OFFICE OF CHEMICAL SAFETY

AND POLLUTION PREVENTION



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

NOV 1 8 2010

Mr. Lewis Ward Certol International, LLC 6120 E. 58th Avenue Commerce City, CO 80022

Subject:

Omni II/ProSpray C-60

EPA Registration No.: 46851-1 Notification Date: 10/29/2010 EPA Receipt Date: 11/01/2010

Dear Mr. Lewis Ward,

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

Proposed Notification

• Addition to include H₁N₂, H₃N₂, and H₅N₁ Influenza A viruses

General Comments

Based on a review of the submitted materials, your notification for the addition to include H_1N_2 , H_1N_2 , and H_1N_2 Influenza A viruses is unacceptable because the product's efficacy data is insufficient to support the claims against the different Influenza A strains. The Agency's guidance for Testing and Labeling Claims against Pandemic 2009 H_1N_1 Influenza A virus is specific to this strain of Influenza A. If you would like to support additional strains of Influenza A, you must submit efficacy data on each strain into the Agency for review.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Jaclyn Carl by telephone at (703) 347-0213 or by e-mail at carl.jaclyn@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Amcerdiy,

cqueline Campbell-McFarlane

Product Manager

Regulatory Management Branch Antimicrobials Division (7510P)

Please read instructions on reverse before c	ting form.	Form Appr	ove MB No. 2	070-0060	Print Form	
United States Environmental Protection Ager Washington, DC 20460		ency	Registra Amenda X Other		OPP Identifier Number	
Application for Pesticide - Section I						
1Company/Product Number Certol International, LLC 46851-1		2. EPA-Product Manager 3. I ShaRon Carlisle		3. Pro	posed Classification	
4. Company/Product (Name) Certol /•Omni II / ProSpray C-60		PM# 34 None Restricted				
5. Name and Address of Applicant (Include ZIP Code) Certol International, LLC 6120 E. 58th Avenue Commerce City, CO 80022 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				e to 		
Explanation: Use additional page(s) if necessary. (For section I and Section II.) Notification for additional Influenza A virus per PR Notice 95-2. See attached explanation page.						
Section - III						
1. Material This Product Will Be Packaged In:						
Child-Resistant Packaging Yes* No * Certification must be submitted Unit Packaging Yes No If "Yes" Unit Packaging wgt.	No. per If "Yo	Water Soluble Packaging Yes No If "Yes" No. per Package wgt Container		2. Type of Container Metal Plastic Glass Paper Other (Specify)		
3. Location of Net Contents Information Label Container	4. Size(s) Retail Cont	s) Retail Container 5. Location of Label Direct On Label On Labeling according			•	
6. Manner in Which Label is Affixed to Product Lithograph Paper glued Stenciled						
Section - IV						
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)						
Name Lewis Ward		DA/OA Managan		Telephone 303-799-	99-9401	
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 knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Dete Application Received (Stamped)	
2. Signature News Wind	3. Title RA/ QA	3. Title RA/ QA Manager				
4. Typed Name Lewis Ward		5. Date October 29, 2010			(((())	

S/ ==

Concentrated Surface Disinfectant and Holding Solution

Tuberculocidal, Virucidal; Bactericidal, Fungicidal

E. P.A. Reg No. 46851-1 E. P.A. Est. No. 46851-CO-003

DANGER

Effective against subtypes of Influenza A viruses H_1N_1 , H_1N_2 , H_3N_2 , and $H_5^2N_1$.

Date Reviewed: NOTATION

Proposed Label