



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OCT 26 2006

Metrex Research Corporation
1717 West Collins Avenue
Orange, CA 92867

Attention: Wendy Urtel

Subject: **Premicide**
EPA Registration No. 46781-10
Amendment Application Date: August 18, 2006
EPA Received Date: August 21, 2006

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable for the following reason.

- Revised labeling and add the following optional statement "Chemical Treated Solid Non-Infectious Medical Waste".

If you have any question or comments concerning this letter, please contact me at (703) 308 6341 or Portia Jenkins at (703) 308-6230.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Swindell".

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

Enclosure

[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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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.
<p>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.</p>	
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>	
<p>NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. <i>See side panel for additional precautionary statements.</i></p>	

Net Contents: XX
Solidifies up to XXXcc

ACCEPTED
OCT 26 2006
The Federal Insecticide, Fungicide and
Rodenticide Act
46781-10

[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.

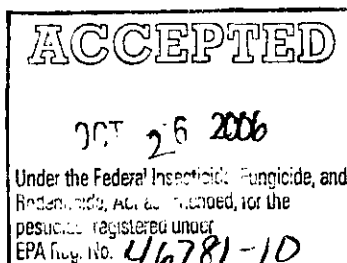
STORAGE AND DISPOSAL

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: Do not reuse container. 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

[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.

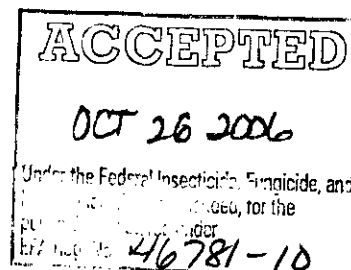
For product or technical information, contact Metrex Customer Care at **800-841-1428** or visit our website at **www.metrex.com**.

EPA Reg. No. 46781-10

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

Reorder No: 00-0000

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



[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.

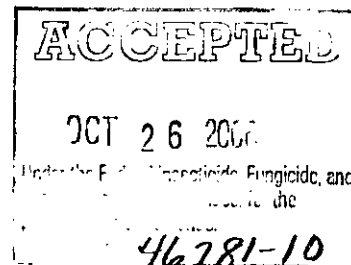
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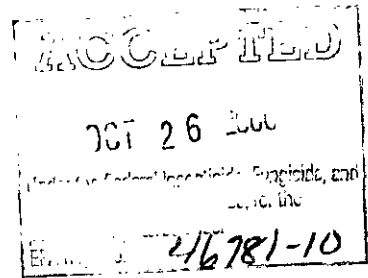
Reorder No: 00-0000

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



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

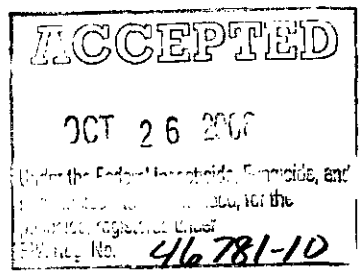
Chemically Treated Solid Non-Infectious Medical Waste



[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
(≤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 x 100 = "C" (Estimate of total percent blood in canister):
Example:

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

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

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.

