



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

NOV 01 2010

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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

Subject: Amendment dated: June 15, 2010
Activate 5.25% Institutional Bleach
EPA Registration 75266-1

Dear Mr. Jones:

The Agency has reviewed your application for amendment submitted in accordance with continuing registration under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), as amended, and determined the action acceptable with the following comments:

- Delete the claim "Meets OSHA Bloodborne Pathogen Standards". The Agency will consider this claim if you can provide written approval from OSHA that your product does meet those standards.
- The claim against *Pseudomonas aeruginosa* is not supported by your data.
- Under Hazards to Humans change "may cause" to "causes"
- Under Hazards to Humans, change "Wash after handling" to "Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet."
- Under Special Instructions on page 3, change the advisory word "should" to the Mandatory word "must".

In summary, you have submitted product performance data in support of specific pathogen claims to be added to your label. With the exception of one study, the Agency has reviewed and accepted the data. See the enclosed review, DP 379982, for additional information.

A stamped copy of the labeling accepted with conditions is enclosed. Submit one copy of your final printed labeling before distributing or selling the product bearing the revised labeling. Should you have any questions or comments concerning this letter, please call Tom Luminello at (703) 308-8075.

Sincerely,

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

2007

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.

deleted

Cleans & disinfects in one step

~~Meets OSHA Bloodborne Pathogen Standards~~

Kills HIV-1 & HBV in 30 Seconds

Kills Bacteria in 2 Minutes:

deleted

- *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

with COMMENTS
in EPA Letter Dated:

NOV 01 2010

NET CONTENTS:
Batch Code:

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

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 75266-1

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must

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 should 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 should 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 TB, 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.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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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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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, may cause 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 after handling. Avoid breathing vapors. Vacate poorly ventilated areas as soon as possible until strong odors have dissipated.

and see letter

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.**

ACCEPTED COMMENTS
in EPA Letter Dated:

Use Activate™ on stainless steel instruments only.

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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.

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the pesticide, registered under EPA Reg. No. 75266-1

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).

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leaf 7

[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:	94.75%
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]

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[Sprayer Head Imprint]

Activate™
Bleach Dilution

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