

65787-3

03/31/2011

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

March 31, 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

FILE COPY

Donna Leventhal
Agent for Alcavis HDC, LLC
c/o Delta Analytical Corp.
12510 Prosperity Dr., Suite 160
Silver Spring, MD, 20904

Subject: Bleach-Wipe 1:50
EPA Reg.#: 65787-3
Notification Date: March 22, 2011
Receipt Date: March 30, 2011

Dear Ms. Leventhal:

This acknowledges the receipt of your notification, submitted under the provision of PR Notice 98-10 and FIFRA section 3(c)9.

Proposed Notification:

Addition of an Alternative Brand Name (ABN) for "Bleach-Wipe 1:50" (EPA Reg# 65787-3).

General Comment:

Based on the review of the material submitted, the notification application for this ABN is acceptable. This notification and a copy of this letter have been inserted in your file for future reference.

If you have further question on this letter, please contact David Liem at 703-305-1284 or by email at liem.david@epa.gov

Sincerely

A handwritten signature in black ink that reads "Wanda Y. Henson".

Wanda Y. Henson
Acting Product Manager (32)
Regulatory Management Branch II
Antimicrobial Division (7510P)



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number
NOTIF

Application for Pesticide - Section I

1. Company/Product Number 65787-3	2. EPA Product Manager Emily Mitchell	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Alcavis HDC, LLC / Bleach-Wipe 1:50	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) Alcavis HDC, LLC c/o Delta Analytical Corp. 12310 Prosperity Dr. Suite 160 Silver Spring MD 20904 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

Amendment - Explain below
 Resubmission in response to Agency letter dated
 Notification - Explain below.

Final printed labels in response to Agency letter dated
 "Me Too" Application.
 Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Notification under PR Notice 98-10 to add alternate brand name. ALCAVIS BLEACH-WIPE 1:50

This notification is consistent with the provisions of pr notice 98-10 and epa regulations at 40 cfr 152.46 and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material this Product will be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted.		If "Yes," Unit Package wgt. No. per container	If "Yes," Unit Package wgt. No. per container

3. Location of Net Contents Information
 Label Container

4. Size(s) of Retail Container

5. Location of Label Direction
 On Label
 On Labeling accompanying product

6. Manner In Which Label Is Affixed to Product
 Lithograph Paper glued Stenciled Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)

Name Donna Leventhal	Title Agent, Alcavis HDC, LLC	Telephone No. (include Area Code) 301-680-7971
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Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any kind of knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature <i>Donna Leventhal</i>	3. Title Agent, Alcavis HDC, LLC	5. Date Application Received (Stamped)
4. Typed Name Donna Leventhal	5. Date March 22, 2011	

[bracketed text may be added or deleted depending on market]

ALCAVIS BLEACH-WIPE 1:50

[Alternate Brand Name: **Alcavis Bleach-Wipe 1:50**]

For wiping hard non-porous environmental surfaces [and patient care equipment]

KEEP OUT OF REACH OF CHILDREN

CAUTION

[See back panel for additional precautionary statements]

Manufactured by:
Alcavis HDC, LLC
8322 Helgerman Court
Gaithersburg, MD 20877
www.AlcavisHDC.com
1-800-726-2308

EPA Reg. No.: 65787-3
EPA Est. No.: 65787-MD-1

8" x 10" Towelette
Net Contents: [# towels, x oz. each]

Active Ingredient:

Sodium Hypochlorite: 00.10%
Other Ingredients:..... 99.90%
Total:..... 100.00%

1:50 Dilution of 5.25% Sodium Hypochlorite Bleach
1,000 ppm Available Chlorine

First Aid	
If in Eyes:	<ul style="list-style-type: none"> Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Contact the Poison Control Center at 1-800-222-1222 for 24 hour emergency medical treatment information.	

BACTERICIDAL

Effective in the presence of a 5% organic soil load against:
Staphylococcus aureus Methicillin Resistant [MRSA][ATCC 33592]
Enterococcus faecalis Vancomycin Resistant [VRE][ATCC 51299]
Streptococcus pneumoniae [ATCC 6303]
Streptococcus pyogenes, [ATCC 12344]
Staphylococcus aureus [ATCC 6538]
Pseudomonas aeruginosa [ATCC 15442]
Salmonella enterica [ATCC 10708]

BLEACH-WIPE 1:50

Wipe has 1,000 ppm available chlorine

NOTIFICATION
DATE REVIEWED: 3/31/2011
PREPARED BY: (S) [Signature]

4/5

Precautionary Statements

Hazards to humans and domestic animals

CAUTION: Causes minimal eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Areas of Use

For use on hard, nonporous surfaces including stainless steel, chrome, metal, glass, vinyl, plastic, laminate, linoleum, glazed ceramic tile, glazed porcelain, and sealed or painted wood. Areas of use include: [Medical, [Dental and Laboratory] Counters], [Exam Tables], [Carts], [Dialysis Machines], [Point of Care Equipment], [Telephones], [Sink Tops], Sinks, Counter Tops, Floors, [Bathrooms], [Tubs], [Handrails], [Door] [Knobs], [Lockers], and [Desks].

Directions for Use

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

- [Use personal protective equipment (gloves) when disinfecting biohazardous surfaces] [*Hospital, Medical and Dental uses only*]
- For heavily soiled surfaces, a preliminary cleaning is required
- Open Wipe packet
- Remove premoistened towelette
- Apply towelette and wipe desired surface to be disinfected
- Treated surface must remain visibly wet for 10 minutes
- Use additional wipe(s) if needed to assure continuous 10 minute wet contact time
- Allow surface area to dry and discard used towelette

[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.] [*Hospital, Medical and Dental uses only*]

Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

Storage: Do not store near heat or open flame. **Product and Container Disposal:** Dispose of towelette in trash after use. Do not flush in toilet. Non-refillable container. Do not reuse or refill this empty container. Offer empty container for recycling. If recycling is not available, discard container in trash.