UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION
PREVENTION

July 26, 2011

MEMORANDUM

SUBJECT: Efficacy Review for Surface Disinfectant Plus;
EPA File Symbol 83831-R;
DP Barcode: D390026

FROM: Karen M. Hill, Ph.D., Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Tajah Blackburn, Ph.D., Team Leader
Product Science Branch
Antimicrobials Division (7510P)

TO: Jacqueline McFarlane PM34/Killian Swift
Regulatory Management Branch II
Antimicrobials Division (7510P)

APPLICANT: Germ Pro Products, Inc.
3810 Gunn Highway
Tampa, FL 33618

FORMULATION FROM THE LABEL:

Active Ingredient(s):	% by wt.
Ethanol	60.0%
Ortho-phenylphenol	0.4%
Para Tertiary Amylphenol	0.3%
3-(trihydroxysilyl) propyldimethyloctadecyl ammonium chloride	0.3%
Inert Ingredients	39.0%
Total	100.00 %

I BACKGROUND

The product, Surface Disinfectant Plus (EPA File Symbol 83831-R), is a new product. The applicant requested to register the product for use as a disinfectant (bactericide, tuberculocide, virucide) on hard, non-porous surfaces in institutional and hospital or medical environments. The label also states that the product provides residual antimicrobial activity for 28 days. Studies were conducted at MICROBIOTEST, located at 105 Carpenter Drive in Sterling, VA 20164; and Antimicrobial Test Laboratories, located at 3000 Joe DiMaggio Boulevard, Suite #32, in Round Rock, TX 78665.

This data package contained a letter from the applicant's representative to EPA (dated April 18, 2011), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-4 (Confidential Statement of Formula), EPA Form 8570-27 (Formulator's Exemption Statement), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), seven studies (MRID 484591-10 through 484591-16), and proposed label. For all seven studies (MRID 484591-10 thru 484594-16) the Statements of No Data Confidentiality Claims, Compliance Statement, and Quality Assurance Statement were submitted. The residual property study (MRID 484591-01) was not in accordance 40 CFR 160.

II USE DIRECTIONS

The product is intended to be a ready to use disinfectant for hard, non-porous surfaces, including: countertops, dental chairs, doorknobs, doors, hand rails, hospital beds, medical equipment, sinks, toilets, and wheelchairs. * [The proposed label does not identify the types of surfaces on which the product may be used (e.g., stainless steel, glass, according to DIS/TSS-15]. Directions on the proposed label provide the following information regarding use of the product:

> As a disinfectant: Clean surface of loose dirt. Hold spray 4-6 inches from surface. Spray surfaces for 3-4 seconds until covered with mist. Allow to dry for 10 minutes.
>
> As a residual antimicrobial treatment: Clean hard surface. Spray thoroughly. Allow to dry for at least 5 minutes before wiping. Reapply at least every 28 days.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

<u>Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments:</u>

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), or the AOAC Hard Surface Carrier Test. 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). To support products labeled as "disinfectants", killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level. To pass performance requirements when using AOAC Hard Surface Carrier Test, tests must result in killing in 58 out of each set of 60 carriers for *Salmonella enterica* ATCC 10708 and *Staphylococcus aureus* ATCC 6538; 57 out of each set of 60 carriers for *Pseudomonas aeruginosa* ATCC 15442.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (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 each specific microorganism 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 microorganism on all carriers is required. In addition, plate count data must be submitted for each microorganism to demonstrate that a concentration of at least 10^4 microorganisms survived the carrier-drying step.

Disinfectants for Use as Tuberculocides (Using the AOAC Tuberculocidal Activity Test Method or the AOAC Germicidal Spray Products Test Method):

Certain chemical classes (i.e., glutaraldehyde and quaternary ammonium compounds) are required to undergo validation testing in addition to basic testing. Products that are formulated with other chemical groups do not require validation testing. Products may be tested using one of four recommended methods: the AOAC Tuberculocidal Test Method, Tuberculocidal Activity of Disinfectants Test Method with significant modification of the standard test conditions of contact time and/or temperature, Quantitative Tuberculocidal Activity Test Method, and AOAC Germicidal Spray Products Test Method.

