

70590-2

11-09-2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

NOV -9 2010

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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

FILE COPY

Subject: PRIA (Decision #437898)
Bleach-Rite Disinfecting Spray With Bleach
EPA Registration No. 70590-2
Submission Dated: June 30, 2010
Receipt Date: July 22, 2010

Dear Ms. Hapak:

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

PRIA Request:

The claims against the following microorganisms are being added to the label: *Acinetobacter baumannii* Carbapenem-resistant *Klebsiella pneumoniae*, *Enterobacter aerogenes*, *Escherichia coli* (ESBL), Human influenza A (H1N1), Norovirus, Respiratory syncytial virus, Rhinovirus type 37, *Trichopyton mentagrophytes* and *Aspergillus brasiliensis* for a 1 minute contact time on hard, non-porous surfaces.

Conditions:

1. On page 1 of the proposed label, change "enamel" to read "baked enamel." Enamel is not a hard, non-porous surface.
2. Provide the ATCC numbers for all listed microorganisms.

General Comments

A stamped copy of the labeling accepted with the 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 contact me at Henson.Wanda@epa.gov or call (703) 308-6345.

Sincerely,

A handwritten signature in black ink, appearing to read "Wanda Y. Henson", is written over a large, stylized "R" or similar mark.

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

Virucidal / Tuberculocidal / Fungicidal

Bleach-Rite®

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.* Contains bleach and detergent to enable cleaning and disinfecting in one step.

Thirty Second Kill Time for: Enterococcus faecium (VRE) and Streptococcus pyogenes.

One Minute Kill Time for: MRSA (Methicillin Resistant Staphylococcus aureus), Human Influenza A (H1N1), Norovirus, Respiratory Syncytial Virus (RSV), Escherichia coli (ESBL), Acinetobacter baumannii, Rhinovirus Type 37, Carbapenem-resistant Klebsiella pneumoniae (CRKP), Aspergillus brasiliensis, Enterobacter aerogenes, Coronavirus, Herpes Simplex Type II, Poliovirus, Hepatitis-A, HIV-1, Rotavirus, Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella enterica and Trichophyton mentagrophytes (Athlete's Foot Fungus). This product has demonstrated effectiveness against Human Influenza A (H1N1) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

Two Minute Tuberculocidal Kill Time for: Mycobacterium bovis BCG (TB).

Active Ingredient: Sodium Hypochlorite.....0.94%
Other Ingredients.....99.06%
Total.....100.00%
Available Chlorine = .9%

EPA Reg. No. 70590-2
EPA Est. 70590-IN-1

Keep Out of Reach of Children.

CAUTION

NET 1 qt. (32 FL. OZ.)
BRSPRAY32

See back panel for additional precautionary statements.

Reorder#:

Avoid contact with clothing to avoid discoloration.

current technologies, inc.

P.O. Box 21, Crawfordsville, IN 47933 USA
Phone: 765-364-0490 • Fax: 765-364-1607

(FRONT OF LABEL)

(BACK OF LABEL)

PRODUCT SPECIFICS / USES

- Places for use: non-critical surfaces & items in clinical / research / industrial labs, hospital areas including ER, OR, ICU, radiology, nursing stations, patient rooms, clinics, dialysis, outpatient. Other sites include blood banks, physician and dental offices, ambulances, nursing homes, veterinarian facilities, wastewater facilities, restrooms, correctional centers, schools, health clubs. Often used for disinfection of blood glucose monitors, counters, outer sides of equipment, IV poles, railings, blood pressure cuffs, gurneys, phlebotomy trays, EMS backboards, wheelchairs, centrifuges.
- Cleans and disinfects hard, non-porous surfaces including stainless steel, plastics, glass, glazed ceramic tile, linoleum, laminated plastic countertops, enamel, floors, Plexiglas and glazed porcelain.

DIRECTIONS FOR USE

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

To Clean and Disinfect in One Step: Thoroughly spray surface until completely wet (ten second spray time), holding bottle 12" from surface. Leave surface wet at least two minutes at room temperature to disinfect a broad range of organisms. Wipe clean with a paper towel or cloth. Some manufacturers of equipment / surfaces (including stainless steel) require rinsing; follow those specific manufacturers' directions for cleaning / disinfecting / rinsing. Remove gross soil prior to cleaning and disinfecting. **Special Instructions for Cleaning and Decontamination Against HIV (AIDS Virus) and Hepatitis A (HAV) 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", until surface is wet. Allow spray to dry without wiping or allow spray to contact treated surface for a minimum of two minutes prior to wiping. Some manufacturers of equipment / surfaces (including stainless steel) require rinsing after cleaning / disinfecting; follow those specific manufacturers' directions for cleaning / rinsing. **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:** This product must be stored in a cool, dry area at room temperature (68° - 77°F) away from sunlight and heat. In case of spill, flood area with large quantities of water. **Product Disposal:** Product or rinsates that cannot be used should be diluted with water before disposal in a sanitary sewer. **Container Disposal:** Nonrefillable container. Do not reuse or refill this container. 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 burning, stay out of smoke.

PRECAUTIONARY STATEMENT

Physical and Chemical Hazards: This product should not be used with / mixed with ammonia, acids (such as vinegar), rust removers, toilet bowl cleaners, reducing agents, or heavy metals such as nickel, cobalt, copper and iron. Will corrode aluminum. For certain grades of stainless steel, follow equipment manufacturers' directions for disinfecting / rinsing to prevent pitting or corrosion. This product is not intended for use on fabrics. Avoid contact with clothing to avoid discoloration.

Expiration Date:

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV - 9 2010

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