



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

JUN 29 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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

FILE COPY

Subject: Activate 5.25% Institutional Bleach
EPA Reg. No. 75266-1
Application Dated: June 2, 2011
Receipt Date: June 3, 2011

Dear Mr. Jones:

The following notification submitted in connection with registration under the provisions of PR Notice 98-10, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9 is acceptable.

Proposed Notification:

- Label revision: correction of typographical error changing 'To kill TB, allow 30 seconds at room temperature' to 'To kill HIV-1 and HBV allow 30 seconds at room temperature'

Comments:

Based on a review of the material submitted, the following comments apply:

This application for notification to revise the product label, as referenced above, is acceptable. A copy has been placed in our records for future reference.

Should you have any questions or comments concerning this letter, please contact me at Henson.Wanda@epa.gov or call (703) 308-6345.

Sincerely,

A handwritten signature in blue ink that reads "Wanda Henson".

Wanda Henson
Acting Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

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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.

Cleans & disinfects in one step

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*

Active Ingredient:

Sodium Hypochlorite..... 5.25%

Other Ingredients:..... 94.75%

TOTAL 100.00%

Contains 5% available chlorine by weight

KEEP OUT OF REACH OF CHILDREN

DANGER

Read Complete Directions and Precautions on Package Rear & Side Panels

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:	<ul style="list-style-type: none"> • 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:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin with plenty of water for 15-20 minutes.
If swallowed:	<ul style="list-style-type: none"> • 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:

Batch Code:

Manufactured by:
Deardorff Fitzsimmons Corporation
PO Box 539
Merlin, OR 97532
1-888-582-2700

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.

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 use directions on Activate Water Bottle label side panel.

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 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.

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 and HBV, allow 30 seconds contact time at room temperature. 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 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 re-use.

STORAGE & DISPOSAL

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

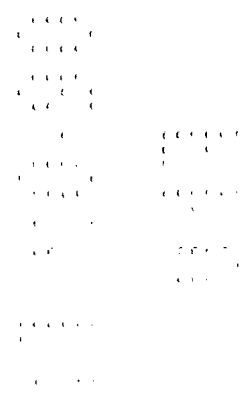
Pesticide Storage

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.



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[Bleach Bottle Label; since this a relatively small label, at minimum, this text will appear on bleach bottle; additional text from the approved label may be added as space permits.]

Activate™ 5.25% Institutional Bleach

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

Contains 5% available chlorine by weight

KEEP OUT OF REACH OF CHILDREN DANGER

See Complete Directions for Use and Precautionary Statements [on Package Rear & Side Panels] [in Package Insert]

EPA Reg. No. 75266-1
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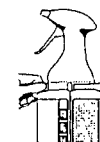
[Water Bottle Label]

WATER BOTTLE For use only with the Activate™ Bleach Dilution Sprayer

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.

Activate™ Bleach Dilution Sprayer Instructions

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.

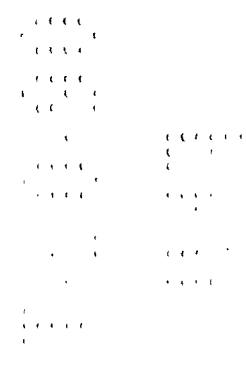


Note that a safety feature ensures the sprayer will not function if either the bleach cartridge or the water bottle is empty.

The water in this bottle is not for human consumption.

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.

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[Sprayer Head Imprint]

**Activate™
Bleach Dilution**

