Technical Summary

8 hr. 2-1 Hand Sanitizer

(346) 293-

A. Introduction:

Antiseptic Hand Rub or Hand Sanitizer: 8hr. 2-1 Foam Hand Sanitizer with Aloe Vera like the gel product is a unique antimicrobial technology that kills on contact, and also has persistent activity designed to help prevent infections that are associated with hospitals, clinics and nursing homes. It is useful in other industry segments where hand transmission of infectious diseases can occur. This includes; food services, money handling, sports and fitness centers, public safety first responders, schools, the transport industry and public amusement attractions. The core of the technology lies in a highly effective proprietary blend of quaternary amines in revolutionary film forming formulation that is highly effective in healthcare environments with specific issues of antibiotic resistant pathogens and frequent glove use is involved. The antimicrobial agents are compliant with FDA regulations and CDC guidelines for non-alcohol hand sanitizer products. **Safe, water-based alcohol-free, it is faster acting and longer lasting than traditional hand sanitizers. As a proprietary antimicrobial blend it is unsurpassed in its ability to kill germs using a new technology with a unique chemo-electro-mechanical mode of action. "ESC" technology described above is available as a foam, gel or hospital grade disinfectant spray.**

B. Efficacy Testing:

1. Rapid Broad Spectrum Activity

8hr. 2-1 Hand sanitizer foam product offers rapid, broad-spectrum kill and persistence. 8hr. 2-1 hand sanitizer foam & Gel products are made to the same formula of active compounds but differ only slightly accounting for the foam vs. gel forms. Within 15 seconds, the product killed more than 99.99% FDA-specified organisms **(See Table 1)**. Shown in this table is time kill test data (Quantitative Suspension Test) as specified in FDA 1994 for the 25 Microbes listed in the OTC Topical Antimicrobial Drug Monograph as well as additional strains and species of public health significance. Test methods include ASTM 2315, European EN 1276 and EN 1040 for Bacteria as well as EN 1275 for Fungi.

Methods: The products were evaluated according to standard Time-Kill protocol and against 45 different microorganisms, listed in the section below, 25 of which are specified in the FDA Tentative Final Monograph. Each test product was evaluated at a 99% concentration, and the percent (%) and log reductions were determined following exposure times of 15, 30, and 60 seconds. All agar-plating was performed in duplicate. A combination of clinical isolates and lab strains were used in the testing. Neutralization studies of each test product were performed to ensure the neutralizing solution employed (Butterfield's Phosphate Buffer solution with product neutralizers) was effective and non-toxic to each of the representative challenge species.

Rapid Broad Spectrum Antimicrobial Activity:

Table 1: Time-Kill Testing Results: 8hr. 2-1 hand sanitizer Foam with Aloe Vera Meets or Exceeds Efficacy Standards in Applicable Regulations

Micro-organism	Time (Seconds)	Log_{10} (%) Reductions
1.Acinetobacter baumannii (ATCC# 25285) [5]	15 Sec	>6.02 (99.9999%)
	30 Sec	>6.02 (99.9999%)
	60 Sec	>6.02 (99.9999%)
2.Bacteroides fragilis (ATCC# 25285) [5]	15 Sec	6.03 (99.9999%)
	30 Sec	6.03 (99.9999%)
	60 Sec	6.03 (99.9999%)
3.Haemophilus influenzae (ATCC #33930) [5]	15 Sec	>6.12 (99.9999%)
	30 Sec	>6.12 (99.9999%)
	60 Sec	>6.12 (99.9999%)
4. Enterobacter aerogenes (ATCC #13048) [5]	15 Sec	>6.02 (99.9999%)
	30 Sec	>6.02 (99.9999%)
	60 Sec	>6.02 (99.9999%)
5. Escherichia coli (ATCC #11229) [3, 5]	15 Sec	>6.01 (99.9999%)
	30 Sec	>6.01 (99.9999%)
	60 Sec	>6.01 (99.9999%)
6. Escherichia coli (ATCC #10536) [5]	15 Sec	>6.78 (99.9999%)
	30 Sec	>6.78 (99.9999%)
	60 Sec	>6.78 (99.9999%)
7. Escherichia coli (ATCC #25922) [4]	30 Sec	>5.0 (99.999%)
	60 Sec	>5.0 (99.999%)
8. Escherichia coli (O157:H7) [1]	15 Sec	>4.0 (99.99%)
9. Klebsiella oxytoca (ATCC #13182) [5]	15 Sec	>6.03 (99.9999%)
	30 Sec	>6.03 (99.9999%)
	60 Sec	>6.03 (99.9999%)
10. Klebsiella pneumoniae (ATCC #51504) [4]	15 Sec	>5.00 (99.999%)
	30 Sec	>5.00 (99.999%)
	60 Sec	>5.00 (99.999%)
11. Klebsiella pneumoniae (ATCC #4352) [5]	15 Sec	>6.04 (99.9999%)
	30 Sec	>6.04 (99.9999%)
	60 Sec	>6.04 (99.9999%)

