

74559-3

(07-15-2011)

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Virox Technologies, Inc
U.S. Agent:
102 1/2 S. Chauncey Street, PO box 1014
Columbia City, Indiana 46725

JUL 15 2011

Attention: David Swain
Agent for Virox Technologies, Inc.

Subject: Accel Tb Wipes
 EPA Reg. No. 74559-3
 Notification Application Dated June 16, 2011

This will acknowledge receipt of your notification for the aforementioned product label, submitted under the provisions of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3© (9). Based on a review of the submitted material, the following apply:

- The Agency accepts the notification on the condition that the statement "All food contact surfaces must be rinsed with potable water" be removed from page 4 of the proposed label. This product is not approved for food contact uses, so any statement that implies that this product can be used on food contact surfaces is not permitted.

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been made a part of your file. Please note that if you desire a stamped label you will need to submit an Amendment.

If you have any questions concerning this letter, please contact Abigail Downs at (703) 305-5259.

Sincerely,

A handwritten signature in black ink that reads "M Swindell".

Marshall Swindell
Product Manager (33)
Regulatory Management Branch I
Antimicrobials Division (7510CP)

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United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

| | | |
|---|---|--|
| 1. Company/Product Number 74559-3 | 2. EPA Product Manager M. Swindell | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) Accel Tb Wipes | PM# 33 | |
| 5. Name and Address of Applicant (Include ZIP Code) Virox Technologies, Inc. 2770 Coventry Road Oakville, ON L6H 6R1 Canada <input type="checkbox"/> Check if this is a new address | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____ | |

Section - II

| | |
|--|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application. |
| <input checked="" type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below. |

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of market claims and addition to Directions for Use. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. Please contact David Swain at 260-244-6273 (fax) with any questions.

Section - III

| | | | | | |
|---|--|---|-------------------|--|---|
| 1. Material This Product Will Be Packaged In: | | | | 2. Type of Container | |
| Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | | <input type="checkbox"/> Metal | <input checked="" type="checkbox"/> Plastic |
| * Certification must be submitted | | If "Yes" Unit Packaging wgt. | No. per container | If "Yes" Package wgt | No. per container |
| | | | | <input type="checkbox"/> Glass | <input type="checkbox"/> Paper |
| | | | | <input type="checkbox"/> Other (Specify) _____ | |
| 3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container 2.6 oz., 1.1 lb., 1 lb. 14 oz., 2 lb. 15 oz. | | 5. Location of Label Directions <input type="checkbox"/> on label | |
| 6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled | | | | <input type="checkbox"/> Other _____ | |

Section - IV

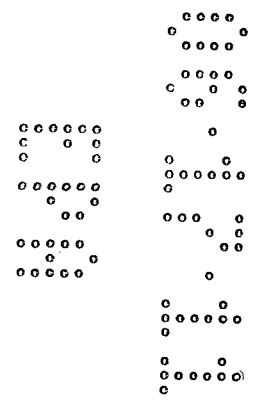
| | | | | | |
|--|--|--|--|---|---|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | | | | |
| Name David Swain | | Title Agent for Virox Technologies, Inc. | | Telephone No. (Include Area Code) 260-244-6270 | |
| Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | | | | 6. Date Application Received (Stamped) |
| 2. Signature | | 3. Title Agent for Virox Technologies, Inc. | | | |
| 4. Typed Name David Swain | | 5. Date 6/16/11 | | | |

SRRC

Scientific & Regulatory
Consultants, Inc.

June 16, 2010

Mr. Marshall Swindell, PM-33
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, 4th Floor One Potomac Yard
2777 S Crystal Drive
Arlington, VA 22202



SUBJECT: Notification per PR Notice 1998-10

Accel Tb Wipes
EPA Reg. No. 74559-3

Dear Mr. Swindell:

On behalf of our client, Virox Technologies, Inc. (Virox), enclosed is a notification adding and revising marketing claims and adding a minor addition to the Directions for Use. These additions are being made to match the Master Label with the market label per Region 5 guidance.. This is a Notification per PR Notice 1998-10; therefore, no PRIA fee is required.

The new text is highlighted in enclosed label. Also attached are two "clean" copies of the labeling with all new claims and revisions included.

