



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

EFT Holdings, Inc.
590 Burbank Street, Suite 220
Broomfield, CO 80020

FEB 26 2010

Attention: Adrian Van Ineveld
Regulatory Manager

Subject: Penetrator 200-5000
EPA Reg. No. 74436-1
Amendment Application Date: March 20, 2008
EPA Received Date: March 24, 2008

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 provided the following label revisions are incorporated:

- ✓ ○ On page 1, under the First Aid section, move the statement for "If on Skin or Clothing" to the top or second from the top. Based on data, the Acute Toxicity category for primary skin is Category I for this product.
- ✓ ○ On page 1, under the Storage and Disposal section, delete the wording "Material is naturally biodegradable." This claim is false and misleading as described in 40 CFR part 156.
- ✓ ○ On page 1, under Product Applications, second bullet, delete the wording "in a broad spectrum of". This claim is false and misleading as described in 40 CFR part 156.
- ✓ ○ On page 1, under Product Applications, third bullet, delete the wording "economical". This claim is false and misleading as described in 40 CFR part 156.
- On page 1, under Product Applications, forth bullet, make the following changes:
 - ✓ ○ In the beginning of that statement, add the wording "When used as directed".
 - ✓ ○ Add the word "kill" and delete the word "inhibit". Data supports the product as disinfectant to treat bacteria.
 - ✓ ○ Delete the wording "on most surfaces" Insert "hard non porous surfaces". Data was not submitted to support claims to kill bacteria on porous and semi-porous areas.
 - ✓ ○ Add the wording "on hard non-porous surfaces, porous, and semi-porous surfaces" to qualify treatments as a deodorizer.

- ✓ On page 2, under **Product Applications**, tenth bullet, delete the wording "household germs and". The overall statement is ambiguous. The household germ claim implies that the product is effective against killing bacteria in most of the use sites listed in that bullet. However, the claim is misleading because the product is used to treat "odors" for certain sites (i.e., septic tank and sewage backup). Therefore, you can revise the statement or accept the proposed changes that were instructed.
- ✓
 - On page 2, under **Product Applications**, eleventh bullet, delete the word "multi-touch". The reference for "cross-contamination" can be implied treatment for public health organisms.
 - For **Water and Smoke Damage Restoration and Sewer Backup and River Flooding** claims, more informative language regarding use directions for remedial treatments is needed in the label. The label implies that professional remedial specialist may use this product to treat odor causing bacteria and fungi on various surface areas, as well as areas that have smoke damage. However, the language regarding remedial treatment or preventative treatment is vague. Language needs to be incorporated that describes a comprehensive remediation program. As a reference, please see EPA Reg. No. 72304-1 for guidance.
 - The proposed language for the **Water and Smoke Damage Restoration and Sewer Backup and River Flooding** sections (that also includes subsections for carpet treatment) is unclear. The Agency has accepted previous claims such as the ones you have proposed and have worked with the registrants to provide acceptable language. See the attached example label for guidance.
- ✓ Under the **Shoe Bath** section, please add the wording "Remove growth filth" at the beginning of the directions. Also, in the body of the directions, include the wording for use on shoes that are "hard non-porous only".
- ✓ Under the **HIV** directions, for **Personal Protection**, delete the word "should" and insert "must". The wording
- ✓ The claim "*Stachybotrys chartam*" must be deleted from the labeling. Submitted data do not support this claim.
- ✓ The claim "Feline Norovirus" must be revised to read "Feline calicivirus (Agency's acceptable surrogate for human norovirus)".
- ✓ You must delete the *C. difficile* claim from your label. The Agency has re-evaluated its acceptance of *Clostridium difficile* (vegetative form) on previously accepted claims and requests for new claims. Peer-reviewed scientific literature and case studies have consistently demonstrated that the *C. difficile* spore is the source of *Clostridium difficile*-associated disease (CDAD), and is an immediate public health concern. After careful consideration, the Agency is certain that claims against the vegetative form of *C. difficile* are misleading (40 CFR 156.10(a) (5)), and imply heightened efficacy. The Agency considers antimicrobial pesticides to be unique because of the critical nature of the threat to public health that may result from ineffective use of products due to obsolete or misleading labeling. As a result, any reference to claims of effectiveness against

Clostridium difficile (vegetative) OR *Clostridium difficile* (without having supporting data against *C. difficile* spores) are unacceptable.

- The claim "*Murine norovirus*" must be deleted from the labeling. Data were not submitted to support this claim.
- All references to "Sanitizer" must be deleted from the labeling. No data were submitted to support this claim.

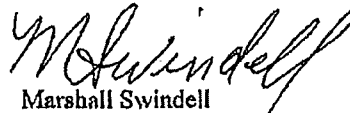
Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) and section 4(a) when the Agency requires all registrants of similar products to submit such data.

