UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION
PREVENTION

May 22, 2012

MEMORANDUM

SUBJECT: Efficacy Review for Saginaw;
EPA Reg. No. 67619-EO;
DP Barcode: D399595

FROM: Karen M. Hill, Ph.D.
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6/15/12

THRU: Tajah Blackburn, Ph.D.
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6/15/22

TO: Jacqueline Campbell-McFarlane RM34/ Jaclyn Carl
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APPLICANT: Clorox Professional Products Company
c/o PS & RC
P.O. Box 493
Pleasanton, CA. 94566-0803

Formulation from the Label:

Active Ingredient(s):	% by wt.
Ethanol	66.34%
Dipropylene glycol	5.31%
Inert Ingredients	26.35%

Total..... 100.00%

I. BACKGROUND

The product, Saginaw (EPA Reg. No. 67619-EO), is new product seeking registration as a disinfectant (bactericidal, fungicidal, and virucidal activity), non-food contact sanitizer on hard non-porous surfaces, and soft-surface sanitizer claims to used in household, institutional, and industrial environments. Studies were conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN. 55121.

This data package contained a letter dated February 10, 2012 from the applicant to EPA (MRID # 487431-00), twenty nine (29) studies (MRID 487431-11 thru 487431-40), a Data Matrix, Statements of No Data Confidentiality Claims for all studies, and the proposed label.

II. USE DIRECTIONS

The product is designed for disinfecting hard, non-porous surfaces, including: appliance exteriors, bathtubs, cabinets, chairs, counter tops, cribs, cupboards, diaper pails, doorknobs, doors, exterior toilet and urinal surfaces, furniture, garbage cans, high chairs, light fixtures, patio furniture, recycling bins, shower doors, showers, sinks, tables, tools, walls, and window blinds. The proposed label indicates that the product may be used on hard, non-porous surfaces, including: enamel, Formica, glazed ceramic, glazed porcelain, glazed tile, chrome, stainless steel, laminated surfaces, Marlite, plastic, Plexiglas, sealed fiberglass, synthetic marble, tile, and vinyl.

Directions on the proposed label provide the following information regarding use of the product:

As a Disinfectant: Hold can upright 6" – 8" from surface. Spray surface until thoroughly wet. Let stand for 5 minutes. [Allow to air dry -or- wipe dry]. Gross or heavy soil must be removed prior to disinfecting. A potable water rinse is required for food contact surfaces.

As a Non-Food Contact Sanitizer: Hold can upright 6" – 8" from surface. Spray surface until thoroughly wet. Let stand for 30 seconds. [Allow to air dry or wipe dry.] Gross or heavy soil must be removed prior to sanitizing.

The product is for use as a spot treatment for surface areas composed of cotton such as couches, chairs, carpets, blinds, curtains, and other soft surfaces. Directions on the proposed label provide the following information regarding use of the product:

As a Soft Surface Sanitizer: Hold can upright 6" – 8" from surface. Spray until fabric is wet. DO NOT SATURATE. Let stand for 30 seconds. Allow to air dry. Gross or heavy soil must be removed prior to sanitizing.

As a Mildewstat: Hold can upright 6" – 8" from surface. Spray surface until wet and repeat every [21 days] [3 weeks] to prevent re-growth. [Gross][Heavy} soil must be removed prior to application to control mold and mildew.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments:

The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products). The tests require that sixty carriers must be tested with each of 3 samples, representing 3 different batches, one of which is at least 60 days old, against *Salmonella enterica* ATCC 10708 (for effectiveness against Gram-negative bacteria), *Staphylococcus aureus* ATCC 6538 (for effectiveness against Gram-positive bacteria), and *Pseudomonas aeruginosa* ATCC 15442 (representative of a nosocomial pathogen). [180 carriers per sample; a total of 540 carriers] To support products labeled as "disinfectants", killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level.

Disinfectants for Use on Hard Surfaces (Against a Broad Spectrum of Bacteria; Additional Bacteria):

Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against specific bacteria with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific bacteria on all carriers is required.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, Using a Modified Method)

The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products) may be modified to conform with the appropriate elements in the AOAC Fungicidal Test. The inoculum in the test must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 product samples representing 2 different product lots must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required.

Note: As an interim policy, EPA is accepting studies with dried carrier counts that are at least 10^4 for *Trichophyton mentagrophytes*, *Aspergillus niger*, and *Candida albicans*. EPA recognizes laboratories are experiencing problems in maintaining dried carrier counts at the 10^6 level. This interim policy will be in effect until EPA determines that the laboratories are able to achieve consistent carrier counts at the 10^6 level.

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is

intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological

technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Sanitizers (For Non-Food Contact Surfaces)

The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048). Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

Spot Soft Surface Sanitization

This study is designed to evaluate the antimicrobial efficacy of spray application sanitizers on pre-cleaned or lightly soiled, non-food contact soft surfaces. For sanitizer products intended for use on soft, non-food contact surfaces, a fabric carrier method is used to generate efficacy data. The test system proposed is a modification of the ASTM approved method for the evaluation of the antimicrobial efficacy of sanitizers on non-food contact surfaces. The method is modified for spray product application. A film of bacterial cells, dried on fabric carriers, is exposed to the test substance for a specified contact time. After exposure, the carriers are transferred to vessel containing neutralizing subculture media and assayed for survivors. Appropriate viability and sterility of organism population and neutralization controls are performed. Carrier type claimed on the label must be consistent with the test system. The test material meets effectiveness requirements if the product kills an average of at least 99.9% (3 log reduction) of the required organism on the 5 replicate carriers.

Products for control of mold and mildew on surfaces (Mildewstats / Fungistats)

The efficacy of products intended to prevent the growth of mold and mildew is greatly affected by the type of surface to which the products are applied. Test methods for representative surfaces are

"Fabric Mildew Fungistatic Test Method", "Hard Surface Mildew Fungistatic Test Method", "Leather Mildew Fungistatic Test Method", and "Wood Block Mildew Fungistatic Test Method". If

the surfaces to be treated, or the methods of application, or the organisms to be controlled by the product, are not the same as those indicated in the method, the method should be modified to reflect these differences. Modifications should also be made so that the method will more clearly reflect actual in-use conditions (including any specialized use situations). For example, tests for Products with funqistatic claims intended for use in shower stalls should include test data to indicate whether leaching will alter the efficacy of the product. Any modifications of test methods must be reported along with justification for the change submitted. Mildewstats should also be tested to determine whether or not bleaching, staining, spotting or other undesirable effects occur on the surfaces, articles, and materials to be protected.

Supplemental Claims:

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

IV. COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 487431-11, "AOAC Germicidal Spray Method", Test Organism: *Staphylococcus aureus* (ATCC 6538)", for product Saginaw, by Nicole Albert. Study conducted at ATS Labs 1285 Corporate Drive, Suite 110 Eagan, MN 55121. Study completion date – September 30, 2011. Project Number A11836.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Three lots of the product (Lot No. 9257-109, Lot No. 9257-110, and Lot No. 9257-86) were tested using the provided ATS Labs protocol CX18062311.GS.2. One lot, Lot No. 9257-86, was ≥60 days old. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The test culture was prepared by inoculating 10 mL of nutrient broth from a stock slant and performing daily consecutive transfers of a minimum of three but less than thirty transfers of 10 µL of culture into 10 mL of culture media. The final culture was incubated 48 – 54 hours at 35 – 37°C. The upper portions were removed of the 48 - 54 hours cultures of the test system after vortex and settling for ≥10 minutes occurred, and 5% fetal bovine serum soil load was added to prepare the complete test system culture. Sixty (60) glass slide carriers (18 mm x 36 mm) per product lot were inoculated uniformly spread over the entire carrier slide with 10 µL of the 48 - 54 hours old suspension of test organism. The carriers were dried for 38 minutes at 35-37°C with 40-43% relative humidity. Each carrier in a horizontal position was sprayed with the product for 3 seconds until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 4 minutes and 30 seconds on test date 8/17/11 at 21°C with 54% relative humidity and for 4 minutes and 45 seconds on test date 8/26/11 at 22°C with 63% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.14% Lecithin and 1.0% Tween 80 to neutralize. All subcultures were incubated for 48 ± 2 hours at 35-37°C. Subcultures were stored at 2 – 8°C for one day prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. If growth

occurred, the presence of the test organism was confirmed using staining and/or a biochemical assay. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note- The test administered on 8/17/11 had an exposure time of 4 minutes and 30 seconds which resulted in a failure of Batch 9257-109 showing 3 carriers with growth out of 60. The test was repeated on 8/26/11 with an exposure time of 4 minutes 45 seconds and the product Batch 9257-109 demonstrated efficacy by not having any growth among the 60 carriers.

2. MRID 487431-12 "AOAC Germicidal Spray Method", Test Organism: *Salmonella enterica* (ATCC 10708)" for product Saginaw, by Nicole Albert. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN. 55121. Study completion date – September 30, 2011. Project Number A11837.

