

54289-3

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D C 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Ms Tiana M Rosamilia  
Regulatory Manager for,  
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SEP 13 2012

Subject Peraclean 5  
EPA Registration Number 54289-3  
Your Amendment Dated May 17, 2012  
EPA Received Date May 18, 2012

The amendment referred to above, submitted in connection with under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended,, to add foaming sanitization applications for previously cleaned, hard non-porous food contact surfaces, is acceptable provided that you make the following labeling revisions

The proposed label claims are acceptable regarding use of the product, Peraclean 5, as a sanitizer with foaming application for previously cleaned hard, non-porous surfaces at 100 ppm and 180 ppm use concentrations for a contact time of 1 minute These claims are acceptable as supported by the efficacy data provided you make the following revisions

The following changes are recommended on the proposed label

- 1 Under the section for Foam Sanitization, change the sentence beginning, "Examples included" to, "For example, uses that include operating conveyor belts, vertical or uneven surfaces "
- 2 Under the "Precautionary Statements" section, change "before eating, drinking, or using tobacco" to read "before eating, drinking, chewing gum, using tobacco, or using the toilet"
- 3 Add ATCC numbers that are required for all microorganisms in one of these locations,

On the data matrix

The master label (as optional text) with the listing of the organisms

As the final page of the master label (as optional text)

As the final page of the master label (as optional text)

- 4 Change the "Pseudomonas Auriginosa" to "Pseudomonas aeruginosa"
- 5 Change "E coli 0157 H7" to "E coli 0157 H7 "
- 6 Change "Salmonella choleraesuis" to "Salmonella enteria "

The submitted efficacy data (MRID NO 488325-10) support the use of the product, Peraclean 5, as a foaming sanitizer against Escherichia coli (ATCC # 11229) on hard, Non-porous surfaces in the presence of 400 ppm hard water for a contact time of 30 Seconds at use concentrations of 100 ppm and 180 ppm One of the two product lots Tested was at least 60 days old at the time of testing Bacterial reductions of at least 99 999% over the parallel control were observed within 30 second contact time Sterility Controls did not show growth The concentration of the active ingredient, at the time of Testing, or upon receipt is absent This information is necessary for comparison of the Confidential Statement of Formula, to the tested product, to the proposed label

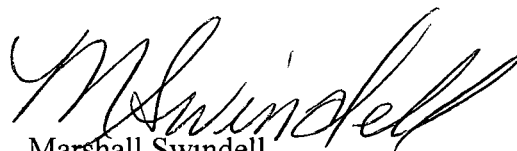
A stamped copy of the labeling is enclosed Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling

Submit and/or cite all data required for registration /reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e) Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions

If you have any questions concerning this letter, please contact Karen M Leavy-Munk at (703)-308-6237

Sincerely,



Marshall Swindell  
Product Manager 33  
Regulatory Management Branch I  
Antimicrobial Division(7510P)