Micro-organism	Time (Seconds)	Log_{10} (%) Reductions
12. Pseudomonas aeruginosa) (ATCC #9027) [7]	15 Sec	>6.78 (99.9999%)
	30 Sec	>6.78 (99.9999%)
	60 Sec	>6.78 (99.9999%)
13. Pseudomonas aeruginosa (ATCC #27853) [5]	15 Sec	>6.23 (99.9999%)
	30 Sec	>6.23 (99.9999%)
	60 Sec	>6.23 (99.9999%)
14. Pseudomonas aeruginosa (ATCC #27853) [5]	15 Sec	>5.00 (99.999%)
	30 Sec	>5.00 (99.999%)
	60 Sec	>5.00 (99.999%)
15. Pseudomonas aeruginosa ((ATCC #15442) [2, 3]	15 Sec	>5.00 (99.999%)
	30 Sec	>5.00 (99.999%)
	60 Sec	>5.00 (99.999%)
16. Proteus mirabilis (ATCC #7002) [5]	15 Sec	>6.12 (99.9999%)
	30 Sec	>6.12 (99.9999%)
	60 Sec	>6.12 (99.9999%)
17. Serratia marcescens (ATCC #14756) [5]	15 Sec	>6.12 (99.9999%)
	30 Sec	>6.12 (99.9999%)
	60 Sec	>6.12 (99.9999%)
18. Salmonella enterica (ATCC #10398) [3]	60 Sec	>5.0 (99.999%)
19. Salmonella typhimurium [1]	15 Sec	>4.0 (99.99%)
20. Staphylococcus aureus (ATCC #6538) [3, 7]	15 Sec	>6.76 (99.9999%)
	30 Sec	>6.76 (99.9999%)
	60 Sec	>6.76 (99.9999%)
21. Staphylococcus aureus (ATCC #29213) [4, 5]	15 Sec	>6.11 (99.9999%)
	30 Sec	>6.11 (99.9999%)
	60 Sec	>6.11 (99.9999%)
22. Staphylococcus epidermidis (ATCC #12228) [5]	15 Sec	>6.22 (99.9999%)
	30 Sec	>6.22 (99.9999%)
	60 Sec	>6.22 (99.9999%)
23. Staphylococcus hominis (ATCC #27844) [5]	15 Sec	>6.21 (99.9999%)
	30 Sec	>6.21 (99.9999%)
	60 Sec	>6.21 (99.9999%)
24. Staphylococcus haemolyticus (ATCC #43253) [4]	15 Sec	>5.00 (99.999%)
	30 Sec	>5.00 (99.999%)
	60 Sec	>5.00 (99.999%)
25. Staphylococcus haemolyticus (ATCC #29970) [5]	15 Sec	>6.12 (99.9999%)
	30 Sec	>6.12 (99.9999%)
	60 Sec	>6.12 (99.9999%)

Micro-organism	Time (Seconds)	Log_{10} (%) Reductions
26. Staphylococcus saprophyticus (ATCC #35552) [5]	15 Sec	>6.11 (99.9999%)
	30 Sec	>6.11 (99.9999%)
	60 Sec	>6.11 (99.9999%)
27. Micrococcus luteus (ATCC #7468) [5]	15 Sec	>6.22 (99.9999%)
	30 Sec	>6.22 (99.9999%)
	60 Sec	>6.22 (99.9999%)
28. Streptococcus pyogenes (ATCC #19615) [3, 7]	15 Sec	>6.03 (99.9999%)
	30 Sec	>6.03 (99.9999%)
	60 Sec	>6.03 (99.9999%)
29. Enterococcus faecalis (ATCC# 29212) [5]	15 Sec	>6.01 (99.9999%)
	30 Sec	>6.01 (99.9999%)
	60 Sec	>6.01 (99.9999%)
30. Enterococcus hirae (ATCC #6057) [7]	15 Sec	>6.76 (99.9999%)
	30 Sec	>6.76 (99.9999%)
	60 Sec	>6.76 (99.9999%)
31. Streptococcus pneumoniae (ATCC #6303) [5]	15 Sec	>6.06 (99.9999%)
	30 Sec	>6.06 (99.9999%)
	60 Sec	>6.06 (99.9999%)
32. Candida albicans (ATCC# 10231) [6]	15 Sec	>5.12 (99.999%)
	30 Sec	>5.12 (99.999%)
	60 Sec	>5.12 (99.999%)
33. Aspergillus niger (ATCC# 16404) [6]	15 Sec	>5.44 (99.9995%)
	30 Sec	>5.44 (99.9995%)
	60 Sec	>5.44 (99.9995%)

2. Burkholderia Cepacia_Assessment Of Time Kil Activity Using ASTM E2315-16

Burkholderia cepacia is a bacterial species that has been found by the FDA to contaminate health care products during the manufacturing process. Burkholderia cepacia showed growth to 57,000 cfu in 2.0% Chlorhexidine gluconate Hand Sanitizer wipes. Testing Disinfect & Shield Hand Sanitizer Foam in a Time Kill Study using ASTM E 2315 showed a steady decrease in activity over time negating any threat of growth.