This study was conducted against *Salmonella enterica* (ATCC 10708). Three lots (Lot No. 9257-109, Lot No. 9257-110, and Lot No. 9257-86 of the product, Saginaw, were tested using the provided ATS Labs protocol CX18062311.GS.3. One lot, Lot No. 9257-86, was ≥60 days old. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The product was received as a ready-to-use aerosol spray. The test culture was prepared by inoculating 10 mL of nutrient broth from a stock slant and performing daily consecutive transfers of a minimum of three but less than thirty transfers of 10 µL of culture into 10 mL of culture media. The final culture was incubated 48 – 54 hours at 35 – 37°C. The upper portions were removed of the 48 - 54 hours cultures of the test system after vortex and settling for 10 minutes occurred, and soil load of 5% fetal bovine serum was added to prepare the complete test system culture. Sixty (60) glass slide carriers (18 mm x 36 mm) per product lot were inoculated uniformly spread over the entire carrier slide with 10 µL of the 48 - 54 hours old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C with 50% relative humidity. Each carrier in a horizontal position was sprayed with the product for 3 seconds until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 4 minutes and 30 seconds at 21°C and 65% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.14% Lecithin and 1.0% Tween 80 to neutralize. All subcultures were incubated for 48 ± 2 hours at 35-37°C. Subcultures were stored at 2 – 8°C for one day prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. If growth occurred, the presence of the test organism was confirmed using staining and/or a biochemical assay. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

3. MRID 487431-13 "AOAC Germicidal Spray Method", Test Organism: *Pseudomonas aeruginosa* (ATCC 15442)" for Saginaw, by Nicole Albert. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121. Study completion date – September 30, 2011. Project Number A11835.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Three lots (Lot No. 9257-109, Lot No. 9257-110, and Lot No. 9257-86) of the product, Saginaw, were tested using the provided ATS Lab protocol CX18062311.GS.1. One lot, Lot No. 9257-86, was ≥60 days old. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The product was received as a ready-to-use aerosol spray. The test culture was prepared by inoculating 10 mL of nutrient broth from a stock slant

and performing daily consecutive transfers of a minimum of three but less than thirty transfers of 10 µL of culture into 10 mL of culture media. The final culture was incubated 48 – 54 hours at 35 – 37°C. On the day of use, the pellicle was aspirated from the tubes by tilting to allow any remains of pellicle to slide back and away while the culture was aseptically pulled away from the pellicle and transferred to a sterile tube. Afterwards, the upper portions were removed of the 48 - 54 hours cultures of the test system after vortex and settling for ≥10 minutes occurred, and 5% fetal bovine serum soil load was added to prepare the complete test system culture. Sixty (60) glass slide carriers (18 mm x 36 mm) per product lot were inoculated uniformly spread over the entire carrier slide with 10 µL of the 48 - 54 hours old suspension of test organism. The carriers were dried for 38 minutes at 35-37°C with 40% relative humidity. Each carrier in a horizontal position was sprayed with the product for 3 seconds until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 4 minutes and 30 seconds at 21°C and 49% relative humidity on 8/17/11 and 4 minutes and 45 seconds at 22°C and 63% relative humidity on 8/26/11. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.14% Lecithin and 1.0% Tween 80 to neutralize. All subcultures were incubated for 48 ± 2 hours at 35-37°C. For test date 8/26/11, subcultures were stored at 2 – 8°C for one day prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. If growth occurred, the presence of the test organism was confirmed using staining and/or a biochemical assay. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note- The test administered on 8/17/11 had an exposure time of 4 minutes and 30 seconds which resulted in a failure of Batch 9257-110 showing 2 carriers with growth out of 60. The test was repeated on 8/26/11 with an exposure time of 4 minutes 45 seconds and the product Batch 9257-110 demonstrated efficacy by not having any growth among the 60 carriers.

4. MRID 487431-14 "AOAC Germicidal Spray Method", Test Organism: Extended Spectrum Beta Lactamase producing *Escherichia coli* (ESBL) (ATCC BAA-196)" for product Saginaw, by Becky Lien. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121. Study completion date – September 29, 2011. Project Number A11861.

This study was conducted against Extended Spectrum Beta-Lactamase (ESBL) producing *Escherichia coli* (ATCC BAA-196). Two lots (Lot No. 9257-109 and Lot No. 9257-110) of the product, Saginaw, were tested using the provided ATS Labs protocol CX18060111.GS.2. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The product was received as a ready-to-use aerosol spray. The test culture was prepared by inoculating 10 mL of nutrient broth from a stock slant and performing daily consecutive transfers of a minimum of three but less than thirty transfers of 10 µL of culture into 10 mL of culture media. The final culture was incubated 48 – 54 hours at 35 – 37°C. The upper portions were removed of the 48 - 54 hours cultures of the test system after vortex and settling for ≥10 minutes occurred, and 5% fetal bovine serum soil load was added to prepare the complete test system culture. Ten (10) glass slide carriers (18 mm x 36 mm) per product lot were inoculated with 10 µL of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C with 41% relative humidity. Each carrier in a horizontal position was sprayed with the product for 3 seconds until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 4 minutes and 30 seconds at 21.5°C and 45.5% relative humidity. Following exposure, the

remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.14% Lecithin and 1.0% Tween 80 to neutralize. All subcultures were incubated for 48 ± 2 hours at 35-37°C. The subcultures were stored for two days at 2 – 8°C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. If growth occurred, the presence of the test organism was confirmed using staining and/or a biochemical assay. Controls included those for purity, sterility, viability, neutralization confirmation, carrier population, and antibiotic resistance.

Note- Extended Spectrum Beta Lactamase producing *Escherichia coli* (ESBL) (BAA-196) antibiotic resistance was confirmed using Minimum Inhibitory Concentration (MIC) verification of antibiotic resistance using AB BIODISK Etest Method. Positive resistance against Cefotaxime and Ceftazidime was demonstrated.

5. MRID 487431-15 "AOAC Germicidal Spray Method", Test Organism: *Enterobacter aerogenes* (ATCC 13048)" for product Saginaw, by Becky Lien. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121. Study completion date – September 28, 2011. Project Number A11852.

This study was conducted against *Enterobacter aerogenes* (ATCC 13048). Two lots (Lot No. 9257-109 and Lot No. 9257-110) of the product, Saginaw, were tested using the provided ATS Labs protocol CX18060111.GS.3. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The test culture was prepared by inoculating 10 mL of Tryptic Soy Broth from a stock slant and performing daily consecutive transfers of a minimum of three but less than thirty transfers of 10 µL of culture into 10 mL of culture media. The final culture was incubated 48 – 54 hours at 35 – 37°C. The upper portions were removed of the 48 - 54 hours cultures of the test system after vortex and settling for ≥10 minutes occurred, and 5% fetal bovine serum soil load was added to prepare the complete test system culture. Ten (10) glass slide carriers (18 mm x 36 mm) per product lot were inoculated with 10 µL of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C with 40% relative humidity. Each carrier in a horizontal position was sprayed with the product for 3 seconds until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 4 minutes and 30 seconds at 21°C and 55% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.14% Lecithin and 1.0% Tween 80 to neutralize. All subcultures were incubated for 48 ± 2 hours at 25-30°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

6. MRID 487431-16 "AOAC Germicidal Spray Method", Test Organism: *Klebsiella pneumoniae* (ATCC 4352)" for product Saginaw, by Jill Ruhme. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121. Study completion date – October 3, 2011. Project Number A11853.

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352). Three lots (Lot No. 9257-109 and Lot No. 9257-110) of the product, Saginaw, were tested using the provided ATS Labs protocol CX18060111.GS.4. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The test culture was prepared by inoculating 10 mL of

nutrient broth from a stock slant and performing daily consecutive transfers of a minimum of three but less than thirty transfers of 10 µL of culture into 10 mL of culture media. The final culture was incubated 48 – 54 hours at 35 – 37°C. The upper portions were removed of the 48 - 54 hours cultures of the test system after vortex and settling for ≥10 minutes occurred, and 5% fetal bovine serum soil load was added to prepare the complete test system culture. Ten (10) glass slide carriers (18 mm x 36 mm) per product lot were inoculated with 10µL of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. Each carrier in a horizontal position was sprayed with the product for 3 seconds until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 4 minutes and 30 seconds at 21°C and 52% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.14% Lecithin and 1.0% Tween 80 to neutralize. All subcultures were incubated for 48 ± 2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

7. MRID 487431-17 "AOAC Germicidal Spray Method", Test Organism: Methicillin Resistant *Staphylococcus aureus* (ATCC 33592)" for product Saginaw, by Jill Ruhme. Study conducted at ATS Labs 1285 Corporate Drive, Suite 110 Eagan, MN. 55121. Study completion date – October 3, 2011. Project Number A11854.

This study was conducted against Methicillin Resistant *Staphylococcus aureus* (ATCC 33592). Two lots (Lot No. 9257-109 and Lot No. 9257-110) of the product, Saginaw, were tested using the provided ATS Labs protocol CX18060111.GS.5. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The test culture was prepared by inoculating 10 mL of nutrient broth from a stock slant and performing daily consecutive transfers of a minimum of three but less than thirty transfers of 10 µL of culture into 10 mL of culture media. The final culture was incubated 48 – 54 hours at 35 – 37°C. The upper portions were removed of the 48 - 54 hours cultures of the test system after vortex and settling for ≥10 minutes occurred, and 5% fetal bovine serum soil load was added to prepare the complete test system culture. Ten (10) glass slide carriers (18 mm x 36 mm) per product lot were inoculated with 10 µL of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. Each carrier in a horizontal position was sprayed with the product for 3 seconds until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 4 minutes and 30 seconds at 21.15°C and 40.68% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.14% Lecithin and 1.0% Tween 80 to neutralize. All subcultures were incubated for 48 ± 2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, carrier population and antibiotic resistance.

Note- MRSA-*Staphylococcus aureus* (ATCC 33592) antibiotic resistance to oxacillin was verified by performing a Kirby Bauer Susceptibility assay on the day of testing. The analysis of the assay was based on established performance standards of the Clinical and Laboratory Standards Institute.

8. MRID 487431-18 "AOAC Germicidal Spray Method", Test Organism: Penicillin

Resistant *Streptococcus pneumoniae* (ATCC 700677)" for product Saginaw, by Joshua Luedtke. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN. 55121. Study completion date – October 4, 2011. Project Number A11856.

