

✓ 1/10/85 - Part Corrected Copy

U.S. ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (WH-567) WASHINGTON, D.C. 20460	EPA REGISTRATION NO. 7078-14	DATE OF ISSUANCE DEC 19 1985
	TERM OF ISSUANCE	
NOTICE OF PESTICIDE: <input checked="" type="checkbox"/> REGISTRATION <input type="checkbox"/> REREGISTRATION (Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)	NAME OF PESTICIDE PRODUCT Cidex *Long-Life, Activated Dialdehyde Solution	
NAME AND ADDRESS OF REGISTRANT (Include ZIP code):  Surgikos, Inc. P.O. Box 130 Arlington, TX 76010  Attn: Walter J. McGuade		
<b>NOTE:</b> Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.		
On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.		
A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.		
Registration is in no way to be construed as an endorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.		
This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) because:		
1. Submitter/cite all data required for registration/reregistration of your product and FIFRA sec. 3(c)(7) when the Agency requires all registrants of similar products to submit such data.		
2. This labeling changes listed below before you release the product for shipment:		
a. Change name "20% Registration No. 7078-14".		
b. Add the instruction for negative control to specify <u>10 minutes</u> at <u>20°C</u> .		
c. Add the directions for efficacy against <u>M. tuberculosis</u> by adding the statement "before immersion, check and insure that solution temperature is 20°C".		
d. Add the instruction for sterilization to specify <u>10 hours</u> at <u>20°C</u> .		
e. Add the instruction "Do not use activated solution beyond <u>28 days</u> ".		
<input checked="" type="checkbox"/> ATTACHMENT IS APPLICABLE		
SIGNATURE OF APPROVING OFFICIAL		DATE



3/11  
3. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure for a further description of final printed labeling.

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

A stamped copy of the label is enclosed for your records.

Sincerely yours,

John H. Lee  
Product Manager (31)  
Disinfectants Branch  
Registration Division (TS-767C)

Enclosure

FRONT PANEL

Reorder Number

2785

Active Ingredients

Glutaraldehyde .....3.2%  
Inert Ingredients...96.8%  
Total.....100.0%

Sterilizing and Disinfecting Solution

Rapid-Acting/Non-Staining/Non-Rusting  
Sporicidal                   Tuberculocidal  
Virucidal+                   Bactericidal  
Fungicidal                   Pseudomonacidal

ESPECIALLY FORMULATED FOR REUSE

CIDEX\* Long-Life Activated  
Dialdehyde Solution

Keep out of reach of children.

DANGER: See right side panel for precautions

+ See Directions for Use

SURGIKOS

Note - Attached vial  
contents must be added  
to solution before this  
product is effective.  
See Directions for Activating.

EPA Reg. No. 7078-14  
EPA Est. No. 36126-PR-1

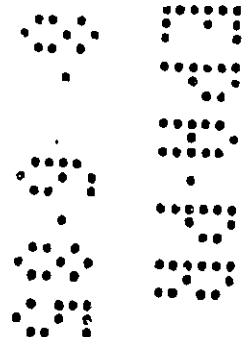
\*Trademark © SURGIKOS 1985

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

DEC 19 1985

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.

7078-14



LEFT PANEL

For complete sterilization or disinfection of medical instruments and equipment, thoroughly clean, rinse and rough dry objects before immersing in CIDEX\* Long-Life Solution. Cleanse and rinse the lumens of hollow instruments before filling with CIDEX Long-Life Solution.

Directions for Activating

Add contents of attached vial to this container of CIDEX Fluid. Shake, solution is ready to use. When activated, solution changes color to green.

In addition to the standard bioburden challenge, this product has also demonstrated efficacy in the presence of 2% organic soil contamination during reuse. This solution may be used and reused for up to 28 days after activation. Efficacy of this product during its use-life can be verified by the CIDEX Long-Life Activated Dialdehyde Solution Effectiveness Test Kit.

Directions for Use

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

For repeated use in manual (bucket and tray) systems.

**Disinfection:** Immerse completely for a minimum of 10 minutes to destroy vegetative organisms including Psuedomonas aeruginosa, pathogenic fungi, and viruses (Poliovirus Type I, Adenovirus Type 2; Herpes simplex Type 1, 2; Influenza Type A [WS/33]; Vaccinia; Coronavirus, Cytomegalovirus; Rhinovirus Type 14; Coxsackievirus B-1) on inanimate surfaces. Immerse completely for a minimum of 20 minutes at 25°C to destroy Mycobacterium tuberculosis on inanimate surfaces. Remove equipment from the solution and rinse thoroughly.

**Sterilization:** Immerse equipment completely for a minimum of 10 hours to destroy resistant pathogenic spores including Clostridium sporogenes and Bacillus subtilis. Remove equipment from the solution using sterile technique and rinse thoroughly with sterile water.

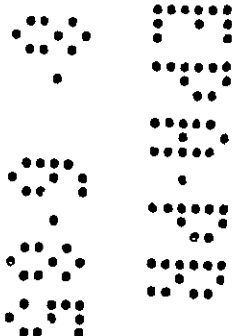
Distributed by  
SURGIKOS  
SURGIKOS, INC., Arlington, Texas 76010

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Under the Federal Insecticide,  
Fungicide and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.

