

# ***DEB SBS Products***

## **Efficacy Data – InstantFOAM™ alcohol hand sanitizer**

Conforms to the US FDA Tentative Final Monograph for Healthcare Personnel Handwash

Conforms to the European legislation regarding cosmetic and hygiene products (Directive 76/768/CE)

### **Test Procedures and Protocols:**

1. Fifteen (15) second exposure Time in vitro kill studies were performed utilizing Thirty One (31) challenge micro-organisms.
2. The challenge inoculums were introduced to the test product at time zero; a portion of sample was removed and placed in neutralizing media at the appropriate time (15 seconds). Standard plate counting techniques were used to enumerate viable challenge microorganisms.

### **Test Results/Conclusion:**

The Test Results are as follows after 15 second exposure for InstantFOAM™ alcohol hand sanitizer. A 6 log<sub>10</sub> or greater reduction (>99.9999%) in numbers of test organisms was shown for all test organisms. Product demonstrated a very effective reduction of Gram-negative and Gram-positive bacteria including MRSA, VRE and Fungicidal/Yeast.

<b>Test Micro-organisms</b>	<b>ATCC No.</b>	<b>Percent Reduction</b>
<b><i>Yeast &amp; Fungi</i></b>		
<i>Candida albicans</i>	10231	>99.9999
<i>Candida tropicalis</i>	750	>99.9999
<b>Test Micro-organisms</b>	<b>ATCC No.</b>	<b>Percent Reduction</b>
<b><i>Gram Negative Bacteria</i></b>		
<i>Acinetobacter sp.</i>	9957	>99.9999

<i>Escherichia coli</i>	11229	>99.9999
<i>Escherichia coli</i>	25922	>99.9999
<i>Klebsiella oxytoca</i>	15764	>99.9999
<i>Haemophilus influenzae</i>	19418	>99.9999
<i>Klebsiella pneumonia</i>	51503	>99.9999
<i>Pseudomonas aeruginosa</i>	27853	>99.9999
<i>Proteus mirabilis</i>	7002	>99.9999
<i>Pseudomonas aeruginosa</i>	15442	>99.9999
<i>Salmonella choleraesuis</i>	10708	>99.9999
<i>Serratia marcescens</i>	14756	>99.9999
<b>Gram Positive Bacteria</b>		
<i>Bacterioides fragilis</i>	25285	>99.9999
<i>Enterobacter aerogenes</i>	13048	>99.9999
<i>Enterococcus faecalis</i>	29212	>99.9999
<i>Enterococcus faecalis</i>	51559	>99.9999
<i>Enterococcus faecium (VRE)</i>	51299	>99.9999
<i>Enterococcus hirae</i>	10541	>99.9999
<i>Listeria monocytogenes</i>	19111	>99.9999
<i>Micrococcus luteus</i>	7468	>99.9999
<i>Staphylococcus aureus</i>	29213	>99.9999
<i>Staphylococcus aureus (MRSA)</i>	33591	>99.9999
<i>Staphylococcus aureus (MRSA)</i>	33592	>99.9999
<i>Staphylococcus aureus</i>	6538	>99.9999
<i>Staphylococcus haemolyticus</i>	29970	>99.9999
<i>Staphylococcus epidermidis</i>	12228	>99.9999
<i>Staphylococcus hominis</i>	51624	>99.9999
<i>Staphylococcus saprophyticus</i>	15305	>99.9999
<i>Streptococcus pyogenes</i>	19615	>99.9999

The Tests were conducted by Deb Worldwide Healthcare, Inc.

<i>Clostridium difficile</i> (Vegetative forms) <b>Bioscience Laboratories</b>	Contact time 15 sec.	>99.9999 % Reduction
--	----------------------------	-------------------------

<b>EN 1276</b> HygCen (Prof. Werner) GERMANY	Contact time: 1 minute No interfering substance. Log <sub>10</sub> reduction: 5	<ul style="list-style-type: none"> <li>➤ <i>Pseudomonas aeruginosa</i> ATCC 15442</li> <li>➤ <i>Escherichia coli</i> ATCC 10536</li> <li>➤ <i>Staphylococcus aureus</i> ATCC 6538</li> <li>➤ <i>Enterococcus hirae</i> ATCC 10541</li> </ul>
<b>EN 1275</b> HygCen (Prof. Werner) GERMANY	Contact time: 1 minute Interfering substance = none Log <sub>10</sub> reduction: 4	<ul style="list-style-type: none"> <li>➤ <i>Candida albicans</i> ATTC10231</li> <li>➤ <i>Aspergillus niger</i> ATTC 16404</li> </ul>