Results: B. cepacia ATCC#25416								
Lab#	Sample ID	Lot#	Exposure Time	Replicate	Cfu/ml	Average (cfu/ml)	% Reduction	Log Reduction Sample
-	Control	-	0 min	1	$1.10x10^8$	$1.06x10^8$	-	-
				2	$1.02x10^8$			
129332	Hand Sanitizer	38L17 Ex 09/19 Jan 22.2018	2 min	1	$6.2x10^6$	$6.4x10^6$	93.96%	1.2192
				2	$6.6x10^6$			
			5 min	1	$2.8x10^6$	$3.4x10^6$	96.79%	1.4939
				2	$4.0x10^6$			
			10 min	1	$4.4x10^4$	$4.8x10^4$	99.95%	3.3441
				2	$5.2x10^4$			

CONCLUSION: Sample ID: Hand Sanitizer Lot# 38L17 Ex 09/19 Jan 22, 2018 showed 93.96% anti-microbial activity against B. cepacia at 2 min, 96.79% at 5 min and 99.95% at 10 min of contact time against Burkholderia cepacia ATCC# 25416.

3. Healthcare Hand Rub Efficacy Testing (EN 1500)

EN 1500 testing is used as the European standard method for qualifying hand rubs that are to be used in healthcare settings. 20 test subjects are used in each test group and performance of test product is compared to a standard reference alcohol rub. In this case Propan-2-ol. 60% (v/v) as per test method was used. Hands were contaminated with 2 x 10_8 of E scherichia coli strain # K13 NCTC 10538. For both reference alcohol and test product, 6 mL applied -3.0mL for 30 seconds, a further 3.0mL for another 30 seconds totaling 60 seconds rubbing time and hands are sampled and compared to control inoculum levels. To be EN 1500 compliant test product must surpass reference alcohol by a convincing margin or via statistical analysis of results. Data from this testing is presented in **Table 2** below.

Table 2: 8hr. 2-1 Hand Sanitizer with Aloe Vera antimicrobial activity on Hands using BS EN 1500:2013 Test Method (EN 1500 Compliant)

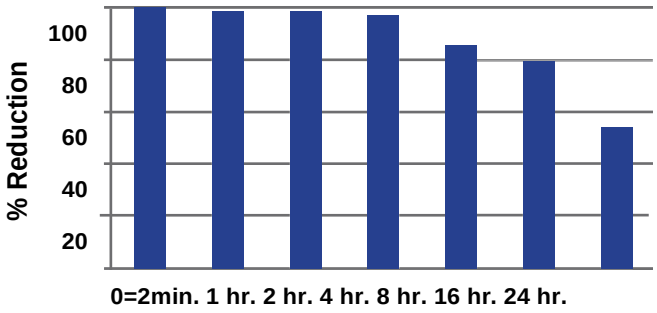
Healthcare Hand Rub Testing[8]	Reference Alcohol	8hr. 2-1 Foam Hand Sanitizer w/ Aloe
Pre Log_{10} Inoculum Values (SD)	6.43 (0.69)	6.62 (0.73)
Post Treatment Log_{10} Values (SD)	2.53 (0.35)	2.38 (0.23)
Log_{10} Reduction Values	3.90	4.23

4. Long Term Sustained Activity when Needed

A. 8hr. 2-1 Hand Sanitizer with Aloe Vera: Sustained kill against Gram-Positive & Gram-negative bacteria when not removed from the skin.

As shown in **Figure 1** (with data in **Table 3B**), in an ex-vivo test using a pigskin model (using ASTME2897-12 & ASTM WK36911), 8hr. 2-1 Hand Sanitizer with Aloe Vera was applied to the skin. After the specified amount of time, the skin samples were challenged with S. aureus (ATCC #12600)[9]. From the data presented in **Table 3A**, ESC AV killed more than 98% of both the gram-positive and gram-negative antibiotic resistant bacteria introduced at 1 hour after application, and around 90% at 4 hours. Activity against all three antibiotic resistant strains MRSA, VRE and CRE **(Figure 2)** is consistent with testing on S. aureus that showed continued killing even after 24 hours after application. 8hr. 2-1 Hand Sanitizer with Aloe Vera testing was conducted at an independent laboratory, Eurofins Microbiology Laboratory in Lancaster, PA. It should be noted that the CRE strain used in this testing, Klebsiella pneumoniae[10] is also known as Klebsiella pneumoniae Carbapenemase (KPC).

Figure 1. 8hr 2-1 Hand Sanitizer Sustained Kill Shown up to 24 Hours[9]



Time Period Post Skin Treatment w/8hr. 2-1 Hand Sanitizer

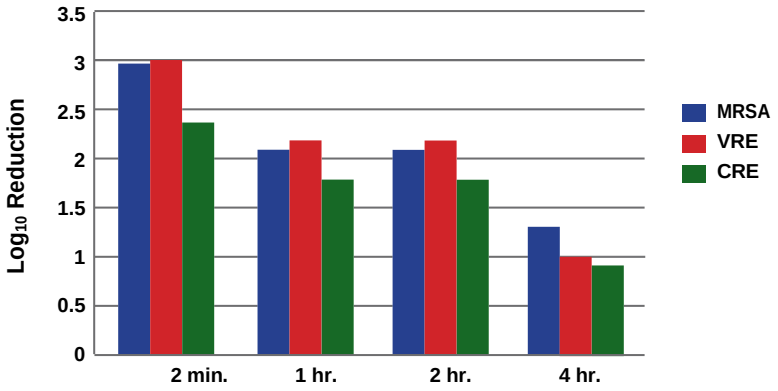
B. Sustained Activity of 8hr. 2-1 Hand Sanitizer with Aloe Vera (AV) against Antibiotic Resistant Strains

