



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

April 24, 2012

OPP Decision Number: D-4590229

Jeff Jones, Agent  
Deardorff Fitzsimmons Corporation  
c/o Delta Analytical Corp.  
12510 Prosperity Drive, Suite 160  
Silver Spring, MD 20904

Subject: Activate 5.25% Institutional Bleach  
EPA Registration Number: 75266-1  
Application Date: December 20, 2011  
EPA Receipt Date: 21, 2011

Dear Mr. Jones:

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 with the following label comments:

Proposed amendment:

- Add claims and directions for *Clostridium difficile*

Acceptable data

The submitted efficacy data (MRID 486977-01) support the use of a 1:10 dilution of the product, Activate 5.25% Institutional Bleach, as a disinfectant against spores of *Clostridium difficile* on pre-cleaned, hard, non-porous surfaces in the presence of 400 ppm hard water for a 4-minute contact time.

Acceptable label directions:

The proposed label claims that the product, Activate 5.25% Institutional Bleach, is an effective disinfectant against spores of *Clostridium difficile* on pre-cleaned, hard, non-porous surfaces for 4-minute contact time, are acceptable as they are supported by the submitted data.

Other labeling comments:

1. Remove the following statement from the top of the first aid statement and place it at the bottom of the first aid statement or provide justification for placing the statement in its current location:

*“Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.”*

Refer to PR Notice 2001-1 for detailed information.

2. Revise the precautionary statement to read as follows:

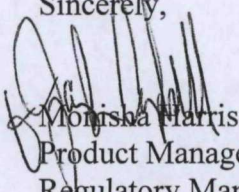
**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMAN AND DOMESTIC ANIMALS  
DANGER**

**CORROSIVE:** Causes irreversible eye damage and skin burn. Avoid breathing spray vapors. Vacate poorly ventilated areas as soon as possible until strong orders have dissipated. Wear safety glasses and rubber gloves when handling this product. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Should you have any questions or comments concerning this letter, please contact Adam Heyward via email at [heyward.adam@epa.gov](mailto:heyward.adam@epa.gov) or by telephone at (703) 347-0274 during the hours of 6:00 am to 2:30 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

A stamped copy of the label and efficacy review dated April 4, 2012 is enclosed for your record.

Sincerely,



Monisha Harris  
Product Manager (32)  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Enclosure: A copy of stamped labeling & efficacy review

\*\*\* {Bleach Bottle Label; this is a 3-page, peel-back, resealing label, and since it is relatively small, at minimum, this text will appear on the front page; additional text from the approved label may be added to this front page as space permits. Except for the Water Bottle text, the remaining text will appear on the inner 2 pages of the peel-back label.}\*\*\*

# Activate™ 5.25% Institutional Bleach

For use only with the Activate™ Bleach Dilution Sprayer

The Activate™ Bleach Dilution Sprayer automatically dilutes and mixes this product to a ready-to-use 10% solution (9:1 ratio of water to bleach) equal to approximately 5,000 ppm available chlorine for hospital, laboratory and veterinary use on hard, non-porous surfaces.

- [Hospital Cleaner & Disinfectant]
- [Cleans & Disinfects in One Step]
- Kills HIV-1 & HBV in 30 Seconds
- Kills *Clostridium difficile* [Spores] in 4 Minutes [on Pre-cleaned, Hard, Non-porous Surfaces]
- Kills Bacteria in 2 Minutes
- [For Hospital, Veterinary and Food-contact Use on Hard, Non-porous Surfaces]
- [For Instrument Pre-cleaning & Disinfection of Non-critical Instruments]

<b>Active Ingredient:</b>	
Sodium Hypochlorite .....	5.25%
<b>Other Ingredients:</b> .....	94.75%
<b>TOTAL</b>	<b>100.00%</b>

Contains 5% available chlorine by weight

## Keep Out of Reach of Children DANGER

Peel open here. Read complete directions and precautions inside before using.

### FIRST AID

Call poison control center or doctor for treatment advice. Have product container or label with you when you call a poison control center or doctor or when going for treatment.

