

1007-99

2/25/2014

1/4



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Zoetis Inc.
333 Portage Street
Kalamazoo, Michigan 49007-4931
Attn: John B. Baker

FEB 25 2014

Subject: Label Correction
EPA Reg. No. 1007-99
Notification Letter Dated January 17, 2014

This letter acknowledges receipt of the Notification identified above submitted under the provisions of section 3(c)(9) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10. This Notification requests to correct the current label. The following label change is acceptable:

- Addition of manufacturer's advisory statement "Preserve from freezing"


Based on a review of the submitted information, this notification is acceptable. This information has been made a part of your file.

Should you have any questions concerning this letter, please contact Seiichi Murasaki at murasaki.seiichi@epa.gov or (703) 347-0163.

Sincerely,

A handwritten signature in black ink that reads "Marshall Swindell".

Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510P)

 <p>United States Environmental Protection Agency Washington, DC 20460</p>	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 1007-99	2. EPA Product Manager M. Swindell	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Nolvasan Solution	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Zoetis Inc. 333 Portage Street, Kalamazoo, MI 49007 <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 _____
<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.

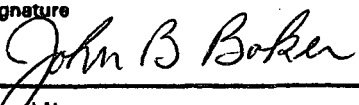
Explanation: Use additional page(s) if necessary. (For section I and Section II.)

The manufacturer's advisory statement "Preserve from Freezing" was inadvertently left off of labeling approved by EPA 8MARCH2013. For quality purposes, we will add this phrase back to the label as shown in the enclosed example. Final printed labels will be submitted once they are available.

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) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <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 John B Baker	Title Associate Director	Telephone No. (Include Area Code) 269 653 3904
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 Associate Director	
4. Typed Name John B Baker	5. Date 17 January, 2014	

John B Baker
Associate Director
Regulatory Affairs

Zoetis
333 Portage Street
Kalamazoo, MI 49007

T 269 833 3904
F 269 833 2707
M 269 366 5265
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3/4



January 17, 2014

Marshall Swindell, PM 33
c/o Document Processing Desk
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

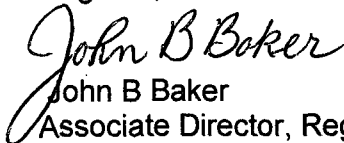
Re: Nolvasan Solution, EPA Reg. No. 1007-99

Dear Mr. Swindell

The labeling for the product above which was approved by EPA on March 8, 2013 inadvertently left off a manufacturer's advisory statement "Protect from freezing." This was not a statement required by EPA, but does appear in previous versions of the approved label. In order to protect product quality, we will add this statement back to the label at the next printing. I have enclosed an editor's copy of the label showing where the statement previously appeared and will be added back. Labeling that has been printed without the statement will be used, but will have the statement "Preserve from freezing" added by laser printer to the imprint area next to the lot number. We will submit copies of the final printed labeling when it becomes available.

Please let me know if you have any questions or concerns.

Regards,


John B Baker

Associate Director, Regulatory Affairs