When using the existing or modified AOAC Tuberculocidal Activity Test Methods, or the AOAC Germicidal Spray Products Test Method, ten (10) carriers for each of two samples, representing two different batches of product, must be tested against *Mycobacterium bovis* BCG (a member of the *Mycobacterium tuberculosis* species complex). When using the existing or modified AOAC Tuberculocidal Activity Test Method, or the AOAC Germicidal Spray Products Test Method, killing on all carriers/slides as demonstrated in Modified Proskauer-Beck Broth, and no growth in any of the inoculated tubes of two additional media (i.e., Middlebrook 7H9 Broth Difco B, Kirchners Medium, and/or TB Broth Base) is required. Agency standards are presented in EPA DIS/TSS-6, Subdivision G Guidelines, and "EPA Data Call-in Notice for Tuberculocidal Claims," dated June 13, 1986.

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. If the product is intended to be represented as a one-step (ready to use) virucidal, an appropriate organic soil (i.e.- 5 percent blood serum) should be included with the viral inoculum.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 484591-01 "Study of Properties of Surface Disinfectant Plus as Disinfectant for 97 Days," Test Organism: *Escherichia Coli*, for Germ Pro Surface Disinfectant, by Robert A Monticello. Study conducted at AEGIS Laboratory International. Study completion date- September 16, 2010. Laboratory Project Identification Number 7903.

This study was conducted against *Escherichia coli*. The cells used in this study were JIS Z2801-2000 (ACTM 0550). The protocol used for this study was not submitted. The lots P-tert Disinfectant and P-tert Disinfectant with AEM (a letter dated April 15, 2011 by Director Randall W. Kraff states that P-tert Disinfectant AEM is the same formulation as Germ Pro Surface Disinfectant Plus) were tested. The products were not tested in the presence of a 5% organic soil load. Glass slide carriers (50 mm x 50mm) were inoculated with 50µL of test organism. Separate carriers were introduced to each product. The manner in which the carriers were treated with product was not given. The carriers were allowed to remain wet for 2 hours (temperature is not specified). Following the exposure period, the remaining liquid was drained from each carrier. Individual carriers were transferred to 10 mL of D/E Broth to neutralize. Glass cover slips were used (25mm X 25mm). The $\log_{10}$ of the starting bacteria after the 2 hours time point, and the bacteria reduction from untreated carriers were given for each product tested as $\log_{10}$ measurements at 3, 10, 16, 28, 56, and 96 days after treatment.

Note--The ATCC number for the *E. coli* microorganism used in the study was not given. The cells JIS Z2801-2000 (ACTM 0550) origination was not given.

Note- The protocol used for this study was not submitted.

Note- The manner in which the carriers were treated with product was not given (i.e.- spray, immersion, etc.).

Note- The temperature at which the exposure was done is not known.

Note- Study was not performed in accordance to 40 CFR 160. The registrant did not follow the Agency approved method nor met the performance standard to support residual sanitizing claims. This protocol is limited to residential use only and must also meet the standards for sanitizer in order to make claims as a residual sanitizing claim.

2. MRID 484591-10 "AOAC Tuberculocidal Activity of a Germicidal Spray," Test Organism: *Mycobacterium bovis* BCG, for Germ Pro Surface Disinfectant, by M. Hamid Bashir. Study conducted at MICROBIOTEST. Study completion date – July 20, 2010. Laboratory Project Identification Number 738-101.

This study was conducted against *Mycobacterium bovis* BCG (obtained from Organon Teknika Corporation). Two lots (Lot Nos. 09910A and 09910B) of the product, Germ Pro Surface Disinfectant, were tested using the MICROBIOTEST Protocol GER.2.03.12.10. The product was received ready-to-use. A culture of the challenge microorganism was prepared in accordance with the published AOAC method, with the following exceptions: (1) the culture was incubated for 21-25 days at 37±2°C; and (2) the culture suspension was diluted with Modified Proskauer-Beck Medium, as necessary, to give 17-20%T at 650 nm (which differs from the AOAC method specification of diluting the culture suspension to give 20%T at 650 nm). The product was not tested in the presence of a 5% organic soil load. Ten (10) glass slide carriers (1 inch x 3 inches) per product lot were inoculated with 0.02 mL of a 21-25 day old suspension of test organism. Inoculum was transferred onto a one square inch area of each carrier and immediately spread uniformly over the entire area. The carriers were dried for 30 minutes at 37±2°C. For each lot of product, separate carriers were sprayed with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 10 minutes at 20°C. Following the exposure period, the remaining liquid was drained from each carrier. Following the exposure period, individual carriers were transferred to tubes containing 20 mL of DE Neutralizing Broth. Tubes containing neutralizer were shaken thoroughly after addition of the carrier, as specified in the AOAC method. The carriers were transferred to individual tubes containing 20 mL of Modified Proskauer-Beck Medium. From each tube of neutralizer, 2 mL were cultured to tubes containing 20 mL of Middlebrook 7H9 Broth and 2 mL were cultured to tubes containing 20 mL of Kirchner's Medium. All tubes used for secondary transfers were shaken thoroughly and incubated for 60 days at 37±2°C. The tubes were incubated for an additional 30 days because no growth was observed after 60 days. Following incubation, the subcultures were examined for the presence or absence of visible growth.

