



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

APR 17 2009

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Ms. Tiana M. Rosamilia  
Regulatory Manager for,  
Evonik Degussa Corporation  
379 Interpace Parkway  
Parsippany, NJ 07054

Subject: Peraclean \* 15  
EPA Registration Number 54289-4  
Your Amendment Dated November 11<sup>th</sup>, 2008  
EPA Received Date December 2<sup>nd</sup>, 2008

The amendment referred to above, submitted in connection with under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to add additional efficacy organisms to the labeling, is acceptable provided that you make the following labeling revisions:

1. On page 5 and 9 of the proposed label, change "tile" to read "glazed tile". Tile is a porous site.
2. Under the "Precautionary Statements" section, change "before eating, drinking, or using tobacco" to read "before eating, drinking, chewing gum, using tobacco, or using the toilet".
3. On page 6 of the proposed label, change "Escherichia coli O157:H7" to read "Escherichia coli O157:H7."
4. On page 9 of the proposed label, change "For heavily soiled areas, a preliminary Cleaning is recommended" to read "For heavily soiled areas, a preliminary cleaning is required."
5. On page 9 of the proposed label, delete one of the references to "linoleum" as it is listed twice as a surface of use.
6. On page 9 of the proposed label, change "Vancomycin-Resistant Enterococcus" to read "Vancomycin-Resistant Enterococcus faecalis."
7. On page 10 of the proposed label, move "Human coronavirus strain 229e" so that it is listed under the "Human viruses" subheading.

- 8. On page 10 of the proposed label, delete "Tuberculosis" listed under the "Human viruses" subheading: Human hepatitis B virus, Human hepatitis C virus, and Norovirus.
- 9. On page 11 of the proposed label, change "or incineration" to read "or by incineration."
- 10. Add ATCC numbers for each of the bacteria, fungi, and viruses identified.

Please note that the efficacy against Clostridium perfringens was demonstrated for a 1-minute contact time. Efficacy at a 3-minute contact time was demonstrated for Streptococcus pneumoniae. For this reason, on page 9 of the proposed label, change "3-minute contact time for Clostridium perfringens" to read "3 minute contact time for Streptococcus pneumoniae." A similar change must be made to page 10 of the proposed label.

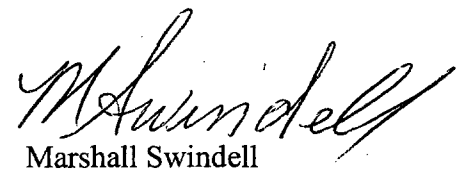
A stamped copy of the labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration /reregistration of your product under FIFRA section 3(c)(5) 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.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,



Marshall Swindell  
Product Manager 33  
Regulatory Management Branch I  
Antimicrobial Division(7510P)

# PERACLEAN® 15 (Peroxyacetic Acid Solution)

PERACLEAN® 15 is a peroxyacetic acid-based sanitizer/disinfectant developed for the following uses:

### Institutional/Industrial Sanitizing of Previously Cleaned Non-Porous Food Contact Surfaces in:

- Dairies
- Wineries
- Breweries
- Food and Beverage Plants
- Disinfecting Poultry Premises
- Poultry Hatcheries
- Animal Housing Facilities
- Reverse Osmosis Membranes and Ultra Filtration
- Colleges
- Veterinary Clinics
- Animal Life Science Laboratories
- Industrial Facilities
- Office Buildings
- Recreational Facilities
- Retail and Wholesale Establishments

### Hard Surface Disinfection in:

- Hospitals
- Health Care Facilities
- Schools
- Bacteria, Fungi, and Slime Control in:
- Pulp and Paper Mill Systems
- Dispersed Pigments
- Cooling Water Systems
- Coatings Preservation

### Active Ingredients:

Hydrogen Peroxide	22.0%
Peroxyacetic Acid	15.0%
Inert Ingredients:	63.0%
Total:	100%

EPA Reg. No. 54289-4

EPA Estab. No.