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.

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

Sincerely



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



EASYDECON Part 1

For use as a Disinfectant, Middle-strength, Intermediate-strength, and Full-strength. For use in Hospitals, Nursing Homes, Homes, Hotel & Motels, Industrial, Institutional, Schools, Poultry/turkey, Farm, and Harvesting Equipment. Only for use when added to EasyDECON Part 2 (EPA Reg. No. 74435-2).

ACTIVE INGREDIENTS:

- p-Alky (C12-C16)-N, N-dimethyl-N-benzylammonium chloride.....3.20%
- INERT INGREDIENTS.....96.80%
- TOTAL.....100.000%

E.P.A. Reg. No. 74436-1

E.P.A. Est. No. 85056-CO-01

KEEP OUT OF THE REACH OF CHILDREN
DANGER

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

CORROSIVE: Can cause irreversible eye damage. Can cause skin irritation. Harmful if inhaled. Do not breathe the vapor or spray mist. Do not get in eyes, on skin, or on clothing. Wear protective clothing such as safety glasses, chemical resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove and wash contaminated clothing before reuse.

FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE

1-800-338-3626

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. **NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against shock, respiratory depression, and convulsion may be needed. This product is not to be used as a terminal sterile/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.

ADDED PRECAUTIONARY STATEMENTS FOR FINISHED BLENDS:

if inhaled, move to fresh air. if breathing becomes labored consider oxygen, get medical attention. Give rescue breathing if breathing stops, get medical attention.

FIRST AID

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

IF SWALLOWED: Have person promptly drink large quantities of water. Do not give vomit-inducing or cathartic agents. If breathing by mouth to an unconscious person. Call poison control center or doctor for further treatment advice.

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

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, AND FEED BY STORAGE OR DISPOSAL Product should be kept in the original container in a cool dry area not susceptible to UV light. Sealed containers exposed to fire may burst. Do not store in metal containers. Store product containers in an upright position. Avoid creasing or impeding of sidewalls.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray, or mixture of residue is a violation of Federal Law; if these wastes cannot be disposed of by user according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office 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: Material is naturally biodegradable. For small spills, flush with copious amounts of water. Keep out of water supplies.

PRODUCT APPLICATIONS

When used as directed, this product will deodorize hard surfaces where bacteria growth can cause malodors. Cross-contamination is a major housekeeping concern. This product has been formulated to aid in the reduction of cross-contamination on treated surfaces not only in hospitals, but also in schools, institutions, and industries.

This product is a concentrated hospital-use disinfectant that is effective against bacteria, is virucidal*, and eliminates odor causing bacteria when used as directed.

This product is a solution that can be used with a mop and bucket, trigger sprayer, sponges, soaking, or in a coarse-spray apparatus.

This product is a versatile Disinfectant for Veterinarian, Veterinary Practices, Animal Care, Animal Laboratory, and Agricultural and Farm Premise applications.

This product kills bacterial growth on surfaces and deodorizes by killing microorganisms that cause offensive odors. *Hand non-porous, porous, & semi-porous areas.*

*ACCIDENTS
CALL
FEDERAL
HAZARDOUS
WASTE
CONTROL
ACT*

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Hand non-porous, porous, & semi-porous

areas.

direct

ACCEPTED
FOR COMMENT
DATE: 10/20/10
BY: [Signature]

- This product is for use as a disinfectant on hard non-porous surfaces. A potable water tank or other container must be used for application on food contact surfaces.
- This product is a one-step disinfectant that is effective against a broad spectrum of bacteria, viruses, and fungi. It kills mold and inhibits the growth of mold and mildew and odors when used as directed.
- This product may be applied through low-pressure sprayers, and fogging (wet mist) systems.
- This product neutralizes musty odors and tough odors from smoke, pet accidents, and spills on contact.
- This product is specially formulated to effectively eliminate offensive odors caused by mold and mildew.
- This product is effective against household odors and odors caused by animal waste, septic tank or sewage backup, smoke and bathroom and kitchen odors.
- Use this product on multi-touch surfaces responsible for cross-contamination.
- This product is effective at controlling mold and mildew on shower curtains. Use this product to clean, sanitize and disinfect non-porous ambulance equipment and surfaces by rinsing all equipment that comes in prolonged contact with skin before reuse with clean warm water (about 120°F), and allow to air dry.
- Hospital use Disinfectant, Institutional Disinfectant

TO PREPARE AND USE FINISHED BLEND

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

Mixing and Usage Instructions: DO NOT MIX IN METAL CONTAINERS

Pour the complete contents of the EasyDECON Part 1 (EPA Reg. No. 74436-1) container into a mixing container (plastic or glass) large enough to hold both components when completely mixed. Add the complete contents of the EasyDECON Part 2 (EPA Reg. No. 74436-2) container into the mixing container holding the EasyDECON Part 1 (EPA Reg. No. 74436-1) and stir the solution until it is well mixed (15-20 seconds). The mixture is now ready to apply.