Note- Controls should include those for carrier count, sterility, viability, neutralizer effectiveness, and confirmation of the challenge microorganism. The data for these controls were not submitted in the results section.

3. MRID 484591-11 "Virucidal Efficacy Test Human Influenza A Virus (H1N1)" for Germ Pro Surface Disinfectant, by Salimatu Jibril. Study

conducted at MICROBIOTEST. Study completion date – September 8, 2010. Laboratory Project Identification Number 738-102.

This study was conducted against Human influenza A virus (H1N1) (Strain A/PR/8/34; obtained from Charles River Laboratories), using MDCK cells (ATCC CCL-34) as the host system. Two lots (Lot Nos. 09910A and 09910C) of the product, Germ Pro Surface Disinfectant, were tested according to a MICROBIOTEST protocol titled "Virucidal Efficacy Test - Human Influenza A Virus (H1N1)," dated August 16, 2010 (Protocol #738.1.08.16.10). The product was received ready-to-use. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 24 minutes at ambient temperature. For each lot of product, separate dried virus films were sprayed with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 5 minutes at 19°C. Following exposure, the plates were neutralized with 2.0 mL of fetal bovine serum with 1% Polysorbate 80 and 0.5% Lecithin. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephacryl columns, and diluted serially in Minimal Essential Medium with 1.0 µg/mL Trypsin. MDCK cells in multi-well culture dishes were inoculated in quadruplicate with the dilutions. The cultures were incubated for 4-6 days at 36±2°C in 5±1% CO_2. Following incubation, the cultures were examined microscopically for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference (both product lots). The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

4. MRID 484591-12 "AOAC Use Dilution Test," Test Organisms: Methicillin Resistant *Staphylococcus aureus* and Vancomycin Resistant *Enterococcus faecalis*, for Germ Pro Surface Disinfectant, by Angela L. Hollingsworth. Study conducted at MICROBIOTEST. Study completion date – September 13, 2010. Laboratory Project Identification Number 738-104.

This study was conducted against Methicillin Resistant *Staphylococcus aureus* (ATCC 33591) and Vancomycin Resistant *Enterococcus faecalis* (ATCC 51299). Two lots (Lot Nos. 09910A and 09910C) of the product, Germ Pro Surface Disinfectant, were tested using MICROBIOTEST Protocol #738.1.08.13.10. The product was received ready-to-use. The cultures were incubated at 48-54 hours at 37±2°C. The product was not tested in the presence of a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot per microorganism were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 20 carriers per tube of 20 mL broth. The carriers were dried for 20-40 minutes at 37±2°C. Each carrier was placed in 10 mL of the product for 5 minutes at 20°C. The tubes containing the product were swirled after addition of the carriers. Following exposure, individual carriers were transferred to DE Neutralizing Broth to neutralize. The tubes containing neutralizer were shaken thoroughly after addition of the carriers. All subcultures were incubated for 48±2 hours at 37±2°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, neutralizer effectiveness, bacteriostasis, confirmation of the challenge microorganisms, and antibiotic resistance.

Note: Antibiotic resistance of Methicillin Resistant *Staphylococcus aureus* (ATCC 33591) was verified on a representative culture. An individual Mueller Hinton Agar was streaked with the prepared culture in a crosshatch pattern. After crosshatching, an antibiotic disk was added to the center of the plate. The plate was incubated for 24±2 hours at 37±2°C. Following incubation the zone of inhibition was measured and documented. The measured zone of inhibition (i.e., 6.5 mm) confirmed antibiotic resistance of Methicillin Resistant *Staphylococcus aureus* (ATCC 33591) to oxacillin.