**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.

**If on skin or clothing:** ▪ Take off contaminated clothing. ▪ Rinse skin with plenty of water for 15-20 minutes.

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

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

EPA Reg. No. 75266-1  
EPA Est. No. 75266-OR-001

### NET CONTENTS:

**Manufactured by:**  
Deardorff Fitzsimmons Corporation  
PO Box 539  
Merlin, OR 97532  
541-476-6065

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

APR 24 2012  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.

75266-1

\*\*\* {The following text will appear on the inner 2 pages of the peel-back label :} \*\*\*

**ACTIVATE™ 5.25% INSTITUTIONAL BLEACH**

For use in hospitals, laboratories, nursing homes, clinics, physicians offices, dental operatories, veterinary hospitals, schools, institutions, reception areas, kitchen areas, and restrooms. For use on hard, non-porous surfaces such as glazed ceramic tile, stainless steel, chrome, enameled walls & ceilings, laminated plastic countertops & cabinets, sealed fiberglass, glass, and glazed porcelain.

**Kills HIV-1 & HBV in 30 Seconds**

**Kills Bacteria in 2 Minutes:**

- Staphylococcus aureus*
- Methicillin resistant Staphylococcus aureus (MRSA)*
- Pseudomonas aeruginosa*
- Salmonella enterica*
- Streptococcus pyogenes*
- Vancomycin resistant Enterococcus faecalis (VRE)*
- Acinetobacter baumannii*

**Kills Clostridium difficile Spores in 4 minutes**

**PRECAUTIONARY STATEMENTS**

**Hazards to Humans and Domestic Animals**

DANGER: Corrosive, causes severe skin and eye irritation or chemical burns to broken skin. Can cause eye damage. Wear safety glasses and rubber gloves when handling this product. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid breathing vapors. Vacate poorly ventilated areas as soon as possible until strong odors have dissipated.

**Physical or Chemical Hazards**

Strong oxidizer. Flush drains before and after use. Do not use or mix with other chemicals, such as toilet bowl cleaners, rust removers, acid or ammonia containing products. To do so will release hazardous gasses. Prolonged contact with metal may cause pitting or discoloration.

**DIRECTIONS FOR USE**

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

**Install Activate™ Bleach cartridge onto Activate™ Bleach Dilution Sprayer by following Sprayer Instructions below.**

**To Clean and Disinfect in One Step:** Spray Activate™ 6- 8" from surface until surface is thoroughly wet; let stand for 2 minutes. To kill HIV-1 and HBV, allow 30 seconds contact time at room temperature. Wipe with a clean cloth or paper towel and allow to air dry. For food contact surfaces, rinse with potable water. Always remove gross dirt and debris from surface prior to disinfection.

**Special Instructions for Cleaning Prior to Disinfecting against Clostridium difficile spores: Personal Protection:** Wear appropriate barrier protection such as gloves, gowns, masks, or eye covering.

**Cleaning Procedure:** Thoroughly clean fecal matter/waste from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with Activate™. Vigorously wipe and/or scrub surfaces/objects until all visible soil is removed. Pay special attention to high-touch surfaces. Clean surfaces in patient rooms in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Clean restrooms last. Do not reuse soiled cloths.

**Infectious Materials Disposal:** Immediately dispose of materials used in the cleaning process that may contain feces/waste in accordance with local regulations for infectious materials disposal.

**Disinfection Procedure:** Spray Activate™ 6- 8" from surface until surface is thoroughly wet; let stand for 4 minutes. Wipe with a clean, damp cloth or paper towel, or allow to air dry.

**To Pre-clean Instruments Prior to Terminal Sterilization:** Place instruments in a suitable container. Spray Activate™ on instruments until all surfaces are thoroughly wet. Allow to stand for up to 10 minutes. Rinse

instruments with water, and follow with an appropriate sterilization/high-level disinfecting process. **Cleaning of critical and semi-critical devices must be followed by an appropriate terminal sterilization/high-level disinfection process.**

**Use Activate™ on stainless steel instruments only.**

**To disinfect non-critical, pre-cleaned instruments:** Instruments first must be thoroughly cleaned to remove gross dirt and debris, rinsed, and dried. Place instruments in a suitable container. Spray Activate™ on instruments until all surfaces are thoroughly wet; let stand for 2 minutes. To kill HIV-1 and HBV, allow 30 seconds contact time at room temperature. To kill *Clostridium difficile* spores, let stand for 4 minutes. Wipe with a clean, damp cloth or paper towel, and allow to air dry.