Net contents as stated on container

### Manufactured by:

Evonik Degussa Corporation  
379 Interpace Parkway, P.O. Box 677  
Parsippany, New Jersey 07054-0677

ACCEPTED  
with COMMENTS  
in EPA Reg. No. 54289-4

APR 17 2009

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, the following pesticide registration number is hereby assigned: No.

54289-4

Before Using This Product, Please Read This Entire Label Carefully.

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

**FIRST AID**

If in eyes: Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call poison control center or doctor for treatment advice.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call poison control center or doctor for treatment advice.

If swallowed: Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person. Call poison control center or doctor for treatment advice.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER. CORROSIVE.** Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not breathe vapors or spray mist. Do not get in eyes on skin or on clothing. Wear goggles and/or face shield and rubber gloves when handling. Do not enter an enclosed area without proper respiratory protection. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

**PHYSICAL AND CHEMICAL HAZARDS**

**STRONG OXIDIZING AGENT.** Corrosive. Mix only with water. Product must be diluted in accordance with label directions prior to use. PERACLEAN® 15 is not combustible; however, at temperatures exceeding 156°F, decomposition occurs releasing oxygen. The oxygen released could initiate combustion.

**ENVIRONMENTAL HAZARDS**

This pesticide is toxic to birds, fish, and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk. 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 authority 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 US Environmental Protection Agency.

**DIRECTIONS FOR USE**

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

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

54289-4

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

SANITIZATION

NOTE: FOR MECHANICAL OPERATIONS prepared use solution may not be used for subsequent sanitizing but may be reused for other purposes such as cleaning.

FOR MANUAL OPERATIONS fresh sanitizing solutions should be prepared at least daily or more often if the solution becomes diluted or soiled.

PERACLEAN® 15 peroxyacetic acid sanitizer is recommended for use on precleaned surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in dairies, breweries, wineries, beverage and food processing/packing plants, egg processing/packing equipment surfaces, and eating establishments. This product is effective as a sanitizer when solution is prepared in water of up to 400 ppm hardness as CaCO3. This product has demonstrated greater than a 99.999% reduction of survivors after a 30 second exposure period in the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants study.

SANITIZING FOOD CONTACT SURFACES

Effective against Staphylococcus aureus and Escherichia coli.

Prior to sanitizing, remove gross food particles, then wash with a detergent solution, followed by a potable water rinse. Sanitize with a concentration of 0.33 fluid ounce PERACLEAN® 15 dissolved in 5 gallons of water (0.053% v/v concentration). This will provide 88 ppm of peroxyacetic acid. At this dilution PERACLEAN® 15 is effective against Staphylococcus aureus and Escherichia coli. Use immersion, coarse spray or circulation techniques as appropriate to the equipment. All surfaces should be exposed to the sanitizing solution for a period of at least 60 seconds or more if specified by governing sanitary code. Drain thoroughly and allow to air dry. Do not rinse.

Sanitizing, Eating, Drinking, and Food Prep Utensils

Remove gross food particles by a prescrape, a preflush and, when necessary, a presoak treatment. Wash with a recommended detergent. Rinse with clean water. Sanitize in a solution of 0.33 fluid ounce PERACLEAN® 15 dissolved in 5 gallons of water. Immerse all utensils for at least 60 seconds or contact time specified by governing sanitary code. Drain and air dry.

SANITIZING TABLEWARE

For sanitizing tableware in low temperature warewashing machines, inject PERACLEAN® 15 into the final rinse water at a concentration of 0.33 fluid ounce PERACLEAN® 15 dissolved in 5 gallons of water. Do not exceed 0.053 % v/v. This will provide 88 ppm of peroxyacetic acid. Air dry.

To insure that the PERACLEAN® 15 sanitizer concentration does not fall below 48 ppm peroxyacetic acid, periodically test the rinse solution with a suitable test kit and adjust the dispensing rate accordingly. Consult your technical service representative for assistance and further information on sanitizing tableware in warewashing machines.

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Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended in the past, this registration number EPA Reg. No.