Note: Antibiotic resistance of Vancomycin Resistant *Enterococcus faecalis* (ATCC 51299) was verified on a representative culture. An individual Mueller Hinton Agar was streaked with the prepared culture in a crosshatch pattern. After crosshatching, an antibiotic disk was added to the center of the plate. The plate was incubated for 24±2 hours at 37±2°C. Following incubation the zone of inhibition was measured and documented. The measured zone of inhibition (i.e., 13.5 mm) confirmed antibiotic resistance of Vancomycin Resistant *Enterococcus faecalis* (ATCC 51299) to vancomycin.

5. MRID 484591-13 "Virucidal Efficacy Test Rhinovirus" for Germ Pro Surface Disinfectant, by Salimatu Jibril. Study conducted at MICROBIOTEST. Study completion date – September 13, 2010. Laboratory Project Identification Number 738-103.

This study was conducted against Rhinovirus type 14 (ATCC VR-284), using H1-HeLa cells (ATCC CRL-1958) as the host system. Two lots (Lot Nos. 09910A and 09910C) of the product, Germ Pro Surface Disinfectant, were tested according to a MICROBIOTEST protocol titled "Virucidal Efficacy Test - Rhinovirus," dated August 16, 2010 (Protocol # 738.2.08.16.10). The product was received ready-to-use. The product was not tested in the presence of a 5% organic soil load. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes at ambient temperature. For each lot of product, separate dried virus films were sprayed with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 5 minutes at 20°C. Following exposure, the plates were neutralized with 2.0 mL of fetal bovine serum with 1% Polysorbate 80 and 0.5% Lecithin. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephacryl columns, and diluted serially in RPMI 1640 with 5% fetal bovine serum. H1-HeLa cells in multi-well culture dishes were inoculated in quadruplicate with the dilutions. The cultures were incubated for 6-9 days at 33±2°C in 5±1% CO_2. Following incubation, the cultures were examined microscopically for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference for both product lots. The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

6. MRID 484591-14 "AOAC Germicidal Spray Products as Disinfectants Test Method," Test Organism: *Salmonella enterica* (ATCC 10708), for Germ Pro Surface Disinfectant, by Ashley Rex. Study conducted at Antimicrobial

Test Laboratories. Study completion date – July 8, 2010. Study Identification Number GLP1041.

This study was conducted against *Salmonella enterica* (ATCC 10708). Three lots (Lot Nos. 09910A, 09910B, and 09910C) of the product, Germ Pro Surface Disinfectant, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the Antimicrobial Test Laboratories (Protocol# P1045). At least one of the product lots tested (i.e., Lot No. 09910C) was at least 60 days old at the time of testing. The product was received ready-to-use. A culture of the challenge microorganism was incubated for 48-54 hours at 36±1°C. The product was not tested in the presence of a 5% organic soil load. Sixty (60) 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. Inoculum was spread over a one square inch area of each carrier. The carriers were dried for 20-40 minutes at 36±1°C. For each lot of product, separate carriers were sprayed (3 sprays or until wet) with the product from a distance of 6-8 inches from the carrier surface. The carriers were allowed to remain wet for 5 minutes at 23±2°C. Following the exposure period, the remaining liquid was drained from each carrier. Individual carriers were transferred to 20 mL of Letheen Broth to neutralize. The tubes containing neutralizer were shaken after addition of the carriers. All subcultures were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier enumeration, sterility, viability, and neutralization confirmation (all three product lots).

7. MRID 484591-15 "AOAC Germicidal Spray Products as Disinfectants Test Method," Test Organism: *Pseudomonas aeruginosa* (ATCC 15442), for Germ Pro Surface Disinfectant, by Ashley Rex. Study conducted at Antimicrobial Test Laboratories. Study completion date – July 8, 2010. Study Identification Number GLP1039.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Three lots (Lot Nos. 09910A, 09910B, and 09910C) of the product, Germ Pro Surface Disinfectant, were tested using the Antimicrobial Test Laboratories protocol P1043. At least one of the product lots tested (i.e., Lot No. 09910C) was at least 60 days old at the time of testing. The product was received ready-to-use. A culture of the challenge microorganism was incubated for 48-54 hours at 36±1°C. The product was not tested in the presence of a 5% organic soil load. Sixty (60) 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. Inoculum was spread over a one square inch area of each carrier. The carriers were dried for 20-40 minutes at 36±1°C. For each lot of product, separate carriers were sprayed (3 sprays or until wet) with the product from a distance of 6-8 inches from the carrier surface. The carriers were allowed to remain wet for 5 minutes at 23±2°C. Following the exposure period, the remaining liquid was drained from each carrier. Individual carriers were transferred to 20 mL of Letheen Broth to neutralize. The tubes containing neutralizer were shaken after addition of the carriers. All subcultures were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier enumeration, sterility, viability, and neutralization confirmation (all three product lots).

