

46851-10

10/18/2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

November 10, 2004

Steve Cassinis  
Vice President  
Cottrell International, LLC  
6120 E. 58<sup>th</sup> Avenue  
Commerce City, CO 80022

Subject: **ProSpray Wipes**  
EPA Registration Number 46851-10  
Application dated October 18, 2004  
Receipt date: October 25, 2004

Dear Mr. Cassinis:

This will acknowledge receipt of your notification, submitted under the provisions of PR Notice 98-10, FIFRA section 3 (c) 9.

**Proposed Notification:**

- addition of the words "Lemon Scent"

**General Comment:**

Based on a review of the material submitted, the following comment apply.

The notification is acceptable and a copy of the notification has been inserted in your file for future reference.

Should you have any questions concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,

*Renae L. Whitaker*  
Adam Heyward  
Product Manager 34  
Regulatory Management Branch II

Antimicrobials Division (7510C)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							



Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-29-95

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United States  
Environmental Protection Agency  
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number 46851-10	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Cottrell International, LLC / ProSpray Wipes	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Cottrell International, LLC 6120 E. 58th Ave., Commerce City, CO 80022  <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

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	<b>NOTIFICATION</b> Date Reviewed: _____ Reviewed By: _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Notification of Odor (Lemon Scent) added to label per PR Notice 98-10. 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 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:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
<i>Certification must be submitted</i> If "Yes" Unit Packaging wgt.      No. per container 34.7 oz(1080 gr)                      72		If "Yes" Package wgt      No. per container _____                      _____			
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 72 Pre-moisten Towelettes		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input checked="" type="checkbox"/> Other flexographic or roto gravure		

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Steve Cassinis	Title Vice President	Telephone No. (Include Area Code) 303-799-9401
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Vice President	
4. Typed Name Steve Cassinis	5. Date 10/18/04	

including Trichophyton mentagrophytes, and the following viruses: Polio virus 1, Herpes simplex virus types 1 & 2, Vaccinia virus, Influenza virus type A 1 (New Jersey) and Influenza B (Maryland).

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 blood stream or normally sterile areas of the body, (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise 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.

Preparation of Dispenser: Lift up tab and pull back to expose the entire opening. Do Not Remove Peel & Seal Tab. Grasp exposed edge of towelette and pull out. Close Peel & Seal tab to prevent evaporation, by returning it to its original position and press down firmly.

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

# ProSpray wipes

## Disinfectant Towelettes

Tuberculocidal, Virucidal,  
Bactericidal, Fungicidal

Active Ingredients	
o-phenylphenol	0.28%
o-benzyl-p-chlorophenol	0.03%
Inert Ingredients	99.69%
Total	100.00%

Reorder No: PSW

### NOTIFICATION

Date Reviewed: 10-27-04  
Reviewed By: [Signature] (CA)

## with Lemon Scent

72 Pre-moistened Towelettes

9 x 10 in. (22.86 x 25.4 cm)  
Packet Net Contents: 34.7 oz (1080 grams)

CAUTION: Keep Out of Reach of Children

MANUFACTURED FOR:  
**CERTOL**  
INTERNATIONAL, LLC  
6120 E. 58<sup>th</sup> AVE.  
COMMERCE CITY, CO 80022 USA  
1 800 THE EDGE  
(1-800-843-3343)

EPA Reg. No. 46851-10  
EPA Est. No. 70805-OH-001  
DIN02231483



PSWSP72A.01

**\*KILLS HIV 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 human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OF SURFACES OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS.**

**PERSONAL PROTECTION:** When handling items soiled with blood or body fluids or when conducting procedures which might lead to contact with blood or body fluids always wear items such as heavy-duty nitrile gloves, gowns, masks, and eye coverings.

**CLEANING PROCEDURES:** Blood and body fluids must be thoroughly cleaned from surfaces and objects prior to disinfection. Apply ProSpray wipes, Disinfectant Towelettes directly to the surface to be cleaned and then discard.

**DISPOSAL OF INFECTIOUS MATERIAL:** Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

**PRECAUTIONARY STATEMENTS**  
**CAUTION:** Avoid contact with eyes and clothing. Protective gloves should be worn.

**STATEMENT OF PRACTICAL TREATMENT:** If in eyes - flush with plenty of water. Seek medical attention if irritation persists.

**STORAGE AND DISPOSAL:** Store at room temperature. Do not reuse towelettes. Dispose of used towelettes and empty packets in regular trash.