

46781-10

1/14/2010

10/11

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



United States
Environmental Protection
Agency

Office of Pesticide Programs

Metrex Research Corporation
1717 West Collins Avenue
Orange, CA 92867

JAN 14 2010

Attention: Wendy Garman, Manager
Regulatory Affairs

Subject: Premicide

EPA Registration No. 46781-10
Notification Dated December 14, 2009

This will acknowledge receipt of your notification, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

Proposed Notification

Label change per PR Notice 2007-4

General Comments

The Notification dated December 14, 2009 is in compliance with PR Notice 98-10 and is acceptable. The 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 cursive script that reads "Martha Terry".

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

2011



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 / 46781-10	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 / Premicide	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.)

Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for 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 the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, 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 <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 Wendy Garman	Title Director, Regulatory Affairs	Telephone No. (Include Area Code) 714-516-7602
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 Director, Regulatory Affairs	
4. Typed Name Wendy Garman	5. Date 12-14-09	

30411



SYBRON DENTAL SPECIALTIES

December 14, 2009

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

Re: LABEL NOTIFICATION PER PR-NOTICE 2007-4
Product: Premicide, EPA Reg. No. 46781-10
Company: Metrex Research Corporation

Dear Sir or Madam:

Enclosed is a LABEL NOTIFICATION to revise the label for Premicide, EPA Reg. No. 46781-10, per PR-Notice 2007-4.

The following documents are being submitted in support of this LABEL NOTIFICATION:

Two (2) copies of the Application for Pesticide Form 8570-1	Section 1
One (1) copy: Current Premicide EPA Stamp Approved Label dated Dec 6, 2007	Section 2
One (1) copy: Proposed Premicide Label (Version 12-1-2009) With Changes Highlighted	Section 3

** Please treat the information contained in Sections 1-3 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. (714) 516-7419 or W. Garman (714) 516-7602
 Fax Number: (714) 516-7488
 Email addresses: orlando.tadeo@sybrondental.com or wendy.garman@sybrondental.com
 Company Address: Metrex Research Corporation
 1717 West Collins Avenue
 Orange, CA 92867

Sincerely,

Wendy Garman
Director, Regulatory Affairs

Enclosures

40911

[Center Panel]

PREMICIDE
Sanitizer/Solidifier

The efficacy of this product has been demonstrated in the presence of 100% blood serum.

ACTIVE INGREDIENTS:

Glutaraldehyde 9.61%

OTHER INGREDIENTS:..... 90.39%

Total..... 100.00%

KEEP OUT OF REACH OF CHILDREN
DANGER

FIRST AID

If in eyes

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

If on skin or clothing

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for further treatment advice.

If swallowed

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

If inhaled

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a poison control center or doctor for further treatment advice.

For emergency information on product, call Metrex at 1-800-841-1428, Monday through Friday between 6 a.m. and 4 p.m. Pacific Time. After 4 p.m., call Chemtrec 24-Hour Emergency Service at 1-800-424-9300.

THE INFORMATION IN THIS BOX IS NOT PART OF THE LABELING
Statements in brackets, [], are optional or instructional. Italicized words in brackets are not 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.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

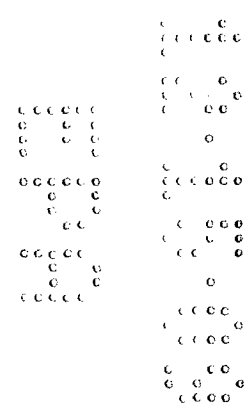
NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage.

See side panel for additional precautionary statements.

Net Contents: XX

Solidifies up to XXXXcc



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60911

[Side Panel]

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

DANGER

Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if inhaled. Harmful if swallowed. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Causes asthmatic signs and symptoms in hyper-reactive individuals.

- Do not get in eyes, on skin or on clothing.
- Avoid breathing vapor.
- Do not swallow.
- Wear goggles, protective clothing and rubber gloves.
- Wash thoroughly with soap and water after handling.
- Remove contaminated clothing and wash before reuse.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry, well-ventilated area.

