

70590-2

07/13/2005

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

July 13, 2005

Susan Hapak
Current Technologies, Inc.
P.O. Box 21
Crawfordsville, IN 47933

Subject: Disinfecting Spray with Bleach
EPA Registration No. 70590-2
Application Date: January 10, 2005
Receipt Date: February 7, 2005

Dear Ms. Hapak:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended to add additional organisms, is accepted with conditions.

Conditions

1. Provide species and genus for the organisms on the front of the label- ***Mycobacterium bovis BCG*** (TB), ***Staphylococcus aureus*** (MRSA), ***Enterococcus faecium*** (VRE), and ***Clostridium difficile***.
2. This product is not efficacious against spores of *Clostridium difficile*, it is only effective against "vegetative cells of *Clostridium difficile*." Therefore, this label has been revised to read "vegetative cells of *Clostridium difficile*."

General Comments

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.

CONCURRENCES							
SYMBOL	7510C	7510C					
SURNAME	Henson	Hutchins					
DATE	7-13-05	7-13-05					

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

Sincerely,

Emily H. Mitchell
Product Manager - Team 32
Regulatory Management Branch II
Antimicrobials Division (7510C)

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Disinfecting Spray with Bleach

HOSPITAL CLEANER – DISINFECTANT SPRAY WITH BLEACH

Clean and Disinfect in One Step: Counters, Equipment and Other Hard, Nonporous Surfaces

Pre-Mixed, Ready-to-Use Solution Contains at Least a 1:10 Dilution
(0.55% by weight or 5500 ppm) of NaOCl (Bleach) at Expiration with Proper Storage*

Thirty Second Kill Time for:

VRE, TB *Streptococcus pyogenes* and *C. difficile*

One Minute Kill Time for:

Coronavirus, Hepatitis-A, Herpes Simplex Type II, HIV-1, Poliovirus, *Pseudomonas aeruginosa*, Rotavirus,
Staphylococcus aureus, MRSA and *Salmonella choleraesuis*

Active Ingredient: Sodium Hypochlorite	0.94%
Other Ingredients	99.06%
Total	100.00%

Keep Out of Reach of Children

CAUTION

See back panel for additional
precautionary statements.

current technologies, inc.

P.O. Box 21

Crawfordsville, IN 47933 USA

Phone: 765-364-0490 Fax: 765-364-1607

ACCEPTED

with COMMENTS
EPA Letter Dated:

JUL - 8 2005

Reorder # _____

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

EPA Reg. No. 70590-2

EPA Est. 70590-IN-1

NET ____ FL OZ

{Back Panel}

Product Specifics / Uses

- Cleans and disinfects hard, nonporous surfaces including stainless steel, plastics, glass, glazed ceramics, tile, linoleum, laminated plastic countertops, enamel, vinyl and glazed porcelain.
- For use on non-critical surfaces/items 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 restrooms.

DIRECTIONS FOR USE

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

Disinfecting Spray with Bleach [This product] kills the following organisms with a 30-second contact time:
Enterococcus faecium (VRE), *Streptococcus pyogenes* ATCC 19615, and *Mycobacterium bovis* BCG (TB) and
Clostridium difficile 9689.

Disinfecting Spray with Bleach [This product] kills the following organisms with a 1-minute contact time: Coronavirus ATCC VR-470, Hepatitis-A Virus (HAV), Herpes Simplex Virus Type II ATCC VR-734, Human Immunodeficiency Virus Type 1 (HIV-1), Poliovirus Type I ATCC VR-59, Pseudomonas aeruginosa ATCC 15442, Rotavirus strain WA ATCC VR-2018, Salmonella choleraesuis ATCC 10708, Staphylococcus aureus ATCC 6538 and Staphylococcus aureus (MRSA) ATCC 33591.

To Clean and Disinfect in One Step: 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 soiled with blood/body fluids in health care settings (or 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 latex 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 inches, until surface is wet. Allow spray to dry without wiping or allow spray to contact treated surface for a minimum of 1 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 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 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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

Storage and Disposal

***Storage:** Store in a cool, dry area 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, stay 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: {MM/DD/YY}

{NFPA Graphic with Legend}

[] Denotes alternate/optional language

{ } Denotes language that does not appear on the market labeling