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FINAL SANITIZING BOTTLE RINSE

PERACLEAN® 15 may be used as a final sanitizing rinse for returnable and non-returnable bottles at a 0.053% dilution (0.33 fluid ounce PERACLEAN® 15 dissolved in 5 gallons of water). This will provide 88 ppm of peroxyacetic acid.

Batch Sanitization (NON-FOOD CONTACT SURFACES) of Ultra Filtration and Reverse Osmosis (RO) Membranes

PERACLEAN® 15 can be used for the sanitization of ultra filtration, medical and non-medical institutional/industrial reverse osmosis (RO) membranes and their associated distribution systems.

This product has been shown to be an effective disinfectant when tested by AOAC and EPA methods. This product may not eliminate all vegetative microorganisms in reverse osmosis membranes and their associated piping systems due to their construction and/or assembly, but can be relied upon to reduce the number of microorganisms to acceptable levels when used as directed. Check with equipment manufacturer for membrane compatibility with PERACLEAN® 15.

Remove biological or organic fouling from the membrane or other parts of the system with an appropriate cleaner. Flush the system with RO permeate or similar quality water. Remove mineral deposits with suitable acidic cleaner prior to sanitizing the membranes with PERACLEAN® 15. Flush the system again with the RO permeate or similar quality water. Prepare an appropriate volume of 1% solution of the product (0.33 gallon of PERACLEAN® 15 to 100 gallons of water). This will provide 568 ppm of peroxyacetic acid and 834 ppm hydrogen peroxide. Fill the entire water circuit to be sanitized with the dilute solution and allow the solution to reach a minimum of 20°C (68°F). Recirculate the dilute solution of PERACLEAN® 15 for a minimum of 10 minutes. Allow membrane elements to soak in the solution for a minimum of 20 minutes. Rinse the RO system and test for residuals to ensure that there is less than 3 ppm peroxygen. Diverting product water to drain can reduce residuals.

Batch Sanitization (NON-FOOD CONTACT SURFACES) of Piping Systems Associated with RO Membranes

Isolate incompatible equipment from piping system. This includes activated carbon filters and ion exchange equipment. Turn off power to ultraviolet light units. Estimate total volume of water contained in the system (tanks, rinse stations and piping). Prepare an appropriate volume of 0.33 to 0.5% PERACLEAN® 15 by adding 0.33 to 0.5 gallons of the product for every 100 gallons of solution prepared. Use RO permeate or similar quality water for dilution. This will provide 554 to 840 ppm peroxyacetic acid and 813 to 1232 ppm hydrogen peroxide. Recirculate the dilute PERACLEAN® 15 solution through the system for a minimum of 4 hours. Process usage valves should be opened and closed to expose internals to the PERACLEAN® 15. Completely drain the system of dilute PERACLEAN® 15 solution. Thoroughly rinse the system by filling with RO permeate or similar quality water and recirculate before drainage. Repeat the process until test for residuals indicates there is less than 3 ppm peroxygen.

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Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the use of the registered active ingredient, No.

54789-4

Continuous/Intermittent addition to minimize the Accumulation of Biological Matter Between Intermittent Sanitizing Episodes in Piping Systems Associated with RO Membranes (NON-FOOD CONTACT SURFACES)

PERACLEAN® 15, as received or diluted, may be added continuously to the feed water system, between system sanitizing episodes, to aid in minimizing the regrowth/accumulation of biological matter. The peroxygen residual in the system which will be effective will vary with the design and usage characteristics of the system. Adjust the addition rate of PERACLEAN® 15 or the solution and periodically monitor residual peroxygen so that the desired effect is obtained. For continuous addition, do not exceed 7 ppm (0.33 fluid ounce of product per 440 gallons of water) PERACLEAN® 15. This will give 1 ppm peroxyacetic acid and 1.4 ppm hydrogen peroxide. For intermittent feed, do not exceed 750 ppm (8.5 fluid ounces of product per 100 gallons of water) PERACLEAN® 15. This will give 110 ppm peroxyacetic acid and 160 ppm hydrogen peroxide.

