

74559-1

12/20/2006

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DEC 20 2006

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Virox Technology, Inc.
2815 Bristol Circle, Unit #4
Oakville, Ontario L6H 6X5 Canada

AGENT: Scientific and Regulatory Consultants, Inc.
P. O. Box 1014
Columbia City, IN 46725

Attention: Ann M. Cozad

Subject: Accel TB
EPA Registration No. 74559-1
Amendment Dated May 25, 2006 and
Letter Dated October 18, 2006

The amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, to add a label claim for efficacy versus Avian Influenza, is acceptable, provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3©(5) and sec. 4 when the Agency requires all registrants of similar products to submit such data.
2. Avian Influenza A label claims are accepted for this product since the submitted efficacy data is acceptable to support this label claim. The label must be clear that this use is only for surfaces which are not conducive to treatment by immersion or excess liquid (e.g., cages, equipment tables, lab benches, faucet handles, door knobs, and similar "high touch" surfaces.) For uses in hospital/medical/health facilities, the directions for use for hospital disinfection must be followed. For all other use sites, general disinfection directions for use must be followed.
3. Include complete Non-Food contact Surface use directions on page 6 of the label.

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4. Featured statements/phrases emphasized/enlarged lettering, special graphics, or any product name that employs the terms "Avian influenza A" or "Bird Flu" are unacceptable. Featured statements/phrases, emphasized/enlarged lettering or special graphics that are employed for the primary purpose of especially promoting or drawing attention to product efficacy against avian influenza A, are also unacceptable. For example, a featured, incomplete phrase such as "Kills avian influenza A" will not be permitted, but the phrase "Kills avian influenza A on pre-cleaned environmental surfaces" is acceptable.

5. Since the only animal pathogen listed on the label is avian influenza A, on page 4 of 9 and 6 of 9, remove the heading and paragraph starting with "Animal Housing Facilities."

6. Revise Avian influenza (ATCC VR-2072) to read Avian influenza A (ATCC VR-2072) everywhere it appears on the label.

7. Submit two (2) copies of final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the "accepted" product labeling is enclosed for your records.

A copy of the Efficacy Review is enclosed for your information.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely



Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)

Enclosures

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with COMMENTS
EPA Letter Dated:
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Hydrogen Peroxide (logo) patent pending

[USA PAT#: patent pending]
[CAN PAT#: patent pending]

Under the Federal Insecticide,
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Ready to Use
One-Step Disinfectant
Cleaner Disinfectant Deodorizer
General *Virucide, Bactericide, Tuberculocide, Fungicide, Sanitizer

Active Ingredient:	
Hydrogen Peroxide	0.5%
Other Ingredients	99.5%
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

[All claims backed by third party validation. Reports available at Virox website @
www.virox.com.]

[See reference sheet [enclosed in each case] for [a complete list of pathogenic organisms]
[additional features, claims] [claimed for this product] [for Accel™ TB]].
{the reference sheet is on page 2 and page 9 of the label}

Net Contents: {insert package contents here}

EPA Reg. No. 74559-1

EPA Est. No. 74559-CN-1

Manufactured By:
Virox Technologies Inc.
2815 Bristol Circle, Unit #4
Oakville, ON, L6H 6X5
1 800 387-7578 www.virox.com

Note: Bracketed[]information is optional text. Text separated by a comma(,)denotes-and/or-options.
{Bracketed Text} is for administrative purposes only and will not appear on the printed label.

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{This list of organisms is for informational purposes. The organisms and related claims may or may not be listed on the final printed label or on a reference sheet and if listed may use a different format.}

VIRUCIDAL in the presence of 5% serum load and 1 minute contact time at 20°C on hard, non-porous environmental surfaces

Poliovirus Type 1, Strain Brunhilde (ATCC VR-1000)
HIV-1 (AIDS Virus), Strain HTLV-III_B (HIV-1), (Acquired from Adv. Biotechnologies, Inc.)
Feline Calicivirus, Strain F9 (ATCC VR-782)
Human Coronavirus (ATCC VR-740)
Influenza A/Hong Kong (ATCC VR-544)
Herpes Simplex Virus, Type 1 (HSV-1) (ATCC VR-733)
Herpes Simplex Virus, Type 2 (HSV-2) (ATCC VR-734)
Rhinovirus Type 37, Strain 151-1 (ATCC VR-1147)
Rotavirus WA (Acquired from University of Ottawa)
Hepatitis C Virus (HCV)
Hepatitis B Virus (HBV)
*Avian Influenza (ATCC VR-2072)

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Virucidal activity was determined by the efficacy test methods for virucidal agents intended for inanimate environmental surfaces; ASTM 1053-97 Standard Test Method for Efficacy of Virucidal Agents Intended for Inanimate Environmental Surfaces and EPA protocols for surrogate viral testing.

