Summary of Studies Performed on Sklar® Disinfectant / Soak Cleaning Solutions
US EPA Registration No. 70144-1-(31118)
November 2012

DESCRIPTION:
Sklar Disinfectant and Soak are the EPA approved brand names for a proprietary antimicrobial liquid chemical solution sub-registered to Sklar Instruments Inc. Meets blood-borne pathogen standard of the Occupational Safety and Health Administration (OSHA), US Department of Labor. Produced adhering to FDA Good Manufacturing Practices.

Sklar Disinfectant’s unique formulation is produced through a combination of a number of solvents, sequestering agents, chelating agents, nonionic detergents and other ingredients acting in synergy with three distinct antimicrobial active agents. This product may be safely applied to soft or hard surfaces as an effective decontaminant / sanitizer / disinfectant / cleaner.

STUDIES PERFORMED AT INDEPENDENT EPA APPROVED LABORATORIES

(1) Bactericidal / Fungicidal Efficacy

<table>
<thead>
<tr>
<th>Pathogen</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Acinetobacter baumannii</td>
<td>Mycobacterium tuberculosis (TB)</td>
</tr>
<tr>
<td>Enterobacter aerogenese</td>
<td>Pseudomonas aeruginosa</td>
</tr>
<tr>
<td>Escherichia coli (ESBL Strain)</td>
<td>Salmonella choleraesuis</td>
</tr>
<tr>
<td>Klebsiella Pneumoniae (Carbapenem Resistant strain) (KPC)</td>
<td>Serratia marcescens</td>
</tr>
<tr>
<td>Listeria monocytogenes</td>
<td>Staphylococcus aureus</td>
</tr>
<tr>
<td>Methicillin Resistant Staphylococcus Aureus (MRSA)</td>
<td>Trichophyton mentagrophytes</td>
</tr>
<tr>
<td></td>
<td>Vancomycin Resistant Enterococcus (VRE)</td>
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</tbody>
</table>

(2) Virucidal Efficacy

<table>
<thead>
<tr>
<th>Virus</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Avian (Bird-flu) Influenza Virus</td>
<td>Human Immunodeficiency Virus (HIV-1)</td>
</tr>
<tr>
<td>Hepatitis B Virus (HBV)</td>
<td>Influenza A Viruses</td>
</tr>
<tr>
<td>Hepatitis C Virus (HCV)</td>
<td>Rotaviruses</td>
</tr>
<tr>
<td>Herpes Simplex Virus (HSV)</td>
<td>Swine Influenza Virus (H1N1 strain)</td>
</tr>
</tbody>
</table>

(3) Decontamination / Cleaning Studies

Removal of C. difficile spore contaminated soil

(4) Toxicity / Irritation Studies

<table>
<thead>
<tr>
<th>Toxicity / Irritation Studies</th>
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<tbody>
<tr>
<td>Oral Toxicity</td>
<td>Dermal Toxicity / Irritation / Sensitization</td>
</tr>
<tr>
<td>Inhalation Toxicity</td>
<td>Ocular Irritation</td>
</tr>
</tbody>
</table>
### Summary of Studies Performed on Sklar Disinfectant / Soak Cleaning Solutions

**Bactericidal / Fungicidal Study Titles:** (AOAC - Association of Official Analytical Chemists)

1. **AOAC Germicidal Test – Acinetobacter baumannii**
   - Sklar Disinfectant passed the spray test at 2 minutes.

2. **AOAC Non-food Contact Sanitizing Soft Surface Test** - Enterobacter aerogenes
   - Sklar Disinfectant passed the AOAC Sanitizer Spray Test at 10 seconds.

3. **AOAC Escherichia coli (ESBL Strain) Germicidal Test**
   - Sklar Disinfectant passed the AOAC Germicidal Spray test with a 2 minute contact time.

4. **AOAC Klebsiella Pneumoniae (Carbapenem Resistant strain) (KPC) Germicidal Test.**
   - Sklar Disinfectant passed the AOAC Germicidal Spray test with a 2 minute contact time.

5. **AOAC Listeria monocytogenes Germicidal Test**
   - Sklar Disinfectant passed the AOAC Germicidal Spray test with a 2 minute contact time.

6. **AOAC Methicillin Resistant Staphylococcus Aureus (MRSA) Germicidal Test**
   - Sklar Disinfectant passed the AOAC Germicidal Spray test with a 2 minute contact time.

7. **AOAC Immersion Test for Determining Tuberculocidal Activity**
   - The results show Sklar Disinfectant to be an effective tuberculocidal agent at 2 minutes.

8. **AOAC Mycobacterium Tuberculocidal Spray Test Study**
   - Sklar Disinfectant exhibited no growth of mycobacterium bovis tuberculocidal BCG test at 2 minutes.

9. **AOAC Confirmative Tuberculocidal Spray Test**
   - Sklar Disinfectant killed mycobacterium bovis BCG at 2 minutes.

10. **AOAC Germicidal Spray Test - Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella enterica**
    - Sklar Disinfectant passed the spray test at 2 minutes.

