

15 OCT 1984

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

Attn: Mr. W.J. McQuade

Subject: Cidex Formula 7\* Long-Life Activated  
Dialdehyde Solution  
EPA Reg. No. 7078-4  
Submission dated September 6, 1984

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable, and a stamped copy is enclosed for your records.

However, clarification is required for the discrepancies between the glutaraldehyde concentrations reported for the two lots of solution of this product after 14 days reuse in the "Cidematic" machine. The cover letter dated 9/6/84 reports the values for the two lots as 1.05% and 1.04%, respectively; whereas the submitted "Enclosure 1 - Test Kit Description" reports the values as 1.05% and 1.07%, respectively.

If all "Cidematic" machines used with this product are modified with new timers and heaters for achieving the longer contact time higher temperature necessary for tuberculocidal activity, as stated in your letter of 9/21/84, special label directions to achieve these conditions would not be required. In lieu of this, special label directions in this regard would be required, as stated in the previous review.

Sincerely yours,



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

Enclosure

Enclosure 3

Front Panel

Reorder Number

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Active Ingredients

Glutaraldehyde ... 2.0%  
Inert Ingredients... 98.0%  
Total.....100.0%

Contains Sodium Nitrite  
as a corrosion inhibitor

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

EPA Reg. No. 7078-4  
EPA Est. No. 36126-PR-1

\*Trademark

**REUSABLE**

Sterilizing and Disinfecting Solution

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

CIDEX FORMULA 7\* Long-Life Activated  
Dialdehyde Solution

Keep out of reach of children.

**DANGER:** See right side panel for  
precautions

† See Directions for Use

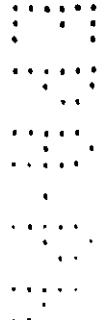
SURGIKOS

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

OCT 15 1984

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

7078-4



Left Panel

For complete sterilization or disinfection of medical instruments and equipment, thoroughly clean, rinse and rough dry objects before immersing in CIDEX FORMULA 7\* Long-Life Activated Dialdehyde Solution. Cleanse and rinse the lumens of hollow instruments before filling with CIDEX FORMULA 7 Solution.

**DIRECTIONS FOR ACTIVATING**

Add contents of attached vial to this container of CIDEX FORMULA 7 Solution. Shake, solution is ready to use. When activated, solution changes color to green.

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 FORMULA 7 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 to destroy vegetative organisms and pathogenic fungi, Pseudomonas aeruginosa and viruses (Poliovirus type 1; adenovirus type 2; Herpes simplex type 1,2; Influenza type A(WS/33); Vaccina; Coronavirus; Cytomegalovirus; Rhinovirus type 14; Coxsackievirus B-1) on inanimate surfaces. For Mycobacterium tuberculosis, CIDEX FORMULA 7 Solution destroys 98.4% in 10 minutes and 100% in 90 minutes at 25°C on inanimate surfaces. Remove equipment from CIDEX FORMULA 7 Solution and rinse thoroughly.

**Sterilization:** Immerse equipment completely for a minimum of 10 hours to destroy resistant pathogenic spores as represented by Clostridium sporogenes and Bacillus subtilis. Remove equipment from CIDEX FORMULA 7 Solution using sterile technique and rinse thoroughly with sterile water.

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

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Right Panel

**Precautionary Statements**

**Danger:**

**HAZARD TO HUMANS**

**FOLLOW ALL LABEL DIRECTIONS**

**Eyes - Contact with eyes causes damage. In case of contact, flush with water immediately and get medical attention.**

**Ingestion - Avoid contamination of food. Harmful if swallowed.**

**Inhalation - Use in ventilated area.**

**Skin - Avoid skin contact, as possibility of sensitization exists. May cause skin irritation. For skin contact, flush thoroughly with water.**

**Especially recommended for sterilization or disinfection of ...**

Anesthesia equipment

Rubber objects

Respiratory therapy equipment

Plastic objects

Metallic equipment or instruments

Thermometers

**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.**

**Control Number on Bottom**

**SURGIKOS**

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Front

Activator for use with

CIDEX FORMULA 7\* 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.

Control Number On Bottom

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