Virox recently had a shipment of the subject product refused entry in the US due to the label review completed by the EPA Region 5 office. Even though the market label had been approved by all 50 states, the Region 5 office rejected the shipment and informed Virox the labels were misbranded. Therefore, Virox must submit this notification to make the EPA Master Label read word-for-word exactly as the market label. Region 5 indicated Virox is not allowed to combine and blend marketing claims.

Virox is also sending a letter to Dennis Edwards to explain the situation, ask for an interpretation regarding misbranding, and request his help to understand Region 5's label review policies. We have asked for AD's review of the market labels to determine whether they are indeed misbranded.

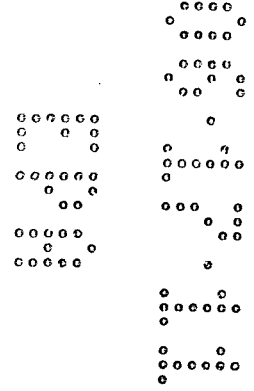
This notification, as stipulated by the guidance, is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec, 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action, and penalties under sections 12 and 14 of FIFRA.

We look forward to a timely review of this submission. If you need any clarification or issues arise during the review of this information, please contact me immediately at 260-244-6270 for resolution.

Sincerely,



David Swain
Agent for Virox Technologies, Inc.
Cc: Babak Givehchi



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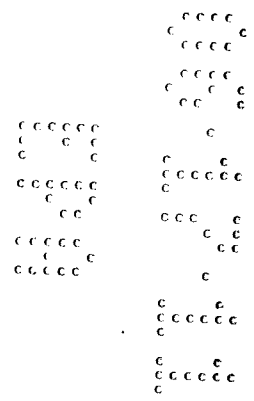
{Administrative note: any language which appears between { } and is italicized will NOT appear on final printed labels.
Any language that appears between [] is considered interchangeable language which may appear on final printed labeling}

Accel Tb Wipes

[Ready to Use] [Easy to Use] [Towelette] [Wipe]
 One-Step Disinfectant and Deodorizing Wipes
 Sanitizer • Sanitizing Wipes • Cleaner • Disinfectant • Deodorizer
 *Virucidal • Bactericidal • [Fungicidal] • Tuberculocidal
 Meets OSHA Bloodborne Pathogen Standard for HBV, HCV & HIV-1
 Kills Norovirus • Kills Rhinovirus [Type 14]
 Use on non-food contact surfaces, including: [Grocery Cart Handles] [Cash Registers]
 [Telephones] [Doorknobs]
 Just pull, wipe & toss! • Eliminates Buckets • No need to Spray!
 Pre-moistened • Pre-measured • Always Ready-to-Use
 No measuring or mixing required

[Hydrogen Peroxide]

For [Commercial] [Industrial] [&] [Institutional] Use [Only]



| | |
|---|---------------|
| ACTIVE INGREDIENT: | |
| Hydrogen Peroxide..... | 0.5% |
| INERT [OTHER] INGREDIENTS: | 99.5% |
| TOTAL: | 100.0% |

KEEP OUT OF REACH OF CHILDREN

[See reference sheet [enclosed in each case] for [a complete list of organisms] [additional [features] [claims] [directions for use]] [for this product]].

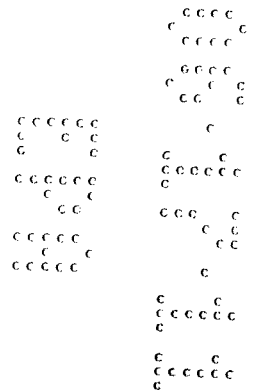
Net Contents:

- 160 sheets [wipes] (6" X 6.75") (15.24 cm X 17.14 cm) 1 pound (lb.) 14 ounces (850 grams)
- 160 sheets [wipes] (8" X 9") (20.32 cm X 22.86 cm) 2 pounds (lbs.) 15 ounces (1347 grams)
- 60 sheets [wipes] (7" X 8") (17.8 cm X 20.3 cm) 1.1 pounds (lb.) (493 g)
- 10 sheets [wipes] (7.48" x 10") (19.0 cm x 25.4 cm) 2.6 ounces (75 grams) {for re-sealable package}

{Administrative note: any language which appears between { } and is italicized will NOT appear on final printed labels.
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{MARKETING CLAIMS}:

