74436-2

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UNITED STATES **ENVIRO** AL PROTE

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

> OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

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

FEB 2 6 2010

Attention: Adrian Van Ineveld Regulatory Manager

Subject: Easy DECON Part 2 EPA Reg. No. 74436-2 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**, fifth 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**, eleventh bullet, delete the wording "germs". The overall statement is ambiguous. The term "germs" should be qualified to alert the user what particular organisms can be treated.
- On page 2 under **To Prepare and Use Finished Blends**, change "Salmonella choleraesuis" to read "Salmonella enterica"
- On page 3, 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.
- On page 3, 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.
- On page 3, 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 the word"must".
- 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

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



FIRST AID

OWNENTIS, e this skikment for other Dated closer to TINEYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove Insecticitian control center or doctor for treatment advice.

EasyDECON Part 2

Amalaida and Rodenni Deodorizer for Hospitals, Nursing Homes, Hotel & Motels, Industrial, Instructional, for the posticidu, Schools, Poultry/turkey, Farm, and Harvesting Equipment. Only for use when added to center or doctor for treatment advice JF SWALLOWED: Have person promptly drink large quantities of water. Do not give -14436-2

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: Jake 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 impacting of sidewalls.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray, or mixture of rinsate 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 of bacteria, is virucidal*, and eliminates odor causing bacteria when used as directed.
- sprayer, sponge, soaking, or in a coarse-spray apparatus.

therused This product is a versatile Disinfectant in the second for Veterinarian, Veterinary Practices, Animal Care, Animal Laboratory, and Agricultural and Farm Premise applications. , nord non-porous surfaces KIU>

d'recter This product deliver bacterial growth on the state and deodorizes by killing microorganisms that cause offensive odors on hand non-porous, porous, & sem i- T POROUS ARELSI

EasyDECON Part 1 (EPA Reg. No. 74436-1).

ACTIVE INGREDIENTS:

Hydrogen Peroxide	7.999%
INERT INGREDIENTS:	<u>92.001%</u>
TOTAL	

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

E.P.A. Reg. No. 74436-2

DANGER PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

KEEP OUT OF THE REACH OF CHILDREN

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 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.

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.

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- This product is for use as a disinfectant on hard non-porous surfaces. A potable water rinse is required after application on food contact surfaces.
- This product is a one-step disinfectant that is effective against a broad spectrum of bacteria is a factor of virucidal* (including HIV-1), kills mold and inhibits the growth of mold and mildew and their is a construct solution of order 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 and and odors caused by animal waste, septic tank or sewage backup, smoke and bathroom and kitchen odors.
- σ 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

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, out-patient surgical centers, labs, blood collection rooms, central supply, housekeeping & janitorial rooms, 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.

 Police stations, courthouses, correctional facilities, jails, prisons, correctional institutions, municipal government buildings, penitentiaries, bus stations, train stations.

Institutions, schools and colleges, churches, classrooms, community colleges, universities, athletic facilities, locker rooms, exercise rooms, exercise facilities, gymnasiums.

Household and automotive garages, boats, ships, barges, campers, trailers, mobile homes, cars, trucks, buses, trains, taxis, airplanes, helicopters, automobile interiors.

- Veterinary clinics, animal life science laboratories, kennels, dog/cat animal kennels, breeding and grooming establishments, pet animal quarters, zoos, pet shops, tack shops, and other animal care facilities.
- Cruise lines, airline terminals, airports, shipping terminals, public transportation.
- Basements, cellars, bedrooms, attics, living rooms, and porches.

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 2 (EPA Reg. No. 74436-2) 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 1 (EPA Reg. No. 74436-1) container into the mixing container holding the 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. **WHEN USING THE OPTIONAL BOOSTER** Pour the complete contents of the EasyDECON Part 2 (EPA Reg. No. 74436-2) 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 1 (EPA Reg. No. 74436-2) 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 1 (EPA Reg. No. 74436-1) container into the mixing container holding the EasyDECON Part 2 (EPA Reg. No. 74436-2) and stir the solution until it is well mixed (15-20 seconds). Add the complete contents of the Booster container into the mixing container holding the EasyDECON Part 2 (EPA Reg. No. 74436-2) and 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.

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 composition (ATCC 10708), Composition (March 1997)

Pseudomonas aeruginosa (ATCC 15442), Staphylococcus aureus MRSA (Methicillin resistant) (ATCC 33592)

Fungicidal against:

Aspergillus niger (ATCC 16404), Penicillium digitatum (ATCC 90595)

enterica

S. EPA Letter Dated

*Virucidal performance: The final mixture treated according to the Virucidal qualification of hard inanimate surfaces, modified in the presence of 5% organic serum against the place in with a 10 minute contact time:

Feline Manual s calicivinus HIV type 1 (AIDS virus)

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United Barlesel Insectio Hepatitis A Rhino Virus 16 Target and Rodenticide concerned, for the pesticide,

(Ageny's acceptable surrante for human non viergeneed under EPA Red M Disinfection/* Virucidal/Fungicidal Directions: Apply the mixture at a rate of 1 gallon per744 36-2 30,000 cubic feet (1L/225M³) 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. *KILLS 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: Cleanut 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.

ost. 14 Contact Time: Keep all surfaces to be disinfected wet for 10 minutes with the mixture.

SHOE BATH SANITIZER DIRECTIONS:'To prevent cross contamination from area to area in animal areas and in the packaging and storage areas of food plants, shoe baths containing one inch of freshly made mixture should be placed at all entrances to buildings, hatcheries, and at all the entrances to the production and packing areas. Change the sanitizing solution every 8 hours or when the solution gets dirty.

Hard Non-POGUUS WATER AND SMOKE DAMAGE RESTORATION: The mixture is effective against odor_causing narticu hacteri ub floors



SEWER BACKUP AND RIVER FLOODING: Remove sub floors drvw source for the d heav for 10 may he ised in schools Vool Vacuun area.

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 guart 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 NIOS/MSHA, goggles, long sleeves and long pants.

FOGGING IS TO BE USED AS AN ADJUCNT 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

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 PLATS 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:

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

Net Content:

Lot Number:

ACCEPTED COMMENTS MUERA Loney Dand MEB 2 6 2010

University Redsont Insecticide, Renchedie, and Rodenticide Acta: executed, for the posticide, regulational under EPA Red. No.

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