

46781-6

11/9/2006

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

NOV -9 2006



United States  
Environmental Protection  
Agency

Office of Pesticide Programs

Metrex Research Corporation  
1717 West Collins Avenue  
Orange, CA 92867

Attention: Wendy Urtel, Manager  
**Regulatory Affairs**

**Subject: Cavicide**  
EPA Registration No. 46781-6  
Notification Dated October 6, 2006

This will acknowledge receipt of your notification to add proposed optional verbiage which may appear on the product labeling and/or promotional materials, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely

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

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

285

Please read instructions on reverse before completing form.

Form Approved OMB No. 2070-0060, Approval expires 2-28-95



United States  
Environmental Protection Agency  
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number 46781 / 46781-6	2. EPA Product Manager M. Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Metrex Research Corporation / Cavicide	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Metrex Research Corporation 1717 West Collins Avenue Orange, CA 92867 <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.)  
 RESUBMISSION OF NOTIFICATION TO ADD PROPOSED VERBIAGE TO THE LABELING FOR CAVICIDE, EPA REG. NO. 46781-6, WHICH IS INTENDED TO PROMOTE CAVIWIPES, EPA REG. NO. 46781-8, AND WILL ACCOMPANY SHIPMENTS OF CAVICIDE IN THE FORM OF AN OPTIONAL HANG TAG. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and 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. Section 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 I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

### Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
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		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Glass
					<input type="checkbox"/> Paper
					<input type="checkbox"/> Other (Specify) _____
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 Wendy Urtel	Title Manager, Regulatory Affairs	Telephone No. (Include Area Code) 949-255-8767
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<b>Certification</b> 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 Manager, Regulatory Affairs		
4. Typed Name Wendy Urtel	5. Date 9-13-06		



SYBRON DENTAL SPECIALTIES

September 14, 2006

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
US Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202-4501

Re: **RESUBMISSION OF NOTIFICATION TO ADD PROPOSED OPTIONAL VERBIAGE WHICH MAY APPEAR ON THE PRODUCT LABELING AND/OR PROMOTIONAL MATERIALS FOR CAVICIDE**

Product: Cavicide, EPA Reg. No. 46781-6  
Company: Metrex Research Corporation

Dear Sir or Madam:

According to the US EPA letter dated August 9, 2006, the proposed statements meant to appear on product labeling and/or promotional material for Cavicide, EPA Reg. No. 46781-6, were found to be unacceptable. The proposed statements were considered implied safety and heightened efficacy claims not permitted on product labeling.

On September 6, 2006 a telephone conversation between Metrex Research Corporation and Marshall Swindell was held during which the proposed claims were re-reviewed and discussed. M. Swindell understands the objective of the proposed claims and he had no objections to the statements below. The following were mutually agreed upon; therefore the notification to add these proposed statements is being resubmitted to US EPA for approval.

New Claims and 40% Faster Kill  
New Claims and Faster Contact Times  
New Kill Claims [*must specify what claims are new*]  
New Claims – Kills TB in 3 Minutes  
New Claims – Kills TB 40% Faster  
New – Saves Time – It's 40% Faster  
New – Kills TB in 3 Minutes

This submission is in follow-up to the CaviCide label amendment approved on March 1, 2003, whereby new claims were added and lower contact times were established. Therefore, the purpose of this resubmitted notification is to obtain Agency approval on various marketing statements that may be used to promote the recently approved claims. The statements are optional and may appear on the Cavicide product label and/or in promotional materials.

The following documents are being submitted in support of this notification:

- Two copies of Form 8570-1, Application for Pesticide Form (Section 1)\*
- One copy of the list of proposed statements (Section 2)\*

*\* Please treat the information contained in Sections 1-2 as proprietary and confidential as covered in the provisions of FIFRA Section 10.*

If you have any questions regarding this submission, please contact Orlando Tadeo, Jr. or me at any of the following numbers/addresses:

Phone Numbers: O. Tadeo, Jr. (949) 255-8768 or W. Urtel (949) 255-8767  
 Fax Number: (949) 255-8763  
 Email addresses: orlando.tadeo@sybrondental.com or wendy.urtel@sybrondental.com  
 Contact Address: Sybron Dental Specialties  
 100 Bayview Circle, Suite 6000  
 Newport Beach, CA 92660

Sincerely,



Wendy Urtel  
Manager, Regulatory Affairs

Enclosures

[The following statements are optional verbiage to be used for marketing purposes and may appear on the product label and/or in promotional materials for Cavicide, EPA Reg. No. 46781-6.]

[New Claims and 40% Faster Kill]

[New Claims and Faster Contact Times]

[New Kill Claims [*must specify what claims are new*]]

[New Claims - Kills TB in 3 Minutes]

[New Claims - Kills TB 40% Faster]

[New - Saves Time - It's 40% Faster]

[New - Kills TB in 3 Minutes]

**THE INFORMATION IN THIS BOX IS NOT PART OF THE LABELING**

Statements in brackets, [ ], are optional or instructional. Italicized words in brackets are included on production labels. Sequence of statements is optional unless specified in 40 CFR 156.10. Capitalizing, pluralizing, singularizing, bolding, italicizing and abbreviating are variable unless specified in 40 CFR. Lists of uses and use sites may be used partially or in their entirety.