HARD SURFACE DISINFECTION

PERACLEAN® 15 disinfects as it cleans in one operation. PERACLEAN® 15 can be used to disinfect floors, walls and other hard nonporous surfaces such as tables, chairs, countertops, bathroom fixtures, sinks, bed frames, shelves, racks, carts, refrigerators, coolers, glazed tile, linoleum, vinyl, non-porous glazed porcelain, plastic (such as polypropylene and polyethylene), stainless steel, or glass.

Areas of use in hospitals: PERACLEAN® 15 may be used for surgical and obstetrical suites; housekeeping services; physical therapy departments; nursing services; autopsy facilities. Also, use PERACLEAN® 15 in nursing homes, other health-care facilities, schools, colleges, veterinary clinics, animal life science laboratories, industrial facilities, dietary areas, office buildings, recreational facilities, retail and wholesale establishments. 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 bloodstream 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.

COMBINATION DISINFECTION AND CLEANING

PERACLEAN® 15 is effective against Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa, Trichophyton mentagrophytes, and Escherichia coli O157:H7 at 0.08% (0.5 fl. oz./5 gal.) in hard water (400 ppm as CaCO3) and 5% fetal bovine serum on hard nonporous surfaces. For heavily soiled areas a pre-cleaning step is required. Apply solution with mop, cloth, sponge, brush, scrubber, or coarse spray device, or by soaking so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, then remove solution and entrapped soil with a clean wet mop, cloth, or wet vacuum pickup. Prepare a fresh solution daily or when it becomes soiled or diluted.

PERACLEAN® 15 is designed for use in animal hospitals, animal laboratories, kennels, pet shops, zoos, pet animal quarters, poultry premises, poultry hatcheries, and livestock quarters. When used as directed, PERACLEAN® 15 is specifically designed to disinfect.

ACCEPTED  
with COMMENTS  
Last Date Discd:

APR 17 2009

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

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deodorize and clean inanimate, hard, surfaces such as walls, floors, sink tops, furniture, operating tables, kennel runs, cages, and feeding and watering equipment. In addition PERACLEAN® 15 will deodorize those areas which are generally hard to keep smelling fresh such as garbage storage areas, empty garbage bins and cans, and any other areas which are prone to odors caused by microorganisms.

All treated equipment that will contact food, feed, or drinking water must be rinsed with potable water before reuse.

For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use.

**DISINFECTION OF POULTRY PREMISES, TRUCKS, COOPS AND CRATES**

Poultry Hatchery Disinfection

Remove all poultry and feeds from premises, trucks, coops and crates. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry. Empty all troughs, racks and other feeding and watering appliances.

Thoroughly clean all surfaces with a detergent and rinse with water. Saturate surfaces with a 0.08% (0.5 fl. oz./5 gal.) solution of PERACLEAN® 15 for a period of 10 minutes. Ventilate buildings, coops and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with a detergent and rinse with potable water before reuse. See your technical representative for specific recommendations for all cleaning and rinsing requirements.

DISINFECTION AND DEODORIZING OF ANIMAL HOUSING FACILITIES (BARNS, KENNELS, HUTCHES, ETC.)

Do not use in milking stalls, milking parlors, or milk houses (for phenolics, cresylic acid, and pine oils). Remove animals and feed from premises, vehicles, and enclosures.

Remove litter, waste matter, and gross soils from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals.

Empty all troughs, racks and other feeding and watering equipment. Thoroughly clean all surfaces with a detergent and rinse with water. Saturate surfaces with a 0.08% (0.5 fl. oz./5 gal.) solution of PERACLEAN® 15 for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings, cars, boats, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

FOR SANITIZING OF HATCHING EGGS

Prepare a solution of PERACLEAN® 15 by diluting 0.33 fluid ounce PERACLEAN® 15 with 5 gallons of water. As eggs are gathered or prior to setting, apply solution as a coarse spray so as to lightly wet all shell surfaces.