Table 3A. Persistent Activity as an Adjunct to Frequent Hand Hygiene

34. Methicillin-Resistant S. aureus (MRSA; ATCC #33592) [10]	2 min	>99.9	(>3.0)
	1 hr	99.2	(2.1)
	2 hrs	97.4	(1.6)
	4 hrs	95.2	(1.3)
35. Vancomycin-Resistant Enterococcus (VRE; ATCC #51575) [10]	2 min	>99.9	(>3.0)
	1 hr	99.4	(2.2)
	2 hrs	98.1	(1.7)
	4 hrs	90.9	(1.0)
36. Carbapenem-Resistant Enterobacteriaceae (CRE / KPC); Klebsiella pneumoniae ATCC #BAA-1705) [10]	2 min	99.6	(2.4)
	1 hr	98.3	(1.8)
	2 hrs	93.9	(1.2)
	4 hrs	87.9	(0.9)

Table 3B. Persistent Activity Against S. aureus for 24 hours			
37. Staphylococcus aureus (ATCC #12600)[9] Data presented in Figure 1 above	2 min	>99.9	(3.2)
	1 hr	99.0	(2.0)
	2 hrs	98.3	(1.8)
	4 hrs	96.9	(1.5)
	8 hrs	84.9	(0.8)
	16 hrs	79.5	(0.7)
	24 hrs	54.1	(0.3)

Figure 2. 8hr. 2-1 Hand Sanitizer Sustained Kill Activity Against Antibiotic Resistant Strains: MRSA, VRE & CRE (KPC)



Time Period Post Skin Treatment With Disinfect & Shield AV

C. Sustained Activity of the 8hr 2-1 Hand Sanitizer on Hands and when Gloves are Worn (ASTM E1115) 11

To assess persistent activity on hands when used in clinical settings incorporating periods of glove use, ASTM Test method E1115-11 was used with 20 human volunteers. This method is typically used to evaluate surgical hand scrub formulations. When tested in accordance with ASTM E1115-11, 8hr. 2-1 Hand Sanitizer Foam with Aloe Vera possesses Immediate Activity and Persistent Activity. Immediate activity results demonstrated that bacterial reduction of hand flora after using the product was greater than a 5.8 Log_{10} reduction factor. Persistent activity suppressing regrowth of skin bacteria was shown to be in the same order of magnitude (5.8 Log_{10}) at 3 hours and 6 hours post treatment. Even at 12 hours after product application with hands kept occluded within surgical gloves, only a minimal lowering of antibacterial activity (suppression of growth) was observed. Persistent activity at 3 and 6 hours was > 99.999% (>5 Log_{10}) while geometric mean persistent antibacterial reduction value at 12 hours was seen to be 99.99% (4.0 Log_{10}). This is consistent with data obtained in the ex-vivo studies demonstrating 24-hour activity and persistence against antibiotic resistant strains.

1. Challenge Testing as Further Proof of Wide Spectrum Activity

Challenge testing of products regulated by FDA as over-the-counter antimicrobial drugs is the ultimate test of effectiveness of individual formulations as instead of just killing germs on hands or in suspension tests, multiple high count inoculation and long term incubation is used. Thus both biocidal (bactericidal and fungicidal) activity and persistence effectiveness is determined.

Table 4 provides results of testing in accordance with both ASTM E640-0 6 (Reapproved 2012), USP 35-NF30 51, and EP7.0-5.1.3[13,14]. As a variation of the ASTM E640 testing a wide range of microbial strains and types were selected. As shown in Table 4A & 4B, 8hr. 2-1 Hand Sanitizer with Aloe Vera possesses bactericidal and fungicidal reduction of microbial species in double challenge testing as well as testing to normal US and EU standards, thus satisfies all applicable test standards including ASTM E640-06 (2012)[12].

Table 4A. Efficacy Testing as per ASTM E640-12 a Double 28 day Challenge 12

			2nd Inoculum Counts (28 day duration)
5. Escherichia coli	11229	2×106	3×106
11. Klebsiella pneumoniae	4352	2×106	5×106
15. Pseudomonas aeruginosa	15442	2×106	5×106
20. Staphylococcus aureus	6538	2×106	3×106
32. Candida albicans	10231	2×106	5×106
38. Burkholderia cepacia capacia	25416	2×106	6×106
39. Bacillus subtilis	6051	2×106	5×106
40. Aspergillus niger	1015	2×106	5×106
41. Penicillium luteum	10466	2×106	1×106

Table 4B. Antimicrobial Effectiveness Testing as per USP35-NF30 51 & EP7.0

			EP7.0-5.1.3
42. Escherichia coli	8739	X	
12. Pseudomonas aeruginosa	9027	X	X
20. Staphylococcus aureus	6538	X	X
32. Candida albicans	10231	X	X
40. Aspergillus niger	16404	X	X

2. Antiviral Activity

A. Norovirus Ex-Vivo Testing of 8hr. 2-1 Hand Sanitizer

Norovirus is the leading cause of gastroenteritis, causing diarrhea, vomiting, and severe abdominal pain. Alcohol sanitizers have been shown to be somewhat ineffective against the Norovirus[25]. In an ex-vivo test using porcine skin (using ASTM E2897-12 & ASTM WK3 6911) against a Norovirus surrogate, murine norovirus[1] (MNV- 1), 8 hr. 2-1 hand sanitizer was demonstrated to reduce the Norovirus by 2.0 $\log_{10}$ (99%) during the time required for the product to dry on porcine skin (1-2 minutes)[15, 16].

