

Surgikos, Inc.
P.O. Box 130
Arlington, TX 76010



FEB - 6 1989

Attention: Walter J. McQuade

Gentlemen:

Subject: Cidex Plus 28 Day Solution Section II
EPA Registration No. 7078-14
Your Amended Application Dated March 14, 1988

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling.
 - a. Refer to the enclosed Efficacy Evaluation and Technical Efficacy Review - II, and revise your labeling in accordance with the labeling comments outlined there.
 - b. Refer to the enclosed document "Label Requirements for Antimicrobial Pesticides Used on Hard Surfaces Against HIV-1 (AIDS Virus)" for EPA's current labeling policy for efficacy claims. Your labeling must be revised in accordance with the requirements outlined in this policy notice.
 - c. Revise the referral statement to read:

See right side panel for additional precautionary statements.
 - d. Delete the term "General Classification" from the label.
 - e. Revise the statement "Hazards to Humans" to read "Hazards to Humans and Domestic Animals."
 - f. Refer to the PR Notice 83-3 for the appropriate storage and disposal statements.

54701:I:Leavy:LL-07:KENCO:12/20/88:02/03/89:aw:VO:EK:AS

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

2016


-2-

2. Submit five (5) copies of your final printed labeling before you release the product for shipment.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

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

Sincerely yours,

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

Enclosures

Reorder No.
2785

Sterilizing and Disinfecting Solution

Rapid-Acting / Non-Staining / Non-Rusting

Sporicidal
Virucidal†
Fungicidal

Tuberculocidal
Bactericidal
Pseudomonacidal

ESPECIALLY FORMULATED FOR REUSE

Cidexplus*

28 day solution

PA REG. No. 7078-14
EPA EST. No. 36126-PR-1

Active Ingredient	
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.

Keep out of reach of children.

DANGER: See right side panel for precautions

† See Directions for Use

*TRADEMARK

SURGIKOS

ACCEPTED
with COMMENTS
in EPA Letter Dated:

FEB - 6 1989

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

7078-14

BEST AVAILABLE COPY

4076

For complete sterilization or disinfection of medical instruments and equipment, thoroughly clean, rinse and rough dry objects before immersing in CIDEX PLUS® 28 Day Solution. Cleanse and rinse the lumens of hollow instruments before filling with this solution.

DIRECTIONS FOR ACTIVATING:

Add contents of attached vial to this container. 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. Do not use activated solution beyond 28 days. Efficacy of this product during its use-life can be verified by the CIDEX PLUS 28 Day Solution Effectiveness Test Kit.

DIRECTIONS FOR USE:

General Classification: 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.

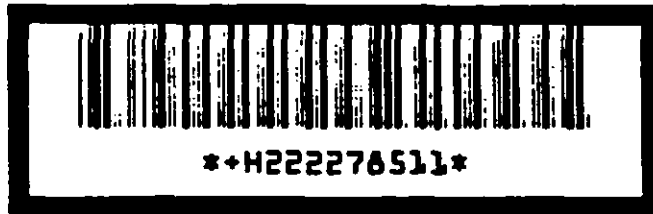
Disinfection: Immerse completely for a minimum of 10 minutes at 20°C or higher to destroy vegetative organisms including *Pseudomonas aeruginosa*, pathogenic fungi, and viruses (Poliovirus Type 1, Adenovirus Type 2; Herpes simplex Type 1, 2; Influenza Type A (WSN/33); Vaccinia; Coronavirus, Cytomegalovirus; Rhinovirus Type 14; Coxsackievirus B-1) on inanimate surfaces. To destroy *Mycobacterium tuberculosis* on inanimate surfaces, check and insure that solution temperature is 25°C, before immersing completely for a minimum of 20 minutes. Remove equipment from the solution and rinse thoroughly.

Sterilization: Immerse equipment completely for a minimum of 10 hours at 20°C or higher 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.

Add: HIV-1; (to be added after Herpes Simplex Type 1,2;)

NOTE DATES HERE

MOONG DATE _____ EXPIRATION DATE _____



DISTRIBUTED BY:

SURGIKOS

a Johnson & Johnson company

SURGIKOS, INC., ARLINGTON, TEXAS 76010

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ACCEPTED
with COMMENTS
in EPA Letter Dated:



FEB - 6 1989

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

7678-14



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Soft

**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 with water immediately and get medical attention.

Ingestion — Harmful if swallowed. Avoid contamination of food.

Inhalation — Avoid splage. Use in 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.

Especially recommended for sterilization or disinfection of . . .

Rubber, most plastic**, glass or metallic objects or instruments such as: anesthesia and respiratory therapy equipment, nonlensed surgical instruments and thermometers.

CONTENTS ONE GAL (128 FLUID OZ.)
MADE IN U.S.A.
PAT. NO. 4,435,754
CONTROL NUMBER ON BOTTOM
2785 C1-2

SURGIKOS

**Use with polycarbonate plastics
could cause equipment failure.

CIDEX PLUS 1 GAL.

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in EPA Letter Dated:

FEB - 6 1989

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

7028-1.4

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6066

Cidexplus*

28 day solution

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.

Activator Vial

For Use With One Gallon Container CIDEX PLUS
28 Day

NET CONTENTS: 158 GRAMS
MADE IN U.S.A.
PAT. NO. 4,438,754
CONTROL NUMBER ON BOTTOM

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SURGIKOS, INC., ARLINGTON, TEXAS 76010
2785 V10 © SURGIKOS 1988

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ACCEPTED
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in EPA Letter Dated:

[REDACTED]

FEB - 6 1989

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
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7078-14



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