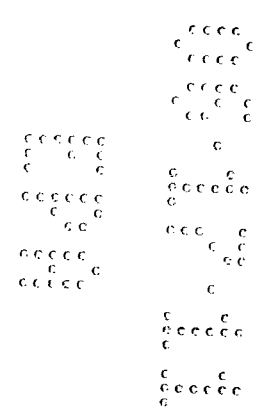
- A disinfectant cloth for use on telephone surfaces and other telecommunications equipment surfaces
- A Hydrogen Peroxide solution impregnated in a wiping cloth
- Aids in reducing [or in the reduction of] cross contamination between treated surfaces
- Always ready to use
- An effective counter cleaner
- An effective way to clean, deodorize against odor-causing organisms and disinfect hard, non-porous surfaces
- An effective way to disinfect hard, non-porous environmental surfaces
- Antibacterial
- Antibacterial [surface] Cleaner [cloth]
- Antibacterial Cell phone Wipe
- Antibacterial Surface Cleaner [Cloth]
- Anti-microbial cleaner [cloth]
- Anti-viral* [Anti-Virus*] [Surface] Cleaner
- Assures proper dilution strength for product effectiveness
- Bactericidal Cleaner
- Bactericidal
- Built-in Scrubbing Fibers
- Clean & disinfect any room, any time
- Clean & disinfect hard non-porous surfaces
- Clean & disinfect hard non-porous surfaces easily
- Cleans without scratching surface[s]
- Cleaner
- Cleaner and disinfectant towel [or cloth]
- Clean[s] and deodorize[s]
- Cleans and disinfects
- Cleans and disinfects [cell phone surfaces] [telephone equipment] [telephone equipment surfaces] [dictating equipment surfaces] [telecommunications equipment surfaces] [devices]
- Cleans and disinfects common hard, non-porous surfaces
- Cleans effectively
- Clean hard-to-remove stains
- Cleans, deodorizes and disinfects
- Cloth
- Convenient
- Convenient, quick & easy cleaning all around [the office] [business] [workplace]
- Cuts grease
- Cuts the toughest grime and grease without scratching surfaces
- Disinfectant [disinfecting] surface cleaner [cloth]
- Disinfects against *Staphylococcus aureus*, *Salmonella enterica*, and *Pseudomonas aeruginosa*
- Disinfects environmental surfaces
- Disinfects hard, non-porous environmental surfaces
- Disinfects headsets and telephones
- Disposable
- Each pre-moistened towelette [disposable wipe] cleans, deodorizes and kills listed bacteria all around you [office] [business] [workplace]
- Easy flip-top lid
- Effective against flu virus [Influenza A/Hong Kong] [Hong Kong Flu]
- Effective daily cleaner
- Effective in 1 minute against *Staphylococcus aureus*, *Salmonella enterica*, and *Pseudomonas aeruginosa*
- Effectively disinfects hard, non-porous surfaces
- Effectively disinfects in the presence of organic soil [5% blood serum]
- Everyday, every room disinfectant
- Exhibits effective virucidal activity: kills Influenza A/Hong Kong and Herpes Simplex Type 2 [cause of Genital Herpes]
- For hard, non-porous surfaces
- For use in critical care areas [where control of the hazards of cross-contamination between treated surfaces is of prime importance]
- For your toughest bathroom messes



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- Grease Cutting Formula
- Great for grease cutting
- Great for on-the-go cleaning
- Great on-the-go disinfectant [cloth]
- Hard non-porous surface [cleaning &] disinfecting made easy
- Heavy-duty cleaner [or cleaning] [cloth]
- Kills Avian Influenza A virus on pre-cleaned environmental surfaces
- Kills *Staphylococcus aureus*, *Salmonella enterica*, and *Pseudomonas aeruginosa*
- Kills the flu virus Influenza A
- Kills Norovirus [Norwalk virus]
- Kills Human Coronavirus
- Kills antibiotic-resistant organisms
- Kills HIV-1 [AIDS virus] [HTLV-III₂]
- Kills HCV
- Kills HBV
- Kills Rhinovirus [Type 14]
- No mixing
- No streaking
- Non-woven disposable cloth
- On-the-go disinfectant
- Accel Tb Wipes control the spread of listed bacteria on treated hard, non-porous environmental surfaces
- Accel Tb Wipes help control listed bacteria on treated surfaces while keeping your office [or workstation or workplace or business] clean and dust-free
- Pre-measured
- Pre-moistened [towelettes]
- Pre-soaked [cloth or towelette]
- Quick and easy cleaning everywhere
- Quick drying
- Removes tough stains
- Restroom Disinfectant Wipes
- Restroom Wipes [for hard, non-porous surfaces]
- Scrubbing surface cleaner
- Stay-moist package
- Strong towelettes [or wipes]
- Telephone [cleaner [and] disinfectant] wipes
- These wipes are a convenient way to disinfect surfaces all around your [business] [office] [workplace]
- Towel
- Use on hard, non-porous surfaces only. [Test wipe on a small inconspicuous area first]
- Use to disinfectant shopping [or grocery] cart handles
- Versatile disinfectant [or disinfecting] cleaner
- Virucidal* [or] Kills viruses* *Influenza A/Hong Kong [Hong Kong flu], Herpes Simplex Type 2, HCV, HBV, HIV-1
- Virus killing cleaner*
- Wipe down grocery [or shopping] cart handles



