



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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MAY 2 2007

JohnsonDiversey  
8310 16<sup>th</sup> Street  
P.O. Box 902  
Sturtevant, WI. 53177-0902

MAY 2 2007

Attention: Kresti A. Lyddon  
Regulatory Specialist

Subject: Oxivir Tb  
EPA Reg. No. 70627-56  
Amendment Letter Dated December 13, 2006

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable. Below are some minor labeling revisions that should be incorporated:

- On page 4 of the proposed label, remove the word "with" in # 2 direction, bottom of the page.
- It is recommended that "Tb" be changed to "TB".
- It is recommended that the statement "Kills Norovirus (and Feline Calcivirus) when used as directed" .....to read, "Kills Feline Calcivirus (surrogate for Norovirus) when used as a directed.
- The registrant needs to change "*Salmonella choleraesuis*" to "*Salmonella enterica*".
- On the front page of the proposed label, please remove the term, "Intermediate Disinfectant". The Agency does not classify disinfectants as "intermediate".

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) and section 4(a) when the Agency requires all registrants of similar products to submit such data.

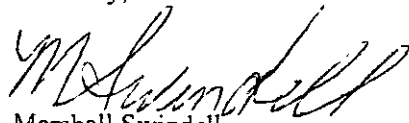
If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the accepted labeling is enclosed. Submit three copies of your final printed labeling to the Agency before distributing or selling the product bearing the revised labeling.

2 7 11

If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Swindell". The signature is fluid and cursive, with the first letter "M" being particularly large and stylized.

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

(Note to Agency: Text appearing in parenthesis or brackets is done to show optional text.)

3 7 11

Johnson Diversey



**OXIVIR TB**  
(Ready to Use)  
One-Step Disinfectant and Deodorizer  
General \*Virucide, Bactericide, Tuberculocide, Fungicide, Sanitizer  
Cleaner Disinfectant Deodorizer



(Hydrogen Peroxide)

For (Commercial) (Industrial) (&) (Institutional) Use (Only)

<b>ACTIVE INGREDIENTS:</b>	
Hydrogen Peroxide .....	0.5%
<b>OTHER (INERT) INGREDIENTS</b> .....	<u>99.5%</u>
<b>TOTAL:</b> .....	100.0%

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

(See additional precautionary statements on (back) (side) (left) (right) (panel) (of) (label) (below).)

See reference sheet (enclosed in each case) for (a completed list of organisms) (additional (features) (claims) (directions for use)) (for this product).

**ACCEPTED**  
with **COMMENTS**  
in EPA Letter Dated:  
MAY 2 2007

Net Contents:

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No 70687-56

Product of U.S.A.

(Note to Agency: Text appearing in parenthesis or brackets is done to show optional text.)

**(MARKETING CLAIMS):**

**(FEATURES, CLAIMS & USES:)**

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

*(General Uses)*

OXIVIR 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 & colleges, (medical) (dental) offices, veterinary clinics, pet shops, equine farms, animal & life science laboratories, transportation terminals (airports, train stations, bus stations, truck stops, rest (stops) areas), hotels, motels, casinos, cruise ships, other institutional/commercial buildings, homes cleaned by (home cleaning services,)(professional cleaning services,)(medical assistance services,) and office buildings.

OXIVIR'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): (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, fixtures, glazed tile, sinks – almost any washable (food and non-food contact) surface where disinfection is required. A potable water rinse is required for food contact surfaces. Do not use on glasses, dishes and utensils.

*(Hospitals/Health Care Facilities/Dental Offices/Life Science Laboratories)*

OXIVIR 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. OXIVIR cleans quickly by removing dirt, grime, food residue, dead skin, blood and other organic matter commonly found in Hospitals, (in Health Care Facilities), (laboratory settings). It also eliminates odors, leaving (restroom) surfaces smelling clean and fresh. Use where odors are a problem.

OXIVIR 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, 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 (food and non-food contact) surface (where disinfection is required). A potable water rinse is required when disinfecting food contact surfaces. Do not use on glasses, dishes and utensils.

*(Animal Housing Facilities)*

OXIVIR cleans by removing dirt, grime, blood, urine, fecal matter and other common soils found in animal housing facilities, grooming facilities, farms, kennels, ~~ACCEPTED~~ ~~in EPA Letter Dated:~~ ~~70627-56~~ veterinary clinics, laboratories or other small animal facilities. It (also) eliminates odors leaving surfaces smelling clean and fresh.