8. MRID 484591-16 "AOAC Germicidal Spray Products as Disinfectants Test Method," Test Organism: *Staphylococcus aureus* (ATCC 6538), for Germ Pro Surface Disinfectant, by Ashley Rex. Study conducted at Antimicrobial Test Laboratories. Study completion date – July 8, 2010. Study Identification Number GLP1040.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Three lots (Lot Nos. 09910A, 09910B, and 09910C) of the product, Germ Pro Surface Disinfectant, were tested using the Antimicrobial Test Laboratories protocol P1044. At least one of the product lots tested (i.e., Lot No. 09910C) was at least 60 days old at the time of testing. The product was received ready-to-use. A culture of the challenge microorganism was incubated for 48-54 hours at 36±1°C. The product was not tested in the presence of a 5% organic soil load. Sixty (60) 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. Inoculum was spread over a one square inch area of each carrier. The carriers were dried for 20 minutes at 36±1°C. For each lot of product, separate carriers were sprayed (3 sprays or until wet) with the product from a distance of 6-8 inches from the carrier surface. The carriers were allowed to remain wet for 5 minutes at 23±2°C. Following the exposure period, the remaining liquid was drained from each carrier. Individual carriers were transferred to 20 mL of Letheen Broth to neutralize. The tubes containing neutralizer were shaken after addition of the carriers. All subcultures were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier enumeration, sterility, viability, and neutralization confirmation (all three product lots).

V RESULTS

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested			Carrier Count (CFU/ carrier)
		Lot No. 09910A	Lot No. 09910B	Lot No. 09910C	
5-Minute Exposure Time					
484591-12	Methicillin Resistant *Staphylococcus aureus*	0/10	---	0/10	1.6×10^6
484591-12	Vancomycin Resistant *Enterococcus faecalis*	0/10	---	0/10	3.9×10^6
484591-14	*Salmonella enterica*	0/60 --- ---	--- 0/60 ---	--- --- 0/60	1.17×10^6 1.50×10^6 4.98×10^6
484591-15	*Pseudomonas aeruginosa*	0/60 --- ---	--- 0/60 ---	--- --- 0/60	1.23×10^6 2.39×10^6 4.68×10^6
484591-16	*Staphylococcus aureus*	0/60 --- ---	--- 0/60 ---	--- --- 0/60	1.52×10^6 1.33×10^6 5.57×10^6

MRID Number	Organism	Media	No. Exhibiting Growth/ Total No. Tested

			Lot No. 09910A, 90 Days	Lot No. 09910B, 90 Days
10-Minute Exposure Time				
484591-10	*Mycobacterium bovis* BCG Carrier Count: 3.8 x 10^5 CFU/carrier	Modified Proskauer-Beck Medium	0/10	0/10
		Middlebrook 7H9 Broth	0/10	0/10
		Kirchner's Medium	0/10	0/10

MRID Number	Organism	Results			Plate Recovery Control
			Lot No. 09910A	Lot No. 09910C	
5-Minute Exposure Time					
484591-11	Human influenza A virus (H1N1)	10^{-2} dilution	Cytotoxicity	Cytotoxicity	$10^{7.00}$ $TCID_{50}$/mL
		10^{-3} dilution	Complete inactivation	Cytotoxicity	
		10^{-3} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	
		$TCID_{50}$/mL	$\leq 10^{2.50}$	$\leq 10^{3.50}$	
		Log reduction	≥4.50 $\log_{10}$	≥3.50 $\log_{10}$	
484591-13	Rhinovirus	10^{-2} dilution	Cytotoxicity	Cytotoxicity	$10^{7.25}$ $TCID_{50}$/mL
		10^{-3} dilution	Complete inactivation	Cytotoxicity	
		10^{-4} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	
		$TCID_{50}$/mL	$\geq 10^{2.50}$	$\geq 10^{3.50}$	
		Log reduction	4.75 $\log_{10}$	3.75 $\log_{10}$	

