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California Notice 2009-9 Revision  
November 16, 2009

TO: Pesticide Product Stakeholders

SUBJECT: POLICY REGARDING LABEL CLAIMS AGAINST THE 2009 H1N1  
INFLUENZA A VIRUS (FORMERLY KNOWN AS SWINE FLU)

In response to the U.S. Environmental Protection Agency's (U.S. EPA) recent on-line [Guidance Document for Testing and Labeling Claims Against Pandemic 2009 H1N1 Influenza A Virus](#), the California Department of Pesticide Regulation's (DPR's) Pesticide Registration Branch (PRB) is providing its policy with regard to the acceptance of amendments to the labels of currently registered products to add claims against the 2009 H1N1 influenza A virus.

Effective immediately, applicants that wish to amend the labels of their currently registered disinfectant products to add the following claims against Pandemic 2009 H1N1 influenza A virus may do so **through DPR's special notification process, without additional data or fee until the close of business on June 30, 2010**. This notice pertains only to disinfectant products that bear label claims against human, avian, or swine influenza A virus, and for which the registrant has submitted to, and received from DPR, acceptance of efficacy data to support those claims.

After June 30, 2010, all requests to amend pesticide product labels to add claims against the H1N1 influenza A virus will be subject to DPR's normal amendment process; supporting data and fee may apply.

### **Label Amendments that Qualify for this Notification Process**

DPR will accept through a special notification process the addition of the following label claims to registered disinfectant products that currently bear label claims against human, avian, or swine influenza A virus, and for which the registrant has submitted to, and received from DPR, acceptance of efficacy data, **provided no other changes are made to the product label:**

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. This product (Product Name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).



- This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.
- This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus.

The amended label(s) may be submitted to DPR **concurrently** with submission of the amended label(s) to U.S. EPA for federal approval if the proposed label claims are identical to those identified.

DPR will accept through its special notification process variations of the label claims listed above, provided the applicant can submit written proof of federal acceptance. Since written proof must be provided, DPR will not accept such submissions **concurrently** with submission of the amended label(s) to U.S. EPA.

The label claims **must** be limited to use of the product on hard, nonporous surfaces. DPR will not accept the above 2009 H1N1 influenza A virus claims with respect to porous surfaces through this process. Such claims must be submitted through the normal amendment process; supporting data and fee may apply.

### **Data Requirements**

Please note that applicants must have data on file with DPR to support an influenza A claim or have relied upon data previously submitted and accepted by the Department to support such a claim. Applicants that referenced efficacy data previously submitted to DPR by a different company or a pesticide product(s) of a different company, subject to the same efficacy data requirements, may incur data compensation obligations as outlined in California Food and Agricultural Code section 12811.5.

### **What Must be Included in Your Submission to DPR**

DPR will accept notification applications submitted concurrently with the applicant's submission to U.S. EPA for federal acceptance, provided the applicant provides DPR with the following:

1. A cover letter detailing your request.
2. A completed and signed DPR Notification Form for Minor Changes (DPR Form #39-031). The form is located online at <http://www.cdpr.ca.gov/docs/registration/regforms/notify/notifymenu.htm>. Check the box titled "H1N1 Virus Claims."
3. Three copies of your proposed label with the change clearly marked. The labels must be printer's proof or final printed labels, or copies thereof.
4. Copy of your completed U.S. EPA Application for Registration (EPA Form 8570-1)

As previously noted, if your proposed label claim varies from the claims listed above, you must also include proof of U.S. EPA **acceptance** (cannot be submitted concurrently) of the varied label claim.

Submit all documents to:

California Department of Pesticide Regulation  
Pesticide Registration Branch  
**H1N1 Notification**  
P.O. Box 4015  
Sacramento, California 95812

### **Application Review Period**

For applications containing a claim consistent with the statements listed above, DPR expects to complete its review of the applicant's submission within 20 business days from the date received by DPR. If your label statement varies from those listed above, DPR may need additional review time.

### **Acceptance of Amended Labels**

DPR **will not** provide letters of acceptance to applicants. However, if the applicant's e-mail address is included on line 5 of the Notification Form for Minor Changes (DPR Form #39-031), DPR will provide e-mail confirmation of acceptance. The absence of a DPR e-mail accepting your proposed label amendments within the 20-day time period **does not constitute approval** of the amended label. Applicants that provide an e-mail address but do not receive notification of

acceptance within 30 business days are encouraged to contact Ms. Rachel Kubiak, Pesticide Registration Branch Ombudsman (see contact information listed below).

**Posting of Accepted Products**

DPR will post all decisions to accept H1N1 claims through notification on our Website at <http://www.cdpr.ca.gov/docs/registration/prodamends/prodamends.htm>.

**Amendments Not Allowed through Notification**

Applicants who do not currently have influenza A virus claim(s) on their label and wish to add such claims with supporting data must submit their package through DPR's label amendment process. The submission will not be accepted as a notification and will be returned to the applicant.

If DPR finds that additional revisions have been made to the product label, the amended label will not be accepted through the notification process under this notice. Please note that a product distributed or sold with an amended label submitted under this notice, that does not comply with the criteria listed above, is considered unregistered and subject to enforcement action. **DPR will return notification submissions that do not meet the criteria outlined in this notice with a letter outlining the reasons for rejection.**

DPR may depart from this notice where circumstances warrant and without prior notice.

If you have any questions, please contact Ms. Rachel Kubiak in the Pesticide Registration Branch by e-mail at [rkubiak@cdpr.ca.gov](mailto:rkubiak@cdpr.ca.gov) or by telephone at (916) 324-3939.

*Original signed by*

*November 16, 2009*

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Ann M. Prichard, Chief  
Pesticide Registration Branch

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Date