



U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Antimicrobials Division (7510P)  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460

EPA Reg. Number:

65787-4

Date of Issuance:

11/23/15

NOTICE OF PESTICIDE:

Registration  
 Reregistration  
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Bleach-Wipe 1:100

Name and Address of Registrant (include ZIP Code):

Susan Stracquatano, Agent  
Angelini Pharma Inc. c/o Delta Analytical Corporation  
12510 Prosperity Drive, Suite 160  
Siver Spring, MD 20904

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Demson Fuller, Product Manager 32  
Registration Management Branch II  
Antimicrobials Division (7510P)

Date:

11/23/15

2. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
3. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, “EPA Reg. No. 65787-4.”
4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 11/20/2015
- Alternate CSF 1 dated 11/20/2015
- Alternate CSF 2 dated 11/20/2015

If you have any questions, please contact Ben Chambliss by phone at (703) 308-8170, or via email at [chambliss.ben@epa.gov](mailto:chambliss.ben@epa.gov).

Sincerely,



Demson Fuller, Product Manager 32  
Regulatory Management Branch II  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

Enclosure: Stamped label

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

# Alcavis

## BLEACH-WIPE 1:100

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]

*Staphylococcus aureus* [ATCC 6538]  
*Salmonella enterica*, [ATCC 10708]  
*Pseudomonas aeruginosa* [ATCC 15442]

Manufactured by:  
Angelini Pharma Inc.  
8322 Helgerman Court  
Gaithersburg, MD 20877  
1-800-726-2308

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

[#][Premoistened] 8" x 10" Towelette or [Wipe]  
[[#] Wipes per Packet] [[#] Packets per Box]

**Net Contents: [weight]**

**Active Ingredient:**  
**Sodium Hypochlorite:**..... 00.075%  
**Other Ingredients:**..... 99.925%  
**Total:**..... 100.000%

1:100 dilution of Sodium Hypochlorite Bleach  
600 ppm Available Chlorine

<b>First Aid</b>	
<i>If in Eyes:</i>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
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* [ATCC 6538]  
*Salmonella enterica* [ATCC 10708]  
*Pseudomonas aeruginosa* [ATCC 15442]

**ACCEPTED**

11/23/2015

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 65787-4

## BLEACH-WIPE 1:100

Wipe has 600 ppm available chlorine.

### **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 5 minutes
- Use additional wipe(s) if needed to assure continuous 5 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 pre-clean 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 or disposal.

**Storage:** Do not store near heat or open flame. **Towelette Disposal:** Do not reuse towelette. Dispose of used towelette and empty packet in trash after use. Do not flush in toilet.