ACCEPTED  
in EPA Letter Dated:  
MAY 2 2007

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This product 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:) plated or stainless steel, 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 Oxivir TB Into Smaller Containers:

[Oxivir 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.

**(CLAIMS:)**

(When used as directed, this product (is) highly effective against a wide variety (broad-spectrum) of pathogenic microorganisms (including bacteria, antibiotic resistant bacteria, viruses, fungi, mold and mildew. See reference sheet (enclosed in each case) for a complete list of organisms).

**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. (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)  
*Escherichia coli* 0157:H7 (ATCC 35150)  
*Acinetobacter baumannii* (ATCC 19606)

*Staphylococcus aureus* (ATCC 6538)  
*Staphylococcus aureus* MRSA (ATCC 33592)  
*Clostridium difficile* (vegetative) (ATCC 9689)

*Salmonella enterica* (ATCC 10708)  
*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):**

Poliovirus Type 1, Strain Brunhilde (ATCC VR-1000)  
Human Coronavirus (ATCC VR-740)  
Herpes Simplex Virus, Type 2 (HSV-2) (ATCC VR-734)  
Hepatitis C Virus (HCV)  
(Acquired from National Veterinary Services Laboratories)

HIV-1 (AIDS Virus), Strain HTLV-III<sub>B</sub> (HIV-1),  
(Acquired from Adv. Biotechnologies, Inc.)  
Influenza A/Hong Kong (ATCC VR-544)  
Rhinovirus Type 37, Strain 151-1 (ATCC VR-1147)  
Hepatitis B Virus (HBV)  
(Acquired from Hepadnavirus Testing)

Feline Calicivirus, Strain F9  
(ATCC VR-782)  
Herpes Simplex Virus, Type 1 (HSV-1)  
(ATCC VR-733)  
Rotavirus WA (Acquired from University of Ottawa)

Kills Norovirus (and Feline Calicivirus) when used as directed on hard, non-porous inanimate surfaces with a 1 minute contact time.

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

*Mycobacterium bovis* (Tb) (OT 451C150)

**ACCEPTED**  
**with COMMENTS**  
**in EPA Letter Dated:**  
**MAY 2 2007**

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No 70627-56

(Note to Agency: Text appearing in parenthesis or brackets is done to show optional text.)

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

*Tricophyton mentagrophytes* (ATCC 9533)

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

*Klebsiella pneumoniae* (ATCC 4352)  
*Staphylococcus aureus* (ATCC 6538)  
*Escherichia coli* 0157:H7 (ATCC 35150)

*Salmonella enterica* (ATCC 10708)  
*Staphylococcus aureus* MRSA (ATCC 33592)

*Pseudomonas aeruginosa* (ATCC 15442)  
*Enterococcus faecalis* VRE (ATCC 51575)

**Malodor(s) (Activity) (Counteractancy)** – eliminates (destroys) odors and odor-causing bacteria in restroom areas, behind and under sinks and counters, and storage areas (and other places where bacterial growth can cause malodors).

**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 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 time for fungi.
4. Wipe surfaces dry (or rinse) (or allow to air dry).

Note: Rinsing is not necessary unless floors are to be coated with finish or restorer. All food contact surfaces must be rinsed with potable water. Do not use on glassware, utensils, or dishes.

**For Use as a Cleaner and/or Deodorizer:**

Apply to surfaces by spray, cloth, sponge, or mop. Wipe surfaces dry (or rinse) (or allow to air dry).

**For Use to Clean and Disinfect Life Science Laboratory Surfaces:**

1. Pre-clean heavily soiled areas.
2. Apply Solution by spray, cloth, disposable wipe (paper towel) or mop to hard, non-porous environmental surfaces.
3. Allow the surface to remain wet for 1 minute. Use a 5 minute contact time for TB and a 10 minute contact time for fungi.
4. Wipe surfaces dry (or rinse) (or allow to air dry).
5. Change solution after each use (application).

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Label Amendment 12/13/2006  
Oxivir Tb  
EPA Reg. No. 70627-56  
Page 4 of 9

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**For Use as a Tuberculocide:**

1. Pre-clean heavily soiled areas.
2. Apply Solution with cloth, disposable wipe or mop to hard, non-porous environmental surfaces.
3. Allow the surface to remain wet for 5 minutes.
4. Wipe surfaces dry (or rinse) (or allow to air dry).
5. Change solution after each use (application).

