



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

September 25, 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Susan Hapak, President
Current Technologies, Inc.
Post Office Box 21
Crawfordsville, IN 47933

Subject: PRIA A570 Label Amendment with Efficacy Data Review Results
Product Name: **"Bleach-Rite Disinfecting Spray With Bleach"**
EPA Registration Number: **70590-2**
Application Date: May 2, 2012
Application Receipt: May 10, 2012

Dear Ms. Hapak:

This acknowledges receipt of the Amendment Application, submitted pursuant to registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

Proposed Amendment:

The product, **Bleach-Rite Disinfecting Spray with Bleach** (EPA Reg. No. 70590-2), is an EPA-approved disinfectant (bactericide, fungicide, tuberculocide, and virucide) mildewcide, and deodorizer for use on hard, non-porous surfaces in healthcare settings, and clinical/ research/ industrial labs. The applicant requested to amend the registration to add claims of effectiveness against *Clostridium difficile* spores. The study was conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained one study (MRID 488250-01), a Statement of No Data Confidentiality Claims for the study, and the proposed label.

General Comments:

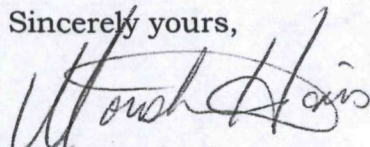
The submitted efficacy data (MRID 488250-01) support the use of the product, **Bleach-Rite Disinfecting Spray with Bleach**, as a disinfectant against *Clostridium difficile* (spore form) on pre-cleaned, hard, non-porous surfaces for a 5-minute contact time at the ready to use preparation. A >6-log reduction in viable spores was reported by the laboratory. Carrier counts met the acceptance criterion of $\geq 1.0 \times 10^6$ spores/carrier. Neutralization confirmation testing demonstrated that the neutralizer was not sporicidal and was effective in neutralizing the product. Purity controls were reported as pure. Sterility controls did not show growth. Test spores showed resistance to acid for >5 minutes.

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The proposed label claims are acceptable regarding the use of the product, **Bleach-Rite Disinfecting Spray with Bleach**, as a sporicide against *Clostridium difficile* (spore form) on pre-cleaned, hard, non-porous surfaces for a 5-minute contact time at the ready to use preparation. This claim is acceptable as it is supported by the submitted data.

If you have any questions or comments concerning this Agency Letter, please contact Killian Swift via email at swift.killian@epa.gov or by telephone at **703-308-6346**. When you are submitting information or data in response to this Agency Letter, send a copy of this Agency Letter to accompany the follow-on submission in order to facilitate processing.

Sincerely yours,



Monisha Harris,
Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: EPA stamped **Accepted** Product Label

Bleach-Rite®

Disinfecting Spray with Bleach

Hospital Cleaner — Disinfectant Spray with Bleach

Ready-to-Use Solution disinfects counters, equipment and hard, non-porous surfaces. Contains at least 1:10 Dilution of bleach and detergent at expiration with proper storage.

Kill Time	Leave wet on hard surfaces to kill these pathogens:
Thirty Seconds	Bacteria • Enterococcus faecium (VRE) • Streptococcus pyogenes Bacteria • Acinetobacter baumannii • Carbapenem-resistant Klebsiella pneumoniae (CRKP) • Enterobacter aerogenes • Escherichia coli (ESBL) • Pseudomonas aeruginosa • Salmonella enterica • Staphylococcus aureus (MRSA) • Staphylococcus aureus Fungi • Aspergillus brasiliensis • Trichophyton mentagrophytes (Athlete's Foot Fungus) • Mycobacterium bovis (BCG) TB - Tuberculoicidal Viruses • Coronavirus • Hepatitis A Virus (HAV) • Herpes Simplex Virus (HSV-2) • HIV-1 (AIDS) • Influenza A H1N1 Virus • Influenza A Virus • Norovirus • Poliovirus • Respiratory Syncytial Virus (RSV) • Rhinovirus • Rotavirus
One Minute	Bacteria • Enterococcus faecium (VRE) • Streptococcus pyogenes Bacteria • Acinetobacter baumannii • Carbapenem-resistant Klebsiella pneumoniae (CRKP) • Enterobacter aerogenes • Escherichia coli (ESBL) • Pseudomonas aeruginosa • Salmonella enterica • Staphylococcus aureus (MRSA) • Staphylococcus aureus Fungi • Aspergillus brasiliensis • Trichophyton mentagrophytes (Athlete's Foot Fungus) • Mycobacterium bovis (BCG) TB - Tuberculoicidal Viruses • Coronavirus • Hepatitis A Virus (HAV) • Herpes Simplex Virus (HSV-2) • HIV-1 (AIDS) • Influenza A H1N1 Virus • Influenza A Virus • Norovirus • Poliovirus • Respiratory Syncytial Virus (RSV) • Rhinovirus • Rotavirus
Two Minutes	Bacteria • Enterococcus faecium (VRE) • Streptococcus pyogenes Bacteria • Acinetobacter baumannii • Carbapenem-resistant Klebsiella pneumoniae (CRKP) • Enterobacter aerogenes • Escherichia coli (ESBL) • Pseudomonas aeruginosa • Salmonella enterica • Staphylococcus aureus (MRSA) • Staphylococcus aureus Fungi • Aspergillus brasiliensis • Trichophyton mentagrophytes (Athlete's Foot Fungus) • Mycobacterium bovis (BCG) TB - Tuberculoicidal Viruses • Coronavirus • Hepatitis A Virus (HAV) • Herpes Simplex Virus (HSV-2) • HIV-1 (AIDS) • Influenza A H1N1 Virus • Influenza A Virus • Norovirus • Poliovirus • Respiratory Syncytial Virus (RSV) • Rhinovirus • Rotavirus
Five Minutes	Bacteria • Enterococcus faecium (VRE) • Streptococcus pyogenes Bacteria • Acinetobacter baumannii • Carbapenem-resistant Klebsiella pneumoniae (CRKP) • Enterobacter aerogenes • Escherichia coli (ESBL) • Pseudomonas aeruginosa • Salmonella enterica • Staphylococcus aureus (MRSA) • Staphylococcus aureus Fungi • Aspergillus brasiliensis • Trichophyton mentagrophytes (Athlete's Foot Fungus) • Mycobacterium bovis (BCG) TB - Tuberculoicidal Viruses • Coronavirus • Hepatitis A Virus (HAV) • Herpes Simplex Virus (HSV-2) • HIV-1 (AIDS) • Influenza A H1N1 Virus • Influenza A Virus • Norovirus • Poliovirus • Respiratory Syncytial Virus (RSV) • Rhinovirus • Rotavirus