WHEN USING THE OPTIONAL BOOSTER: Pour the complete contents of the EasyDECON Part 1 (EPA Reg. No. 74436-1) container into a mixing container (plastic or glass), large enough to hold all three components when completely mixed. Add the complete contents of the EasyDECON Part 2 (EPA Reg. No. 74436-2) container into the mixing container holding the EasyDECON Part 1 (EPA Reg. No. 74436-1) and EasyDECON Part 2 (EPA Reg. No. 74436-2) and stir the solution until it is well mixed (15-20 seconds). The mixture is now ready to apply.

Contact time for contaminated surfaces: After using one of the above methods to apply the mixture, keep the surfaces wet for 10 minutes. The mixture must be reapplied if it dries out or becomes diluted by any liquid during the 10 minute contact time.

This product is bactericidal according to the AOAC Use Dilution Test method on hard inanimate surfaces with a 10 minute contact time:

Staphylococcus aureus (ATCC 6538), *Escherichia coli* 0157:H7 (ATCC 35150)
Salmonella enteritidis (ATCC 10708), *Shigella flexneri* (ATCC 49619)
Pseudomonas aeruginosa (ATCC 35442), *Staphylococcus aureus* MRSA (Methicillin resistant) (ATCC 33592)
 Fungicidal against:
Aspergillus niger (ATCC 16404), *Penicillium digitatum* (ATCC 90395)

- For use in:
- Hospitals, nursing homes, medical and dental offices and clinics, physician offices, operating rooms/theaters, isolation wards, quarantine areas, ophthalmic/optometric facilities, and medical research facilities, cadaver processing areas.
 - Patient care rooms & facilities, recovery rooms, anesthesia rooms, Emergency Rooms, X-Ray cat labs, orthopedics, footbath surfaces, outpatient surgical centers, exam rooms, radiology rooms.
 - EMS & fire facilities, emergency vehicles, ambulances, ambulance equipment/surfaces, police cars, fire trucks.
 - Acute care centers, alternate care institutions, home healthcare institutions.
 - Life care retirement communities, elderly care facilities.
 - Crime scenes, funeral homes, mortuaries, burial vaults, mausoleums, autopsy rooms.
 - Institutional facilities, laboratories, factories, business and office buildings, restrooms, hotels and motels and transportation terminals.
 - Hotel, motel, dormitories.
 - Homes (households), apartments.

ACCEPTED COMMENTS

*Viral performance: The final mixture treated according to the Viral Inactivation Test...
hard inanimate surfaces, modified in the presence of 5% organic serum against the following
with a 10 minute contact time:

~~Poliovirus~~
HIV type 1 (AIDS virus)
Hepatitis A
Rhino Virus 16
for human use

Disinfectant
30,000 cubic feet (21,225 m³) to hard, inanimate, non-porous surfaces, thoroughly wetting
the surface as recommended and required, with a cloth, mop, sponge, or sprayer. For heavily
soiled areas, a preliminary cleaning is required. For spray applications, use a coarse spray
device. Spray 6 to 8 inches from the surface. Do not breathe the spray. All treated areas must
stay wet for at least 10 minutes.

Before using this product, food products and packaging materials must be removed from the
room or carefully protected. After use, all surfaces in the area must be thoroughly rinsed with
potable water. Prepare a fresh solution every 8 hours or when the mixture becomes soiled.
**WALLS HIV-1 ON PRECLEANED ENVIRONMENTAL SURFACES PREVIOUSLY SOILED WITH BODY
FLUIDS:** in health care settings or other settings in which there is an expected likelihood of
soiling of inanimate surfaces with body fluids and in which the surfaces likely to be soiled with
blood or other body fluids can be associated with the potential for transmission of human
immunodeficiency virus Type 1 (HIV-1 associated with AIDS), follow these **SPECIAL**

**INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES
SOILED WITH BLOOD/BODY FLUIDS:**

Personal Protection: Cleanup always be done wearing protective latex gloves, gowns,
masks and eye protection. [Specific barrier protection items to be used when handling items
soiled with blood or body fluids as disposable latex gloves, gowns, masks or eye coverings.]

Cleaning Procedure: Blood and other body fluids containing HIV-1 must be thoroughly
cleaned from surfaces and other objects before applying this product.

Disposal of Infectious Materials: Blood, body fluids, cleaning materials and clothing should be
autoclaved and disposed of according to federal, state, and local regulations for infectious
waste disposal.

Contact Times: Keep all surfaces to be disinfected wet for 10 minutes with the mixture.

