

70590-1

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

January 22, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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

Subject: PRIA 2_A570 Label Amendment with Efficacy Data
Product Name: **Hype-Wipe Disinfecting Towel With Bleach**
EPA Registration Number: **70590-1**
Application Date: September 7, 2012
Application Receipt: September 10, 2012

Dear Ms. Hapak:

This is to report to you the Agency Decision results of your Label Amendment with efficacy data, submitted pursuant to the Pesticide Registration improvement Act under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 3 (c) 9, as amended.

Proposed Amendment:

Current Technologies, inc. requested to amend the registration of the product to add sporicidal claims against the organism ***Clostridium difficile***. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121. The Data Package contained a letter from the applicant to EPA, dated September 7, 2012 (MRID 489337-00), three studies (MRID 489337-01 thru 489337-03 Statement of No Data Confidentiality Claims for all studies, and the proposed label.)

General Comments:

The submitted efficacy data **does support** the use of the product, Hype-Wipe Disinfecting Towel With Bleach, as a sporicide against the following microorganism on hard, non-porous surfaces for a 4-minute contact time.

Clostridium difficile.....MRIDs 489337-01 thru 489337-03

Results show no positive growth on all carriers/tubes tested in 10 minutes or less. Control carrier counts were greater than 10⁶ spores/carrier. Growth was observed after at least 2 minutes exposure in the HCI resistance testing for the organism used in the examinations. Passing wetness determination for the contact period was demonstrated for all of the lots tested. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth. Neutralization controls did not demonstrate growth.

The proposed label claims that the Product, Hype-Wipe Disinfecting Towel With Bleach, is an effective disinfectant towelette against the following microorganism on hard, non-porous surfaces for a 4-minute contact time.

Clostridium difficile.....ATCC 43598

These are **Acceptable** as they **are supported** by the submitted data.

The Product Label must be revised as follows:

Under "Special Cleaning Procedure Before Disinfecting Against (*C. diff*) Spores" section, the pre cleaning step specifies cleaning with use of a "clean cloth, mop, and/or sponge with the disinfectant product." This product is a towelette, therefore the statement must be changed to "clean cloth, mop, and/or sponge saturated with a disinfectant product" or specify the disinfectant product that is in a Ready-To-Use liquid formulation that can be used by the application described.

Under the Directions For Use, the nomenclature of the organism must be listed or (*C. diff*) can appear in italics in parenthesis.

(*C. diff*) **Claim** must state kills and /or inactivates spores Clostridium difficile on hard, non-porous surfaces.

All of the following **Special Label Instructions For Cleaning Prior To Disinfection Against Clostridium difficile spores must be included on the Product Label:**

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.

Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with clean cloth, mop, and/or sponge saturated with the disinfectant 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 I 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.

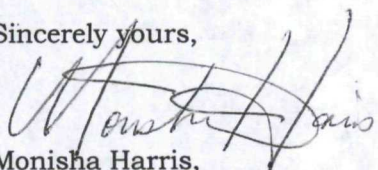
Infectious Materials Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

As a result of the PRIA 3 "Clean Label" procedure, the Product Label has been revised successfully to comply with December 5, 2012 Efficacy Review by Dr. Karen Hill, Ph.D.

A stamped, **Accepted** Product Label is enclosed for your Company record.

If you have any question or comments with regard to the 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, please send a copy of this agency letter with your response in order to facilitate processing.

Sincerely yours,



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

- Enclosure: 1.) Efficacy Review by Dr. Karen Hill, Ph.D. dated December 5, 2012;
- 2.) Stamped **Accepted** Product Label.

ACCEPTED
 JAN 22 2013
 Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 70590-1

AVOID CONTACT WITH CLOTHING TO AVOID DISCOLORATION



HYPE-WIPE® DISINFECTING TOWEL WITH BLEACH

Hospital Cleaner - Disinfectant Kills (*C. diff*) spores in 4 Minutes

Ready-to-use towelettes saturated with 1:10 dilution of stabilized bleach and detergent solution. Contains at least 5500 ppm bleach at expiration with proper storage*. Meets OSHA, NCCLS, CDC blood-borne pathogen standards for disinfection.