HOSPITAL DISINFECTANT: BACTERICIDAL in the presence of 5% serum load and 1 minute contact time at 20°C on hard, non-porous environmental surfaces against

Pseudomonas aeruginosa (ATCC 15442) *Staphylococcus aureus* (ATCC 6538) *Salmonella choleraesuis* (ATCC 10708) *Escherichia Coli O157:H7* (ATCC 35150) *Staphylococcus aureus* MRSA (ATCC 33592) *Enterococcus faecalis* VRE (ATCC 51575) *Acinetobacter baumannii* (ATCC 19606)

Bactericidal activity was determined by the AOAC Use Dilution Test Method.

TUBERCULOCIDAL in the presence of 5% serum load and 5 minute contact time at 20°C on hard, non-porous environmental surfaces

Mycobacterium bovis (BCG) (OT 451C150)

Tuberculocidal activity was determined by the EPA Quantitative Tuberculocidal Activity Test Method.

FUNGICIDAL in the presence of 5% serum load and 10 minute contact time at 20°C on hard, non-porous environmental surfaces

Trichophyton mentagrophytes (ATCC 9533)

Fungicidal activity was determined by the AOAC Fungicidal Activity of Disinfectants Method.

BROAD-SPECTRUM NON-FOOD CONTACT SANITIZING in the presence of 5% serum load and 30 second contact time at 20°C on hard, non-porous environmental surfaces

Klebsiella pneumoniae (ATCC 4352) *Salmonella choleraesuis* (ATCC 10708) *Pseudomonas aeruginosa* (ATCC 15442) *Staphylococcus aureus* (ATCC 6538) *Staphylococcus aureus* MRSA (ATCC 33592) *Enterococcus faecalis* VRE (ATCC 51575) *Escherichia Coli O157:H7* (ATCC 35150)

Sanitizing activity was determined by the EPA Sanitizer Test for Inanimate, Non-Food Contact Surfaces and ASTM E1153 Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces.

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For Use in Health Care, Veterinary, Animal Housing, Dental, [Life Science] Laboratory, Medical, Industrial & Institutional Facilities, Food Processing Establishments, and Hospitals

{General Uses}

Accel TB is a one-step [hospital-use] germicidal [disinfectant] cleaner and deodorant [odor-counteractant] [odor neutralizer] designed for general cleaning, [and] disinfecting, [deodorizing] [of] hard, non-porous environmental surfaces. It cleans quickly by removing dirt, grime, mold, mildew, and other common soils found in hospitals, nursing homes, schools and colleges, [medical] [dental] offices, veterinary clinics, pet shops, equine farms, animal & life science laboratories.

Accel TB's non-dulling formula eliminates the time and labor normally required for rinsing. It is designed for use on [Use daily on] [the following] [hard, non-porous environmental surfaces listed on this label made from:] [vinyl], [Naugahyde], painted surfaces, plastic [surfaces], glazed ceramic, glazed porcelain, chrome, stainless steel, aluminum, laminated surfaces and baked enamel surfaces associated with floors, walls, ceilings, tables, chairs, countertops, telephones, glazed tile, sinks. A potable water rinse is required for food contact surfaces. Do not use on glasses, dishes, utensils and cookware.

{Hospitals/Health Care Facilities/Dental Offices/ Life Science Laboratories}

Accel TB is a one-step [hospital-use] [laboratory-use] germicidal [disinfectant] cleaner and deodorant [odor-counteractant] [odor neutralizer] designed for general cleaning, [and] disinfecting, [deodorizing] [of] hard, non-porous environmental surfaces. Accel TB cleans quickly by removing dirt, grime, food residue, dead skin, blood and other organic matter commonly found in hospitals [in health care facilities] [on medical surfaces] [laboratory settings]. It [also] eliminates odors, leaving [restroom] surfaces smelling clean and fresh. Use where odors are a problem.