8hr. 2-1 hand Sanitizer Foam Demonstrated Effective Against other Viruses[17]

8hr. 2-1 Hand Sanitizer Foam with Aloe Vera can be declared as virucidal against Rhinovirus cause of the common cold (ATCC VR-482), Influenza virus (ATCC VR -1741) and Enterovirus 71 (Hand, Foot & Mouth Disease Virus). 8hr. 2-1 Hand Sanitizer Foam with Aloe Vera demonstrated effectiveness as dilute 80% solutions against Rhinovirus (common cold), Influenza virus and Enterovirus 71 a cause of Hand, Foot & Mouth Disease (ATCC VR-177 5) using BS EN 14476:205 with an expected 4 Log_{10} reduction after a contact time of 60 minutes. Testing demonstrated activity meant to establish the 4 Log_{10} benchmark allowing the disinfectant virucidal claim to be made. It should be noted that formulas of hand sanitizer using the same active ingredients (at similar concentrations) as in the 8hr. 2-1 Hand Sanitizer have been shown to be effective against numerous virus family groups including the Human Coronavirus family[18].

C. R&D On Corona Virus, MERS CoV Surrogate, Feline Infectious Peritonitis Virus On Human Hands

A four person human hand study was conducted by Dr. Kelly Reynolds at The University of Arizona using 8hr. 2-1 Hand Sanitizer Foam after exposing the hands to Feline Infectious Peritonitis virus, a MERS surrogate. MERS CoV is a corona virus associated with camels and their barnyard environment. It has infected 2266 patients with 804 deaths. Many health care providers had been infected. How the virus transferred is still undetermined. In this study hands were infected with the MERS surrogate, dried and 8hr. 2-1 Hand Sanitizer Foam was applied and allowed to dry. The infected area was swabbed. Results were 8hr. 2-1 Hand Sanitizer Foam is effective at reducing feline infectious peritonitis virus on hands by at least 99.9% following manufacturer's instruction"

8hr. 2-1 Hand Sanitizer Test Using Four Human Subjects
Against Feline Infectious Peritonitis Virus (FIPV)

Human Subject Designation	Sample Id	Viral Titer (Log10 per mL)a	Log10 Reduction	Percent Reduction
Human Subject No. 1	Pre-Exposure Control	6.00	N.A.	
	Post-Exposure Test	≤ 2.50	> 3.50	> 99.97%
Human Subject No. 2	Pre-Exposure Control	5.75	N.A.	
	Post-Exposure Test	≤ 2.50	> 3.25	> 99.94%
Human Subject No. 3	Pre-Exposure Control	5.00	N.A.	
	Post-Exposure Test	≤ 2.50	> 2.50	> 99.97%
Human Subject No. 4	Pre-Exposure Control	6.00	N.A.	
	Post-Exposure Test	≤ 2.50	> 3.50	> 99.97%
Average	**Pre-Exposure Control**	**5.69**	**N.A.**	
	Post-Exposure Test	**< 2.50**	**> 3.19**	**> 99.99%**

a Detection Limit = ≤ 2.50 log10 per ml

C. Clinical Trials

1. Hospital Associated Infection Rates - Clinical Trial [19]

To test product practical value in healthcare a pilot clinical study was conducted over an 8-day period, in surgical and orthopedic wards of a US hospital. Microbial surveys of healthcare workers hands (~40) were obtained with 624 microbial cultures taken randomly for 4 days using standard alcohol hand sanitizer and for 4 days using 8 hr. 2-1 Hand Sanitizer with Aloe Vera (ESC AV). The use of the 8hr. 2-1 Hand Sanitizer was demonstrated to reduce the frequency of commonly identified opportunistic pathogens responsible for hospital-associated infections on hands for each ward by around 50% when compared to standard alcohol hand sanitizer use. This efficacy is a direct result of the persistent activity demonstrated in testing described earlier.

D. Lack of Skin Irritation-Safe for Repeated Application

The active ingredient of 8hr. 2-1 Hand Sanitizer Foam & Gel products with Aloe Vera, Benzalkonium Chloride is a mixture of alkylbenzyldimethylammonium chlorides with the following chain lengths 50% C12, 30% C14, 17% C16, 3% C18 [18]. The ingredient is used in cosmetic products as a foaming cleansing and bactericidal agent at concentrations up to 5.0%. The compound was found to be non-mutagenic in several different cell assays. It has been found to be an ocular irritant at concentrations greater than 0.1%. This cosmetic ingredient is not a sensitizer to normal humans at concentrations of 0.1%, but may be to individuals with sensitive skin. It is concluded that Benzalkonium Chloride can be safely used as an antimicrobial agent at concentrations up to 0.1%[20]. Benzalkonium chloride (0.1.1%-0.13%) is generally recognized as safe (GRAS) and effective by the US FDA for use in topically applied anti-bacterial products such as hand sanitizers.