SHOCK BATHS AND WETTER DIRECTIONS: (overseas) from area to area...
bacteria and fungi found in homes, institutions, industries and hospitals. This product is
particularly suitable for use in water damage restoration projects against water-damaged
bacteria on the following porous and semi-porous materials: carpets, carpets, cushions,
upholstered drapery, wall, trim, frame, bubble, tape, signs, any paneling using
the mixture, saturate these areas with enough solution to remain wet for 10 minutes. When
doing this type of restoration use proper ventilation.

~~**SMOKE DAMAGE RESTORATION:** The mixture is suitable for use in smoke damage restoration
situations. Instructions for using the mixture are given in the following paragraphs and instructions
materials. Clean up any residue left behind by the mixture. Do not use the mixture on any
lumber, brick, tile, or masonry. The mixture is as effective in the Water Damage
Restoration section. Use proper ventilation.~~

~~**SEWER BACKUP AND RIVER FLOODING:** Remove gross filth or heavy soil along with non-
flammable materials. During mitigation procedures, use the mixture to saturate all affected
areas with a daily utility coarse spray. Store and use cautiously and accurately
sprayer. Pushy, pushy, pushy, pushy, pushy, pushy, pushy, pushy, pushy, pushy, pushy, pushy,
drainage, drainage, drainage, drainage, drainage, drainage, drainage, drainage, drainage, drainage,
source, exact, exact, exact, exact, exact, exact, exact, exact, exact, exact, exact, exact, exact,
for the flooring, feet of the floor, with, with, with, with, with, with, with, with, with, with,
heat, heat, heat, heat, heat, heat, heat, heat, heat, heat, heat, heat, heat, heat, heat, heat,
materials, flush, flush, flush, flush, flush, flush, flush, flush, flush, flush, flush, flush, flush,
minutes. Follow with the rough extraction. Dry rapidly and thoroughly.
Special instructions for cleaning Carpet against Carpeting Bacteriae: This product may be
used in industry and institutions. Treat surfaces of 25 tomes, motels and hotels, including homes,
schools, and hospitals. For use on most desirable synthetic fibers. Do not use on Wo-
Vaccinate the carpet before using. Do not use on wool or other natural fibers. A hidden
area. Use the mixture. Careful extraction is required. Do not use on wool or other natural fibers.
Do not use on the primary carpeting products. Follow the cleaning instructions
specify by the manufacturer. After using this product, do not use on the carpet
product. Do not use on the carpet. Do not use on the carpet. Do not use on the carpet. Do not
apply to a clean carpet. Do not use on the carpet. Do not use on the carpet. Do not use on the
carpet manufacturer's directions once the carpet is dried.~~

Directions for Fogging: Prior to fogging, food products and packaging material must be
removed from the room or carefully protected. After cleaning, fog desired areas using one
quart of the mixture per 5000 cubic feet of room area (16,000 ppm). Vacate area of all
personnel during fogging and for a minimum of 8 hours after fogging. All food contact
surfaces must be thoroughly rinsed prior to reuse with potable water.

NOTE: The fog generated is irritating to the eyes, skin and mucous membranes. Under no
circumstances should a room or building be entered by anyone within eight hours of the
actual fogging, if the building must be entered, than the individual entering the building must
wear a self-contained respirator approved by NIOSH/MSHA, goggles, long sleeves and long
pants.

**FOGGING IS TO BE USED AS AN ADDUCT TO ACCEPTABLE MANUAL CLEANING AND
DISINFECTING OF ROOMS AND MACHINE SURFACES.**

HATCHERY ROOMS USING FOGGING DEVICES: Remove all animals and feed from
premises, vehicles and enclosures. Remove all litter and manure from floors, walls and
surfaces of the room to be treated. Empty all troughs, racks and other feeding and watering
appliances. Close room off so fog is confined to room treated. Using the mixture, insert the
nozzle of the fogger through a suitable opening into the room. With the setting at maximum
output, fog using one quart for each 5,000 cubic feet of space in the room. When fogging is

*Remove
Pills
Keep
Mixer
Part
Machinery*

completed, ventilate building and any other closed space. Do not house livestock or employ equipment until the treated area has completely dried. Thoroughly clean all surfaces with soap or detergent and rinse with water.

FOOD PROCESSING PLANTS USING FOGGING DEVICES Prior to fogging, food products and packaging materials must be removed from the room or carefully protected. After cleaning, fog desired areas using one quart of the mixture per 5,000 cubic feet of room area. Vacate the area of all personnel for a minimum of 8 hours after fogging. All food contact surfaces must be thoroughly rinsed prior to reuse with potable water.

Manufactured For:

EFT Holdings, Inc.
590 Burbank Street, Suite 2210
Broomfield, Colorado 80020

Net Content:

Lot Number:

ACCEPTED
EQUIPMENT
FOR LEASING
FEB 26 2010
EFT Holdings, Inc.
Broomfield, CO
Registered for
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