VI CONCLUSIONS

1. The submitted efficacy data do not support the use of the product, Germ Pro Surface Disinfectant, as a disinfectant with bactericidal activity against the following microorganisms on pre-cleaned, hard, non-porous surfaces for a 5-minute contact time:

Salmonella enterica	MRID 484591-14
Pseudomonas aeruginosa	MRID 484591-15
Staphylococcus aureus	MRID 484591-16

Although complete killing was observed in the subcultures of the required number of carriers tested against the required number of product lots, efficacy data was not generated at the lower certified limits (LCL) consistent with the CSF. In testing against *Staphylococcus aureus*, *Salmonella enterica*, and *Pseudomonas aeruginosa*, at least one of the product lots tested was at least 60 days old at the time of testing. Neutralization confirmation (and neutralizer effectiveness) testing showed positive growth of the microorganisms. Viability controls were positive for growth. Sterility controls did not show growth.

2. The submitted efficacy data support the use of the product, Germ Pro Surface Disinfectant, as a disinfectant with bactericidal activity against the following microorganisms on pre-cleaned, hard, non-porous surfaces for a 5-minute contact time:

Methicillin Resistant *Staphylococcus aureus*	MRID 484591-12
Vancomycin Resistant *Enterococcus faecalis*	MRID 484591-12

Complete killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation (and neutralizer effectiveness) testing showed positive growth of the microorganisms. Viability controls were positive for growth. Sterility controls did not show growth. Efficacy data for additional microorganisms is acceptable at the nominal limits.

2. The submitted efficacy data support the use of the product, Germ Pro Surface Disinfectant, as a disinfectant with virucidal activity against the following microorganisms on pre-cleaned, hard, non-porous surfaces for a 5-minute contact time:

Human influenza A virus (H1N1)	MRID 484591-11
Rhinovirus	MRID 484591-13

Recoverable virus titers of at least 10^4 were achieved. Cytotoxicity was observed in the 10^{-2} dilution for Lot No. 09910A and in the 10^{-3} dilution for Lot No. 09910C in both Human Influenza A virus (H1N1) and Rhinovirus studies. In each of these viral studies, complete inactivation (no growth) was indicated in all higher dilutions tested beyond the cytotoxic level. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level. Testing at the nominal concentration is acceptable for additional microorganisms.

3. The submitted efficacy data (MRID 484591-10) conditionally supports the use of the product, Germ Pro Surface Disinfectant, as a disinfectant with tuberculocidal activity against *Mycobacterium bovis* BCG on pre-cleaned, hard, non-porous surfaces for a 10-minute contact time. Complete killing was observed in the subcultures of the required number of carriers against the required number of product lots. No growth was observed in the subcultures of the two extra media. Neutralizer effectiveness testing results were not given. Viability controls results were not given. Sterility controls were not given. These required control results must be submitted in order to support the acceptability of this study.

4. The submitted efficacy data (MRID 484591-01) does not support the claims that the product, Surface Disinfectant Plus, has residual properties. The $\log_{10}$ of the starting bacteria after the 2 hours time point, and the bacteria reduction from untreated carriers were given for each product tested as $\log_{10}$ measurements at 3, 10, 16, 28, 56, and 96 days after treatment. There was a reduction in the $\log_{10}$ after the 2 hours time point for the 3, 10, 17, and 28 days after treatment. Although the log reduction was given, the amount of log reduction was not calculated and submitted with data. The protocol used for the study was not submitted and the ATCC number for *E. coli* microorganism was not provided. The manner in which the carriers were treated with product was not given (i.e. spray, immersion). The temperature at which the exposure was done is not known. The study was not performed in accordance to 40 CFR 160. The registrant did not follow the

Agency's approved method (limited to residential use sites) nor did the data meet the performance standard to support residual sanitizing claims. Finally, in order to claim residual sanitizing claims, the product must initially qualify as a non-food contact sanitizer.