At time of formula creation every precaution was taken to develop a product that did not irritate the skin with repeated use. Qualified skin care product experts reviewed every aspect of the formulation. Now with several years successfully manufacturing and distributing these products in the US, Australia and New Zealand, a clinical trial in a health care facility, low irritation potential of an 8hr. 2-1 alcohol-free Hand Sanitizer with Aloe Vera is well established for both gel and liquid (foam) products. The hospital trial also demonstrated skin compatibility in a well-monitored population of healthcare professionals. Numerous school trials of similar hand sanitizer formulated with the same active ingredient Benzalkonium chloride have show n skin compatibility where hand and skin monitoring clearly demonstrated this to be a positive endpoint. The various production runs of the product represent positive experiences by 70,000 to 90,000 individuals using these products in a wide variety of settings from households, schools and healthcare to prisons"[20].

E. Effective Unique Patented Technology

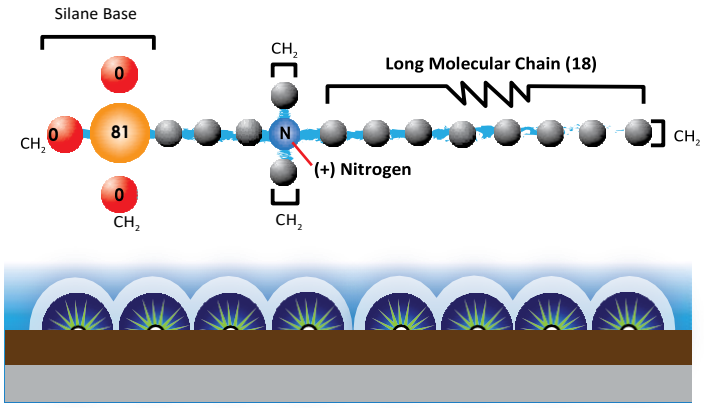
8hr. 2-1 Hand Sanitizer AV Foam & Gel products use patented technology[21] and are based on the same proprietary formula. The core of this new technology lies in a highly effective proprietary blend of three (3 or 4) quaternary amines in revolutionary film forming formulation that is highly effective in healthcare environments with specific issues of antibiotic resistant and hard to kill microbial pathogens. Antimicrobial action is achieved by a synergism of the chemical components resulting in chemo-electro-mechanical destruction of target microbe.

A. The backbone is a Triethoxy Silyl Propyl Ammonium Chloride (QAS) that forms a safe and stable polymer or monomer or both on the skin.

B. This bonds to surfaces and within that film the active ingredient, Benzalkonium Chloride (QAC) is found, along with;

C. The highly active Polyamino Biguanidine (PB), a low concentration high kill preservative often used in eye drops consisting of a mixture of different chain length antimicrobials that ply their action as the QAS perturbates or damages microbial membrane structures with its high Zeta potential.

Figure 3. Chemical Diagram of Polymeric Structural Component providing a Matrix for active ingredients forming a safe skin coating with positive charged Micelles



F. Glove Compatibility

Numerous Benzalkonium Chloride based hand sanitize formulations are advertised as ideal for environments where a non-alcohol hand sanitizer is required and compatible with vinyl, nitrile and latex gloves[20].

G. Product Registrations

8hr Hand Sanitizer Foam and Gel with Aloe Vera has been registered with the US National Library of Medicine[22] and with the New Zealand Ministry of Agriculture and Forestry for use as a hand and foot sanitizer in government regulated facilities processing animal products[20]. The 8hr. 2-1 Hand Sanitizer with Aloe Vera liquid solution (Foam) is registered with the Canadian Food Inspection Agency for use for hand sanitizer applications in government regulated facilities processing food products[20]. 8hr 2-1 Hospital Grade-Surface Spray Disinfectant is registered in accordance with the Therapeutic Goods Act (TGA) of the Commonwealth of Australia[23].

China Testing Of Disinfect & Shield Hand Sanitizer Foam By Guangdong Detection Center Of Microbiology

8hr. 2-1 Hand Sanitizer Foam results showed the product was efficacious (log 5 kill) against E Coli 8099 and Staphylococcus aureus ATCC 6538 with the statement that “all test results can met the standards and the neutralizer being tested was qualified”

广 微 测
Gmicro Testing

2015191236Q

中国认可
国际互认
检测
TESTING
CNAS L1747

广东省微生物分析检测中心

GUANGDONG DETECTION CENTER OF MICROBIOLOGY

分 析 检 测 报 告

REPORT FOR ANALYSIS

报告编号（Report №.）2018FM02163R01D 校验码（Verification Code）：34970612

样品名称 Name of Sample	迈安科 泡沫免洗洗手液 M&K Hand Sanitizer Foam	检测类型 Test Type	委托检测 Entrustment Test
委托单位 Applicant	厦门迈安科模具有限公司 M&K International Healthcare Group Limited	地 址 Address	福建省厦门市翔安区火炬高新区火炬(翔安)产业区翔明路 18 号 ZTC Technology Park No. 18 Xiang Ming Road Xiang An,Xianmen.
样品来源 Sample Source	委托方送检 Submitted for Testing by the Applicant	样品数量 Sample Quantity	1L*2 瓶 1L*Two bottles
样品规格和批号 Spec and Lot № of Sample	45mL	样品状态和特性 State and Characteristic	液体 Liquid
接样日期 Sample Received Date	2018-03-21	检测完成日期 Completion Date	2018-04-03
检测依据和方法 Test Standard and Method	《消毒技术规范》2002 年版-2.1.1.7.4 悬液定量杀菌试验 Technical Standard for Disinfection (2002 Ministry of Health P.R.China)-2.1.1.7.4 Suspension quantitative germicidal test 《消毒技术规范》2002 年版-2.1.1.5.5 中和剂悬液定量鉴定试验 Technical Standard for Disinfection (2002 Ministry of Health P.R.China)-2.1.1.5.5 Quantitative determination of neutralizer suspension		
检测项目 Item Tested	悬液定量杀菌试验，中和剂悬液定量鉴定试验 Suspension quantitative germicidal test，Quantitative determination of neutralizer suspension		
检测结论 Test Conclusion	该样品所检项目的实测数据见本检测报告续页。 The test data of the sample(s) is attached to the page(s) of this report. 签发日期：2018-04-04 Issue Date （机构盖章 Official Seal）		
备注 Remarks	1.品牌方：厦门迈安科模具有限公司。（由委托方提供） Brand party：M&K International Healthcare Group Limited. (provided by the applicant) 2..送检方：厦门莱恩迪贸易发展有限公司。（由委托方提供） Manufacturer：Landy International. (provided by the applicant)		