[FEATURES, CLAIMS & USES:]

[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.]]

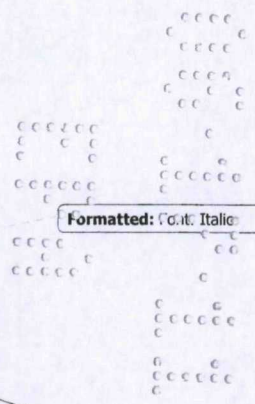
For Use in Health Care, Veterinary, Animal Housing, Dental, [Life Science] Laboratory, Medical, Industrial & Institutional Facilities, Food Processing Establishments, and Hospitals

[This product [These] is [are] [is a] non-woven, disposable [towelette[s]] [wipe[s]], pre-saturated with Hydrogen Peroxide [based] disinfectant cleaner.]

{Administrative note: any language which appears between { } and is italicized will NOT appear on final printed labels. Any language that appears between [] is considered interchangeable language which may appear on final printed labeling}

This product is a one-step [hospital-use] [germicidal] [disinfectant] cleaner and deodorant [odor-counteractant] [odor, neutralizer] designed for general cleaning, [and] disinfecting, [and] [deodorizing] [of] hard, non-porous environmental surfaces. It cleans quickly by removing dirt, grime, dead skin, blood, body soils and other common soils [organic matter] commonly found in hospitals, nursing homes, [acute] [and] [long-term] care facilities, [office buildings], [schools and colleges], [universities], [laboratory settings], [day care centers], [medical], [dental] offices, [funeral homes], [transportation facilities], [train] [depots], [stations] [bus] [depots] [stations], [airports], [casinos], [cruise ships], [correctional facilities], [athletic facilities], [athletic equipment], [playgrounds], [locker rooms], [health clubs], [exercise equipment], [barber/beauty {salons} [shops], [veterinary clinics], [pet shops], [equine farms], [animal life science laboratories], [hotels, motels], [public areas and restrooms], [homes] [cleaned by {home cleaning services,} [professional cleaning services,] [medical assistance services,] [and office buildings].

This product cleans, disinfects and deodorizes hard, non-porous environmental surfaces in one step with no rinsing required. *{The following sentence is considered optional}* This product's [non-dulling] [advanced] [quick cleaning] [convenient] [easy-to-use] [highly effective] formula eliminates the time and labor normally required for rinsing. It [It's non-abrasive formula] is designed for use on [Use daily on] [the following] [hard, non-porous environmental [inanimate] surfaces: vinyl, Naugahyde, painted surfaces, plastic [surfaces], [glass], [mirrors], glazed ceramic, glazed porcelain, chrome, stainless steel, aluminum, laminated surfaces and baked enamel surfaces associated with floors, walls, ceilings, tables, chairs, [non-food contact] countertops, telephones, [fixtures], [athletic equipment], [exercise equipment], glazed tile, [exterior surfaces of toilets], [exterior surfaces of urinals], sinks, [sink basins], [faucets], [tubs], [chrome], [stainless steel], [shower rooms and locker room areas] - [any washable] [non-food contact] [surface where disinfection is required]. This product's [non-dulling] [advanced] [quick cleaning] [convenient] [easy-to-use] [highly effective] formula eliminates the time and labor normally required for rinsing. All food contact surfaces must be rinsed with potable water. Do not use on glassware, dishes and utensils. [Not recommended for use on brass, copper or marble.]



