

8383-1

4/12/2005

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 12, 2005

Robert Schattner
Agent for Sporicidin International, Inc.
Laird's Regulatory Consultants, Inc.
121 Congressional Lane
Rockville, MD 20852

Subject: Permacide Brand (Ristex)
EPA Registration Number 8383-1
Application Date: February 4, 2005
EPA Received Date: February 10, 2005

Dear Dr. Schattner:

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

Proposed Notification

- Revised labeling

General Comments

Based on a review of the materials submitted, the following comments apply:

The notification application is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at 703-308-6422.

Sincerely,

Adam Heyward

CONCURRENCES

Product Manager 34

Regulatory Management Branch I

Antimicrobials Division (7510-C)

SYMBOL	7510c						
SURNAME	Heyward						
DATE	4-12-05						

	United States Environmental Protection Agency Washington, DC 20460	<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 <p style="text-align: center;">8383-1</p>	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) PERMACIDE Brand (Ristex)	PM# <p style="text-align: center;">34</p>	
5. Name and Address of Applicant (Include ZIP Code) Sporocidin International, Inc 121 Congressional Lane Rockville, Maryland 20852 <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. <u>8383-1</u> Product Name <u>PERMACIDE Brand (Ristex)</u>

Section - II

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.
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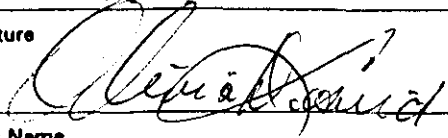
Explanation: Use additional page(s) if necessary. (For section I and Section II.)

By this Notification, in accordance with our agreement during the Phenol Mitigation meetings, I submit this along with the attached letter and label on which we have deleted the use of this product in paint. The required Certification Statement is attached. Thank you for making this a part of the record for this application.

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 <i>Certification must be submitted</i>	Unit Packaging <input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container _____ 4 & 12	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt No. per container _____ _____		<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 16 oz and 1 gallon		5. Location of Label Directions <input type="checkbox"/> on label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Stenciled					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Laird's Regulatory Consultants, Inc.	Title Agent/Consultants	Telephone No. (Include Area Code)
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. Date Application Received (Stamped) 
Signature 	3. Title President/Owner	
4. Typed Name FOR - Dr. Robert Schattner	5. Date February 4, 2005	

February 4, 2005

CERTIFICATION STATEMENT

"Notification 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, Deletion of the paint use from the label, no other changes have been made to the labeling or the 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 SporidIn International may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."


Robert I. Schattner, D.D.S.
President

February 4, 2005

Ms. Connie Welsh, Chief
Environmental Protection Agency
Antimicrobial Division (7510C)
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460


Subject: PERMACIDE Brand (Ristex)
EPA Reg. No. 8383-1
Deletion of the Paint Use

Dear Ms. Welsh:

Regarding EPA discussions with Olivia Laird, this letter will serve as our agreement to delete paint from the registered label for the product referenced above. Our submission, label attached, indicates that paint will be deleted. This should satisfy the requirement of the RED that is currently in progress.

Should you have questions, please contact Ms. Olivia Laird, our representative, at (703) 669-0509.

Sincerely,

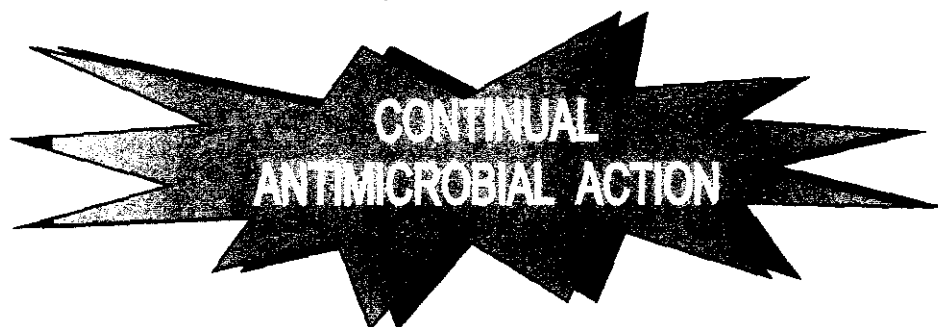

Robert I. Schattner, D.D.S.
President

cc: Ben Chambliss, Reregistration Team Leader
Killian Swift, Phenols Chemical Review Manager
Adam Heyward, PM 34

PERMACIDE

BRAND (RISTEX)

**INDUSTRIAL ADDITIVE FOR POLISHES,
CLEANSERS, AND PROTECTANTS**



AGAINST BACTERIA, MOLDS AND MILDEW

ACTIVE INGREDIENTS:

Phenol	1.4%
Sodium Tetraborate	0.47%
Sodium Phenate	0.24%

INERT INGREDIENTS: 97.89%

Caution

KEEP OUT OF REACH OF CHILDREN

RISTEX BIOCHEMICALS

A DIVISION OF
SPORICIDIN INTERNATIONAL, INC.
121 CONGRESSIONAL LANE #600
ROCKVILLE, MARYLAND 20852

NEW !

PERMACIDE is a biostat with residual action which stops the growth of infectious organisms.

USES:

Permacide is especially adapted to impart self-sanitizing action that continually reduces the number of bacteria as long as it remains on the surface. It protects against *Escherichia coli*, *Staphylococcus aureus* and group A alpha and beta hemolytic *Streptococcus*.

DIRECTIONS:

Add 2.5% by weight of active ingredients, according to directions of the manufacturer.

See technical brochure for detailed recommendations and directions... for manufacturing use only.

NET CONTENTS: 5 gallons

Rinse empty container thoroughly with water and discard it.

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EPA EST. NO. 047179-IL-001

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