NOTE: This product at its use dilution is compatible with stainless steel and aluminum surfaces. If product is intended to be used on any other surface, it is recommended that

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EPA  
EPA Label Used

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

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you apply product to a smaller test area to determine compatibility before proceeding with its use.

FOR TREATMENT OF RAW, UNPROCESSED FRUIT AND VEGETABLE SURFACES

PERACLEAN® 15 can be applied as a dip or spray to control the growth of non-public health microorganisms that may cause decay and/or spoilage on raw, post-harvest fruits and vegetables during the washing process. This product can be applied during physical cleaning processes, including at the roller spreader, washer manifold, dip tank, on the brushes or elsewhere in the washing process prior to, simultaneously with or after detergent wash.

1. Prepare treating solution by diluting 1 fluid ounces per 16 gallons of potable water. This will provide 85 ppm peroxyacetic acid and 125 ppm hydrogen peroxide.
2. Apply the diluted sanitizer solution using a coarse spray directed at the fruits or vegetables, or by soaking the fruits and vegetables in the solution. Allow a contact time of at least 45 seconds.
3. The treated produce can be drain dried without a potable water rinse.
4. Do not reuse solution after treatment.

BIOFOULING CONTROL IN PULP AND PAPER MILL SYSTEMS

For use in the manufacture of paper and paperboard intended for food-contact and non-food contact.

PERACLEAN® 15 can be used to control bacteria, fungi, and fresh water organisms in paper, paperboard, or nonwoven process water and influent water systems. Suitable dosing points include but are not limited to: stock chests, pulpers, the white water loop and white water storage systems and influent water streams.

ACCEPTED  
with COMMENTS  
in EPA Letter Request

APR 17 2009  
Under the Federal Food, Drug, and Cosmetic Act, this product is considered to be a pesticide.

Influent Water Systems:

PERACLEAN® 15 should be fed continuously to incoming fresh water streams (nonpotable use only) at dosages ranging from 10 to 975 ppm peroxyacetic acid (65 to 6500 ppm PERACLEAN® 15).

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Mill Process Waters:

- Continuous Feed – PERACLEAN® 15 should be fed continuously at dosages ranging from 10 to 975 ppm peroxyacetic acid (65 to 6500 ppm PERACLEAN® 15). This range is equivalent to 0.13 to 13 lbs. PERACLEAN® 15 per ton (dry basis) of pulp or paper produced.
- Intermittent Feed – PERACLEAN® 15 should be fed intermittently (6 to 8 times per day) at dosages ranging from 10 to 975 ppm peroxyacetic acid (65 to 6500 ppm PERACLEAN® 15). This range is equivalent to 0.13 to 13 lbs. PERACLEAN® 15 per ton (dry basis) of pulp or paper produced.
- Shock Dose – PERACLEAN® 15 should be shock dosed at dosages ranging from 98 to 2048 ppm peroxyacetic acid (648 to 13,638 ppm PERACLEAN® 15). This range

is equivalent to 1.3 to 27.3 lbs. PERACLEAN® 15 per ton (dry basis) of pulp or paper produced.

CONTROL OF BACTERIA AND FUNGI IN NON-FOOD CONTACT DISPERSED PIGMENTS

PERACLEAN® 15 can be used in the control of bacteria and fungi in the manufacture and storage of dispersed pigments such as kaolin clay, titanium dioxide, calcium carbonate, calcium sulfate, barium sulfate, magnesium silicate and diatomaceous earth used in paint and paper production.

Add 0.1 to 0.5 lbs. (1.4 to 6.85 fl. oz.) of PERACLEAN® 15 to each 1000 lbs. of pigment slurry. This will provide 15 to 75 ppm peroxyacetic acid (100 to 500 ppm PERACLEAN® 15).