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[Hospitals/Healthcare Facilities/Dental Offices/Life Science Laboratories]

This product is one-step [hospital-use] [laboratory-use] germicidal [disinfectant] cleaner and deodorant [odor-counteractant] [odor neutralizer] towelette designed for general cleaning, [and] disinfecting, [deodorizing] [of] hard, non-porous environmental surfaces. This product cleans quickly by removing dirt, grime, food residue, dead skin, blood, body soils and other organic matter commonly found in Dental Clinics, [Hospitals], [in Health Care Facilities], [laboratory settings]. It also eliminates odors, leaving [restroom] surfaces smelling clean and fresh. Use where odors are a problem.

This product 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:] [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, non-food contact countertops, telephones, fixtures, 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 be used to pre-clean and disinfect hospital items: wheelchairs, [hospital] [patient] bedrails and linings [patient bed linings] [vinyl mattress covers], wash basins, bed pans, non-critical medical equipment surfaces - almost any washable non-food contact surface [where disinfection is required].

[Bathroom] [Restroom] Disinfectant Cleaner:]

This product is a one-step disinfectant cleaner and deodorant [odor-counteractant] [odor-neutralizer] designed for general cleaning, [and] disinfecting, [deodorizing] on hard, non-porous environmental surfaces.

This product cleans, disinfects and deodorizes surfaces by killing odor-causing microorganisms. Its [non-dulling] [advanced] [quick cleaning] [convenient] [easy-to-use] [highly effective] formula is designed for use on [Use it daily] on [hard, non-porous environmental] restroom surfaces: glazed ceramic [restroom] tiles, glazed porcelain, chrome, stainless steel and plastic surfaces associated with floors, walls, fixtures, exterior [surfaces] of toilets, exterior [surfaces] of urinals, sinks, shower rooms and locker rooms. Not recommended for use on brass, copper or marble.

[Animal Housing Facilities]

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{Administrative note: any language which appears between { } and is italicized will **NOT** appear on final printed labels. Any language that appears between [] is considered interchangeable language which may appear on final printed labeling}

This product cleans by removing dirt, grime, blood, urine, fecal matter and other common soils found in animal housing 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.

This product cleans, disinfects and deodorizes hard, non-porous environmental surfaces in one step. Its [non-dulling] [advanced] [quick cleaning] [convenient] [easy-to-use] [highly effective] formula is designed for use on [Use it daily] [Use daily to clean and disinfect] [hard, non-porous surfaces:] plated or stainless steel, chrome, glazed porcelain, glazed tile, laminated surfaces, [associated with floors, walls, non-food contact countertops, cages, kennels, animal equipment] found in [barns, pens and stalls] animal housing facilities.

[CLAIMS:]

[When used as directed, this product [is] highly effective against a wide variety [broad-spectrum] of pathogenic microorganisms [including bacteria, tuberculosis, antibiotic resistant bacteria, viruses and fungi. See reference sheet [enclosed in each case] for a complete list or organism].

HOSPITAL DISINFECTANT: BACTERICIDAL in the presence of 5% serum load and 1 minute contact time at 20°C (68°F) on hard, non-porous environmental surfaces.

Bactericidal Activity:

Pseudomonas aeruginosa [ATCC 15442] *Staphylococcus aureus* [ATCC 6538] *Escherichia coli* O157:H7 [ATCC 35150]
Salmonella enterica [ATCC 10708] *Acinetobacter baumannii* [ATCC 19606]
[formally know as *Salmonella choleraesuis*]

Antibiotic-Resistant [Strains of] Bacteria [Antibiotic-Resistant Bactericidal Activity]-

Staphylococcus aureus MRSA [ATCC 33592] *Enterococcus faecalis* VRE [ATCC 51575]

***VIRUCIDAL** in the presence of 5% serum load and 1 minute contact time at 20°C (68°F) on hard, non-porous environmental surfaces.

Viruses [*Virucidal Activity]:

Herpes Simplex Virus, Type 1 [HSV-1] Herpes Simplex Virus, Type 2 [HSV-2] Human Coronavirus [ATCC VR-740]
[ATCC VR-733] [ATCC VR-734] Rhinovirus, Type 14 [ATCC VR-284]
Influenza A/Hong Kong [ATCC VR-544] Poliovirus Type 1, Strain Brunhilde Rotavirus WA
[ATCC VR-1000]

Kills HIV-1 [AIDS virus] [HTLV-III_B] when used as directed on hard, non-porous inanimate surfaces with a 1 minute contact time.
Kills HBV & HCV when used as directed on hard, non-porous inanimate surfaces with a 1 minute contact time.

