NON-GLP STUDY REPORT

STUDY TITLE

Ex-Vivo Antibacterial Evaluation of Topical Products Using a Vitro-Skin® Model

TEST ORGANISM: Staphylococcus aureus (ATCC 6538)

PRODUCT IDENTITY: C-220 Copper Sheet 0.050" Thickness

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STUDY COMPLETION DATE
October 27, 2017

PERFORMING LABORATORY
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STUDY REPORT

GENERAL STUDY INFORMATION

Study Title:	Ex-Vivo Antibacterial Evaluation of Topical Products Using a Vitro-Skin® Model
Project Number:	A24209
Protocol Number:	BOV002100917. EXVO

TEST SUBSTANCE IDENTITY

Test Substance Name:	C-220 Copper Sheet 0.050" Thickness

STUDY DATES

Date Sample Received:	October 11, 2017
Study Initiation Date:	October 18, 2017
Experimental Start Date:	October 24, 2017
Experimental End Date:	October 26, 2017
Study Completion Date:	October 27, 2017

Test Organism	Designation #	Growth Medium	Incubation Parameter
Staphylococcus aureus	6538	Tryptic Soy Agar with 5% Sheep Blood (BAP)	35-37° C, aerobic

The test organisms used in this study were obtained from the American Type Culture Collection (ATCC), Manassas, VA.

Test Substance Preparation:	Ready to Use (RTU) copper bar
Test Exposure Time:	1 minute (*rubbing the bar on the inoculated and dried Vitro-Skin®*)
Exposure Temperature:	Ambient (*20° C with 28% relative humidity*)
Number of Carriers Tested:	2 test and 2 control carriers
Organic Soil Load:	None
Neutralizer:	Letheen broth (*20 m l*)
Agar Plate Medium:	Tryptic Soy Agar with 5% Sheep Blood

EXPERIMENTAL DESIGN

A film of the test organism dried onto a 1" x 1" demarcated area of 1.5" x 1.5" rehydrated Vitro-Skin® carriers was treated by rubbing the copper bar test material in circles, with light to medium pressure, over the inoculated surface for the exposure time. Following exposure, each carrier was neutralized and assayed for survivors. Appropriate culture purity, neutralizer sterility, carrier sterility and population controls were performed. Percent and Log10 reductions were determined for the test based on the test population control results.
Per Sponsor's direction, the study was not required to be conducted under U.S. EPA 40 CFR Part 160 or U.S. FDA 21 CFR Part 58.

STUDY RESULTS

TABLE 1: CONTROL RESULTS
The following results from controls confirmed study validity:

Type of Control		Results
Purity	Staphylococcus aureus (ATCC 6538)	Pure
Neutralizer Sterility Control		No Growth
Carrier Sterility Control		No Growth

TABLE 2: POPULATION CONTROL RESULTS

Test Organism	Carrier #	CFU/Carrier	Log10 of CFU/Carrier	Average Log10	Geometric Mean (CFU/Carrier)
Staphylococcus aureus (ATCC 6538)	1	2.36×10^5	5.37	5.38	2.40×10^5
	2	2.44×10^5	5.39		

CFU = Colony Forming Unit

TABLE 3: TEST RESULTS AGAINST *Staphylococcus aureus* (ATCC 6538)

Dilution (Volume Plated)	Survivors	
	Replicate #1	Replicate #2
10° (1.00 ml)	T,T	T,T
10° (0.100 ml)	86,83	53,63
10^{-1} (0.100 ml)	12,12	7,5
10^{-2}(0.100 ml)	1,0	2,2
CFU/Carrier	1.7×10^4	1.2×10^4
Log10 CFU/Carrier	4.23	4.08
Average Log10	4.16	
Geometric Mean	1.45×10^4	
Log10 Reduction =	1.22	
Percent Reduction=	94.0%	

CFU = Colony Forming Units
T = Too Numerous to Count (>300)

CONTROL RESULTS

The control results for culture purity, neutralizer sterility and carrier sterility were all acceptable.

ANALYSIS

C-220 Copper Sheet 0.050" Thickness, ready to use, demonstrated a 94.0% (1.22 10910) reduction of *Staphylococcus aureus* (ATCC 6538) following a 1 minute rubbing exposure time at ambient temperature (20° C).