

70590-1

1-5-2004

1/4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 5 2004

Ms. Kim Davis
Current Technologies, Inc.
c/o RegWest Company
30856 Rocky Road
Greeley, CO 80631-9375

Subject: Hype-Wipe®
EPA Registration Number 70590-1
Application Date: August 28, 2003
Receipt Date: September 3, 2003

Dear Ms. Davis:

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

- To add new efficacy claims and related verbiage

Conditions

- The proposed label includes disinfectant claims against the following viruses: Coronavirus, Hepatitis A virus, Herpes simplex type II virus, HIV-1, Poliovirus I and Rotavirus.

The data packages provided did not include efficacy data to support these claims. The letter to EPA (dated August 28, 2003) indicated that EPA should rely on efficacy data submitted on behalf of the spray product, Disinfecting Spray with Bleach (EPA Reg. No. 70590-2). Reliance on efficacy data developed on the liquid product which is used to saturate the Hype-Wipe® towelettes is not acceptable. You must submit efficacy data developed on the towelette product, Hype-Wipe® against these viruses, or delete all references to use of the product as a virucide.

- On pages 1 and 2, "Staphylococcus aureus (MSRA)" should read "Staphylococcus aureus (MRSA)".
- On page 2, "Coronavirus ATCC VR-70" should read "Coronavirus ATCC VR-740".

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

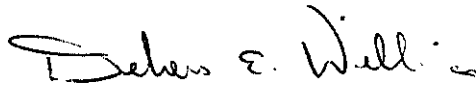
- 2/4
4. On page 1 of the proposed label, indicates that the product may be used on grout, which is a porous surface. You must remove the label reference to use of the product on grout.

General Comments

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies 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 (703) 308-6372.

Sincerely,



Delores E. Williams
Product Reviewer
Regulatory Management Branch II
Antimicrobials Division (7510C)

3/4

{Front Side of Pouch}

WHEN OPENING: AVOID CONTACT WITH CLOTHING

←===== Tear Here =====>

Hype-Wipe®

DISINFECTING TOWEL WITH BLEACH

Clean and Disinfect in One-Step Counters, Equipment
and other Hard, Non-Porous Surfaces.

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:

[REDACTED] TB, *Pseudomonas aeruginosa*, [REDACTED]
Salmonella choleraesuis and *Streptococcus pyogenes*

Two-Minute Kill Time For:

Staphylococcus aureus, *Staphylococcus aureus* (MRSA) and *Enterococcus faecium* (VRE)]

Active Ingredient:

Sodium Hypochlorite	0.94%
Other Ingredients	99.06%
Total	100.00%

Towel: Folded 6" x 12" nonwoven polypropylene
EPA Reg. No. 70590-1 EPA Est. 70590-IN-1
Net Wt. 12.2 grams (excludes towel)

**ACCEPTED
with COMMENTS
EPA Letter Dated:**

JAN 5 2004

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

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 Fax: 765-364-1607

Reorder # _____

{Back Side of Pouch}

WHEN OPENING: AVOID CONTACT WITH CLOTHING

←===== Tear Here =====>

- Cleans and disinfects hard, non-porous surfaces including stainless steel, plastics, glass, glazed ceramics, tile, linoleum, laminated plastic countertops, enamel, vinyl, glazed porcelain, [REDACTED]
- For use on non-critical surfaces/items in clinical/research/industrial labs and hospital areas including ER, OR, radiology, nursing stations, wards, clinics, dialysis and outpatient. Also for use in blood banks, physician and dental offices, ambulances, nursing homes, veterinarian facilities, wastewater facilities and restrooms.

414

DIRECTIONS FOR USE

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

Hype-Wipe [This product] kills the following organisms with a 1-minute contact time:

Coronavirus ATCC VR-799

Mycobacterium bovis BCG, *Pseudomonas aeruginosa* ATCC 15442,

Salmonella choleraesuis ATCC 10708 and *Streptococcus*

pyogenes ATCC 19615.

Hype-Wipe [This product] kills the following organisms with a 2-minute contact time:

Staphylococcus aureus ATCC 6538, *Staphylococcus aureus* (MRSA) ATCC 33591 and *Enterococcus faecium* (VRE) ATCC 51559.

1. Remove all gross filth and heavy soil from surfaces to be disinfected.
2. Open pouch, remove towel. Use towel and excess liquid to wipe surface.
3. Allow solution to contact surface for 2 minutes to inactivate a broad range of organisms before wiping or allow to air dry. Discard towel in appropriate waste container.

Special Instructions for Cleaning and Decontamination Against HIV 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:** Wipe surface with towel until surface is wet. Allow liquid to dry without wiping or allow liquid to contact treated surface for a minimum of 1 minute prior to wiping. **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 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

***Storage:** Store in a cool, dry area away from sunlight and heat to inhibit deterioration/reduced concentration of bleach solution. **Disposal:** Do not reuse empty pouch; wrap and put in trash.

PRECAUTIONARY STATEMENT

Physical or Chemical Hazards

Do not use this product with ammonia, acids (such as vinegar), rust removers, toilet bowl cleaners. Will corrode aluminum.

Expiration Date: {MM/DD/YY}

- [] Denotes alternate/optional language
- { } Denotes language that does not appear on the market label

ACCEPTED
with **COMMENTS**
EPA Letter Dated:

JAN 5 2004

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

70590-1