**To Kill Fungi:**

1. Pre-clean heavily soiled areas.
2. Apply Solution to hard, non-porous inanimate surfaces.
3. Allow surface to remain wet for 10 minutes.
4. Wipe surfaces dry (or rinse) (or allow to air dry).

**\*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 DECONTAMINATING AGAINST HIV-1 (AIDS Virus), HBV OR HCV 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 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 Tb and a 10 minute contact for fungi.

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

**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 or detergent and rinse with potable water. Saturate surfaces by wiping or spraying with product for a period of 1 minute. Use a 5 minute contact time for TB and a 10 minute contact time for fungi.
5. 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.
6. Ventilate buildings and other closed spaces.
7. 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.

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**For use as a Non-Food Contact Sanitizer:**

1. Pre-clean heavily soiled areas.
2. Apply Solution with cloth, disposable wipe or mop to 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 solution after each use (application).

(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 a 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 of 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 incineration, or, if allowed by state and local authorities, by burning. 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.

**ENVIRONMENTAL HAZARDS** (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.

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9 7 11

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**IN CASE OF EMERGENCY, CALL A POISON CONTROL CENTER OR DOCTOR FOR TREATMENT ADVICE.  
1-800-851-7145**

Have the product container or label with you when calling a Poison Control Center or doctor or going in for treatment.

Si no puede leer en ingles, pregunte a su supervisor sobre las instrucciones de uso apropiadas antes de trabajar con este producto.

EPA Reg. No. 70627-56

EPA Est. No.

Lot code indicates site of manufacture.

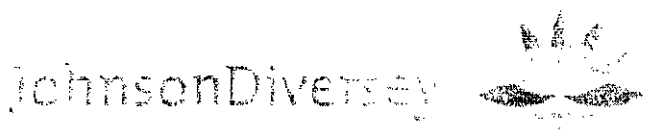
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ACCEPTED  
with COMMENTS  
in EPA Letter Dated

MAY 2, 2005

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# OXIVIR TB REFERENCE SHEET

20°C (68°F) on hard, non-porous environmental surfaces. (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:

- |  |   |   |
|--|---|---|
| <i>Pseudomonas aeruginosa</i> (ATCC 15442)   | <i>Staphylococcus aureus</i> (ATCC 6538)              | <i>Salmonella choleraesuis</i> (ATCC 10708)   |
| <i>Escherichia coli</i> 0157:H7 (ATCC 35150) | <i>Staphylococcus aureus</i> MRSA (ATCC 33592)        | <i>Enterococcus faecalis</i> VRE (ATCC 51575) |
| <i>Acinetobacter baumannii</i> (ATCC 19606)  | <i>Clostridium difficile</i> (vegetative) (ATCC 9689) |   |

(\*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):

- |   |  |  |
|---|--|--|
| Poliovirus Type 1, Strain Brunhilde (ATCC VR-1000)                                | HIV-1 (AIDS Virus), Strain HTLV-III <sub>B</sub> (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) (Acquired from National Veterinary Services Laboratories) | Hepatitis B Virus (HBV) (Acquired from Hepadnavirus Testing)   |  |

Kills Norovirus (and Feline Calicivirus) when used as directed on hard, non-porous inanimate surfaces with a 1 minute contact time.

**TUBERCULOCIDAL** in the presence of a 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, *Tricophyton mentagrophytes* (ATCC 9533) (the fungus which causes Athlete's Foot) in the presence of a 5% serum load and 10 minute contact time at 20°C (68°F) when used as directed on hard surfaces found in bathrooms, shower stalls, locker rooms, or other clean, non-porous, hard surfaces commonly contacted by bare feet.

*Tricophyton mentagrophytes* (ATCC 9533)

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Page 8 of 9

11 8 11

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

*Klebsiella pneumoniae* (ATCC 4352)  
*Staphylococcus aureus* (ATCC 6538)  
*Escherichia coli* 0157:H7 (ATCC 35150)

*Salmonella choleraesuis* (ATCC 10708)  
*Staphylococcus aureus* MRSA (ATCC 33592)

*Pseudomonas aeruginosa* (ATCC 15442)  
*Enterococcus faecalis* VRE (ATCC 51575)

**Malodor(s) (Activity) (Counteractancy)** – eliminates (destroys) odors and odor-causing bacteria 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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