

65787-2

08-15-2011

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

AUG 15 2011

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

**FILE COPY**

Donna Leventhal  
Agent for Alcavis HDC, LLC  
Delta Analytical Corporation  
12510 Prosperity Drive  
Suite 160  
Silver Spring, MD 20904

Subject: Bleach Wipe  
EPA Reg. No. 65787-2  
Application Dated: July 15, 2011  
Receipt Date: July 22, 2011

Dear Ms. Leventhal:

The following notification submitted in connection with registration under the provisions of PR Notice 98-10, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9 is acceptable.

**Proposed Notification:**

- Alternate Brand Name "Alcavis Bleach-Wipe"

**General Comments:**

Based on a review of the material submitted, the following comments apply:

This application for notification to add an alternate brand name, as referenced above, is acceptable. A copy has been placed in our records for future reference.

Should you have any questions or comments concerning this letter, please contact Wanda Henson at [Henson.Wanda@epa.gov](mailto:Henson.Wanda@epa.gov) or call (703) 308-6345.

Sincerely,

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



United States  
**Environmental Protection Agency**  
 Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier Number  
**ABN**

**Application for Pesticide - Section I**

1. Company/Product Number <b>65787-2</b>	2. EPA Product Manager <b>Emily Mitchell</b>	3. Proposed Classification  <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>Alcavis HDC, LLC / Bleach-Wipe</b>	PM# <b>32</b>	
5. Name and Address of Applicant (Include ZIP Code) <b>Alcavis HDC, LLC</b> <b>c/o Delta Analytical Corp.</b> <b>12310 Prosperity Dr. Suite 160</b> <b>Silver Spring MD 20904</b> <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> 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**

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) _____
* <b>Certification must be submitted.</b>			

3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) of Retail Container	5. Location of Label Direction <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner In Which Label Is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____		

**Section - IV**

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

Name <b>Donna Leventhal</b>	Title <b>Agent, Alcavis HDC, LLC</b>	Telephone No. (Include Area Code) <b>301-680-7971</b>
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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 	3. Title <b>Agent, Alcavis HDC, LLC</b>	6. Date Application Received <b>(Stamped)</b>
4. Typed Name <b>Donna Leventhal</b>	5. Date <b>July 15, 2011</b>	



[LOGO]

[CAT # [09041][09053]]

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# BLEACH-WIPE

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

FOR INSTITUTIONAL AND COMMERCIAL USE ONLY

Bleach Disinfectant Wipe

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

Active ingredient:

Sodium hypochlorite: .....	0.525%
Other ingredients:.....	99.475%
Total:.....	100.000%

5,000 ppm Available Chlorine

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

[See [back][reverse] [label][side] for additional precautionary statements]

FIRST AID	
If in eyes:	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15 - 20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>
If on skin or clothing:	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15 - 20 minutes.</li> </ul>
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. In an emergency, call a doctor or Poison Control Center at 1-800-222-1222.	

Manufactured by:  
Alcavis HDC, LLC  
8322 Helgerman Ct.  
Gaithersburg, MD 20877  
800-726-2308

**NOTIFICATION**  
Date Reviewed: 8/15/2011  
Reviewed By: M. Harris

EPA Reg. No. 65787-2  
EPA Est. No. 65787-MD-001

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PREMOISTENED [8" x 10"] [5" x 8"] TOWELETTE  
Net Contents: [0.7] [0.4] oz.

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### PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

**CAUTION:** Harmful if absorbed through skin. Liquid may cause moderate eye irritation. Avoid contact with skin, eyes or clothing. Wear gloves for sensitive skin or prolonged use since it may cause skin irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

#### DIRECTIONS FOR USE:

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

Suggested areas of usage:

Medical, Dental and Laboratory Counters, Exam Tables, Carts, Point of Care Equipment, Telephones, Sink Tops.

- Always use personal protective equipment (gloves).
- Open wipe packet.
- Remove premoistened towelette.
- Apply towelette to hard non-porous surface to be disinfected.
- Thoroughly wet surface making sure treated surface remains visibly wet for [one] [1] full minute.
- Use additional wipe if needed to assure continuous [one] [1] minute wet contact time.
- Allow surface area to air dry and discard used towelette.
- Do not re-use used towelette.

Do not use this product as a terminal sterilant/high level disinfectant on any surface or instrument that is introduced directly into human body, either into or in contact with the bloodstream or normally sterile areas of the body, or 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 AND DISPOSAL

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

**Storage:** Store this product in a cool, dry, and well-ventilated area away from direct sunlight and heat. **Towelette Disposal:** Do not reuse towelette. Dispose of used towelette and empty pack in trash. Do not flush in toilet.

[Optional claims:]

[Bleach-Wipe is a 1:10 dilution of 5.25% sodium hypochlorite solution with filtered water to comply with recommended infection control protocol.]

[Tuberculocidal] [and] [Bactericidal]

[One [1] minute minimum contact time]

[Maximum surface area that can be disinfected per towelette is [3' x 3'] [3' x 1.5']]

[batch code]