This study was conducted against Penicillin Resistant *Streptococcus pneumoniae* (ATCC 700677). Two lots (Lot No. 9257-109 and Lot No. 9257-110) of the product, Saginaw, were tested using the provided ATS Labs protocol CX18060111.GS.6. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The test organism culture was prepared by inoculating Tryptic Soy + Sheep Blood agar plates from a stock plate and incubating the plates for two days at 35 – 37°C with 6% CO_2. Growth from the plates was harvested using a sterile swab and transferred to Fluid Thioglycollate Medium. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers (18 mm x 36 mm) per product lot were inoculated with 10 µL of a 2 day old suspension of test organism. The carriers were dried for 30 minutes at 25-30°C at 65% relative humidity. Each carrier in a horizontal position was sprayed with the product for 3 seconds until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 4 minutes and 30 seconds at 21.05°C and 49.35% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Brain Heart Infusion Broth containing 0.14% Lecithin and 1.0% Tween 80 to neutralize. All subcultures were incubated for 48 ± 2 hours at 35-37°C in CO_2. Subcultures were stored at 2 – 8°C for two days prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, carrier population and antibiotic resistance.

Note- Antibiotic resistance of Penicillin Resistant *Streptococcus pneumoniae* (ATCC 70677) was verified using an E-Test assay. The E-Test assay results demonstrated the acceptable MIC value range of penicillin antibiotic resistance for Penicillin Resistant *Streptococcus pneumoniae* (ATCC 70677).

9. MRID 487431-19 "AOAC Germicidal Spray Method", Test Organism: Community Associated Methicillin Resistant *Staphylococcus aureus* CA-MRSA (NARSA NRS 123) (Genotype USA 400)" for product Saginaw, by Joshua Luedtke. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN. 55121. Study completion date – October 4, 2011. Project Number A11862.

This study was conducted against Community Associated Methicillin Resistant *Staphylococcus aureus* CA-MRSA (NARSA NRS 123)(Genotype USA 400). Two lots (Lot No. 9257-109 and Lot No. 9257-110) of the product, Saginaw, were tested using the provided ATS Labs protocol CX18060111.GS.7. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The test culture was prepared by inoculating 10 mL of nutrient broth from a stock slant and performing daily consecutive transfers of a minimum of three but less than thirty transfers of 10 µL of culture into 10 mL of culture media. The final culture was incubated 48 – 54 hours at 35 – 37°C. The upper portions were removed of the 48 - 54 hours cultures of the test system after vortex and settling for ≥10 minutes occurred, and 5% fetal bovine serum soil load was added to prepare the complete test system culture. Ten (10) glass slide carriers (18 mm x 36 mm) per product lot were inoculated with 10 µL of a 48-54 hour old suspension of

test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. Each carrier in a horizontal position was sprayed with the product for 3 seconds until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 4 minutes and 30 seconds at 21.80°C with 48.21% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.14% Lecithin and 1.0% Tween 80 to neutralize. All subcultures were incubated for 48 ± 2 hours at 35-37°C. Subcultures were stored at 2 – 8°C for two days prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, carrier population and antibiotic resistance.

Note- Methicillin Resistant -*Staphylococcus aureus*- CA-MRSA (NARSA NRS123) (Genotype USA 400) antibiotic resistance to oxacillin was verified by performing a Kirby Bauer Susceptibility assay on the day of testing. The analysis of the assay was based on established performance standards of the Clinical and Laboratory Standards Institute.

10. MRID 487431-20 "AOAC Germicidal Spray Method", Test Organism: *Acinetobacter baumannii* (ATCC 19606)" for product Saginaw, by Joshua Luedtke. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN. 55121. Study completion date – October 4, 2011. Project Number A11863.

This study was conducted against *Acinetobacter baumannii* (ATCC 19606). Two lots (Lot No. 9257-109 and Lot No. 9257-110) of the product, Saginaw, were tested using the provided ATS Labs protocol CX18060111.GS.8. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The test culture was prepared by inoculating 10 mL of nutrient broth from a stock slant and performing daily consecutive transfers of a minimum of three but less than thirty transfers of 10 µL of culture into 10 mL of culture media. The final culture was incubated 48 – 54 hours at 35 – 37°C. The upper portions were removed of the 48 - 54 hours cultures of the test system after vortex and settling for ≥10 minutes occurred, and 5% fetal bovine serum soil load was added to prepare the complete test system culture. Ten (10) glass slide carriers (18 mm x 36 mm) per product lot were inoculated with 10 µL of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C at 41% relative humidity. Each carrier in a horizontal position was sprayed with the product for 3 seconds until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 4 minutes and 30 seconds at 20°C with 60% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.14% Lecithin and 1.0% Tween 80 to neutralize. All subcultures were incubated for 48 ± 2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population

11. MRID 487431-21 "AOAC Germicidal Spray Method", Test Organism: Multidrug Resistant *Enterococcus faecium* (ATCC 51559)" for product Saginaw, by Joshua Luedtke. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan MN. 55121. Study completion date – October 4, 2011. Project Number A11855.

This study was conducted against Multidrug Resistant *Enterococcus faecium* (ATCC

51559). Two lots (Lot No. 9257-109 and Lot No. 9257-110) of the product, Saginaw, were tested using the provided ATS Labs protocol CX18071911.GS. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The test culture was prepared by inoculating 10 mL of Fluid Thioglycollate media from a stock slant and performing daily consecutive transfers of a minimum of three but less than thirty transfers of 10 µL of culture into 10 mL of culture media. The final culture was incubated 48 – 54 hours at 35 – 37°C. The upper portions were removed of the 48 - 54 hours cultures of the test system after vortex and settling for ≥10 minutes occurred, and 5% fetal bovine serum soil load was added to prepare the complete test system culture. Ten (10) glass slide carriers (18 mm x 36 mm) per product lot were inoculated with 10 µL of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 25-30°C at 65% relative humidity. Each carrier in a horizontal position was sprayed with the product for 3 seconds until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 4 minutes and 30 seconds at 24°C and 37.6% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.14% Lecithin and 1.0% Tween 80 to neutralize. All subcultures were incubated for 48 ± 2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, carrier population and antibiotic resistance.

Note- Antibiotic resistance was tested at the University of Minnesota Physicians Outreach Laboratory in Minneapolis, Minnesota. The testing was not performed under EPA Good Laboratory Practices. The test demonstrated Multidrug Resistant *Enterococcus faecium* (ATCC 51559) resistant to Ampicillin, Penicillin, and Gentamicin.

12. MRID 487431-22 "AOAC Germicidal Spray Method", Test Organism: Multidrug Resistant *Klebsiella pneumoniae* (ATCC 51503)" for product Saginaw, by Matthew Sathe. Study conducted at ATS Labs 1285 Corporate Center Drive Suite 110 Eagan, MN 55121. Study completion date – October 12, 2011. Project Number A11897.

This study was conducted against Multidrug Resistant *Klebsiella pneumoniae* (ATCC 51503). Two lots (Lot No. 9257-109 and Lot No. 9257-110) of the product, Saginaw, were tested using the provided ATS Labs protocol CX18082311.GS. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The test culture was prepared by inoculating 10 mL of nutrient broth from a stock slant and performing daily consecutive transfers of a minimum of three but less than thirty transfers of 10 µL of culture into 10 mL of culture media. The final culture was incubated 48 – 54 hours at 35 – 37°C. The upper portions were removed of the 48 - 54 hours cultures of the test system after vortex and settling for ≥10 minutes occurred, and 5% fetal bovine serum soil load was added to prepare the complete test system culture. Ten (10) glass slide carriers (18 mm x 36 mm) per product lot were inoculated with 10 µL of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C with 50% relative humidity. Each carrier in a horizontal position was sprayed with the product for 3 seconds until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 4 minutes and 30 seconds at 23°C and 34.32% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.14% Lecithin and 1.0% Tween 80 to

neutralize. All subcultures were incubated for 48 ± 2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, carrier population and antibiotic resistance.

Note- Antibiotic resistance was tested at the University of Minnesota Physicians Outreach Laboratory in Minneapolis, Minnesota. The testing was not performed under EPA Good Laboratory Practices. The test demonstrated Multidrug Resistant *Klebsiella pneumoniae* (ATCC 51503) resistant to Ampicillin, Ampicillin/Sulbactam, Cefazolin, Cefepime, Ceftazidime, Ceftriaxone, Gentamicin, and Trimethoprim/Sulfa.

13. MRID 487431-23 "AOAC Germicidal Spray Method", Test Organism: Vancomycin Resistant *Enterococcus faecalis* - *VRE* (ATCC 51575)" for product Saginaw, by Jill Ruhme. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121. Study completion date – October 13, 2011. Project Number A11940.

This study was conducted against Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575). Two lots (Lot No. 9257-109 and Lot No. 9257-110) of the product, Saginaw, were tested using the provided ATS Labs protocol CX18060111.GS.9. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The test culture was prepared by inoculating 10 mL of Fluid Thioglycollate media from a stock slant and performing daily consecutive transfers of a minimum of three but less than thirty transfers of 10 µL of culture into 10 mL of culture media. The final culture was incubated 48 – 54 hours at 35 – 37°C. The upper portions were removed of the 48 - 54 hours cultures of the test system after vortex and settling for ≥10 minutes occurred, and 5% fetal bovine serum soil load was added to prepare the complete test system culture. Ten (10) glass slide carriers (18 mm x 36 mm) per product lot were inoculated with 10 µL of a 48-54 hour old suspension of test organism. The carriers were dried for 30 minutes at 25-30°C at 65% relative humidity. Each carrier in a horizontal position was sprayed with the product for 3 seconds until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 4 minutes and 30 seconds at 22.26°C with 25.42% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.14% Lecithin and 1.0% Tween 80 to neutralize. All subcultures were incubated for 48 ± 2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, carrier population and antibiotic resistance.

Note- Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575) antibiotic resistance to vancomycin was verified by performing a Kirby Bauer Susceptibility assay on the day of testing. The analysis of the assay was based on established performance standards of the Clinical and Laboratory Standards Institute.

