₀ and percent reductions observed following exposures of Influenza A/Swine/Iowa/15/30 (ATCC #VR-333) to the test product.

TABLE 1

Test Product: GentleCare Non-alcohol Hand & Skin Sanitizer formulation
 Virus/Strain: Swine Influenza A H1N1/A/Swine/Iowa/15/30 (ATCC #VR-333)

Dilution (- Log ₁₀)	Virus Control	Test exposure time			Cytotoxicity Control	Neutralization Control	Cell Control (negative control)
		30 seconds	60 seconds	2 minutes			
							0000
-3	++++	0000	0000	0000	0000	++++	
-4	++++	0000	0000	0000	0000	++++	
-5	++++	0000	0000	0000	NT	++++	
-6	++++	0000	0000	0000	NT	++++	
-7	0+0+	0000	0000	0000	NT	000+	
TCID ₅₀	7.00 Log ₁₀	2.50 Log ₁₀	2.50 Log ₁₀	2.50 Log ₁₀	N/A	6.75 Log ₁₀	
Log₁₀ Reduction	N/A	4.50 Log₁₀	4.50 Log₁₀	4.50 Log₁₀	N/A		
Percent Reduction	N/A	>99.99%	>99.99%	>99.99%			

+ CPE (cytopathic/cytotoxic effect) present
 0 CPE (cytopathic/cytotoxic effect) not detected
 NT Not tested
 N/A Not applicable

- Questions regarding validity of this information should be directed to GentleCare by calling (800)262-8670.
- The date presented does not constitute any product labeling claims and is for informational purpose only.