Kills Norovirus [Feline Calicivirus as the surrogate] [VR-782] when used as directed on hard, non-porous inanimate surfaces with a 1 minute contact time.

[Veterinary Viruses:]

Avian Influenza A, [H3N2] [ATCC VR-2072] Feline Calicivirus, Strain F9 [ATCC VR-782]

TUBERCULOCIDAL in the presence of 5% serum load and 5 minute contact time at 20°C (68°F) on hard, non-porous environmental surfaces.

Mycobacterium bovis [Tb] [OT 451C150]

[FUNGICIDAL This product is fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes* [ATCC 9533] [the fungus which causes Athlete's Foot] in the presence of 5% serum load and 10 minute contact time at 20°C (68°F) when used as directed on hard surfaces found in bathroom, shower stalls, locker rooms, or other clean, non-porous, hard surfaces commonly contacted by bare feet.]

[*Trichophyton mentagrophytes* [ATCC 9533]]

Non-Food Contact Surface Sanitizer for hard non-porous surfaces - in the presence of 5% serum load and 30 second contact time at 20°C (68°F) on hard, non-porous environmental surfaces.

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Klebsiella pneumoniae [ATCC 4352] *Salmonella enterica* [ATCC 10708] *Pseudomonas aeruginosa* [ATCC 15442]
Staphylococcus aureus [ATCC 6538] [formally know as *Salmonella choleraesuis*] *Enterococcus faecalis* VRE [ATCC 51575]
Escherichia coli O157:H7 [ATCC 35150] *Staphylococcus aureus* MRSA [ATCC 33592]

Malodor[s] [Activity] [Counteractancy] – eliminates [destroys] odors and odor-causing bacteria on hard, non-porous surfaces in restroom areas, behind and under sinks and counters, and storage areas [and other places where bacterial growth can cause malodors].

(Note to reviewer: We will choose one or more of these statements depending on available space on the product label.)

- *Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus. (This product or product name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against Influenza Type A2 (Hong Kong), (VR-544), and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- *This product has demonstrated effectiveness against Influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 Influenza A virus.
- *This product has demonstrated effectiveness against Influenza Type A2 (Hong Kong), (VR-544), and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- *Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu).
- *Kills Pandemic 2009 H1N1 Influenza A virus.

(Note: the following section on summery of claims is optional and might be inserted in a band at the bottom of the label)

FUNGICIDAL: 10 MIN.
TUBERCULOCIDAL: 5 MIN.
***VIRUCIDAL: 1 MIN.**
BACTERICIDAL: 1 MIN.
BROAD-SPECTRUM NON-FOOD CONTACT SANITIZER: 30 SEC.

DIRECTIONS FOR USE:

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

Not for personal cleansing. This is not a baby wipe. Do not flush in toilet.

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 [Daily] [One-Step] Cleaner/Disinfectant [product]:

1. Pre-clean heavily soiled areas
2. Pull towelette from dispenser [canister] and wipe hard, non-porous environmental surfaces.
3. All surfaces must remain visibly wet for 1 minute. Use a 5 minute contact time for Tuberculosis [Tb]. [Use a 10 minute contact time for fungi.] [Use additional towelettes if needed to ensure the correct wet contact time.]
4. Allow to air dry [Wipe surface dry] [or rinse] [with potable water if necessary].

Note: All food contact surfaces must be rinsed with potable water. Do not use on glassware, utensils, or dishes.

For Use as [Daily] [Bathroom] [Restroom] [Shower Rooms] [Locker Rooms] [Athletic Equipment] [One-Step] Cleaner/Disinfectant:

1. Pre-clean heavily soiled areas
2. Pull towelette from dispenser [canister] and wipe hard, non-porous environmental surfaces.
3. To disinfect, all surfaces must remain wet for one [1] minutes. Use a 5 minute contact time for Tuberculosis. [Use a 10 minute contact time for fungi.]
4. Wipe surfaces dry [or rinse] [allow to air dry].