7078-14



FRONT

Activator for use with

CIDEX\* Long-Life Activated  
Dialdehyde Solution

BACK

Danger: Contact with eyes causes damage. In case of contact with eyes, flush with water immediately and get medical attention. For skin contact, flush thoroughly with water.

**Disposal:**

Rinse empty container thoroughly with water and discard it.

Content (158 grams)

Made in U.S.A.

Pat. No.

Control Number on Bottom

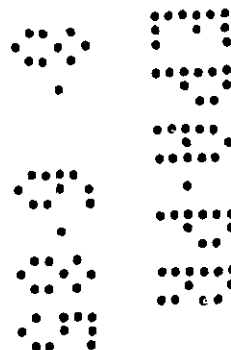
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Arlington, Texas 76010  
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Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.

7028-14



RIGHT PANEL

Precautionary Statements

Danger:

HAZARD TO HUMANS

FOLLOW ALL LABEL DIRECTIONS

Prevent contact with eyes by using eye protection when handling or pouring.

EYES - Corrosive, causes eye damage. Do not get in eyes. In case of contact flush water immediately and get medical attention.

INGESTION - Harmful if swallowed. Avoid contamination of food.

INHALATION - Avoid spillage. Use in a well ventilated area.

SKIN - Avoid skin contact, as possibility of sensitization exists. Can cause skin irritation. For skin contact, wash thoroughly with water. Get medical attention if irritation occurs.

STORAGE AND DISPOSAL

Keep in a cool place. Triple rinse empty container with water and dispose in an incinerator or landfill approved for pesticide containers or bury in a safe place.

Content One Gal. (128 Fluid Oz.)

Made in U.S.A.

Pat. No.

Control Number On Bottom

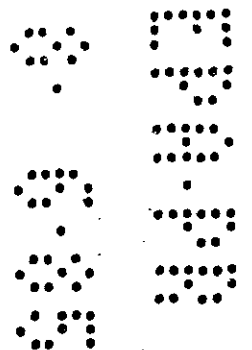
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DEC 19 1985

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.

7078-14



1/1 550 Final Corrected Copy

<b>U.S. ENVIRONMENTAL PROTECTION AGENCY</b> <b>OFFICE OF PESTICIDES PROGRAMS</b> <b>REGISTRATION DIVISION (WH-567)</b> <b>WASHINGTON, D.C. 20460</b>	<b>EPA REGISTRATION NO.</b> 7078-14	<b>DATE OF ISSUANCE</b> <b>DEC 19 1985</b>
	<b>TERM OF ISSUANCE</b>	
<b>NOTICE OF PESTICIDE:</b> <input checked="" type="checkbox"/> REGISTRATION <input type="checkbox"/> REREGISTRATION <i>(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)</i>	<b>NAME OF PESTICIDE PRODUCT</b> Cidex *Long-Life, Activated Dialdehyde Solution	

**NAME AND ADDRESS OF REGISTRANT (Include ZIP code)**

Surgikos, Inc.   
 P.O. Box 130  
 Arlington, TX 76010  
  
 Attn: Walter J. McQuade

**NOTE:** Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit within 90 days all data required for registration (by registration of your product under FIFRA sec. 3(c)(5)) and the Agency requires all registrants of similar products to submit such data.

2. Make the following changes listed below before you release the product to the consumer:

- Change the "EPA Registration No." to "7078-14".
- Change the instructions for vegetative organisms to specify 10 minutes of contact.
- Revise the directions for efficacy against M. tuberculosis by adding: "Before immersion, check and insure that solution temperature is 20°C".
- Change the instructions for utilization to specify 10 hours at 20°C minimum.
- Change the instructions to "Do not use activated solution beyond 22 days".

ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL

DATE



U.S. ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF PESTICIDES PROGRAMS  
REGISTRATION DIVISION (WH-567)  
WASHINGTON, D.C. 20460

EPA REGISTRATION NO.  
7078-4

DATE OF ISSUANCE

TERM OF ISSUANCE

DEC 19 1985

NOTICE OF PESTICIDE:  REGISTRATION  
 REREGISTRATION

(Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended)

NAME OF PESTICIDE PRODUCT

Cidox Mono-life Activated  
Dichloride Solution

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

Cidox, Inc.  
P.O. Box 130  
Wilmington, N.C. 27610  
   
Attn: Walter L. Adams

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The registrant is hereby notified that the following conditions apply to the registration of this product:

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

2. Make the labeling changes listed below before you release the product shipment:

- Add the phrase "EPA Registration No. 7078-4".
- Expand the directions for vegetative organisms to specify 11 minutes at 20°C or higher.
- Expand the directions for efficacy against M. tuberculosis by adding the statement "before immersion, check and insure that solution temperature is 25°C."
- Expand the directions for sterilization to specify 10 hours at 20°C or higher.
- Restore the statement "Do not use activated solution beyond 28 days".

ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL

DATE

2/1

3. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure for a further description of final printed labeling.