制 表：**Editor** 陈颖婷　　审 核：**Verifier** 邱炬辰　　批 准：**Approver** 林怀保

第 2 页 共 5 页

广微测 Gmicro Testing

2015191236Q

中国认可 国际互认 检测 TESTING CNAS L1747

广东省微生物分析检测中心

GUANGDONG DETECTION CENTER OF MICROBIOLOGY

分 析 检 测 结 果

ANALYSIS AND TEST RESULT

报告编号（Report №.）：2018FM02163R01D

1. 检测项目：悬液定量杀菌试验
Test Item: Suspension quantitative germicidal test
1.1 检测方法：《消毒技术规范》2002 年版-2.1.1.7.4 悬液定量杀菌试验
Test Method: Technical Standard for Disinfection (2002 Ministry of Health P.R.China)-2.1.1.7.4 Suspension quantitative germicidal test
1.2 试验结果 Test Result

作用浓度及时间 Action concentration and action time	测试微生物 The tested organism	序号 Serial Number	对照组菌落总数 The number of bacteria in the control sample (cfu/mL)	对照组平均菌落总数 The average number of colonies in the control group (cfu/mL)	试验组菌落总数 The number of bacteria in the test sample (cfu/mL)	杀灭对数值 Sterilization logarithm	杀灭率 Killing rate (%)
原液 Original 10 min	大肠杆菌（*Escherichia coli*）8099	1	3.0×10^7	3.3×10^7	＜10	≥5.00	＞99.999
		2	3.3×10^7		＜10	≥5.00	＞99.999
		3	3.5×10^7		＜10	≥5.00	＞99.999
	金黄色葡萄球菌（*Staphylococcus aureus*）ATCC 6538	1	4.2×10^7	4.2×10^7	＜10	≥5.00	＞99.999
		2	3.9×10^7		＜10	≥5.00	＞99.999
		3	4.5×10^7		＜10	≥5.00	＞99.999

(接下页 Continued on the next page)

References

1. Stainback L. 2011. Disinfect & Shield Hand Sanitizer Evaluation. Unpublished Report-Triad Forensics Independent Services Laboratory (Winston-Salem, North Carolina, USA) test report dated 2/24/2011.

2. Rex A. 2010. Suspension Time-Kill Study Report- ESC Hand Sanitizer Aloe Vera (Foam). Unpublished Antimicrobial Test Laboratories (Round Rock, Texas, USA) test report dated 8/23/2010.

3. Drabble D. 2012. Effect of Hand Sanitizer on Selected Organisms- Report. Unpublished Marble Laboratories LLC. (Winston-Salem, North Carolina, USA) test report TP015 dated 10/14/2012.

4. Drabble D. 2013. Effects of ESC Disinfect & Shield Hand Sanitizer Aloe Vera on Selected Organisms- Report. Unpublished Marble Laboratories LLC. (Winston-Salem, North Carolina, USA) test report TP021 dated 6/2/2013.

5. Walsh T. 2014. Testing of ESC Disinfect & Shield Hand Sanitizer Liquid (Foam) with Aloe using Test method BS EN 1040:2005 a Time/ Kill Suspension test. CNT Laboratories Testing and Certification Ltd. (Guangzhou, China), Test Report No. CNT14011201015, dated 1/20/2014.

6. Walsh T. 2013. Testing of ESC Disinfect & Shield Hand Sanitizer Liquid (Foam) with Aloe using Test method BS EN1275:2005. Time/Kill Suspension test – Fungi. CNT Laboratories Testing and Certification Ltd. (Guangzhou, China), Test Report No. CNT13011211037 dated 1/25/2013.

7. Walsh T. 2013. Testing of ESC Disinfect & Shield Hand Sanitizer Liquid (Foam) with Aloe using Test method BS EN 1276:2005. Time/Kill Suspension test-Bacteria under clean & dirty conditions. CNT Labs Testing and Certification Ltd. (Guangzhou, China), Test Report No. CNT1311251043 dated 1/25/2013.

8. Adenaver J, Walsh T. 2014. ESC Disinfect & Shield Hand Sanitizer Liquid (Foam) with Aloe Vera BS EN 1500:2013 Testing. CNT Labs Testing and Certification Ltd. (Guangzhou, China), Test Report No. CNT1401271184.

