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•		EPA REGISTRATION NO.	DATE OF ISSUANCE
	NVIRONMENTAL PROTECTION AGENCY Fice of pesticides programs	7078-14	<u>NEC 19 1900</u>
1	REGISTRATION DIVISION (WH-567) WASHINGTON, D.C. 20460	TERM OF ISSUANCE	
NOTICE	OF PESTICIDE: REGISTRATION	NAME OF PESTICIDE PRODU	CT
(Ind	The Federal Insecticide, Fungicide,	Cidex *Long-Life Activated Dialdehyde Solution	
•	nd Rodenticide Act, as amended)		
NAME AND AD	DRESS OF REGISTRANT (Include ZIP code)		
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	kos, Inc.		
	BOX 130		
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	of information furnished by the registrant, the Insecticide, Fungicide, and Rodenticide Act.	above named pesticide is here	by Registered/Reregistered unde
A copy of the	e labeling accepted in connection vith this Re	gistration/Reregistration is ret	urned herewith.
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	rdance with the Act. The acceptance of any na be construed as giving the registrant a right to		stration of a product under this
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- U.S. E	NVIRONMENTAL PROTECTION AGENCY	EPA REGISTRATION NO. 7078-4	DATE OF ISSUANCE	
0F	FICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (WH-567) WASHINGTON, D.C. 20460	TERM OF ISSUANCE	<u> </u>	
	_	NAME OF PESTICIDE PRODUCT		
	OF PESTICIDE:	Cidex Mirro-Life Activity		
(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)		(1) aligning solution		
NAME AND AD	DRESS OF REGISTRANT (Include ZIP code)			
F	erikas, Inc.	-1		
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submitted to	ges in labeling formula differing in substance and accepted by the Registration Division pri ys refer to the above U.S. EPA registration nu	or to use of the label in commerc		
	of information furnished by the registrant, the Insecticide, Fungicide, and Rodenticide Act.	e above named pesticide is hereb	by Registered/Reregistered un	
A copy of the	e labeling accepted in connection with this R	egistration/Reregistration is ret	urned herewith.	
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r h ymar	Sumit and $(-c)$ to all data mapping and $(-c)$ to all data mapping (-3) and (-3) and (-3) and (-5) a	(F) when the alling re		
	Make the labeline changes lies	rod below before you a	viense the conduct	
	a. Add the obrase "EPA Penish	ratice No. 7078-0".		
	b. Expand the directions for at <u>20°C or sigher</u> .	volatativ organisme (e specify himitation	
	c. Expand the directions for a the statement "Refore immer temperature is 25°C."			
	d. Expand the directions for or higher.	sterilization to speci	ty 10 hours at 20°C	
	a Pacture the statement "in.	oot use activated solu	tion beyond 28 days	
	C. CHOICE OF STRUCTURE ST			
ATTACH	MENT IS APPLICABLE			

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. f(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 Pranch Registration Division (TS-767C)

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Enclosure

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FRONT PANEL

Reorder Number

2785

Active Ingredients

Glutaraldehyde3.2% Inert Ingredients...<u>96.8%</u> 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

*Trademark @ SURGIKOS 1985

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

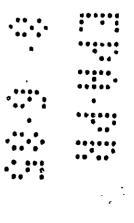
+ See Directions for Use

SURGIKOS

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.



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 <u>used and reused</u> 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 <u>Psuedomonas aeruginosa</u>, pathogenic fungi, and viruses (Poliovirus TypeI, 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 <u>Mycobacterium tuberculosis</u> on inanimate surfaces. Remove equipment from the solution and rinse thoroughly.

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

Distributed by SURGIKOS SURGIKOS, INC., Arlington, Texas 76010 ACCEPTED WILL COMMENTS & BPA Letter Dated

DEC 1 9 1985 Under the Protocol Insecucide, Fungiende and Rodenticule Act as amended, for the pesticide registered under EPA Reg. No.