Pesticide Disposal: Dispose of waste according to Federal, State and local regulations.

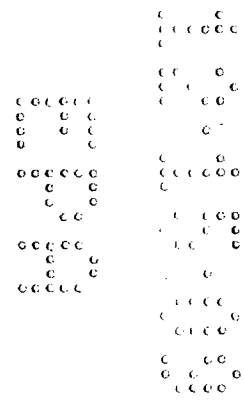
Container Disposal: **Nonrefillable container. Do not reuse or refill this container.**

[Choose one of the following recycling statements.]

[a]
[Offer for recycling, if available.]

[b]
[Triple rinse. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.]

FOR SINGLE USE ONLY



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7 of 11

[Side Panel A -The following verbiage will appear only on the 500cc, 1200cc, 1500cc, 2000cc and 3000cc bottles]

Fast-acting encapsulant which contains scented dry glutaraldehyde to sanitize and solidify liquid medical waste and laboratory, human and animal wastes. Antibacterial. Controls odor formation by destroying odor-causing bacteria.

The efficacy of this product has been demonstrated in the presence of 100% blood serum.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

To help prevent the blood from clotting inside the suction canister, immediately dispense PremiCide following the end of surgery or after the suction canister has been completely filled.

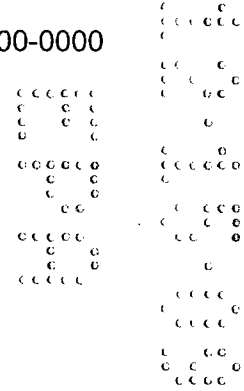
- Wear hand, eye and face protection when handling infectious waste and using PremiCide.
- Shake and squeeze bottle to loosen any settled material.
- Following surgery, open the appropriate port and place the PremiCide cap onto the open port and push down to secure proper fitting.
- Following surgery, turn off suction and remove the patient tubing. Close all ports and activate suction. Firmly grasp the base of the cap and pull upward on the bottle. Suction will pull the PremiCide powder into the canister.
- Once the PremiCide bottle is empty, tap the side of the bottle to remove any remaining powder. Push down on the bottle to close the system. Once the liquid waste is solidified, remove the bottle by gripping the base of the PremiCide cap and lift up. Replace the port cap on the suction canister. To assure thorough treatment of the suction canister, invert solidified canister and dispose of according to institutional procedures and Federal, State and local regulations.

For product or technical information, contact Metrex Customer Care at **800-841-1428** or visit our website at **www.metrex.com**.

EPA Reg. No. 46781-10

EPA Est. No. 72075-WI-001
46781-MI-001
51435-WI-004

Reorder No: 00-0000



Packed For: [or] Manufactured By:
Metrex Research Corporation
28210 Wick Road
Romulus, Michigan 48174

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8011

[Side Panel B -The following verbiage will appear only on the 10000cc multi-dose bottle]

Fast-acting encapsulant which contains scented dry glutaraldehyde to sanitize and solidify liquid medical waste and laboratory, human and animal wastes. Antibacterial. Controls odor formation by destroying odor-causing bacteria.

The efficacy of this product has been demonstrated in the presence of 100% blood serum.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

To help prevent the blood from clotting inside the suction canister, immediately dispense PremiCide following the end of surgery or after the suction canister has been completely filled.

- Wear hand, eye and face protection when handling infectious waste and using PremiCide.
- Shake and squeeze bottle to loosen any settled material.
- Unscrew cap, remove safety seal and recap.
- Open a port in the top of the suction canister or provide access to the liquid waste if other device is used. Remove red cap.
- Insert PremiCide nozzle into opening. Gently squeeze the bottle, injecting PremiCide into the canister. Do not allow the tip of the bottle to touch the liquid waste. Recap port and replace red cap on bottle. Each graduation solidifies 1,000cc's.
- Allow sufficient time for encapsulation before handling.