9. Centrella W, Marshall D. 2014. Persistence of Activity (<24 hrs) of Hand Sanitizers against Staphylococcus aureus using ASTM E2897- 12 & ASTM WK36911 porcine skin test methods (2/17/14). Eurofins Microbiology Laboratories, Inc. Lancaster, PA.

10. Centrella W, Marshall D. 2014. Persistence of Activity of H and Sanitizers against Antibiotic Resistant Microorganisms using ASTM E2897-12 & ASTM WK36911 porcine skin test methods (2/17/14). Eurofins Microbiology Laboratories, Inc. Lancaster, PA.

11. Adenaver J, Walsh T. 2014. ESC Disinfect & Shield Hand Sanitizer Liquid with Aloe Vera ASTM E1115-11 Standard Test Method for Evaluation of Surgical Hand Scrub Formulations. CNT Labs Testing and Certification Ltd. (Guangzhou, China), Test Report No. CNT1401241113 (1/28/2014).

12. Adenaver J, Walsh T. 2014. ESC Disinfect & Shield Hand Sanitizer Gel with Aloe Vera Tested using ASTM E640-06(2012) Standard Test Method for Preservatives in Water-Containing Cosmetics (Bactericidal Reduction & Preservative Adequacy-Challenge Testing. CNT Labs Testing and Certification Ltd. (Guangzhou, China), Test Report No. CNT1401241116 (1/27/2014).

13. Walsh T. 2013. Testing of ESC Disinfect & Shield Liquid with Aloe using Test method USP35-NF30 51 Antimicrobial Effectiveness Testing. CNT Labs Testing and Certification Ltd. (Guangzhou, China), Test Report No. CNT1311151024 dated 12/30/2013.

14. Walsh T. 2013. Testing of ESC Disinfect & Shield Liquid with Aloe using Test method EP7.0.13 Efficacy of antimicrobial preservation. CNT Labs Testing and Certification Ltd. (Guangzhou, China), Test Report No. CNT1311151026 dated 12/30/2013.

15. Drabble D. 2013. Effect of ESC Disinfect & Shield Hand Sanitizer on Murine Norovirus 1 (MNV-1) on Porcine Skin. Unpublished Marble Laboratories LLC. (Winston-Salem, North Carolina, USA) test report TP016.1 dated 5/7/2013.

16. Michaels B. 2013. Norovirus Efficacy Report based on Marble Labs Test Report TPO16.1 (Issued Sept 5, 2013). 17. Adenaver J, Walsh T. 2014. ESC Disinfect & Shield Hand Sanitizer Liquid (Foam) with Aloe Vera BS EN 14476:205 Virucidal quantitative suspension test for human medicine. CNT Labs Testing and Certification Ltd. (Guangzhou, China), Test Report No.CNT1402281220.

18. Saknimit M, Inatsuki I, Sugiyama Y, Yagami K. Virucidal efficacy of physico-chemical treatments against coronaviruses and parvoviruses of laboratory animals. Jikken Dobutsu.1988;37:341-5.

19. Anon. 2013. A Comparison Study Showing the Effectiveness of ESC Disinfect & Shield vs. a Leading Alcohol-based Hand Sanitizer. Unpublished report.

20. Michaels B. 2014. Dermal Compatibility: ESC Disinfect & Shield Hand Sanitizer with Aloe Vera. (Report on File).

21. PATENT APPLIED FOR. 2014. #2014900900. Antimicrobial sanitizer compositions and their use (Application on File)

22. NLM. 2011. National Library of Medicine FDA Label Registration for ESC Disinfect & Shield Aloe Vera Hand Sanitizer (Benzalkonium chloride) aerosol, foam [ESC]. http://dailymed.nlm.nih.gov/dailymed/drugInfo. cfm?id=92354 Accessed 12/5/2013.

23. TGA. 2011. Australian Government, Department of Health and Aging, Therapeutic Goods Administration. Australian Register of Therapeutic Goods Certificate, Issued to Global Future Solutions ESC. Surface Spray Disinfectant-Hospital Grade – Disinfectant, hospital grade. ARTG Identifier: AUST L 184616, ARTG Start date: 6/06/2011.

24. Tehseen Naqvi M. 2018.Assessment of Antimicrobial Activity Using a Time-Kill Procedure ASTM E2315-16: Burkholderia cepacia ATCC # 25416. Unpublished Report – Accugen Laboratories (Addison, Illinois) test report # 129332 report dated 02/05/18

25. Vogel, L. Hand sanitizers may increase norovirus risk. CMAJ. 2011 Sep 6; 183(12): E799–E800. doi: 10.1503/cmaj.109-3922

26. Sexton, J & and Reynolds, R. Disinfect & Shield Hand Sanitizer Efficacy Against Feline Infectious Peritonitis Virus: Hand Trials Final Report. Environment, Exposure Science and Risk Assessment Center Mel and Enid Zuckerman College of Public Health The University of Arizona [Tucson, Arizona).

27. Suspension quantitative germicidal test. Hand Sanitizer Foam. Report number #2018FM02163R01D. Guangdong Detection Center Of Microbiology (Guangzhou, China). Test dated 2018/04/03

28. Suspension quantitative germicidal test. Hand Sanitizer Gel. Report number #2018FM02163R01D. Guangdong Detection Center Of Microbiology (Guangzhou, China). Test dated 2018/04/03