EPA Reg. No. 70590-2 EPA Est. 70590-IN-1 Available Chlorine .3%
 Active Ingredient: Sodium Hypochlorite .094%
 Other Ingredients 99.06%
 Total 100.00%

current technologies, inc.
 P.O. Box 21, Crawfordsville, IN 47933 USA
 Phone: 765-364-0490 • www.curretechinc.com

Reorder #: BRSpray32

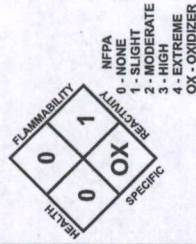
NET 1 qt.
 (32 FL. OZ.)

CAUTION: Keep Out of Reach of Children. Read and follow directions and precautions on back panels.

• Bleach-Rite® Spray cleans / disinfects a broad array of pathogens in healthcare settings and clinical / research / industrial labs. Useful in outbreaks of infectious diseases such as Clostridium difficile and MRSA due to its fast kill times. Meets OSHA Bloodborne Pathogen standards.
 • Disinfects hard, non-porous surfaces including plastics, glass, glazed ceramic tile, linoleum, laminated plastic counters, baked enamel, Plexiglas, glazed porcelain. For stainless steel, follow equipment manufacturers directions; glass may direct surface be rinsed after disinfection.

Disinfecting Site / Applications for Bleach-Rite® Spray:

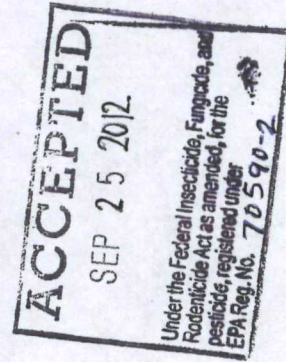
Clinical	POCT Equipment	Other
• ICU / OR / ER • Nursing stations • Patient rooms • Clinics / outpatient • Surgery centers • Blood banks • Radiology • Doctor / dental offices	• Blood glucose meters • Analyzers for Blood Gas, Chemistry, Coagulation • Benchtops / sinks • Assays - C. diff, etc. • Centrifuges / Equipment • Phlebotomy trays	• Wastewater facilities • Restrooms • Ambulances / EMS backboards • Nursing homes / wheelchairs • Veterinarian facilities • Correctional centers • Schools / daycare • Health clubs



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 wet the surface with Bleach-Rite® Spray. Leave surface wet for at least one minute to disinfect a broad spectrum of germs. Leave surface wet at least two minutes to kill TB. Leave surface wet at least 5 minutes to kill C. diff spores. Wipe clean with a paper towel or cloth. Some manufacturers of equipment / surfaces (including stainless steel) require rinsing; follow specific manufacturers' directions for cleaning / disinfecting / rinsing. Remove gross soil prior to cleaning and disinfecting.

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks or eye coverings.
Special Cleaning Procedure before disinfecting against C. diff spores: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with Bleach-Rite® Spray. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of spores. Restrooms are to be cleaned last. Do not reuse soiled cloths. **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 healthcare 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).** Infectious Materials Disposal: Materials used in the cleaning process are to be disposed of in a biohazard container. Do not place in regular trash. Materials are to be disposed of in a biohazard container. **Decontamination of Surfaces/Objects Soiled with Blood/Body Fluids:** Materials are to be disposed of in a biohazard container. Do not place in regular trash. Materials are to be disposed of in a biohazard container. **Storage:** Bleach-Rite® Spray must be stored in a cool, dry area away from sunlight and heat at room temp. (68° - 77°F). In case of spill, flood area with large quantities of water. Pesticide Disposal: Product or rinsates that are to be discarded must be diluted with water before disposal in a sanitary sewer. **PRECAUTIONARY STATEMENTS:** Physical and Chemical Hazards: Do not use this product with ammonia, acids (such as vinegar), rust removers, toilet bowl cleaners, or heavy metals such as copper and iron. Will corrode aluminum. For stainless steel equipment / surfaces, follow equipment manufacturers' directions for disinfecting / rinsing to prevent corrosion. This product is not intended for use on fabrics; may discolor clothing. Caution: Avoid contact with eyes. If in eyes, slowly rinse eye with water for 15-20 minutes. Seek medical guidance.

Expiration Date:



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