Accel TB cleans, disinfects and deodorizes hard, non-porous environmental [hospital] [medical] [dental] [laboratory] surfaces in one step [(with no rinsing required)]. Its non-abrasive formula is designed for use on [Use daily on] [the following] [hard, non-porous environmental surfaces listed on this label made from:] [vinyl], [Naugahyde], painted surfaces, plastic [surfaces], glazed ceramic, glazed porcelain, chrome, stainless steel, laminated surfaces [and baked enamel surfaces associated with floors], walls, ceilings, tables, chairs, countertops, telephones, glazed tile, toilet exteriors, urinal exteriors, sinks found in [health care facilities] [hospitals] [dental offices], [patient rooms], [operating rooms], [ICU areas], [shower rooms], and [locker rooms] [fume hoods and animal cages [found in laboratory settings]]. [It can also be used to pre-clean and disinfect hospital items: wheelchairs, [hospital] [patient] bed rails and linings, wash basins, bed pans, non-critical medical equipment surfaces. A potable water rinse is required when disinfecting food contact surfaces. Do not use on glasses, dishes, utensils and cookware.

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{Animal Housing Facilities}

*{Avian influenza claims are for use only with product sold in containers ≥ 55 gallons}

Accel TB cleans by removing dirt, grime, blood, urine, fecal matter and other common soils found in animal housing facilities, livestock, swine or poultry facilities, grooming facilities, farms, kennels, pet stores, veterinary clinics, laboratories or other small animal facilities. It [also] eliminates odors leaving surfaces smelling clean and fresh.

Accel TB cleans, disinfects and deodorizes hard, non-porous environmental surfaces in one step. Its non-abrasive formula is designed for use on [Use daily on] [Use daily to clean and disinfect] [hard, non-porous surfaces listed on this label made from:] plated or stainless steel, aluminum, chrome, glazed porcelain, glazed tile, laminated surfaces (associated with floors, walls, countertops, cages, kennels, animal equipment) found in [barns, pens and stalls] animal housing facilities.

{Refill}

To Transfer Accel TB Into Smaller Containers:

[Accel TB may be transferred into clean, properly labeled containers for use elsewhere within your facility.] The small container and transfer items (funnels or hand pumps) must be clean and dry. Pour (or pump) product directly into a properly labeled smaller container being careful not to spill any product. Keep containers sealed when not in use. Refill in a well ventilated area.

Effective in the presence of 5% serum load at 20°C on hard, non- porous environmental surfaces

**BACTERICIDAL in 1 minute,
TUBERCULOCIDAL in 5 minutes, and
FUNGICIDAL in 10 minutes against:**

- Pseudomonas aeruginosa*
- Staphylococcus aureus*
- Salmonella choleraesuis*
- Acinetobacter baumannii*
- Enterococcus faecalis* VRE
- Escherichia coli* O157:H7
- Staphylococcus aureus* MRSA
- Mycobacterium bovis*
- Trichophyton mentagrophytes* (athlete's foot fungus)

***VIRUCIDAL in 1 minute [against the following enveloped and non-enveloped viruses]:**

- *Feline Calicivirus
- *Hepatitis C Virus (HCV)
- *Human Coronavirus
- *Herpes Simplex Type 1 (HSV-1)
- *Herpes Simplex Type 2 (HSV-2)
- *HIV-1 (AIDS Virus)
- *Rhinovirus Type 37
- *Rotavirus WA
- *Influenza A/Hong Kong
- *Poliovirus Type 1
- *Hepatitis B Virus (HBV)
- *Avian Influenza [(ATCC VR-2072)]

NON-FOOD CONTACT SANITIZER in 30 seconds against:

- Enterococcus faecalis* VRE
- Escherichia coli* O157:H7
- Klebsiella pneumoniae*
- Pseudomonas aeruginosa*

- Salmonella choleraesuis*
- Staphylococcus aureus*
- Staphylococcus aureus* MRSA

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DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the blood stream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

For Use as a Cleaner and/or Deodorizer:

Apply to surfaces by spray, cloth, sponge, or mop. Wipe surfaces dry [or rinse].