14. MRID 487431-24 "AOAC Germicidal Spray Method", Test Organism: Multidrug Resistant *Staphylococcus aureus* (ATCC 14154)" for product Saginaw, by Matthew Sathe. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN. 55121. Study completion date – December 6, 2011. Project Number A12013.

This study was conducted against Multidrug Resistant *Staphylococcus aureus* (ATCC 14154). Two lots (Lot No. 9257-109 and Lot No. 9257-110) of the product, Saginaw, were tested using the provided ATS Labs protocol CX18082511.GS.1. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The test culture was prepared by inoculating 10 mL of Nutrient broth from a stock slant and performing daily consecutive transfers of a minimum of three but less than thirty transfers of 10 µL of culture into 10 mL of culture media. The final culture was incubated 48 – 54 hours at 35 – 37°C. The upper portions were removed of the 48 - 54 hours cultures of the test system after vortex and settling for ≥10 minutes occurred, and 5% fetal bovine serum soil load was added to prepare the complete test system culture. Ten (10) glass slide carriers (18 mm x 36 mm) per product lot were inoculated with 10 µL of a 48 - 54 hour old suspension of test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. Each carrier in a horizontal position was sprayed with the product for 3 seconds until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 4 minutes and 30 seconds at 22.1°C and 33.7% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth containing 0.14% Lecithin and 1.0% Tween 80 to neutralize. All subcultures were incubated for 48 ± 2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, carrier population and antibiotic resistance.

Note- Antibiotic resistance was tested at the University of Minnesota Physicians Outreach Laboratory in Minneapolis, Minnesota. The testing was not performed under EPA Good Laboratory Practices. The test demonstrated Multidrug Resistant *Staphylococcus aureus* (ATCC 14154) resistant to Clindamycin, Erythromycin, Penicillin, and Tetracycline.

15. MRID 487431-25 "AOAC Germicidal Spray Method", Test Organism: Multi-Drug Resistant *Streptococcus pneumoniae* (ATCC 700677)" for product Saginaw, by Matthew Sathe. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110. Study completion date – December 6, 2011. Project Number A12014.

This study was conducted against Multi-Drug Resistant *Streptococcus pneumoniae* (ATCC 700677). Two lots (Lot No. 9257-109 and Lot No. 9257-110) of the product, Saginaw, were tested using the provided ATS Labs protocol CX18082511.GS.2. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The test culture was prepared by inoculating five (5) Tryptic Soy + 5% Sheep Blood Agar plates with a stock culture. The plates were incubated for 4 days at 35-37°C and 5-7% CO_2 prior to suspending the organism by adding 2.0 mL of Fluid Thioglycollate Medium to each plate. The test culture suspension was collected and vortex mixed to resuspend the organism after a process of centrifuge concentration of culture and removal of 1.50 mL of Fluid Thioglycollate Medium. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers (18 mm x 36 mm) per product lot were inoculated with 10 µL of a 4 day old suspension of test organism. The carriers were dried for 30 minutes at 25-30°C with 65% relative humidity. Each carrier in a horizontal position was sprayed with the product for 3 seconds until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 4 minutes and 30 seconds at 24.3°C and 30.7% relative humidity. Following

exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Brain Heart Infusion Broth containing 0.14% Lecithin and 1.0% Tween 80 to neutralize. All subcultures were incubated for 48 ± 2 hours at 35-37°C in 5-7% CO_2. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, carrier population and antibiotic resistance.

Note- Antibiotic resistance was tested at the University of Minnesota Physicians Outreach Laboratory in Minneapolis, Minnesota. The testing was not performed under EPA Good Laboratory Practices. The test demonstrated Multidrug Resistant *Streptococcus pneumoniae* (ATCC 700677) resistant to Ceftriaxone, Clindamycin, Meropenem, Penicillin, and Azithromycin.

16. MRID 487431-26 "Fungicidal Germicidal Spray Method", Test Organism: *Trichophyton mentagrophytes* (ATCC 9533)" for product Saginaw, by Christine Chan. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN. 55121. Study completion date – October 11, 2011. Project Number A11874.

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Two lots (Lot No. 9257-109 and Lot No. 9257-110) of the product, Saginaw, were tested using the provided ATS Labs protocol CX18062411.FGS. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The test culture was prepared by inoculating Potato Dextrose Agar plates with a stock culture. The plates were incubated for 10 days at 25-30°C prior to removing the mycelia from all plates and transferring the mycelia to a glass bottle containing beads and 0.85% saline + 0.05% Triton X-100. The test culture suspension was mixed thoroughly and filtered through sterile gauze to remove hyphal fragments. The conidial concentration was estimated using a hemacytometer. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers (18 mm x 36 mm) per product lot were inoculated with 10 µL of a 10 day old suspension of test organism. The carriers were dried for 38 minutes at 35-37°C with 40% relative humidity. Each carrier in a horizontal position was sprayed with the product for 3 seconds until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 4 minutes and 30 seconds at 20.96°C and 51.90% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Sabouraud Dextrose Broth containing 0.14% Lecithin and 1.0% Tween 80 to neutralize. All subcultures were incubated for 44-76 hours at 25-30°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

17. MRID 487431-27 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Virus: Coxsackievirus type B3, Strain Nancy, ATCC VR-30, for product Saginaw, by Shanen Conway. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN. 55121. Study completion date – November 7, 2011. Project Number A11899.

This study was conducted against Coxsackievirus type B3 (Strain Nancy; ATCC VR-30), using BGMK cells (Buffalo Green Monkey Kidney cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division) as the host system. Two lots (Lot No. 9257-109 and Lot No. 9257-

110) of the product, Saginaw, were tested according to the provided ATS Labs Protocol No. CX18060111.COX. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The stock virus was prepared by collecting the supernatant fluid from 75 – 100% infected culture cells that were disrupted and cell debris separated from supernatant by centrifugation. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. The stock virus was aliquoted and stored at ≤ -70°C until the day of use. An aliquot of the stock virus is thawed and maintained at a refrigerated temperature until used in the assay on the day of use. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes (100 mm x 15 mm). The virus films were dried for 20 minutes at 20.0°C with 50% relative humidity. One replicate per product lot was tested. For each lot of product, separate dried virus films were sprayed until thoroughly wet (4 seconds) at a distance of 6-8 inches and held covered for 5 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 2% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. BGMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of each dilution. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the Spearman Karber method.

18. MRID 487431-28 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Virus: Hepatitis A virus, Strain HM-175" for product Saginaw, by Shanen Conway. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121. Study completion date – October 27, 2011. Project Number A11881.

This study was conducted against Hepatitis A virus (Strain HM-175; obtained from Apptec Laboratory Services, Camden, N.J.), using FRhK-4 cells (Fetal Rhesus Monkey Kidney cells; ATCC CRL-1688) as the host system. Two lots (Lot No. 9257-109 and Lot No. 9257-110) of the product, Saginaw, were tested according to the provided ATS Labs Protocol No. CX18060111.HAV marked. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The stock virus was prepared by collecting the supernatant fluid from 75 – 100% infected culture cells that were disrupted and cell debris separated from supernatant by centrifugation. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. The stock virus was aliquoted and stored at ≤ -70°C until the day of use. An aliquot of the stock virus was thawed and maintained at a refrigerated temperature until used in the assay on the day of use. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes (100 mm x 15 mm). The virus films were dried for 20 minutes at 20.0°C with 50% relative humidity. For each lot of product, separate dried virus films were sprayed until thoroughly wet (4 seconds) at a distance of 6-8 inches and held covered for 5 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 10% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL

penicillin, 2.5 µg/mL amphotericin B and 2.0 mM L-glutamine. FRhK-4 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of each dilution. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 14 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the Spearman Karber method.

19. MRID 487431-29 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Duck Hepatitis B Virus as a Surrogate Virus for Human Hepatitis B Virus" for product Saginaw, by Mary Miller. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN. 55121. Study completion date – November 22, 2011. Project Number A11993.

This study was conducted against Duck Hepatitis B Virus (Strain 7/31/07; obtained from Hepadnavirus Testing Inc., Palo Alto, CA), using hepatocytes obtained from an *in situ* perfusion of 5 day old Pekin hatchlings (Ducklings obtained from Metzer Farms; verification of absence of Hepatitis virus and perfusion conducted by Valley Research Institute, Hudson, WI) as the host system. Two lots (Lot No. 9257-109 and Lot No. 9257-110) of the product, Saginaw, were tested according to the provided ATS Labs protocol CX18060111.DHBV.1. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The stock virus culture was obtained from congenitally infected ducklings. The stock virus culture was adjusted to contain 5% duck serum as the organic soil load, and was aliquoted and stored at ≤ -70°C until the day of use. On the day of use, two aliquots of stock virus (Lot 7/31/07 pool) were removed, thawed, combined, and maintained at a refrigerated temperature until used in the assay. The host cell line was obtained from hatchlings that blood samples were tested for the presence of test virus via a polymerase chain reaction specific for DHBV by the Center for AIDS Research at Stanford University and found clear of viral presence. The hepatocyte cells used as the host cells were purified at the VRI Laboratory Facility by *in situ* perfusion of the hatchling duck liver utilizing S-MEM medium containing collagenase. Once the hepatocytes were received at ATS Labs, they were seeded in sterile twelve well tissue culture labware. The host cell line culture was maintained at the appropriate density and incubated at 36 – 38°C in a humidified atmosphere with 5 – 7% CO_2. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes (100 mm x 15 mm). The virus films were dried for 30 minutes at 20.0°C with 50% relative humidity. Two replicates per product lot were tested. For each lot of product, separate dried virus films were sprayed until thoroughly wet (4 seconds) at a distance of 6-8 inches and held covered for 1 minute at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in Leibovitz L-15 Medium with 0.1% glucose, 10 µM dexamethasone, 10 µg/mL insulin, 20mM HEPES, 10 µg/mL gentamicin and 100 units/mL penicillin. Primary duck hepatocyctes in multi-well culture dishes were inoculated in quadruplicate with 0.25 mL of each dilution. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 9 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. Log reductions in infectivity were calculated using a Most Probable Number statistical method obtained from M. Hamilton (Big Sky Statistical Analysts LLC, Bozeman, MT).

