

70590-1

11 / 29 / 2011

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 29, 2011

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

FILE COPY

Subject: PRIA (D-451702)
Hype-Wipe Disinfecting Towel with Bleach
EPA Registration No. 70590-1
Application Dated: June 30, 2011
Receipt Dated: July 11, 2011

Dear Ms. Hapak:

This acknowledges the receipt of your Amendment application dated June 30, 2011 in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with comments listed below.

Submission and Proposed Changes

Amend the label and submit supporting efficacy data for Hepatitis B and Hepatitis C. The submitted four efficacy data (MRID#485322-01 through MRID#485322-04) and data matrix dated June 30, 2011 (original data matrix pin punched on July 7/11/2011 and updated pin punched on 11/17/2011) in support for efficacy label claims are acceptable with comments.

Comments and Conditions:

Based on the submitted materials noted above, are acceptable and the following conditions and comments apply:

- a. The amendments for additional efficacy claims for the subject product as a disinfectant with virucidal activity against Hepatitis B virus and Hepatitis C virus on hard, non-porous surfaces in the presence of light to moderate organic soil load for a 1 minute contact time are acceptable.
- b. Under "**DIRECTIONS FOR USE**"
Move Step (4) to Step (1) so that it is clear to user that surfaces must be cleaned of gross filth and heavy soil prior to disinfection.

c. The submitted data matrix included a claim for HIV. However, the proposed product label does not include the HIV claim. If HIV claim is added to the product label, you must provide the HIV claim with the "Special Instructions for Cleaning and Decontamination on Surfaces/Objects Soiled with Blood/Body Fluids" section on the proposed label.

d. Also add the ATCC number (or reference number) for HIV (Human Immunodeficiency Virus) Type 1 and Hepatitis B Virus in one of the following locations
- on the data Matrix;
- on the Master label (as optional text) with listing of the organisms claimed; or
- as a final page of the Master Label (as optional text).

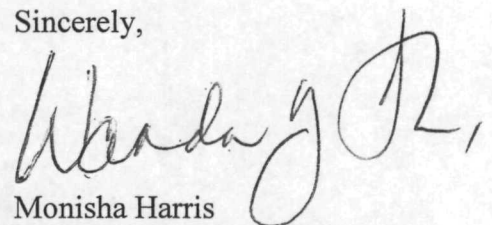
General Comments:

A stamped copy of the label with comments is enclosed. Submit one copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

This amendment and a copy of this letter have been inserted in your file for future reference

If you have any questions or comments concerning this letter, please contact liem.david@epa.gov or call (703) 305-1285.

Sincerely,

for 
Monisha Harris
Product Manager - Team 32
Regulatory Management Branch II
Antimicrobials Division (7510P)

Att: Stamp label with comments

AVOID CONTACT WITH CLOTHING TO AVOID DISCOLORATION



HYPE-WIPE® DISINFECTING TOWEL WITH BLEACH

Tuberculocidal / Virucidal Hospital Cleaner - Disinfectant
Clean and Disinfect in One-Step: Counters, Equipment and other Hard Non-Porous Surfaces. Ready-to-use, pre-moistened towels saturated with bleach and detergent solution. Contains at least a 1:10 dilution (0.55% by weight or 5500 ppm) of NaOCl (bleach) at expiration with proper storage.*

ONE-MINUTE KILL TIME FOR: Mycobacterium bovis BCG (TB), Norovirus, Respiratory Syncytial Virus (RSV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Rotavirus, Human Influenza A (H1N1), Escherichia coli (ESBL), Carbapenem-Resistant Klebsiella pneumoniae (CRKP), Streptococcus pyogenes, Pseudomonas aeruginosa and Salmonella enterica. 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 KILL TIME FOR: Methicillin Resistant Staphylococcus aureus (MRSA), Vancomycin Resistant Enterococcus faecium (VRE), Staphylococcus aureus.

Active Ingredient: Sodium Hypochlorite	0.94%
Other Ingredients	99.06%
Total	100.00%
Available Chlorine = .9%	EPA Reg. No. 70590-1
Towel: Folded 6" x 12"	Net Wt. 12.2 grams (excludes towel) EPA Est. 70590-IN-1

Keep Out of Reach of Children CAUTION

See back panel for additional precautionary statements.

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 29 2011

RE-ORDER # 9103

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

- Meets OSHA bloodborne pathogen standards.
- 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. Useful for disinfection of blood glucose monitors and Point-of-Care equipment, blood gas / coagulation / chemistry analyzers, centrifuges, counter tops, IV poles, railings, blood pressure cuffs, gurneys, phlebotomy trays, EMS backboards, wheelchairs.
- Cleans and disinfects hard, non-porous surfaces including stainless steel, plastics, glass, glazed ceramic tile, linoleum, laminated plastic countertops, baked enamel, Plexiglas, and glazed porcelain. Follow directions below.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. (1) Open pouch, remove towel. Use towel and excess liquid to wipe surface. (2) Allow solution to remain wet on surface for at least two minutes to inactivate a broad range of micro-organisms. See front panel for specific pathogen kill times. (3) Rinsing: Some manufacturers of equipment / surfaces (including stainless steel) require rinsing; follow those specific manufacturers' directions for cleaning / disinfecting / rinsing. (4) Remove all gross filth and heavy soil from surfaces to be disinfected. Gloves should be worn.

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 of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood/body fluids can be associated with the potential for transmission of HBV and HCV. **Personal Protection:** When handling items soiled with blood or body fluids, use appropriate barrier protection such as disposable gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood/body fluids must be thoroughly cleaned from surfaces and objects before disinfecting. **Contact Time:** Leave surfaces wet for one minute. **Disposal of Infection Materials:** Blood, body fluids and cleaning materials 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 membranes but which does not ordinarily penetrate the blood barrier or otherwise enter 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:** Towellets 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 STATEMENT: Physical or 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. This product not intended for use on fabrics.

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