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***KILLS HIV AND 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 B Virus (HBV), or Hepatitis C Virus (HCV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HBV OR HCV ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Disposable latex or vinyl gloves, gowns, face masks, ~~or~~ and 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 and objects before application of this product.

Contact Time: Allow surface to remain wet for 1 minute to kill HIV-1, HBV and HCV. Use a 5 minute contact time for Tuberculosis [Tb] and 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.

For Use as a Tuberculocide:

1. Pre-clean heavily soiled areas.
2. Pull towelette from dispenser [canister] and wipe hard, non-porous environmental surfaces.
3. Allow the surface to remain wet for 5 minutes. Use additional towelettes if needed to ensure the correct wet contact time.
4. Wipe surfaces dry [or rinse] [or allow to air dry].
5. Change towelette after each use [application].

To Kill Fungi:

1. Pre-clean heavily soiled areas.
2. Pull towelette from dispenser [canister] and wipe hard, non-porous environmental surfaces.
3. All surfaces must remain visibly wet for 10 minutes. Use additional towelettes if needed to ensure the correct wet contact time.
4. Wipe surfaces dry [or rinse] [or allow to air dry].

For use as a Non-Food Contact Sanitizer:

1. Pre-clean heavily soiled areas.
2. Pull towelette from dispenser [canister] and wipe hard, non-porous environmental surfaces.
3. Allow the surface to remain wet for 30 seconds.
4. Wipe surfaces dry [or rinse] [or allow to air dry].
5. Change towelette after each use [application].

For Use as a Cleaner and/or Deodorizer:

Pull towelette from dispenser [canister] and wipe hard, non-porous environmental surfaces. Allow to air dry [or rinse [with potable water if necessary]].

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

For cleaning and disinfecting the following hard, non-porous 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 or watering appliances.
4. Thoroughly clean all surfaces with soap and detergent and rinse with potable water. Pull towelette from dispenser [canister] and wipe hard, non-porous environmental surfaces.
5. All surfaces must remain visibly wet for 1 minute.
6. Allow to air dry [or rinse [with potable water if necessary]].
7. Ventilate buildings and other closed spaces.
8. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

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NOTE: Not for use on handling and restraining equipment such as leashes, muzzles, halters or ropes, as well as forks, shovels, and scrapers used for removing litter and manure.

{Optional directions for refill pouch ONLY}

Refill Pouch

1. Open empty canister lid.
2. Open refill pouch [by cutting the top of the pouch] and remove saturated towelettes.
3. Place saturated towelettes in empty canister [invert the contents of the pouch into empty canister].
4. Replace canister lid.
5. [Remove the new lot number /[expiry date] from pouch and place it on top of the old lot number /[expiry date] sticker on the canister]

{Optional directions for refill pouch ONLY}

Re-sealable soft pack

1. Remove the seal (from the place shown on the label)
2. Remove one sheet at a time.
3. Close the seal (to prevent drying between uses)

STORAGE AND DISPOSAL:

Do not contaminate water, food or feed by storage and disposal.

Storage: Store in original container in areas inaccessible to small children. Keep securely closed.

Container Disposal: Non-refillable container. Do no reuse or refill this container. Rinse thoroughly. Offer for recycling if available or [wrap and] discard in trash.

{For product supplied in refillable containers or refill package :}

Towelette Storage/Disposal: Dispose of [wipe] [towelette] [cloth] in trash after use. Do not flush. Reseal container label between uses to retain moisture. Refillable container. Refill this container with refill wipe only. Do not reuse this container for any other purpose. To clean the container before final disposal rinse thoroughly, then offer for recycling if available or discard in trash.

Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

{For product supplied in resealable non-refillable packages :}

Towelette Storage/Disposal: Non-refillable container. Do no reuse or refill this container. Dispose of [wipe] [towelette] [cloth] in trash after use. Do not flush. Reseal container label between uses to retain moisture. Do not reuse empty [Pouch] [Container] [Package]. Discard empty [Pouch] [Container] [Package] in trash.

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.

Read the M.S.D.S. Before Using the Product.

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

[Si no puede leer en ingles, pregunte a se supervisor sobre las instrucciones de uso apropiadas anted de trabajar con este producto.]

EPA Reg. No. 74559-3 EPA Est. No. 74559-CAN-1

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Virox Technologies, Inc.

