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



# SEPA United Status Environmental Protection Office of Pesticide Programs

September 5, 2008

Shannon Payne Current Technologies, Inc. P.O. Box 21 Crawfordsville, IN 47933

Subject:

Bleach-Rite Disinfecting Spray with Bleach

EPA Registration No. 70590-2

Submission Dated: February 22, 2008 Receipt Date: February 25, 2008

Dear Ms. Payne:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, to reinstate Mycobacterium bovis BCG (TB) claim on the label, is accepted with comments/conditions.

## **Conditions**

1. Revise the Ingredient Statement as follows:

Active Ingredient: Sodium Hypochlorite . . . . . 99.06% Total: 100.00%

## Available Chlorine XX%

- 2. Change the designation of the organism formerly called Salmonella choleraesuis to Salmonella enterica. The American Type Culture Collection, which has jurisdiction over nomenclature of microorganisms made the change in 2006, and the Agency has adopted the new name to be more representative of a human, rather than an animal pathogen.
- The cleaning and disinfecting directions for use require a two-step process. Therefore, the term "One Step" has been removed from the use directions.

## **General Comments**

The submitted data supports the effectiveness of this product as a tuberculocidal disinfectant for two minutes as indicated on the proposed label.

A stamped copy of the labeling 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 Wanda Henson at (703) 308-6345.

Sincerely,

Emily Homitchell

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

# Hospital Cleaner—Bisinfectant Spray with Bleach Clean and Disinfect in the country of guarantiant of the Hairly Nonpoints Surfaces Browner Heavy to be solution contains at least at 10 bisinfect in Surfaces Browner Heavy to be solution contains at least at 10 bisinfort in weight of colleging in the CCL (Bleary) at 10 bisinforth properties weight of colleging in the contains at least at 10 bisinforth bisinforth weight of colleging in the contains at least at 10 bisinforth bisinforth weight of colleging in the contains at least at 10 bisinforth bi

## PRODUCT SPECIFICS / USES

- For use on non-critical surfaces/ftems in clinical/research/industrial labs and hospital areas including ER, OR, radiology, nursing stations, wards, clinics, dialysis and outpatient. Also for use in blood banks, physician and dental offices, ambulances, nursing homes, veterinarian facilities, wastewater facilities and resticoms.
- Cleans and disinfects hard, non-porous surfaces including stainless steel, plastics glass, glazed ceramics, tile, linoleum, laminated plastic countertops, enamel, viny and olazed porcelain.

## **DIRECTIONS FOR USE**

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

Bleach-Rite® kills the following organisms with a 30-second contact time Enterococcus faecium (VRE) and Streptococcus pyogenes ATCC 19615.

Bleach-Rite® kills the following organisms with a one-minute contact time: Coronavirus ATCC VR-470. Hepatitis-A Virus (HAV), Herpes Simplex Virus Type II ATCC VR-734, Human Immunodeficiency Virus Type I (HIV-1); Poliovirus Type I ATCC VR-59. Pseudomonas aeruginosa ATCC 15442. Rotavirus strain WA ATCC VR-2018, Salmonella emberatura ATCC 10708, Staphylococcus aureus ATCC 5538 and Staphylococcus aureus (MRSA) ATCC 33591.

Bleach-Rite® is approved as Tuberculocidal with a two-minute contact time for: Mycobacterium bovis BCG (TB).

To Clean and Disinfect in the mean; Remove gross soil prior to cleaning and disinfecting. Thoroughly spray surface until completely wet (ten second spray time) holding bottle 12° from surface. Leave surface wet at least one minute at room temperature to disinfect a broad range of organisms. Wipe clean with a damp paper towel or cloth. No rinsing necessary.

Special Instructions for Cleaning and Decontamination Against HIV on Surfaces/Objects Soiled with Blood/Body Fluids on pre-cleaned environmental surfaces/Objects previously solide with blood/floody fluids in health care settings for other settings in which there is an expected likelihood of soiling of inanimate surfaces/Objects with blood or body fluids, and in which the surfaces/Objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV). Personal Protection: When handling items soiled with blood or body fluids, use appropriate barrier protection such as disposable later gloves, gowns, masks or eye coverings. Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from

surfaces and objects before application of this disinfectant. Contact Time: Spray surface to be treated 10 seconds, from a distance of 12', until surface is wet. Allow synay to dry without wiping or allow spray to contact treated surface for a minimum of one minute prior to wiping. Disposal of Infectious Materials: Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

This product is not to be used as a terminal sterilar/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) confacts infact mucous membrane but which does not ordinarily penetrate the blood barrier or enter otherwise normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfaction.

## STORAGE AND DISPOSAL

"Storage: Store in a cool, dry area at room temperature (68°- 77°F; away from sunlight and heat to inhibit deterioration/reduced concentration of bleach solution. In case of spill, flood area with large quantities of water. Product Disposal: Product that cannot be used according to label directions should be diluted with water then disposed of in a sanitary sewer. 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, slay out of smoke.

### PRECAUTIONARY STATEMENT

Physical and Chemical Hazards: Do not use this product with ammonia and acids (such as vinegar), rust removers or toilet bowl cleaners. Will corrode aluminum

**Expiration Date:** 



ACCEPTED with COMMENTS
EPA Letter Dated:
SFP - 5 2008

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 70590-2