20. MRID 487431-30 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Duck Hepatitis B Virus as a Surrogate Virus for Human Hepatitis B Virus – Confirmatory Study" for product Saginaw, by Shanen Conway. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN. 55121. Study completion date – November 7, 2011. Project Number A11994.

This study was conducted against Duck Hepatitis B Virus (Strain 7/31/07; obtained from Hepadnavirus Testing Inc., Palo Alto, CA), using hepatocytes obtained from an *in situ* perfusion of 4 day old Pekin hatchlings (Ducklings obtained from Metzer Farms; verification of duckling absence of Hepatitis virus and perfusion conducted by Valley Research Institute, Hudson, WI) as the host system. Lot 9257-110) of the product, Saginaw, were tested according to the provided ATS Labs protocol CX18060111.DHBV.2. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The stock virus culture was obtained from congenitally infected ducklings. The stock virus culture was adjusted to contain 5% duck serum as the organic soil load, and was aliquoted and stored at ≤ -70°C until the day of use. On the day of use, one aliquot of stock virus (Lot 7/31/07 pool) was removed, thawed, and maintained at a refrigerated temperature until used in the assay. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes (100 mm x 15 mm). The virus films were dried for 30 minutes at 20.0°C at 50% relative humidity. Two replicates per product lot were tested. For each lot of product, separate dried virus films were sprayed until thoroughly wet (4 seconds) at a distance of 6-8 inches and held covered for 1 minute at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in Leibovitz L-15 Medium with 0.1% glucose, 10 µM dexamethasone, 10 µg/mL insulin, 20mM HEPES, 10 µg/mL gentamicin and 100 units/mL penicillin. Primary duck hepatocyctes in multi-well culture dishes were inoculated in quadruplicate with 0.25 mL of each dilution. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 9 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. Log reductions in infectivity were calculated using a Most Probable Number statistical method obtained from M. Hamilton (Big Sky Statistical Analysts LLC, Bozeman, MT).

21. MRID 487431-31 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Herpes Simplex Virus type 1, Strain F(1), ATCC VR-733" for product Saginaw, by Mary Miller. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN. 55121. Study completion date – November 2, 2011. Project Number A11896.

This study was conducted against Herpes Simplex Virus type 1 (Strain F(1); ATCC VR-733), using RK cells (Rabbit Kidney cells; obtained from ViroMed Laboratories, Inc.) as the host system. Two lots (Lot No. 9257-109 and Lot No. 9257-110) of the product, Saginaw, were tested according to the provided ATS Labs Protocol No. CX18060111.HSV1. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The stock virus was prepared by collecting the supernatant fluid from 75 – 100% infected culture cells that were disrupted and

cell debris separated from supernatant by centrifugation. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. The stock virus was aliquoted and stored at ≤ -70°C until the day of use. An aliquot of the stock virus (ATS Labs H61) was thawed and maintained at a refrigerated temperature until used in the assay on the day of use. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes (100 mm x 15 mm). The virus films were dried for 20 minutes at 20.0°C with 50% relative humidity. For each lot of product, separate dried virus films were sprayed until thoroughly wet (4 seconds) at a distance of 6-8 inches and held covered for 5 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 5% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of each dilution. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

22. MRID 487431-32 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Human Immunodeficiency Virus type 1, Strain HTLV-III_B" for product Saginaw, by Shanen Conway. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN. 55121. Study completion date – October 19, 2011. Project Number A11891.

This study was conducted against Human Immunodeficiency Virus type 1 (Strain HTLV-III_B; obtained from Advanced Biotechnologies, Inc. (Columbia, MD)), using MT-2 cells (human T-cell leukemia cells; obtained from AIDS Research and Reference Reagent Program, NIH.) as the host system. Two lots (Lot No. 9257-109 and Lot No. 9257-110) of the product, Saginaw, were tested according to the provided ATS Labs Protocol No. CX18060111.HIV. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The stock virus was prepared by collecting the supernatant fluid from infected culture cells that were disrupted and cell debris separated from supernatant by centrifugation. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. The stock virus was aliquoted and stored at ≤ -70°C until the day of use. An aliquot of the stock virus (ATS Labs Lot HIV-9) was thawed and maintained at a refrigerated temperature until used in the assay on the day of use. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes (100 mm x 15 mm). The virus films were dried for 25 minutes at 21.0°C with 45.7% relative humidity. For each lot of product, separate dried virus films were sprayed until thoroughly wet (4 seconds) at a distance of 6-8 inches and held covered for 1 minute at 21.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in RPMI-1640 with 15% (v/v) heat-inactivated fetal bovine serum, 50 µg/mL gentamicin, and 2.0mM L-glutamine. MT-2 cells in multi-well culture dishes were inoculated in quadruplicate with 0.2 mL of each dilution. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 10 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and

neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

23. MRID 487431-33 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Influenza A virus, Strain Hong Kong, ATCC VR-544" for product Saginaw, by Shanen Conway. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN. 55121. Study completion date – October 27, 2011. Project Number A11907.

This study was conducted against Influenza A Virus (Strain Hong Kong; ATCC VR-544), using RMK cells (Rhesus Monkey Kidney cells; obtained from Viromed Laboratories, Inc.) as the host system. Two lots (Lot No. 9257-109 and Lot No. 9257-110) of the product, Saginaw, were tested according to the provided ATS Labs Protocol No. CX18060111.FLUA. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The stock virus was prepared by collecting the supernatant fluid from 75 – 100% infected culture cells that were disrupted and cell debris separated from supernatant by centrifugation. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. The stock virus was aliquoted and stored at ≤ -70°C until the day of use. An aliquot of the stock virus (ATS Labs Lot F90) was thawed and maintained at a refrigerated temperature until used in the assay on the day of use. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes (100 mm x 15 mm). The virus films were dried for 20 minutes at 20.0°C with 40% relative humidity. For each lot of product, separate dried virus films were sprayed until thoroughly wet (4 seconds) at a distance of 6-8 inches and held covered for 5 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in Minimal Essential Medium with 1% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of each dilution. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

24. MRID 487431-34 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Respiratory syncytial virus, Strain Long, ATCC VR-26" for product Saginaw, by Mary Miller. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN. 55121. Study completion date – October 11, 2011. Project Number A11892.

This study was conducted against Respiratory Syncytial Virus (Strain Long; ATCC VR-26), using Hep-2 cells (human larynx cells; obtained from Viromed Laboratories, Inc.) as the host system. Two lots (Lot No. 9257-109 and Lot No. 9257-110) of the product, Saginaw, were tested according to the provided ATS Labs Protocol No. CX18060111.RSV marked as proprietary information. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The stock virus was prepared by collecting the supernatant fluid from 75 – 100% infected culture cells that were disrupted and cell debris separated from supernatant by centrifugation. The stock virus culture was adjusted to contain 5% fetal bovine serum as the

organic soil load. The stock virus was aliquoted and stored at ≤ -70°C until the day of use. An aliquot of the stock virus (ATS Labs Lot NRSV-23) was thawed and maintained at a refrigerated temperature until used in the assay on the day of use. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes (100 mm x 15 mm). The virus films were dried for 20 minutes at 20.0°C with 50% relative humidity. For each lot of product, separate dried virus films were sprayed until thoroughly wet (4 seconds) at a distance of 6-8 inches and held covered for 5 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in Eagle's Minimal Essential Medium with 2% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL Fungizone, 10mL HEPES, 10 µg/mL vancomycin, and 2 mM L-glutamine. Hep-2 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of each dilution. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 9 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

25. MRID 487431-35 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Rhinovirus type 37, Strain 151-1, ATCC VR-1147" for product Saginaw, by Mary J. Miller. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN. 55121. Study completion date – November 2, 2011. Project Number A11936.

This study was conducted against Rhinovirus type 37 (Strain 151-1; ATCC VR-1147), using MRC-5 cells (human embryonic lung cells; ATCC CCL-171) as the host system. Two lots (Lot No. 9257-109 and Lot No. 9257-110) of the product, Saginaw, were tested according to the provided ATS Labs Protocol No. CX18060111.R37. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The stock virus was prepared by collecting the supernatant fluid from 75 – 100% infected culture cells that were disrupted and cell debris separated from supernatant by centrifugation. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. The stock virus was aliquoted and stored at ≤ -70°C until the day of use. An aliquot of the stock virus (ATS Labs Lot NR37-14) was thawed and maintained at a refrigerated temperature until used in the assay on the day of use. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes (100 mm x 15 mm). The virus films were dried for 20 minutes at 15.5°C with 50% relative humidity. For each lot of product, separate dried virus films were sprayed until thoroughly wet (4 seconds) at a distance of 6-8 inches and held covered for 5 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in Minimal Essential Medium with 10% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. MRC-5 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of each dilution. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

26. MRID 487431-36 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Rotavirus, Strain WA" for product Saginaw, by Mary J. Miller. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN. 55121. Study completion date – October 19, 2011. Project Number A11935.