**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.**

**Kills HIV-1 and HBV** on pre-cleaned environmental surfaces and objects previously soiled with blood/body fluids in healthcare settings or 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) and Hepatitis B Virus (HBV).

**Special Instructions for Cleaning and Decontaminating Against HIV-1 and HBV on Surfaces/Objects Soiled with Blood/Body Fluids:** When handling items soiled with blood/body fluids, personal protective equipment such as disposable gloves, gowns, masks, and eye coverings must be used. Blood/body fluids must be thoroughly cleaned from surfaces/objects prior to disinfecting. Spray Activate™ on surface/object until all surfaces are thoroughly wet; let stand for 30 seconds. Wipe with a clean cloth or paper towel, and allow to air dry. Blood/body fluids and cleaning materials must be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.

**To Clean and Disinfect in a Veterinary Application:** Use to clean and disinfect hard, non-porous surfaces such as feeding and watering equipment, cages, utensils, instruments, kennels, stables, catteries, etc. Remove all animals and feed from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings, and manure from walls, floors, and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering equipment. Pre-clean all surfaces with soap or detergent and rinse with water. Spray Activate™ on surface/object until all surfaces are saturated; let stand for 2 minutes. To kill HIV-1 and HBV, allow 30 seconds at room temperature. Rinse all surfaces with potable water. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treated surfaces have been thoroughly rinsed with water and allowed to dry. Thoroughly scrub all treating, feeding, and watering appliances with soap or detergent, and rinse with potable water before reuse.

**STORAGE & DISPOSAL**

Do not contaminate food or feed by storage, disposal or cleaning of equipment.

**Pesticide Storage:** This product degrades with age; test active level of sprayed product periodically with high-level chlorine test strips. Store in a cool (50° – 72°F), dry area away from direct sunlight and heat to avoid deterioration. In case of spill, flood area with large quantities of water.

**Pesticide Disposal:** Products or rinsates that cannot be used should be diluted with water before disposal in a sanitary sewer.

**Container Handling:** Non-refillable container. Do not re-use or refill this container. Offer for recycling, if available, or place in trash collection.

\*\*\* {Water Bottle Label} \*\*\*

**Activate™ Bleach Dilution Sprayer Instructions**

**WATER BOTTLE - For use only with the Activate Bleach Dilution Sprayer  
The water in this bottle is not for human consumption.**

The Activate™ Bleach Dilution Sprayer automatically dilutes and mixes Activate™ 5.25% Institutional Bleach to a ready-to-use 10% solution (9:1 ratio of water to bleach) equal to approximately 5,000 ppm available chlorine for hospital, laboratory and veterinary use on hard, non-porous surfaces.

1. Fill the sprayer's empty water bottle with cool tap water, and then insert the sprayer's tube down into the filled water bottle. Close the sprayer tab to lock the water bottle into place on the sprayer.
2. Remove the threaded plastic cap from the bleach cartridge. Do not puncture or tamper with the plug that is in the neck of the bleach cartridge.
3. Lock the bleach cartridge onto the other side of the sprayer.
4. Pointing the sprayer away from you into a sink or basin, pump the trigger 20 times to prime the system.
5. The sprayer is now ready to use. Hold the sprayer 6" to 8" from the surface, and spray thoroughly until surface is completely wet.
6. Refill the water bottle when empty.
7. Always re-prime the system when installing a new bleach cartridge.

Note that a safety feature ensures the sprayer will not function if either the bleach cartridge or the water bottle is empty.

**Container Handling:** Refillable container. Refill this container with water only. Do not re-use this container for any other purpose. Offer for recycling if available or place in trash collection.

**Manufactured by:**

*Deardorff Fitzsimmons Corporation  
PO Box 539  
Merlin, OR 97532  
541-476-6065*

\*\*\* {Sprayer Head Imprint} \*\*\*

**Activate™  
Bleach Dilution**