CONTROL OF SLIME FORMING BACTERIA IN COOLING WATER SYSTEMS (COOLING TOWERS, EVAPORATIVE CONDENSERS)

- Severely fouled systems should be cleaned before adding the PERACLEAN® 15 solution. PERACLEAN® 15 should be added in the system directly and not mixed with any other chemicals or additives. Contamination with other chemicals could result in product decomposition.
- Add PERACLEAN® 15 at a point in the system where uniform mixing and even distribution will occur.
- Use 0.1 to 0.5 lb. (1.4 to 6.85 fl. oz.) of PERACLEAN® 15 per 1000 gallons of solution as a continuous or intermittent slug treatment. This will provide 1.8 to 9 ppm peroxyacetic acid (12 to 60 ppm PERACLEAN® 15). Repeat treatment as required to maintain control.

CONTROL OF BACTERIA AND FUNGI IN COATING PRESERVATION

Not for use in manufacture of material intended for food contact.

PERACLEAN® 15 can be used as an in-container preservative for the control of bacteria and fungi in water-based coatings such as paper coatings.

Add 0.1 to 0.5 lbs. (1.4 to 6.85 fl. oz.) of PERACLEAN® 15 to each 1000 lbs. of preservative. This will provide 15 to 75 ppm peroxyacetic acid (100 to 500 ppm PERACLEAN® 15).

RECEIVED  
WELLS COMPANY  
APR 17 2009

**Bactericidal, Virucidal, Fungicidal, Tuberculocidal**

For use on hard, non-porous surfaces. (For use only with the 3M™ Twist 'n Fill™ System.)

Hard Surface Disinfection for 3M™ Twist 'n Fill™ Application

PERACLEAN® 15 disinfects as it cleans in one operation. PERACLEAN® 15 can be used to disinfect floors, walls and other hard nonporous surfaces such as tables, chairs, countertops, bathroom fixtures, sinks, bed frames, doors, shelves, racks, carts, refrigerators, coolers, glazed tile, linoleum, vinyl, non-porous glazed porcelain, glazed ceramic, plastic (such as polypropylene and polyethylene), stainless steel, glass,

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aluminum, non-porous baked enamel, chrome, laminated or painted surfaces or sealed stone. PERACLEAN® 15 should not be used on marble or brass surfaces.

For health care, institutional, and industrial use.

Areas of use in hospitals: PERACLEAN® 15 may be used for surgical and obstetrical suites; housekeeping surfaces; physical therapy departments; nursing services; dental facilities; autopsy facilities; intensive care units; pharmacies; and clinical laboratories. Also, use PERACLEAN® 15 in nursing homes, other health-care facilities, schools, colleges, veterinary clinics, animal life science laboratories, industrial facilities, office buildings, recreational facilities, industrial facilities; hotels; retail facilities; office buildings; retail and wholesale establishments.

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 bloodstream 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.

The 3M™ Twist 'n Fill™ system will dilute PERACLEAN® 15 with the appropriate amount of water to an effective concentration of 1135ppm Peracetic acid and 1665ppm hydrogen peroxide (0.85 fl. oz per 1 gallon of water). Apply solution with a cloth, mop, sponge, auto-scrubber, or hand pumped trigger sprayer such that all surfaces remain wet for 1 minute to kill bacteria, viruses, and fungi as cited on the label. Use a 3 minute contact time for Streptococcus pneumoniae, and Vancomycin-Resistant Enterococcus faecalis. Use a 10 minute contact time for Poliovirus Type 1 and Mycobacterium bovis (surrogate for TB). Allow surface to air dry. For heavily soiled areas, a preliminary cleaning is required. Prepare a fresh solution daily or more often if the use solution becomes visibly soiled clouded or diluted.

This product is not for use on medical device surfaces.

ACCEPTED  
with COMMENTS  
in EPA Letter D-00-01

APR 17 2009

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended by the FIFRA Act of 1990, this product is registered under EPA Reg. No. 54289-4

PERACLEAN® 15 is effective against the following organisms in 1 minute with 5% organic soil load and 400ppm hard water:

\* Contact time is increased to 10 minutes to be effective against Poliovirus Type 1 and Mycobacterium bovis (TB surrogate).

§ Contact time is increased to 3 minutes to be effective against Streptococcus pneumoniae and Vancomycin resistant Enterococcus faecalis (VRE).