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

A stamped copy of the label is enclosed for your records.

Sincerely yours,

John H. Lee  
Product Manager (31)  
Disinfectants Branch  
Registration Division (TS-767C)

Enclosure

FRONT PANEL

Reorder Number

2785

Active Ingredients

Glutaraldehyde .....3.2%  
Inert Ingredients...96.8%  
Total.....100.0%

Note - Attached vial contents must be added to solution before this product is effective. See Directions for Activating.

EPA Reg. No. 7078-14  
EPA Est. No. 36126-PR-1

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Sterilizing and Disinfecting Solution

Rapid-Acting/Non-Staining/Non-Rusting  
Sporicidal Tuberculocidal  
Virucidal+ Bactericidal  
Fungicidal Pseudomonacidal

ESPECIALLY FORMULATED FOR REUSE

CIDEX\* Long-Life Activated  
Dialdehyde Solution

Keep out of reach of children.

DANGER: See right side panel for precautions

+ See Directions for Use

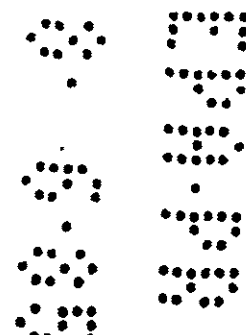
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7078-14



LEFT PANEL

For complete sterilization or disinfection of medical instruments and equipment, thoroughly clean, rinse and rough dry objects before immersing in CIDEX\* Long-Life Solution. Cleanse and rinse the lumens of hollow instruments before filling with CIDEX Long-Life Solution.

Directions for Activating

Add contents of attached vial to this container of CIDEX Fluid. Shake, solution is ready to use. When activated, solution changes color to green.

In addition to the standard bioburden challenge, this product has also demonstrated efficacy in the presence of 2% organic soil contamination during reuse. This solution may be used and reused for up to 28 days after activation. Efficacy of this product during its use-life can be verified by the CIDEX Long-Life Activated Dialdehyde Solution Effectiveness Test Kit.

Directions for Use

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

For repeated use in manual (bucket and tray) systems.

**Disinfection:** Immerse completely for a minimum of 10 minutes to destroy vegetative organisms including Psuedomonas aeruginosa, pathogenic fungi, and viruses (Poliovirus Type I, Adenovirus Type 2; Herpes simplex Type 1, 2; Influenza Type A [WS/33]; Vaccinia; Coronavirus, Cytomegalovirus; Rhinovirus Type 14; Coxsackievirus B-1) on inanimate surfaces. Immerse completely for a minimum of 20 minutes at 25°C to destroy Mycobacterium tuberculosis on inanimate surfaces. Remove equipment from the solution and rinse thoroughly.

**Sterilization:** Immerse equipment completely for a minimum of 10 hours to destroy resistant pathogenic spores including Clostridium sporogenes and Bacillus subtilis. Remove equipment from the solution using sterile technique and rinse thoroughly with sterile water.

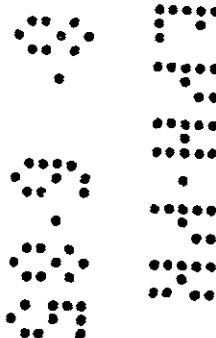
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as amended, for the pesticide  
registered under EPA Reg. No.

7078-14



RIGHT PANEL

Precautionary Statements

Danger:

HAZARD TO HUMANS

FOLLOW ALL LABEL DIRECTIONS

Prevent contact with eyes by using eye protection when handling or pouring.

EYES - Corrosive, causes eye damage. Do not get in eyes. In case of contact flush water immediately and get medical attention.

INGESTION - Harmful if swallowed. Avoid contamination of food.

INHALATION - Avoid spillage. Use in a well ventilated area.

SKIN - Avoid skin contact, as possibility of sensitization exists. Can cause skin irritation. For skin contact, wash thoroughly with water. Get medical attention if irritation occurs.

STORAGE AND DISPOSAL

Keep in a cool place. Triple rinse empty container with water and dispose in an incinerator or landfill approved for pesticide containers or bury in a safe place.

Content One Gal. (128 Fluid Oz.)

Made in U.S.A.

Pat. No.

Control Number On Bottom

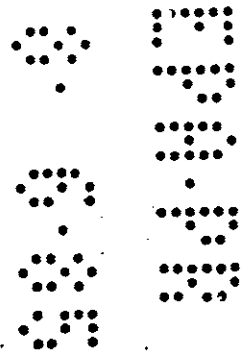
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as amended, for the pesticide  
registered under EPA Reg. No.

7078-14



FRONT

Activator for use with  
CIDEX\* Long-Life Activated  
Dialdehyde Solution

BACK

**Danger:** Contact with eyes causes damage. In case of contact with eyes, flush with water immediately and get medical attention. For skin contact, flush thoroughly with water.

**Disposal:**  
Rinse empty container thoroughly with water and discard it.

Content (158 grams)  
Made in U.S.A.  
Pat. No.  
Control Number on Bottom

SURGIKOS, INC.  
Arlington, Texas 76010  
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