**Accel Tb Wipes
Reference Sheet**

HOSPITAL DISINFECTANT: BACTERICIDAL in the presence of 5% serum load and 1 minute contact time at 20°C (68°F) on hard, non-porous environmental surfaces.

Bactericidal Activity:

Pseudomonas aeruginosa [ATCC 15442] *Staphylococcus aureus* [ATCC 6538] *Escherichia coli* O157:H7 [ATCC 35150]
Salmonella enterica [ATCC 10708] *Acinetobacter baumannii* [ATCC 19606]
[formally know as *Salmonella choleraesuis*]

Antibiotic-Resistant [Strains of] Bacteria [Antibiotic-Resistant Bactericidal Activity]-

Staphylococcus aureus MRSA [ATCC 33592] *Enterococcus faecalis* VRE [ATCC 51575]

***VIRUCIDAL** in the presence of 5% serum load and 1 minute contact time at 20°C (68°F) on hard, non-porous environmental surfaces.

Viruses [*Virucidal Activity]:

Herpes Simplex Virus, Type 1 [HSV-1] Herpes Simplex Virus, Type 2 [HSV-2] Human Coronavirus [ATCC VR-740]
[ATCC VR-733] [ATCC VR-734] Rhinovirus Type 14 [ATCC VR-284]
Influenza A/Hong Kong [ATCC VR-544] Poliovirus Type 1, Strain Brunhilde Rotavirus WA
[ATCC VR-1000]

Kills HIV-1 [AIDS virus] [HTLV-III_B] when used as directed on hard, non-porous inanimate surfaces with a 1 minute contact time.

Kills HBV & HCV when used as directed on hard, non-porous inanimate surfaces with a 1 minute contact time.

Kills Norovirus [Feline Calicivirus as the surrogate] [VR-782] when used as directed on hard, non-porous inanimate surfaces with a 1 minute contact time.

[Veterinary Viruses:]

Avian Influenza A, [H3N2] [ATCC VR-2072] Feline Calicivirus, Strain F9 [ATCC VR-782]

TUBERCULOCIDAL in the presence of 5% serum load and 5 minute contact time at 20°C (68°F) on hard, non-porous environmental surfaces.

Mycobacterium bovis [Tb] [OT 451C150]

FUNGICIDAL This product is fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes* [ATCC 9533] [the fungus which causes Athlete's Foot] in the presence of 5% serum load and 10 minute contact time at 20°C (68°F) when used as directed on hard surfaces found in bathroom, shower stalls, locker rooms, or other clean, non-porous, hard surfaces commonly contacted by bare feet.

Trichophyton mentagrophytes [ATCC 9533]

Non-Food Contact Surface Sanitizer for hard non-porous surfaces - in the presence of 5% serum load and 30 second contact time at 20°C (68°F) on hard, non-porous environmental surfaces.

Klebsiella pneumoniae [ATCC 4352] *Salmonella enterica* [ATCC 10708] *Pseudomonas aeruginosa* [ATCC 15442]
Staphylococcus aureus [ATCC 6538] [formally know as *Salmonella choleraesuis*] *Enterococcus faecalis* VRE [ATCC 51575]
Escherichia coli O157:H7 [ATCC 35150] *Staphylococcus aureus* MRSA [ATCC 33592]

Malodor[s] [Activity] [Counteractancy] – eliminates [destroys] odors and odor-causing bacteria on hard, non-porous surfaces in restroom areas, behind and under sinks and counters, and storage areas [and other places where bacterial growth can cause malodors].

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(Note to reviewer: We will choose one or more of these statements depending on available space on the product label.)

- *Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus. (This product or product name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against Influenza Type A2 (Hong Kong), (VR-544), and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- *This product has demonstrated effectiveness against Influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 Influenza A virus.
- *This product has demonstrated effectiveness against Influenza Type A2 (Hong Kong), (VR-544), and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- *Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu).
- *Kills Pandemic 2009 H1N1 Influenza A virus.

{Note: the following section on summary of claims is optional and might be inserted in a band at the bottom of the label}

FUNGICIDAL: 10 MIN.

TUBERCULOCIDAL: 5 MIN.

VIRUCIDAL: 1 MIN.

BACTERICIDAL: 1 MIN.

BROAD-SPECTRUM NON-FOOD CONTACT SANITIZER: 30 SEC.

EPA Reg. No. 74559-3