**Bacteria**

- Acinetobacter baumannii ATTC 19606
- Clostridium perfringens ATTC 13124
- Community-associated MRSA, USA300 strain (CA-MRSA) CI 08001
- Escherichia coli O157:H7 ATTC 35150
- Klebsiella pneumoniae ATTC 4532
- Listeria monocytogenes ATTC 19111
- Methicillin-resistant Staphylococcus aureus (MRSA) ATTC 33592
- Methicillin-resistant Staphylococcus epidermidis (MRSE) ATTC 51625
- Mycobacterium bovis (TB surrogate)\*
  
- Pseudomonas aeruginosa
  
- Salmonella enterica
  
- Salmonella enterica serovar Typhimurium ATTC 13311
- Serratia marcescens ATTC 13880
- Shigella dysenteriae serotype 1 ATTC 29026
- Staphylococcus aureus
- Streptococcus pneumoniae ATTC 6304
- Streptococcus pyogenes ATTC 19615
- Vancomycin-intermediate Staphylococcus aureus (VISA) ATTC 700787
- Vancomycin-resistant Enterococcus faecalis (VRE) § ATTC 51575
- Vibrio cholerae ATTC 14035
- Yersinia enterocolitica ATTC 35669

**Human viruses**

- Herpes simplex virus Type 1 ATTC VR-260
- Herpes simplex virus Type 2 ATTC VR-734
- Human immunodeficiency virus type 1 (HIV-1)
- Human Influenza A virus
- Human Rotavirus ATTC VR-2018
- Poliovirus Type 1\* ATTC 1562
  
- Respiratory Syncytial Virus ATTC VR-26
  
- Rhinovirus Type 37 ATTC 1147
  
- Vaccinia virus ATTC VR-156
  
- Human Coronavirus strain 229e ATTC VR-740
- Bovine viral diarrhea virus (Human Hepatitis C surrogate) ATTC VR-534
- Duck hepatitis B virus (Human Hepatitis B surrogate)
- Feline calicivirus (Norovirus surrogate)

**Animal viruses**

- Avian influenza ATTC CCL-22

**Fungi**

- Candida albicans ATTC 10231
- Trichophyton mentagrophytes ATTC 9533

ACCEPTED  
with COMMENTS  
by EPA Letter Dated:

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Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, the pesticide registered under FIFRA No.

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Kills HIV-1 (AIDS Virus), HBV, and HCV:

On pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings or other settings in which there is an expected likelihood of soiling of surfaces/ objects with blood or body fluids, and in which the surfaces / objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency virus Type 1 (HIV-1) (associated with AIDS), Hepatitis B Virus, or Hepatitis C Virus.

Special Instructions for cleaning and decontamination against HIV-1 (AIDS Virus), HBV, and HCV of surfaces/ objects soiled with blood/body fluids. Personal Protection: Disposable protective gloves, gowns, face masks, or eye coverings as appropriate must be worn during all cleaning of body fluids, blood and decontamination procedures. Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application. Contact Time: HIV-1, HBV, and HCV are inactivated after 1 minute of contact.

**STORAGE AND DISPOSAL**

**Storage and Disposal**

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

**PESTICIDE STORAGE:** Store in original containers in a cool, well-vented area, away from direct sunlight. Do not allow product to become overheated in storage. This may cause increased degradation of the product, which will decrease product effectiveness. In case of spill, flood area with large quantities of water. Do not store in a manner where cross-contamination with other pesticides or fertilizers could occur.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Open dumping is prohibited. If wastes cannot be disposed of according to label directions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Nonrefillable container. Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container."

**Containers less than 5 gallons:**

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

**Containers greater than 5 gallons:**

Triple rinse (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip the container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand container on its end and tip back and for the several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat the procedure two more times. Then offer for recycling or dispose in a sanitary landfill, or by incineration, if allowed by state and local authorities by burning.

ACCEPTED  
with COMMENTS  
on 5/17/2009 Date:

APR 17 2009

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the products, registered under FIFRA Reg. No.

54289-4