VII RECOMMENDATIONS

1. The proposed label claims are unacceptable regarding the use of the product, Surface Disinfectant Plus, as a disinfectant against the following microorganisms on pre-cleaned, hard, non-porous surfaces for a 5-minute contact time:

Pseudomonas aeruginosa
Salmonella enterica
Staphylococcus aureus

2. The proposed label claims are unacceptable regarding the use of the product, Surface Disinfectant Plus, as a disinfectant against the following microorganisms on pre-cleaned, hard, non-porous surfaces for a 5-minute contact time [see page 2 of the proposed label] or a 10-minute contact time [see page 3 of the proposed label]:

Methicillin Resistant *Staphylococcus aureus*
Vancomycin Resistant *Enterococcus faecalis*
Influenza A virus (H1N1)
Rhinovirus

Acceptable efficacy data is required against the basic three bacteria first, before additional claims can be supported.

3. The proposed label claims that the product, Surface Disinfectant Plus, is an effective tuberculocide on pre-cleaned, hard, non-porous surfaces for a 10-minute contact time. This claim is unacceptable. The controls data were not included in the results. The neutralizer effectiveness confirmation, viability, and sterility controls are required. Furthermore resolution of the LCL testing requirement for the basic three bacteria is required, before additional claims can be supported.

4. The proposed label claims that the product, Surface Disinfectant Plus, provides residual antimicrobial activity for 28 days has residual properties is unacceptable as it is not supported by the submitted data. The deficiencies identified in the Conclusion section must be addressed.

5. The following revisions to the proposed label are recommended:

- Add a statement that surfaces must be pre-cleaned prior to disinfection. On page 3 of the proposed label, under the section "To Disinfect Non-Food Contact Surfaces" section, change "clean surface of loose dirt" to read "clean surface thoroughly with soap or detergent."

- ATCC numbers for all microorganisms used in study are not listed on label and must be present on either the proposed label, data matrix, or the last page of master label.

- The proposed label does not identify the types of surfaces on which the product may be used (e.g., stainless steel, glass.) according to DIS/TSS-15.

- A potable water rinse is required for food contact surfaces that are disinfectant, consistent with DIS/TSS-17.

- Food contact use directions are not clear (i.e. it should instruct to spray).

- The data was not generated in the presence of soil thus the label use directions must include cleaning directions or instructions.

- Identify the types of surfaces on which the product may be used (e.g., chrome, glass, stainless steel, vinyl).

- Under the "To Disinfect Non-Food Contact Surfaces" section on page 3 of the proposed label, change "Allow to dry for 10 minutes." to read "Surfaces must remain wet for 10 minutes."

- Under the "In Food Handling Areas" section on page 3 of the proposed label, change "Allow product to fully dry before contact with food (minimum of 10 minutes)." to read "Surfaces must remain wet for 10 minutes. Then, allow surfaces to dry before contact with food, following potable water rinse."

- Remove the claim "Quick dry formula" from the proposed label. Proper use of the product requires contact times on the order of 5 minutes and 10 minutes.

- Remove the term "fast" from the proposed label. The Agency has not determined the contact time consistent with this claim.

- To support claims for (1) "chemical (poisoning organisms) and mechanical (puncturing cell membranes) killing actions", (2) "conventional chemical antimicrobial ingredients absorbed by living cells and kill by way of poisoning the organism or disrupting a vital process", (3) forms positive charged polymer that molecularly bonds to the treated surface (Think of it as a layer of electrically charged swords", (4) "When a microorganism comes in contact with the treated surface, the positively charged molecular sword punctures the cell membrane and zaps the cell. Since there is nothing transferred to the now dead cell, the antimicrobial doesn't lose strength and the molecule is ready for the next germ to contact it", and (5) "It is most active as a bound polymer matrix attached to a surface", the registrant must provide supporting documentation.

- Remove the claim "nanotechnology antimicrobial", as the Agency has not defined the requirements for nanotechnology.

- Remove the claims "provides an invisible barrier to inhibit the growth of

bacteria", "residual (sanitizing) (antimicrobial) for up to 28 days (between cleaning)", and "inhibits bacteria from coming back for up to 28 days" as these claims have not been supported by acceptable efficacy data.

- Remove the claims "Kill 99.99% Germs on hard non-porous surfaces" and "Kills 99.99% of MRSA and VRE" for the following reasons, (1) the test methods provided are qualitative assessments, not supported by quantitative values; and (2) Germs must be qualified in the absence of testing against all classes of microorganisms; briefly http://www.epa.gov/oppad001/germs.htm.