

SEP 17 1991

Johnson & Johnson Medical, Inc.
2500 Arbrook Boulevard
P.O. Box 130
Arlington, TX 76004-0130

Attention: T.M. Wendt, Ph.D.

Gentlemen:

Subject: Cidex Automatic Machine Disinfecting Solution
EPA Registration No. 7078-5
Your Amendment Dated May 24, 1991

The amendment referred to above, submitted in connection with registration under FIFRA, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:
 - a. Revise the entire precautionary section on the Pesticide Label to read:

**Precautionary Statements
Hazards To Humans and Domestic Animals**

Danger. Corrosive. Causes eye damage and skin irritation. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Use in ventilated area. Causes skin sensitization. Harmful if swallowed.

BEST AVAILABLE COPY

56394; I:WP5.0:DeLaney;C.Disk;KEVRIC;09/06/91;CL;WO;DD;CL

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Statement of Practical Treatment

In case of contact with eyes, immediately flush with water and get medical attention. For skin contact, thoroughly flush with water. If swallowed, drink promptly a large quantity of water. Call a physician. Avoid alcohol.

- b. On the activator's label, revise the precautionary statement to read:

In case of contact with eyes, immediately flush with water, and get medical attention. For skin contact, thoroughly flush with water.


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

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 bearing the amended labeling constitutes acceptance of these conditions.

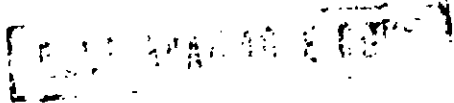
A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Martha DeLaney at (703) 557-6982.

Sincerely yours,

John H. Lee 
Product Manager (31)
Antimicrobial Program Branch
Registration Division (H7505C)

Enclosures



PH31 7078-5

REUSEABLE CUP

Scale: 100% Size: 9.5425 LF x 5 Disk: 2765 CIDEX* C1-6 Job # 17130 1/28/91 Pierce-Davis & Associates
Colors: PMS 137 ORANGE- PMS 113 yellow, Process Black (equiv.) LOGOS-LEGAL PRINT BLACK

For complete disinfection of medical instruments and equipment, thoroughly clean, rinse and rough dry objects before immersing in CIDEX* Automatic Machine Disinfecting Solution. Cleanse and rinse the lumens of hollow instruments before filling with CIDEX Automatic Machine Disinfecting Solution.

Re 2

0.

DIRECTIONS FOR ACTIVATION:

1. Dilute contents of the three (3) 1-gallon containers of CIDEX Automatic Machine Disinfecting Solution Concentrate with twelve (12) gallons of cold tap water.
2. Add contents of 1/2-gallon container of Activator to solution.
3. Mix. When activated, CIDEX Automatic Machine Disinfecting Solution changes color to yellow and is ready to use.

This solution may be used and reused for up to 14 days after activation. Do not use activated solution beyond 14 days. Efficacy of this product can be verified by the CIDEX Automatic Machine Solution Effectiveness Test Kit.

DIRECTIONS FOR USE:

1. It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
1. Follow directions for use of your CIDEMATIC* Decontamination Machine.
2. Do not use until Directions for Activation have been followed.

Disinfection: Immerse completely for a minimum of 10 minutes at 20°C to destroy vegetative organisms including *Pseudomonas aeruginosa*, pathogenic fungi, and viruses (Poliovirus Type 1; Influenza Type A₁; [Hong Kong]; Herpes simplex Type 1) on inanimate surfaces. For *Mycobacterium tuberculosis*, CIDEX Automatic Machine Disinfecting Solution destroys 99.9% in 10 minutes and 100% in 45 minutes at 30°C on inanimate surfaces. Remove equipment from CIDEX Automatic Machine Disinfecting Solution and rinse thoroughly.

REUSABLE

Activated Dialdehyde Disinfecting Solution

Rapid-acting / Non-staining / Non-rusting

Virucidal†	Tuberculocidal	Pseudomonacidal
Fungicidal	Bactericidal	

ESPECIALLY RECOMMENDED FOR REPEATED USE IN THE CIDEMATIC* Decontamination Machine

CONCENTRATE

Cidex*

automatic machine disinfecting solution

Active Ingredient	12.0%
Other Ingredients	88.0%
Total	100.0%

20765 — Contains all essential information for safe use of this product. See Directions for Activation. Contains Safety Alerts as a separate EPA 829. No. 2076-2 EPA 829. No. 2076-1-1

Keep out of reach of children. **DANGER:** See right side panel for additional precautionary statements.

12oz. Directions for Use
*Weight basis
CONTENTS ONE GAL. (128 FLUID OZ.)

Johnson & Johnson MEDICAL

ACCEPTED with COMMENTS to EPA Letter Request

SEP 17 1991
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 7078-5

*Trade dress.

BEST AVAILABLE COPY

SIZE 1000 ALL BLACK including logo ESK: 27071-3 Address for CIDEX CONCENTRATE 2705 (3-GALLON CONTAINER) JOB 1700 12/1/89 PERCE DAVIS & ASSOCIATES

Reorder No. 2705

ACTIVATOR

For Use With 3-One Gallon CIDEX Automatic Machine
Disinfecting Solution Concentrate Only

CONCENTRATE

Cidex*

automatic machine disinfecting solution

NET CONTENTS: 2350 GRAMS

*Trademark

DIRECTIONS FOR ACTIVATION:

1. DILUTE contents of the three (3) 1-gallon containers of CIDEX Automatic Machine Disinfecting Solution Concentrate with twelve (12) gallons of cold tap water.
2. Add contents of this container of activator to solution.
3. Mix. When activated, CIDEX Automatic Machine Disinfecting Solution changes color to yellow and is ready to use.

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 prior to discarding.

CONTAIN BLASTERS ON CARTON

Manufactured by:

**Johnson & Johnson
MEDICAL INC.**

PLANNED TO BE PHASED OUT
MADE IN U.S.A. ESK 27071-3
*Trademark © J&J, Inc. 1989

**ACCEPTED
with COMMENTS
in EPA Letter Dated:**

SEP 17 1991
Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
7078-5