3. IN VIVO BACTERICIDAL TESTS	RESULTS
<p><b>Healthcare Personnel Hand-wash Data,</b> (Hill Top Research Inc.)</p> <p>Determines, on 15 subjects, the ability of the product as an antimicrobial hand-washing agent to give reduction of transient microbial flora (contaminants) when used in a hand-washing procedure with a marker organism (<i>Serratia marcescens</i> ( ATCC No. 14756)</p> <p>It evaluates both the immediate and persistent antimicrobial effects of the product over the course of 10 consecutive microbial contamination/product application cycles.</p>	<p>The test data show excellent antimicrobial efficacy (bacterial count reduction) on the hands. The product achieved 3.0765 log<sub>10</sub> Reduction on the first wash and 2.8173 log<sub>10</sub> reduction following the tenth treatment</p>
<p><b>EN 1500</b> (HygCen - Prof. Wemer - GERMANY &amp; AUSTRIA)</p> <p>Determine the ability of the product as an antimicrobial disinfecting agent to give reduction of transient microbial flora (contaminants) when used with a marker organism (<i>Escherichia coli</i> K12 NCTC).</p>	<p>Contact time: 15 seconds            Effective dose: <u>3 ml minimum</u></p> <p>Product is significantly better than the reference alcohol (60 % v/v propanol-2-ol)</p>

4. TOXICOLOGICAL DATA	CONCLUSIONS
<p><b>Toxicological review</b> (Laboratoire IDEA-France &amp; Intertex – UK) :</p> <p>Done by toxicologist on the base of CAS numbers and chemical names of ingredients</p>	<p>The product has no potential systemic toxicity</p>
<p><b>Healthcare Personnel Hand-wash Data</b> (Hill Top Research Inc. – USA) Antimicrobial hand-washing test</p>	<p>This test was performed under the supervision of a dermatologist and there was no evidence of irritation in the skin attributable to the product.</p>

<p><b>Skin irritation test</b> ( Laboratoire IDEA – France) : Study of acute skin tolerance of a cosmetic product: 48H single patch-test on 10 subjects.</p>	<p>The product did not show any detrimental effect on the skin after repetitive use.</p>
<p><b>Dermatological test</b> RSSL, - UK) : <u>In vivo</u> usage-test done on 29 subjects and validated by a dermatologist.</p>	<p>The product is dermatological tested.</p>
<p><b>Hypoallergenicity test</b> (Intertek – UK) : Reviews of ingredients using various databases, reference books, trade literature and MSDS and the internet using multiple search engines.</p>	<p>Hypoallergenic (the product is formulated to minimize the risk of allergy)</p>
<p><b>After-application skin hydration</b> (Laboratoire IDEA – France): <u>In vivo</u> measurement of skin hydration by Trans Epidermal Loss (TEWL) and corneometry done on a panel of 10 subjects during 2 hours</p>	<p>The product does not dehydrate the skin.</p>
<p><b>Non-taint test</b> (Campden &amp; Chorleywood Food Research Association – UK) : The Triangle Test Method for similarity determines whether the test product has the potential to taint food. The test-product is intended to be used as a leave-on skin sanitizer product.</p>	<p>The results indicate that the Alcohol Foam does not have the potential to taint food when used as a leave-on skin sanitizer.</p>
<p><b>Chemical compatibility with gloves</b> (Rubber Consultants – UK) : Effects of product on the physical properties of the natural rubber (latex) and nitrile medical examination gloves.</p>	<p>Compatible with latex and nitrile gloves</p>

5. IN VITRO VIRUCIDAL TESTS	RESULTS
<ul style="list-style-type: none"> <li>• Bird flu virus H3N8 (MikroLab GmbH – Germany)</li> <li>• Influenza virus-A H3N2 (MikroLab GmbH – Germany)</li> <li>• Herpes virus simplex SV-1 (ATS Labs – USA)</li> <li>• HIV virus (ATS Labs – USA)</li> <li>• HAV Hepatitis virus (ATS Labs – USA)</li> <li>• Rotavirus – Strain Wa (ATS Labs – USA)</li> </ul>	<p>The product showed virucidal power on all the test-viruses.</p>

6. IN VIVO VIRUCIDAL TESTS	RESULTS
<ul style="list-style-type: none"> <li>• Norwalk virus (feline surrogate) – Finger pad method (MikroLab GmbH – Germany)</li> </ul>	<p>The product showed virucidal power on all the test-viruses.</p>