This study was conducted against Rotavirus (Strain WA; obtained from University of Ottawa (Ontario, Canada)), using MA-104 cells (Rhesus Monkey Kidney cells; obtained from Diagnostic Hybrids (Athens, OH)) as the host system. Two lots (Lot No. 9257-109 and Lot No. 9257-110) of the product, Saginaw, were tested according to the provided ATS Labs Protocol No. CX18060111.ROT. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The stock virus was prepared by collecting the supernatant fluid from 75 – 100% infected culture cells that were disrupted and cell debris separated from supernatant by centrifugation. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. The stock virus was aliquoted and stored at ≤ -70°C until the day of use. An aliquot of the stock virus (ATS Labs Lot XR-137) was thawed and maintained at a refrigerated temperature until used in the assay on the day of use. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes (100 mm x 15 mm). The virus films were dried for 20 minutes at 20.0°C with 40% relative humidity. For each lot of product, separate dried virus films were sprayed until thoroughly wet (4 seconds) at a distance of 6-8 inches and held covered for 5 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in Minimal Essential Medium with 10 µg/mL gentamicin, 100 units/mL penicillin, 0.5 µg/mL trypsin, 2.5 µg/mL amphotericin B, and 2.0 mM L-glutamine. MA-104 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of each dilution. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

27. MRID 487431-37 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application)," Test Organisms: Enterobacter aerogenes (ATCC 13048) and Staphylococcus aureus (ATCC 6538), for product Saginaw, by Christine Chan. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN. 55121. Study completion date – October 26, 2011. Project Number A11883.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Three lots (Lot No. 9257-109, Lot No. 9257-110, and Lot No. 9257-86) of the product, Saginaw, were tested according to the provided ATS Labs Protocol No. CX18082411.NFS. One lot was ≥60 days old (Lot No. 9257-86). The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The test culture was prepared by inoculating 10 mL of culture broth from a stock slant and performing daily consecutive transfers of a minimum of three but less than thirty transfers of 10 µL of culture into 10 mL of culture media. The final culture was incubated 48 – 54 hours at 35 – 37°C. The upper two-third

portions of the culture were removed from the 48 - 54 hours cultures of the test system after vortex and settling for ≥15 minutes occurred, and 5% fetal bovine serum soil load was added to prepare the complete test system culture. Five sterile glass (1" x 1") carriers per product lot per microorganism were inoculated with 20 µL of 48-54 hours old suspension of microorganisms. The inoculum was spread to within 1/8 inch of the edges of the carrier. The carriers were dried for 20 minutes at 35-37°C with 40% relative humidity. Each carrier was sprayed with the product for 3 seconds until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 30 seconds at 20°C. After exposure, each carrier was placed into a sterile vessel containing 20 mL of D/E Neutralizing Broth. Following neutralization, the excess liquid from each plastic Petri dish was transferred to the corresponding neutralizer vessel containing the corresponding carrier. The vessels were vortex-mixed to suspend the surviving organisms. Within 30 minutes of the addition of the neutralizer, 1.0 mL aliquots of the 10^0 and 10^{-1} dilutions were plated in duplicate on tryptic soy agar with 5% sheep's blood. All plates were incubated for 48±4 hours at 35-37°C prior to observation for visually enumerated. Controls included those for purity, sterility, carrier quantitation, inoculum count, and neutralization confirmation.

28. MRID 487431-38 "Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Modification for Spray Product Application)," Test Organisms: Staphylococcus aureus (ATCC 6538) and Enterobacter aerogenes (13048) for product Saginaw, by Christine Chan. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN. 55121. Study completion date – October 18, 2011. Project Number A11839.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Three lots (Lot No. 9257-109, Lot No. 9257-110, and Lot No. 9257-86), of the product, Saginaw, were tested according to the provided ATS Labs Protocol No. CX18060111.NFS.2. One lot was ≥60 days old (Lot No. 9257-86). The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. The test culture was prepared by inoculating 10 mL of culture broth from a stock slant and performing daily consecutive transfers of a minimum of three but less than thirty transfers of 10 µL of culture into 10 mL of culture media. The final culture was incubated 48 – 54 hours at 35 – 37°C. The upper two-third portions of the culture were removed from the 48 - 54 hours cultures of the test system after vortex and settling for ≥15 minutes occurred, and 5% fetal bovine serum soil load was added to prepare the complete test system culture. Fetal bovine serum was added to each inoculum to achieve a 5% organic soil load. Five sterile (1" x 1") cotton carriers, each containing 80 x 80 threads/inch of plain cotton weave, per product lot per microorganism were inoculated with 20 µL of 48-54 hours old suspensions of microorganisms. The inoculum was distributed by calibrated pipette evenly over the carrier. The carriers were dried for 20 minutes at 35-37°C with 40% relative humidity. Each carrier was transferred to a plastic Petri dish and was sprayed with the product for 3 seconds until thoroughly wet at a distance of 6-8 inches from the carrier surface. Each carrier remained in contact with the product for 30 seconds at 21.2°C and 50.9% relative humidity. After exposure, each carrier was placed into a sterile vessel containing 20 mL of D/E Neutralizing Broth with glass beads. The glass beads were utilized to aid in organism recovery. Following neutralization, the excess liquid from each plastic Petri dish was transferred to the corresponding neutralizer vessel containing the corresponding carrier. The vessels were vortex mixed to suspend the surviving organisms. Within 30 minutes of the addition of the

neutralizer, the neutralized solution was diluted ten-fold and 1.0 mL aliquots of the 10^0 and 10^{-1} dilutions were plated in duplicate on tryptic soy agar with 5% sheep's blood. All plates were incubated for 48±4 hours. The S. aureus plates were incubated at 35-37°C and the E. aerogenes plates were incubated at 25-30°C prior to observation for visually enumerated. Controls included those for purity, sterility, carrier quantitation, inoculum count, and neutralization confirmation.

29. MRID 487431-39 "Fabric Mildew Fungistatic Test," Test Organisms: *Aspergillus brasiliensis* (ATCC 16404) and *Penicillium variable* (ATCC 52262), for product Saginaw, by Matthew Sathe. Study conducted at ATS Labs 1285 Corporate Drive, Suite 110 Eagan, MN. 55121. Study completion date – January 4, 2011. Project Number A11898.

This study was conducted against *Aspergillus brasiliensis* (ATCC 16404) and *Penicillium variabile* (ATCC 52262). Two lots (Lot No. 9257-109 and Lot No. 9257-110) of the product, Saginaw, were tested according to the provided ATS Labs Protocol No. CX18062411.FMSTAT marked as proprietary information. The product was received as a ready-to-use aerosol spray. The test lots were prepared at the lower certified limit (LCL) in accordance with the Confidential Statement of Formula. *Aspergillus brasiliensis* conidial suspension was prepared by inoculation of Sabouraud Agar (Modified) with the stock culture and incubation for 10 days at 25 – 30°C. Following incubation, sterile glass beads along with saline/Triton solution (0.85% saline + 0.05% Triton X-100) was added and agitated to remove mycelia/conidia from agar. The aspirated conidia suspension was passed through sterile gauze to remove hyphal fragments. Counts were done using a hemacytometer. On the day of testing, the conidial suspension was standardized by adding 2 mL of unadjusted culture with 18 mL 0.85% saline + 0.05% Triton X-100. *Penicillium variabile* culture was prepared by inoculation of 20 agar plates with a stock culture and incubation at 25 – 30°C for 14 days. Following incubation, 2 mL of saline/Triton solution (0.85% saline + 0.05% Triton X-100) was added to each plate and growth was harvested from the agar using a sterile loop and cell scraper. The conidial suspension was passed through sterile gauze to remove hyphal fragments. Counts were done using a hemacytometer and the conidial suspension was not adjusted. After conidial suspensions of the challenge microorganisms were prepared, fetal bovine serum was added to the culture to achieve a 5% organic soil load. Strips measuring 25 x 75 mm each were cut from 136 to 203 g/m2 (4 to 6 oz/yd^2) cotton muslin. All strips were autoclaved, with a subsequent soak in glycerol nutrient solution for 3 minutes. Each fabric strip was dried under sterile conditions before use. Ten dried, nutrient saturated fabric strips per lot were evaluated. Each fabric strip was sprayed, at a distance of 6-8 inches from the strip, on both sides with the product for 2 seconds until thoroughly wet. The strips were hung in a vertical or near vertical position to drain and dry. Ten untreated fabric strips were evaluated as the untreated control. All samples were allowed to dry before inoculation. Equal volumes of *A. brasiliensis* (4.2 x 10^6 conidia/ml) and *P. variabile* (1.34 x 10^7 conidia/ml) suspensions with 5% soil incorporated were mixed together and agitated. Each side of each fabric strip was lightly sprayed to inoculate the mixed conidial suspension using a DeVilbiss atomizer. The fabric samples were suspended in individual 250 ml jars containing approximately 10 ml sterile water, and incubated at 25-30°C. Observations were made and recorded weekly for 4 weeks (minimally 7, 14, 21 and 28 days). The presence or absence of observable mold on the fabric strips was the criterion for determining the efficacy of the test agent. Visible growth was not evident at Day 7, 14, or 21. Visible growth was reported on Day 28. Controls included those for purity and sterility. The reported growth percentages on untreated control strips were at least 50%.