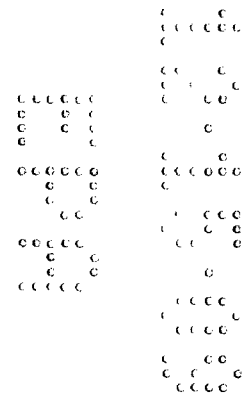
For product or technical information, contact Metrex Customer Care at **800-841-1428** or visit our website at **www.metrex.com**.

EPA Reg. No. 46781-10

EPA Est. No. 72075-WI-001
46781-MI-001
51435-WI-004

Reorder No: 00-0000

Packed For: [or] Manufactured By:
Metrex Research Corporation
28210 Wick Road
Romulus, Michigan 48174

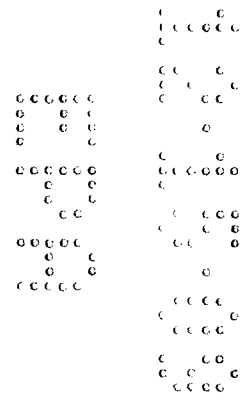


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9011

[The following optional verbiage will appear on a sticker that may be packaged with the product]

Chemically Treated Solid Non-Infectious Medical Waste



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100911

[The following verbiage only appears on labeling for PremiCide CA, Alternate Brand Name of PremiCide]

[Front of sticker label]

PremiCide

Determination of Canister Disposal
(see procedure on back of label)

Canister No. _____

Calculation

- A. Suction canister EBL (Note Amount) _____ cc
- B. Total cc fluid in suction canister (Note Amount) _____ cc
- C. Total % blood in suction canister (A/B x 100 = C) _____ %

Refer to "C" and circle only one (1) of the following:

- White Bag ($\leq 20\%$ blood in canister)
- Red Bag ($> 20\%$ discard as medical waste)

Not for use in post-surgery body cavity drainage.

[Back of sticker label]

Procedure for disposal of suction canister when using PremiCide

Important Note:

Following the completion of surgery it is important to determine the amount of blood contained in a suction canister used during a surgical procedure. The amount of blood in the canister must be determined to properly dispose of the canister.

Instructions:

1. Following the completion of the procedure, the participating anesthesiologist shall calculate the blood content of each suction canister used during surgery. The calculation shall be made using the information generated by the anesthesiologist when calculating the estimated blood loss.
2. The estimate shall be recorded on this PremiCide disposal label, which is then affixed to the suction canisters used during surgery. The label shall be completed as follows:
 - Item A: Record the "EBL" or "Estimate Blood Loss" made by the anesthesiologist in total cc's. Exclude all estimates for laps, spills, or other areas where blood may have been lost but was not captured in suction canisters.
 - Item B: Record the total amount of fluid in cc's in the suction canister. This will include all fluids (blood, irrigants, or other fluids – everything in the canister).
 - Item C: Calculate $A / B \times 100 = "C"$ (Estimate of total percent blood in canister):
Example:

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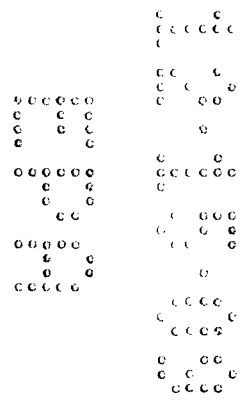
110911

[The following verbiage only appears on labeling for PremiCide CA, Alternate Brand Name of PremiCide]

"A"	/	"B"	x 100 =	"C"
300 cc EBL in canister	/	3000 cc total fluid in canister	=	10% blood

3. Affix label to suction canister.
4. If Item "C" is less than or equal to 20% circle "White Bag" method of disposal. If Item "C" is greater than 20% circle "Red Bag" method of disposal.

For product or technical information, contact your local Metrex representative at 1-800-841-1428 or visit our website at www.metrex.com.



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