



February 6, 2013

Susan Stracquatano
Agent for Deardorff Fitzsimmons Corporation
Delta Analytical Corporation
12510 Prosperity Drive, Suite 160,
Silver Spring, MD 20904

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Subject: Activate™ 5.25% Institutional Bleach
EPA Registration No. 75266-1
Application Dated: November 9, 2012
Receipt Dated: November 13, 2012

Dear Ms. Stracquatano:

This acknowledges the receipt of your Amendment application dated November 9, 2012 in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

Submission and Proposed Changes

Amend to add an alternative dilution direction and application method, marketing language claims, and add Storage and Disposal statement. Initial proposed label dated 11/9/2012 (pin punch 11/13/2012) and was updated on 1/28/2013 (pin punch 1/28/2013).

Comments and Conditions:

Based on the submitted materials, the amended label dated 1/28/2013 (pin punch 1/28/2013) is acceptable.

General Comments:

A stamped accepted copy of the label is enclosed. Submit one copy of your final printed labeling before distributing or selling the product bearing the revised labeling. This amendment and a copy of this letter have been inserted in your file for future reference

If you have any questions or comments concerning this letter, please contact liem.david@epa.gov or call (703) 305-1284.

Sincerely,

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

Att: Accepted stamped label

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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 irreversible eye damage and skin burn. Avoid contact with eyes, skin and clothing. Avoid breathing spray vapors. Vacate poorly ventilated areas as soon as possible until strong odors 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. Remove and wash contaminated clothing before reuse.

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.]

[or]

[Use 1 part Activate™ 5.25% Institutional Bleach to 9 parts water to achieve a 1:10 dilution (~5000 ppm available chlorine). This can be prepared by diluting 14 oz. (1 ¼ cup) Activate™ 5.25% Institutional Bleach per gallon of water.]

To Clean and Disinfect in One Step: Spray Activate™ 6-8" from the surface until surface is thoroughly wet, or apply with a clean cloth, mop or sponge saturated with Activate™; 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, or apply with a clean cloth, mop or sponge saturated with Activate™; 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, or apply with a clean cloth, mop or sponge saturated with Activate™; 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, or apply with a clean cloth, mop or sponge saturated with Activate™; 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 AND DISPOSAL

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

Storage: This product degrades with age; test active level of diluted 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.

Product Disposal: Products or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer.

Container Handling: [For single use cartridges:] Nonrefillable container. Do not reuse or refill this container. Offer container for recycling if available or place in trash.

[For other nonrefillable containers:] Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Dispose of rinsate in sanitary sewer. Offer for recycling if available or place in trash.

*** {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 (1:10 dilution with 1 part bleach to 9 parts water) 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.

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

*** {Sprayer Head Imprint} ***

**Activate™
Bleach Dilution**