V. RESULTS:

Hard Surface Bactericidal & Fungicidal Disinfection Results:

MRID Number	Organism	No. Carriers Exhibiting Growth/ Total No. Tested.			Carrier Population (CFU/Carrier)
		Lot 9257-109	Lot 9257-110	Lot 9257-86 (≥60 days old)	
487431-11	*Staphylococcus aureus* (ATCC 6538)	4 min. 30 sec. Date - 8/17/11: 3/60 4 min. 45 sec. Date - 8/26/11: 0/60	1/60	0/60	Both Dates: 2.04×10^6
487431-12	*Salmonella enterica* (ATCC 10708)	1/60	0/60	1/60	1.2×10^6
487431-13	*Pseudomonas aeruginosa* (ATCC 15442)	4 min. 30 sec. Date - 8/17/11: 2/60 4 min. 45 sec. Date - 8/26/11: 0/60	1/60	1/60	Date - 8/17/11: 2.81×10^6 Date - 8/26/11: 2.09×10^6
4 minutes 30 seconds exposure period for MRID Nos. listed below					
487431-14	Extended Spectrum beta-lactamase (ESBL) producing *Escherichia coli* (ATCC BAA-196)	0/10	0/10	-	5.13×10^4
487431-15	*Enterobacter aerogenes* (ATCC 13048)	0/10	0/10	-	2.08×10^7
487431-16	*Klebsiella pneumoniae* (ATCC 4352)	0/10	0/10	-	5.01×10^5
487431-17	Methicillin resistant *Staphylococcus aureus* (MRSA) (ATCC 33592)	0/10	0/10	-	1.1×10^6
487431-18	Penicillin resistant *Streptococcus pneumoniae* (ATCC 700677)	0/10	0/10	-	1.74×10^5
487431-19	Community Associated Methicillin Resistant *Staphylococcus aureus* - CA-MRSA (NARSA NRS123)	0/10	0/10	-	1.1×10^6
487431-20	*Acinetobacter baumannii* (ATCC 19606)	0/10	0/10	-	2.14×10^6
487431-21	*Enterococcus faecium* (ATCC 51559) (Multi-drug	0/10	0/10	-	7.94×10^5

	resistant)				
487431-22	Multidrug resistant *Klebsiella pneumoniae* (ATCC 51503)	0/10	0/10	-	4.6×10^5
MRID Number	**Organism**	**No. Carriers Exhibiting Growth/ Total No. Tested.**			**Carrier Population** (CFU/Carrier)
		Lot 9257-109	**Lot 9257-110**	**Lot 9257-86** (≥60 days old)	
4 minutes 30 seconds exposure period for MRID Nos. listed below					
487431-23	Vancomycin resistant *Enterococcus faecalis* (VRE) (ATCC 51575)	0/10	0/10	-	4.36×10^4
487431-24	Multidrug resistant *Staphylococcus aureus* (ATCC 14154)	0/10	0/10	-	1.66×10^6
487431-25	Multidrug resistant *Streptococcus pneumoniae* (ATCC 700677)	0/10	0/10	-	1.48×10^5
487431-26	*Trichophyton mentagrophytes* (ATCC 9533)	0/10	0/10	-	8.5×10^4

Hard Surface Virucidal Disinfection Results:

MRID Number	**Organism**	**Results**			**Dried Virus Control** ($TCID_{50}$/0.1mL)
		Description	**Lot 9257-109**	**Lot 9257-110**	
487431-27	Coxsackie Type B3 Virus (ATCC VR-30)	5 minute exposure period			$10^{5.00}$
		10^{-1} to 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	
		TCD_{50}/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		Log Reduction	≥4.50	≥4.50	
487431-28	Hepatitis A Virus Strain HM-175	5 minute exposure period			$10^{5.00}$
		10^{-1} to 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	
		TCD_{50}/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		Log Reduction	≥4.50	≥4.50	
487431-29	Hepatitis B Virus (Duck Hep B virus as surrogate)	1 minute exposure period			$10^{5.50}$
		10^{-1} to 10^{-7} dilutions	Complete Inactivation for Replicate #1 and Replicate #2	Complete Inactivation for Replicate #1 and Replicate #2	

MRID	Organism	Results			Dried
		TCD_{50}/0.25mL	Replicate #1: $\leq 10^{0.50}$	Replicate #1: $\leq 10^{0.50}$	
			Replicate #2: $\leq 10^{0.50}$	Replicate #2: $\leq 10^{0.50}$	
		*MPN Log Reduction	$\geq$5.38	$\geq$5.38	

MRID Number	Organism	Results			Dried Virus Control ($TCID_{50}$/0.1mL)
		Description	Lot 9257-109	Lot 9257-110	
487431-30	Hepatitis B Virus (Duck Hep B virus as surrogate) (Confirmatory)	1 minute exposure period			$10^{5.50}$
		10^{-1} to 10^{-7} dilutions	-	Complete Inactivation for Replicate #1 and Replicate #2	
		TCD_{50}/0.25mL	-	Replicate #1: $\leq 10^{0.50}$	
				Replicate #2: $\leq 10^{0.50}$	
		*MPN Log Reduction	-	$\geq$5.38	
487431-31	Herpes Simplex Virus Type 1 (ATCC VR-733)	5 minutes exposure period			$10^{6.75}$
		10^{-1} to 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	
		TCD_{50}/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		Log Reduction	$\geq$6.25	$\geq$6.25	
487431-32	HIV Type 1 (Strain HTLV-III_B)	1 minute exposure period			$10^{4.75}$
		10^{-1} dilution	Cytotoxicity	Cytotoxicity	
		10^{-2} to 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/0.2mL	$\leq 10^{1.50}$	$\leq 10^{1.50}$	
		Log Reduction	$\geq$3.25	$\geq$3.25	
487431-33	Influenza A Virus (Hong Kong strain) (ATCC VR-544)	5 minutes exposure period			$10^{7.00}$
		10^{-1} to 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		Log Reduction	$\geq$6.50	$\geq$6.50	
487431-34	Respiratory Syncytial Virus (RSV) (ATCC VR-26)	5 minutes exposure period			$10^{4.75}$
		10^{-1} to 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		Log Reduction	$\geq$4.25	$\geq$4.25	
487431-35	Rhinovirus 37 (ATCC VR-1147)	5 minutes exposure period			$10^{4.50}$
		10^{-1} to 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	

MRID	Organism	Results			Dried
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		Log Reduction	≥4.00	≥4.00	
487431-36	Rotavirus (Strain WA)	5 minutes exposure period			$10^{6.75}$
		10^{-1} to 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		Log Reduction	≥6.25	≥6.25	

*MPN- Most Probable Number, for calculating purposes MPN values of zero are reported as <1.000

Hard Surface Non-Food Contact Sanitizer Results:

MRID Number	Organism	Lot No.	Average No. Surviving *(Log CFU/Carrier)	Average CFU/Carrier	Percent Reduction
30 seconds exposure period					
487431-37	*Staphylococcus aureus* (ATCC 6538)	Lot 9257-109	<1.73 *(<5.37 X 10^1)	6.96 *(3.02 X 10^7)	>99.9%
		Lot 9257-110	<2.22 *(<1.66 X 10^2)		>99.9%
		Lot 9257-86	<1.64 *(<4.37 X 10^1)		>99.9%
	Enterobacter aerogenes (ATCC 13048)	Lot 9257-109	<1.80 *(<6.31 X 10^1)	7.48 *(9.12 X 10^6)	>99.9%
		Lot 9257-110	<2.89 *(<7.76 X 10^2)		>99.9%
		Lot 9257-86	<1.30 *(<2.00 X 10^1)		>99.9%

Soft Surface Non-Food Contact Sanitizer Results:

MRID Number	Organism	Lot No.	Average No. Surviving *(Log_{10}CFU/ 100% Cotton Carrier)	Average CFU/Carrier	Percent Reduction
30 seconds exposure period					
487431-38	*Staphylococcus aureus* (ATCC 6538)	Lot 9257-109	<1.30 *(<2 X 10^1)	6.61 *(4.07 X 10^6)	99.9%
		Lot 9257-110	<1.30 *(< 2 X 10^1)		99.9%
		Lot 9257-86	<1.30		99.9%

			*(< 2 X 10^1)		
	Enterobacter aerogenes (ATCC 13048)	Lot 9257-109	<1.30 *(< 2 X 10^1)	5.89 *(7.76 X 10^5)	99.9%
		Lot 9257-110	<1.30 *(< 2 X 10^1)		99.9%
		Lot 9257-86	<1.30 *(< 2 X 10^1)		99.9%

Soft Surface Mildewstat Results:
MRID # 487431-39

Lot No.	Carrier No.	Treated Carrier/Untreated Carrier (Percentage Growth)				
		Day 7	Day 14	Day 21	Day 28	
					Visual	Magnified
Lot 9257-109	1	0% / 95%	0% / 95%	0% / 95%	10% / 95%	Growth
	2	0% / 80%	0% / 80%	0% / 85%	5% / 85%	
	3	0% / 90%	0% / 90%	0% / 95%	20% / 95%	
	4	0% / 85%	0% / 85%	0% / 95%	45% / 95%	
	5	0% / 80%	0% / 80%	0% / 90%	15% / 90%	
	6	0% / 60%	0% / 60%	0% / 75%	20% / 75%	
	7	0% / 50%	0% / 50%	0% / 50%	25% / 50%	
	8	0% / 50%	0% / 50%	0% / 60%	40% / 60%	
	9	0% / 75%	0% / 75%	0% / 90%	10% / 90%	
	10	0% / 80%	0% / 80%	0% / 90%	30% / 90%	
Lot 9257-110	1	0% / 95%	0% / 95%	0% / 95%	30% / 95%	Growth
	2	0% / 80%	0% / 80%	0% / 85%	10% / 85%	
	3	0% / 90%	0% / 90%	0% / 95%	25% / 95%	
	4	0% / 85%	0% / 85%	0% / 95%	50% / 95%	
	5	0% / 80%	0% / 80%	0% / 90%	30% / 90%	
	6	0% / 60%	0% / 60%	0% / 75%	50% / 75%	
	7	0% / 50%	0% / 50%	0% / 50%	15% / 50%	
	8	0% / 50%	0% / 50%	0% / 60%	15% / 60%	
	9	0% / 75%	0% / 75%	0% / 90%	20% / 90%	
	10	0% / 80%	0% / 80%	0% / 90%	50% / 90%	

VI. CONCLUSIONS:

1. The submitted efficacy data support the use of the product, Saginaw, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for 5 minutes contact time:

Staphylococcus aureus	MRID # 487431-11
Salmonella enterica	MRID # 487431-12
Pseudomonas aeruginosa	MRID # 487431-13
Extended Spectrum Beta Lactamase *Escherichia coli*	MRID # 487431-14
Enterobacter aerogenes	MRID # 487431-15
Klebsiella pneumoniae	MRID # 487431-16

Methicillin Resistant *Staphylococcus aureus*	MRID # 487431-17
Penicillin Resistant *Streptococcus pneumoniae*	MRID # 487431-18
Community Assoc. Methicillin Resistant *Staphylococcus aureus*	MRID # 487431-19
Acinetobacter baumanni	MRID # 487431-20
Multidrug Resistant *Enterococcus faecium*	MRID # 487431-21
Multidrug Resistant *Klebsiella pneumoniae*	MRID # 487431-22
Vancomycin Resistant *Enterococcus faecalis*	MRID # 487431-23
Multidrug Resistant *Staphylococcus aureus*	MRID # 487431-24
Multidrug Resistant *Streptococcus pneumoniae*	MRID # 487431-25

Complete killing was observed in the subcultures of the required number of carriers tested against the required number of product lots in all of the above studies. Confirmation of antibiotic resistance was demonstrated for Extended Spectrum Beta Lactamase *Escherichia coli*, Methicillin Resistant *Staphylococcus aureus,* Penicillin Resistant *Streptococcus pneumoniae,* Community Associated Methicillin Resistant *Staphylococcus aureus,* Multidrug Resistant *Enterococcus faecium,* Multidrug Resistant *Klebsiella pneumoniae,* Vancomycin Resistant *Enterococcus faecalis,* Multidrug Resistant *Staphylococcus aureus,* and Multidrug Resistant *Streptococcus pneumoniae*. In all of the above studies: viability controls demonstrated growth; sterility controls demonstrated no growth; neutralization effectiveness controls demonstrated neutralization.