{General Uses}

For Use as a One-Step Cleaner/Disinfectant Product:

1. Pre-clean heavily soiled areas.
2. Apply Solution by spray, cloth, disposable wipe or mop to hard, non-porous environmental surfaces.
3. All surfaces must remain wet for 1 minute. Use a 5 minute contact time for TB and a 10 minute contact for fungi.
4. Wipe surfaces dry [or rinse]. [To avoid build up of surfactants on the surfaces, rinsing is preferred.]

Note – All food contact surfaces must be rinsed with potable water. Do not use on glassware, cookware, utensils, or dishes. If finish or restorer will be applied to floors, rinse the floor prior to applying coating.

For Use To Clean and Disinfect Life Science Laboratory Surfaces, Instruments, and Glassware:

1. Pre-clean heavily soiled areas.
2. Apply Solution by spray, cloth, disposable wipe or mop to hard, non-porous environmental surfaces or completely immerse pre-cleaned glassware and compatible instruments in the solution.
3. Immerse or allow the surface to remain wet for 1 minute. Use a 5 minute contact time for TB and a 10 minute contact for fungi.
4. For glassware/instrument: Rinse surface thoroughly and let air dry before reuse. For surfaces: Wipe surface dry [or rinse].
5. Change immersion solution after each use [application].

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***KILLS HIV, HCV and HBV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings (Hospitals, Nursing Homes) and other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood / body fluids, and in which the surfaces / objects likely to be soiled with blood / body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS), Hepatitis C Virus (HCV) or Hepatitis B Virus (HBV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS Virus), HCV OR HBV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

Personal Protection: Disposable latex or vinyl gloves, gowns, face masks, or eye coverings as appropriate, must be worn during all cleaning of body fluids, blood, and decontamination procedures.

Cleaning Procedures: Blood / body fluids must be thoroughly cleaned from surfaces / objects before application of Accel TB.

Contact Time: Allow surface to remain wet for 1 minute to kill HIV-1, HCV and HBV. Use a 5 minute contact time for TB and a 10 minute contact for fungi.

Disposal of Infectious Material: Blood / body fluids should be autoclaved and disposed of according to Federal, State, and local regulations for infectious waste disposal.

** {Avian influenza claims are for use only with product sold in containers \geq 55 gallons}*

Animal Housing Facilities (Including Veterinary Clinics, [Equine] Farms, Livestock, Swine and Poultry Houses):

For cleaning and disinfecting the following hard nonporous surfaces: feeding and watering equipment, utensils, instruments, cages, kennels, stables, catteries, etc.

1. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc.
2. Remove all litter, droppings and manure from floors, walls and surfaces of facilities (including pens, chutes, and barns) occupied or traversed by animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
Thoroughly clean all surfaces with soap or detergent and rinse with potable water. Saturate surfaces by wiping, spraying or foaming with product for a period of 1 minute. Use a 5 minute contact time for TB and a 10 minute contact for fungi.
4. Immerse handling and restraining equipment such as leashes, muzzles, halters or ropes, as well as forks, shovels, and scrapers used for removing litter and manure.
5. Ventilate buildings and other closed spaces.
6. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, troughs, mangers, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

Broad Spectrum Non-Food Contact Sanitizer

Apply to hard non-porous surface; allow to remain wet for 30 seconds. Wipe dry [or rinse]. [No rinsing is required.] For heavily soiled areas a pre-cleaning is recommended.

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{For sizes 1 gallon or less}

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to small children. Keep securely closed. Do not reuse empty container. Rinse thoroughly. [Wrap and] Discard in trash.

{For sizes over 1 gallon}

STORAGE AND DISPOSAL:

Do not contaminate water, food or feed by storage or disposal. PESTICIDE STORAGE: Store in dry, well ventilated area away from chemicals, direct light, heat or open flame. Do not mix with other cleaning or disinfecting products.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. For more information on the disposal of unused, unwanted product and the clean up of spills, contact the EPA Regional Office or the *Manufacturer for guidance.*

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill; or incinerate, or, if allowed by state and local authorities, burn. If burned, stay out of smoke.

ENVIRONMENTAL HAZARDS

{for labels with veterinary use patterns}

This product is toxic to birds, fish and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk.