<u>FRONT</u>

Activator for use with

CIDEX* Long-Life Activated Dialdehyde Solution

<u>BACK</u>

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.

4

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

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SURGIKOS, INC. Arlington, Texas 76010 *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. 707K - 100

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 immrdiately 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

SURGIKOS

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ACCEPTED with COMMENTS in EPA Letter Dated:

DEC 1 9 1985

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

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U.S. ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS	PA REGISTRATION NO. 7078-14 DATE OF ISSUANCE 0 NFC 19 1985		
REGISTRATION DIVISION (#71-567) Washington, d.C. 20460	TERM OF ISSUANCE		
	NAME OF PESTICIDE PRODUCT		
(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)	Cidex *Long-Life Activated Dialdehyde Solution		
NAME AND ADDRESS OF REGISTRANT (Include ZIP code)			
Surgikos, Inc.	コ		
P.O. Box 130			
Arlington, 28 76010			
Attn: Calter J. Scouade			
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	rom that accepted in connection with this registration must be to use of the label in commerce. In any correspondence on th ber.		
On the basis of information furnished by the registrant, the a the Federal Insecticide, Fungicide, and Rodenticide Act.	above named pesticide is hereby Registered/Reregistered under		
A copy of the labeling accepted in connection with this Reg	sistration/Reregistration is returned herewith.		
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	OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (WH-567) WASHINGTON, D.C. 20460	TERM OF ISSUANCE	- ¹ DEC <u>19</u> 198	
NO.	TICE OF PESTICIDE: REGISTRATION	NAME OF PESTICIDE PRODUC	Ť	
	(Under the Federal Insecticide, Fungicide,	ATION Cider Manuality Activity		
	and Rodenticide Act, as amended)			
NAME AN	ID ADDRESS OF REGISTRANT (Include ZIP code)			
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NOTE:	Changes in labeling formula differing in substance f	from that accepted in connection	with this registration must	
submitte	ed to and accepted by ('Registration Division prio always refer to the abs. J.S. EPA registration num	or to use of the label in commerce		
	basis of information furnished by the registrant, the leral Insecticide, Fungicide, and Rodenticide Act.	above named pesticide is hereby	y Registered/Reregistered	
А сору	of the labeling accepted in connection with this Re	gistration/Reregistration is retu	rned herewith.	
-	ation is in no way to be construed as an indorsemen and the environment, the Administrator, on his motio	n, may at any time suspend or ca	ancel the registration of a p	
	accordance with the Act. The acceptance of any nation to be construed as giving the registrant a right to rs.			
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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. f(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 Pranch Registration Division (TS-767C)

Enclosure

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FRONT PANEL

Reorder Number

2785

の日本を読むすべきの言語

Active Ingredients

Glutaraldehyde3.2% Inert Ingredients...<u>96.8%</u> Total.....100.0%

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

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

*Trademark @ SURGIKOS 1985

SURGIKOS

ACCEPTED With COMMENTS

DEC 19 1985

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

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 <u>used and reused</u> 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 <u>Psuedomonas aeruginosa</u>, pathogenic fungi, and viruses (Poliovirus TypeI, 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 <u>Mycobacterium tuberculosis</u> on inanimate surfaces. Remove equipment from the solution and rinse thoroughly.

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

Distributed by SURGIKOS SURGIKOS, INC., Arlington, Texas 76010 ACCEPTED WILL COMMENTS & EPA Letter Daved:

DEC 1 9 1985

Under the Follow Insecticide, Fungicide, site Redestande Act as anneaded, for the pesticule registered under EPA Reg. Na.

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. Contro! Number On Bottom

SURGIKOS

ACCEPTED with COMMENTS in EPA Letter Dated:

DEC 1 9 1985

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

<u>FRONT</u>

Activator for use with

CIDEX* Long-Life Activated Dialdehyde Solution

<u>BACK</u>

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.

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

> SURGIKOS, INC. Arlington, Texas 76010 *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. 707 K - 10