Kill Time	Bacteria	Viruses
One Minute	Carbapenem-Resistant Klebsiella pneumoniae (CRKP)	Hepatitis B (HBV)
	Escherichia coli (ESBL)	Hepatitis C (HCV)
	Pseudomonas aeruginosa	Influenza A H1N1 (swine flu)
	Salmonella enterica	Norovirus
	Streptococcus pyogenes	Respiratory Syncytial (RSV)
	Tuberculosis - TB (Mycobacterium bovis - BCG)	Rotavirus
	Methicillin Resistant Staphylococcus aureus (MRSA)	
Two Minutes	Staphylococcus aureus	
Four Minutes	Vancomycin Resistant Enterococcus faecium (VRE)	
	Clostridium difficile Spores (<i>C. diff</i>) spores	

Active Ingredient: Sodium Hypochlorite...0.94%
 Other Ingredients.....99.06%
 Total.....100.00%
 Available Chlorine: .9%
 Towel: Folded 6" x 12"
 CAUTION: Keep Out of Reach of Children. Read and follow directions and precautions on back panels.
 EPA Reg. No. 70590-1
 Net Wt. 12.2 grams (excludes towel)
 EPA Est. 70590-IN-1

current technologies, inc.
 P.O. Box 21 • Crawfordsville, IN 47933 U.S.A.
 Phone: 765-364-0490 www.currttechinc.com

RE-ORDER # 9103

AVOID CONTACT WITH CLOTHING TO AVOID DISCOLORATION



HYPE-WIPE® DISINFECTING TOWEL WITH BLEACH

Disinfect hard, non-porous surfaces including plastics, glass, glazed ceramic tile, linoleum, laminated plastic counters, baked enamel, Plexiglas®, glazed porcelain, some grades of stainless steel. For disinfecting stainless steel, follow equipment manufacturers' directions which may require rinsing after Hype-Wipe® application.

Disinfecting Sites / Applications for Hype-Wipe® towels:		
Clinical	POCT Equipment	Other Sites
ICU / OR / ER Nursing stations Patient rooms Clinics/outpatient Surgery centers Surgical banks Specimen collection MD/dental offices	Blood glucose meters Analyzers for Blood Gas, Chemistry, Coagulation Lab Benchtops / sinks Assays - (<i>C. diff</i>), etc. Centrifuges / Equipment Phlebotomy trays	Wastewater facilities Restrooms Ambulance/EMS backboard Nursing home/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. (1) Remove all gross filth and heavy soil from surfaces to be disinfected. Gloves should be worn. (2) Open pouch, remove towel. Use towel and excess liquid to wipe surface. (3) Allow solution to remain wet on surface for at least two minutes to inactivate a broad range of micro-organisms. Leave wet four minutes to kill (*C. diff*) spores. See front panel for specific pathogen kill times. (4) Rinsing: Some equipment / surfaces such as stainless steel may require rinsing; follow those specific manufacturers' directions.

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 the disinfectant 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 spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HEPATITIS B VIRUS (HBV) AND HEPATITIS C VIRUS (HCV) 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/inanimate surfaces / objects with blood or body fluids, and in which the surfaces / objects soiled with blood or body fluids can be associated with the potential for transmission of HBV and HCV.

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.

PERSONAL PROTECTION: Wear appropriate barrier protection such as gloves, gowns, masks or eye coverings. **STORAGE:** Towelettes must be stored in a cool, dry area at room temperature (68° - 77°F) away from sunlight and heat. **DISPOSAL:** Discard used towel and empty pouch in trash.

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.

CAUTION: Avoid contact with eyes. If in eyes, slowly rinse eye with water for 15-20 minutes. Seek medical guidance.