{for containers of 5 gallons or 50 lbs. or more}

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting agency has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

READ M.S.D.S. BEFORE USING PRODUCT

[M.S.D.S. is available on line at www.virox.com]

[Notice to User: Accel TB may not be suitable for all items or surfaces. Prolonged exposure to copper, brass, anodized aluminum and some coatings should be avoided. If you are uncertain as to the material composition of your item, confirm with the manufacturer before proceeding or visit the Compatibility section on www.virox.com for a listing of compatible materials.]

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{Secondary/transfer container label front}

ACCEL TB

Filled by customer

Active Ingredient:	
Hydrogen Peroxide	0.5%
Other Ingredients.....	99.5%
Total.....	100.0%

KEEP OUT OF REACH OF CHILDREN

{Secondary/transfer container label front or back}

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Follow the directions for use on the Accel TB label when applying this product.

or {insert appropriate use sites/directions from master label}

STORAGE AND DISPOSAL

Store in areas inaccessible to small children. Keep securely closed. Do not reuse empty container. Rinse thoroughly. [Wrap and] Discard in trash.

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VIRUCIDAL in the presence of 5% serum load and 1 minute contact time at 20°C on hard, non-porous environmental surfaces

Poliovirus Type 1, Strain Brunhilde (ATCC VR-1000)
 HIV-1 (AIDS Virus), Strain HTLV-III_B (HIV-1), (Acquired from Adv. Biotechnologies, Inc.)
 Feline Calicivirus, Strain F9 (ATCC VR-782)
 Human Coronavirus (ATCC VR-740)
 Influenza A/Hong Kong (ATCC VR-544)
 Herpes Simplex Virus, Type 1 (HSV-1) (ATCC VR-733)
 Herpes Simplex Virus, Type 2 (HSV-2) (ATCC VR-734)
 Rhinovirus Type 37, Strain 151-1 (ATCC VR-1147)
 Rotavirus WA (Acquired from University of Ottawa)
 Hepatitis C Virus (HCV)
 Hepatitis B Virus (HBV)
 *Avian Influenza [(ATCC VR-2072)]

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Virucidal activity was determined by the efficacy test methods for virucidal agents intended for inanimate environmental surfaces; ASTM 1053-97 Standard Test Method for Efficacy of Virucidal Agents Intended for Inanimate Environmental Surfaces and EPA protocols for surrogate viral testing.

HOSPITAL DISINFECTANT: BACTERICIDAL in the presence of 5% serum load and 1 minute contact time at 20°C on hard, non-porous environmental surfaces against

Pseudomonas aeruginosa (ATCC 15442) *Staphylococcus aureus* (ATCC 6538) *Salmonella choleraesuis* (ATCC 10708) *Escherichia Coli O157:H7* (ATCC 35150) *Staphylococcus aureus* MRSA (ATCC 33592) *Enterococcus faecalis* VRE (ATCC 51575) *Acinetobacter baumannii* (ATCC 19606)

Bactericidal activity was determined by the AOAC Use Dilution Test Method.

TUBERCULOCIDAL in the presence of 5% serum load and 5 minute contact time at 20°C on hard, non-porous environmental surfaces

Mycobacterium bovis (BCG) (OT 451C150)

Tuberculocidal activity was determined by the EPA Quantitative Tuberculocidal Activity Test Method.

FUNGICIDAL in the presence of 5% serum load and 10 minute contact time at 20°C on hard, non-porous environmental surfaces

Trichophyton mentagrophytes (ATCC 9533)

Fungicidal activity was determined by the AOAC Fungicidal Activity of Disinfectants Method.

BROAD-SPECTRUM NON-FOOD CONTACT SANITIZING in the presence of 5% serum load and 30 second contact time at 20°C on hard, non-porous environmental surfaces

Klebsiella pneumoniae (ATCC 4352) *Salmonella choleraesuis* (ATCC 10708) *Pseudomonas aeruginosa* (ATCC 15442) *Staphylococcus aureus* (ATCC 6538) *Staphylococcus aureus* MRSA (ATCC 33592) *Enterococcus faecalis* VRE (ATCC 51575) *Escherichia Coli O157:H7* (ATCC 35150)

Sanitizing activity was determined by the EPA Sanitizer Test for Inanimate, Non-Food Contact Surfaces and ASTM E1153 Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces.