

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

November 10, 2014

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

Subject:

Bleach–Rite Disinfecting Spray with Bleach

EPA Registration No. 70590-2 Application Date: 06/16/2014 Receipt Date: 06/18/2014

Dear Ms. Hapak:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 3 (c) 7(A) as amended, is acceptable.

Proposed Amendment:

- Include sporicidal claims against Clostricidium Difficile
- Additional claims against *Bordetella pertussis*, Community acquired methicillin resistant *Staphylococcus aureus*, Vancomycin-resistant *Staphylococcus aureus*, Hepatitis B, Hepatitis C, Canine Parvovirus and Feline Panleukopenia.

General Comments

A stamped label is enclosed for your records. The efficacy review is also enclosed. A stamped label is enclosed for your records. Please submit a final printed label before selling or distributing the product bearing the revised labeling. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you have any questions concerning this letter, you may contact me by telephone at Ben Chambliss at (703) 308-8174 or by email at chambliss.ben@epa.gov during the hours of 8:00 am to 5:30 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany

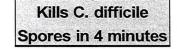
the submission to facilitate processing.

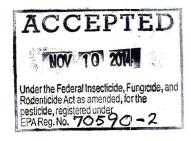
Sincerely,

Demson Fuller

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

Enclosed: Stamped Label Efficacy review





Bleach-Rite® Disinfecting Spray with Bleach

Hospital Cleaner - Disinfectant Spray with Bleach

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

Kill Time	Leave wet on hard surfaces to kill these pathogens:		
Thirty	Bacteria Vancomycin-resistant Enterococcus faecium (VRE)	Viruses	
Seconds	Streptococcus pyogenes		
One	 Acinetobacter baumannii Bordetella pertussis Carbapenem-resistant Klebsiella pneumoniae (CRKP) Community acquired methicillin resistant staphylococcus aureus (CA-MRSA) 	 Coronavirus Hepatitis A (HAV) Hepatitis B (HBV) Hepatitis C (HCV) Herpes Simplex (HSV-2) HIV-1 (AIDS) 	
Minute	 Enterobacter aerogenes Escherichia coli (ESBL) Pseudomonas aeruginosa Salmonella enterica Methicillian Resistant Staphylococcus aureus (MRSA) Staphylococcus aureus 	 Influenza A H1N1 (swine flu) Influenza A Norovirus Poliovirus Respiratory Syncytial (RSV) Rhinovirus Rotavirus 	
	Vancomycin-resistant Staphylococcus aureus (VRSA)	Fungi Aspergillus brasiliensis Trichophyton mentagrophytes (Athlete's Foot Fungus)	
Two Minutes	Tuberculocidal • Mycobacterium bovis (BCG) TB	Viruses Canine Parvovirus Feline Panleukopenia	
Four Minutes	Sporicidal: Clostridium difficile Spores (C. diff spores)		

ine: .9%

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

current technologies, inc.

NET 1 quart (32 FL. OZ.) P.O. Box 21, Crawfordsville, IN 47933 USA Phone: 765-364-0490 • www.currtechinc.com

Reorder #: BRSPRAY32

(front panel)

- 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. 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; those may direct surface be rinsed after disinfection.

Disinfecting Site / Applications for Bleach-Rite® Spray:				
Clinical		POCT Equipment	<u>Other</u>	
• ICU / OR / ER	 External surface of 	Blood glucose meters	Wastewater facilities	
Nursing stations	dialysis / medical /	Analyzers for Blood Gas,	Restrooms	
Patient rooms	respiratory equipment	Chemistry, Coagulation	Ambulances / EMS backboards	
Clinics / outpatient	 Specimen collection 	<u>Lab</u>	 Nursing homes / wheelchairs 	
Surgery centers	 Counters 	Benchtops / sinks	Veterinarian facilities	
Blood banks	 IV poles / pumps 	• Assays – C. Diff, etc.	Correctional centers	
Radiology	Gurneys / bed railings	Centrifuges / Equipment	Schools / daycare	
Doctor / dental offices	Blood pressure cuffs	Phlebotomy trays	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 spray surface until completely wet (ten second spray time), holding bottle 12" from surface. Leave surface wet at least one (1) minute to disinfect a broad spectrum of germs. Leave surface wet at least two (2) minutes to kill TB, Canine Parvovirus, Feline Panleukopenia. Leave surface wet at least four (4) 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.

Special Instruction for Cleaning Prior to Disinfection against Clostridium difficile spores: Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks or eye coverings. Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with product. 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 the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths. Infectious Materials Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal. Special Instructions for Cleaning and Decontamination Against HIV-1, Hepatitis B (HBV) and Hepatitis C (HCV) on Surfaces/Objects Soiled with Blood/Body Fluids: Personal Protection: When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks and eye coverings. Cleaning Procedures: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product. Contact Time: Allow surface / object to remain wet for one (1) minute for HIV-1, HBV and HCV. Disposal of Infectious Materials: Blood and other body fluids must be autoclaved and disposed of according to 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

*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. Container Disposal: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or puncture and dispose of in a sanitary landfill.

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:	(hack nanels)
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