2. The submitted efficacy data support the use of the product, Saginaw, as a disinfectant with fungicidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for 5 minutes contact time:

Trichophyton mentagrophytes	MRID # 487431-26

Complete killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Viability controls demonstrated growth. Sterility controls demonstrated no growth. Neutralization effectiveness controls demonstrated neutralization.

3. The submitted efficacy data support the use of the product, Saginaw, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for 5 minutes contact time:

Coxsackievirus type B3, Strain Nancy	MRID # 487431-27

Hepatitis A Virus, Strain HM-175	MRID # 487431-28
Herpes Simplex Virus type 1, Strain F(1)	MRID # 487431-31
Influenza A Virus, Strain Hong Kong	MRID # 487431-33
Respiratory Syncytial Virus, Strain Long	MRID # 487431-34
Rhinovirus type 37, Strain 151-1	MRID # 487431-35
Rotavirus, Strain WA	MRID # 487431-36

Complete inactivation at all tested dilutions was shown in all of the above listed studies; however for Rotavirus and Herpes Simplex Virus type 1, Strain F(1) a rationale is required to explain the presence of the dried controls virus. All studies controls were acceptable: viability control demonstrated growth; sterility control did not have any growth; and neutralization effectiveness control demonstrated neutralization.

4. The submitted efficacy data support the use of the product, Saginaw, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for 1 minute contact time:

Duck Hepatitis B Virus (Surrogate for Human Hepatitis B Virus)	MRID # 487431-29 & MRID # 487431-30
Human Immunodeficiency Virus type 1, Strain HTLV III_B	MRID # 487431-32

Cytotoxicity was seen in Human Immunodeficiency Virus type 1 study, and at least a 3- log reduction was demonstrated beyond the level of cytotoxicity. No cytotoxicity was seen in the Duck Hepatitis B Virus study and complete inactivation at all tested dilutions was demonstrated. Both studies controls were acceptable: viability control demonstrated growth; sterility control did not have any growth; and neutralization effectiveness control demonstrated neutralization.

5. The submitted efficacy data support the use of the product, Saginaw, as a sanitizer with bactericidal activity against the following microorganisms on hard, inanimate non-food contact surfaces in the presence of a 5% organic soil load for 30 seconds contact time:

Staphylococcus aureus	MRID # 487431-37
Enterobacter aerogenes	MRID # 487431-37

Results show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes (more specifically 30 seconds). The purity controls were pure. The sterility controls demonstrate no growth. Neutralization effectiveness control demonstrated neutralization.

6. The submitted efficacy data support the use of the product, Saginaw, as a sanitizer with bactericidal activity against the following microorganisms on soft, non-food contact surfaces in the presence of a 5% organic soil load for 30 seconds contact time:

Staphylococcus aureus	MRID # 487431-38
Enterobacter aerogenes	MRID # 487431-38

Results show a bacterial reduction of at least 99.9 percent over the parallel control within 5

minutes (more specifically 30 seconds). The purity controls were pure. The sterility controls demonstrate no growth. Neutralization effectiveness control demonstrated neutralization.

7. The submitted efficacy data support the use of the product, Saginaw, as a mildew fungistat with bactericidal activity against the following microorganisms on fabric surfaces in the presence of a 5% organic soil load for 7, 14, & 21 days contact time:

Aspergillus brasiliensis	MRID # 487431-39
Penicillium variable	MRID # 487431-39

Results demonstrate no visible growth for 7, 14, and 21 days. Growth was observed on Day 28. The growth percentages on untreated control strips were at least 50%. The purity controls were pure. The sterility controls demonstrate no growth.

VII. RECOMMENDATIONS:

1. The product, Saginaw, label claims disinfectant efficacy with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for 5 minutes contact time:

Staphylococcus aureus	ATCC 6538
Salmonella enterica	ATCC 10708
Pseudomonas aeruginosa	ATCC 15442
Extended Spectrum Beta Lactamase *Escherichia coli*	ATCC BAA-196
Enterobacter aerogenes	ATCC 13048
Klebsiella pneumoniae	ATCC 4532
Methicillin Resistant *Staphylococcus aureus*	ATCC 33592
Penicillin Resistant *Streptococcus pneumoniae*	ATCC 700677
Community Assoc. Methicillin Resistant *Staphylococcus aureus*	(NARSA NRS 123) (Genotype USA 400)
Acinetobacter baumanni	ATCC 19606
Multidrug Resistant *Enterococcus faecium*	ATCC 51559
Multidrug Resistant *Klebsiella pneumoniae*	ATCC 51503
Vancomycin Resistant *Enterococcus faecalis*	ATCC 51575
Multidrug Resistant *Staphylococcus aureus*	ATCC 14154
Multidrug Resistant *Streptococcus pneumoniae*	ATCC 700677

These claims are **acceptable** as they are supported by the submitted data.

2. The product, Saginaw, label claims disinfectant efficacy with fungicidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for 5 minutes contact time:

Trichophyton mentagrophytes	ATCC 9533

These claims are **acceptable** as they are supported by the submitted data.

3. The product, Saginaw, label claims disinfectant efficacy with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for 5 minutes contact time:

Coxsackievirus type B3, Strain Nancy	ATCC VR-30
Hepatitis A Virus, Strain HM-175	(Apptec Laboratory Services, Camden, N.J.)
Herpes Simplex Virus type 1, Strain F(1)	ATCC VR-733
Influenza A Virus, Strain Hong Kong	ATCC VR-544
Respiratory Syncytial Virus, Strain Long	ATCC VR-26
Rhinovirus type 37, Strain 151-1	ATCC VR-1147
Rotavirus, Strain WA	(University of Ottawa Ontario, Canada)

These claims are **acceptable** as they are supported by the submitted data.

4. The product, Saginaw, label claims disinfectant efficacy with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for 1 minute contact time:

Duck Hepatitis B Virus/(Surrogate for Human Hepatitis B Virus)
(Strain 7/31/07 obtained Hepadnavirus Testing Inc.)

Human Immunodeficiency Virus type 1, ATCC VR-733
(Strain HTLV III_B)

These claims are **acceptable** as they are supported by the submitted data.

5. The product, Saginaw, label claims sanitizer efficacy with bactericidal activity against the following microorganisms on hard, inanimate non-food contact surfaces in the presence of a 5% organic soil load for 30 seconds contact time:

Staphylococcus aureus	ATCC 6538
Enterobacter aerogenes	ATCC 13048

These claims are **acceptable** as they are supported by the submitted data.

6. The product, Saginaw, label claims sanitizer efficacy with bactericidal activity against the following microorganisms on soft, non-food contact surfaces in the presence of a 5% organic soil load for 30 seconds contact time:

Staphylococcus aureus	ATCC 6538
Enterobacter aerogenes	ATCC 13048

These claims are **acceptable** as they are supported by the submitted data.

7. The product, Saginaw, label claims mildew fungistatic efficacy with bactericidal activity against the following microorganisms on fabric surfaces in the presence of a 5% organic soil load for 7, 14, & 21 days contact time:

Aspergillus brasiliensis	ATCC 16404
Penicillium variable	ATCC 52262

These claims are **acceptable** as they are supported by the submitted data.

8. LABEL RECOMMENDATIONS:

- Page 5:

  Place the following in the Allergens section:
  Eliminates –or- reduces [dander] [Pollen] [allergens]
  Eliminates –or- reduces allergy-causing particles, such as pet dander, smoke dust and dust mite matter

  Remove the following, the term sanitary has not been qualified:
  Leaves surfaces sanitary (Also located on Page 6)

Remove "fast acting soft surface sanitizer" and "fast acting sanitizer". The Agency has not defined a contact time consistent with the term "fast".

- Page 6:

  Remove the following: Disinfection claims cannot include quantitative language, this is only allowed in sanitizing claims:
  Disinfects kitchen surfaces including killing [99.9% of] germs -or- Disinfects [washable] kitchen surfaces, including killing [99.9% of] bacteria - and/or- fungi –or- Disinfects [washable] kitchen surfaces including killing [99.9% of] bacteria [,] [and] viruses [,][and] fungi.
  Kills [99.9% of] bacteria
  Kills [99.9% of] germs
  Kills [99.9% of] insert organisms from table X
  and any other items listed that state killing –or- kills 99.9% of

  Remove the following: This claim is considered to be a comparative safety claim which is false or misleading:
  Kills [household] bacteria [without bleaching]