11. **AOAC Serratia marcescens Germicidal Test**
    - Sklar Disinfectant passed the AOAC Germicidal Spray test with a 2 minute contact time.

12. **AOAC Non-food -Contact Sanitizing Hard Surface Test** - Staphylococcus aureus and Enterobacter aerogenes
    - Sklar Disinfectant passed the AOAC Sanitizer Spray Test at 10 seconds.

13. **AOAC Food Contact Sanitizing Hard Surface Test** - Escherichia coli (ESBL Strain) and Staphylococcus aureus
    - Sklar Disinfectant passed the AOAC Food contact Sanitizing Spray test with a 30-second contact time.

14. **AOAC Fungicidal Test**
    - Sklar Disinfectant exhibited no growth of Trichophyton mentagrophytes at 2 minutes.

15. **AOAC Vancomycin Resistant Enterococcus (VRE) Germicidal Test**
    - Sklar Disinfectant passed the AOAC Germicidal Spray test with a 2 minute contact time.
**Virucidal Study Titles:**

- **“Effectiveness of Sklar Disinfectant to Inactivate Avian (Bird flu) Influenza virus”**
  Sklar Disinfectant inactivated the Avian Influenza virus with a 2 minute contact time.

- **“Effectiveness of Sklar Disinfectant to Inactivate Hepatitis B Virus”**
  Sklar Disinfectant inactivated HBV with a 2 minute contact time.

- **“Effectiveness of Sklar Disinfectant to Inactivate Hepatitis C Virus”**
  Sklar Disinfectant inactivated HCV with a 2 minute contact time.

- **“Effectiveness of Sklar Disinfectant to Inactivate Herpes Simplex Virus”**
  Sklar Disinfectant inactivated HSV with a 2 minute contact time.

- **“Effectiveness of Sklar Disinfectant to Inactivate Human Immunodeficiency Virus Type 1 (HIV-1, associated with AIDS)”**
  Sklar Disinfectant inactivated the HIV-1 virus with a 1 minute contact time.

- **“Effectiveness of Sklar Disinfectant to Inactivate Influenza A Viruses”**
  Sklar Disinfectant inactivated the Influenza A virus with a 2 minute contact time.

- **“Effectiveness of Sklar Disinfectant to Inactivate Rotaviruses”**
  Sklar Disinfectant inactivated the Rotavirus with a 2 minute contact time.

- **“Effectiveness of Sklar Disinfectant Spray to Inactivate the Swine Influenza Type A Virus (H1N1 strain)”**
  Sklar Disinfectant inactivated the Swine Flu Virus (H1N1) with a 2 minute contact time.

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**Decontamination / Cleaning Studies**

- **“Efficacy of Sklar Disinfectant Spray, to Remove C. difficile spores from a Hard Surface”**
  When used as directed Sklar Disinfectant Solution removed 100% of soil contaminated with 10^5 C. difficile spores from the tested surfaces.

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**Toxicity / Irritation Study Titles**

- **“Oral Toxicity”**
  Sklar Disinfectant was tested for potential acute oral toxicity in accordance with the procedure outlined in the Pesticide Assessment Guideline, US EPA. No signs of toxicity were exhibited during the 14-day observation period of this study. Based on the results, the acute oral toxicity LD 50 of Sklar Disinfectant is greater than 5g/kg of body weight. This product is not considered an oral toxin.

- **“Acute Inhalation Toxicity”**
  An acute Inhalation Toxicity Study was conducted to determine the potential for Sklar Disinfectant to produce toxicity via the inhalation route at an exposure level of 2.0 mg/L. Based on the results, the single exposure Acute Inhalation LD 50 of the test solution is greater than 2.13 mg/L. The test results show this product to be categorized in the safest category (Cat IV) for chemical pesticides and is not a primary inhalation toxin.
“Primary Dermal Irritation”
Sklar Disinfectant was tested for potential dermal irritation in accordance with the procedures outlined in the Pesticide Assessment Guidelines, US EPA. Sklar Disinfectant exhibited slight reversible redness during the observation period. Based on the results, Sklar Disinfectant may produce some reversible, slight skin irritation if directly applied to skin.

“Acute Dermal Toxicity Study”
Sklar Disinfectant was tested to evaluate its potential dermal toxicity. The specimens did not exhibit any signs of toxicity during the 14-day observation period following exposure. Based on the results of this study the LD 50 is greater that 2.0 g/kg of body weight and is non-toxic to skin.

“Primary Eye Irritation Study”
New Zealand Albino Rabbits weighing 2.0-3.0 kg were employed to evaluate the potential irritant effects of Sklar Disinfectant on the eye mucosa. Based on the criteria outlined in Grades for Ocular Lesions: Pesticide Assessment Guidelines, US EPA, Sklar Disinfectant produced some slight reversible eye irritation. The results indicate that Sklar Disinfectant may produce reversible moderate eye irritation when instilled directly into the eye.

Additional information may be obtained from:

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