

JAN 02 1987

Union Carbide Corporation
Specialty Chemicals Division
P.O. Box 670
Bound Brook, NJ 08805

Attention: Joan E. Young

Gentlemen:

Subject: UCARCIDE® 602 Sterilizing & Disinfection Solution
EPA Registration No. 10352-29
Your Amendment Application Dated November 26, 1986

The amendment referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable provided that you:

1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 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 for shipment bearing the amended labeling:
 - a. On the right panel under Disinfection, the first three pathogens must be in the same type as are on your last accepted label.
 - b. On the right panel, the first letter in the word Mycobacterium must be capitalized.
 - c. On the right panel, add an asterisk after the word viruses.
3. Submit five (5) copies of your final printed labeling before you release the product for shipment.

90176:Lee:L-13:KENCO:12/23/86:1/7/87:de:vo

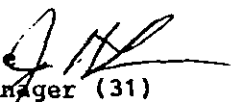
CONCURRENCES

SYMBOL ▶							
SURNAME ▶							
DATE ▶							

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

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EPA

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS

DANGER

KEEP OUT OF REACH OF CHILDREN

Corrosive- Causes irreversible eye damage. May cause skin sensitization. Do not get in eyes, on skin or on clothing. Wear goggles, protective clothing, and rubber gloves. Avoid Breathing Vapors. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

ACCEPTED
WITH COMMENTS
in EPA Letter Dated:

JAN 02 1987

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
10352-29

ENVIRONMENTAL HAZARDS

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

STORAGE AND DISPOSAL

DO NOT REUSE EMPTY CONTAINER (BOTTLES, CANS, BUCKETS)
WRAP CONTAINER AND PLACE IN TRASH



Sterilizing and Disinfectant

A RAPID-ACTING SOLUTION FOR DISINFECTION AND STERILIZATION OF SURFACES AND DENTAL INSTRUMENTS. RESPIRATORY THERAPY

Broad Spectrum Antimicrobial
Sporicidal • Pseudomonacidal •
Bactericidal • Tuberculocidal •

Active Ingredient: Glutalaldehyde
Inert Ingredients

KEEP OUT OF REACH OF CHILDREN

DANGER

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Immediately flush with plenty of water for at least 15 minutes.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.
IF SWALLOWED: DO NOT INDUCE VOMITING. Give at least two glasses of water. Seek medical advice with urgency.
IF INHALED: Remove to fresh air. If breathing is difficult, administer artificial respiration.
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of certain drugs.

Danbury CT 06817 • Offices in Principal Cities
EPA Reg No. 10352-29
UCARCIDE is a registered trade mark
of Union Carbide Corporation

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DIRECTIONS FOR USE

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

DIRECTIONS FOR ACTIVATING

THE ATTACHED ACTIVATOR VIAL MUST BE ADDED
TO THE SOLUTION BEFORE THE PRODUCT IS EFFECTIVE

Add entire contents of attached activator package to this container of UCARCIDE 602 solution. Mix well. Do not dilute UCARCIDE 602 solution. It is now green and ready for use. The shelf life of the activated, unused stock solution is efficacious for 28 days.

For disinfecting or sterilizing medical instruments and equipment, thoroughly clean, rinse and rough dry items before immersing in full strength activated UCARCIDE 602 solution. Flush and lift cleansed lumen of any tubular instrument. Surfactant action will facilitate penetration into hard-to-reach areas.

Disinfection: Immerse item completely for a minimum of 10 minutes at room temperature to destroy vegetative pathogens including Mycobacterium tuberculosis, Pseudomonas aeruginosa and viruses (Coxsackie virus Type B-1, Herpes Simplex Type 1, Influenza Type A 2 (Hong Kong), Poliovirus Type 1) on inanimate surfaces.

Sterilization: Immerse item completely for a minimum of 10 hours at room temperature to destroy resistant bacterial spores including Clostridium sporogenes and Bacillus subtilis.

Remove items from UCARCIDE 602 solution using aseptic technique and rinse thoroughly with sterile water. Discard the used portion of the solution after each day's usage.

LIMITED WARRANTY AND DISCLAIMER

The manufacturer warrants (a) that this product conforms to the chemical description on the label, (b) that this product is reasonably fit for the purposes set forth in the directions for use when it is used in accordance with such direction, and (c) that the directions, warnings and other statements on this label are based upon responsible experts' evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. THE MANUFACTURER NEITHER MAKES NOR INTENDS NOR DOES IT AUTHORIZE ANY AGENT OR REPRESENTATIVE TO MAKE ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, AND IT EXPRESSLY EXCLUDES AND DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. This warranty does not extend to, and the Buyer shall be solely responsible for, any and all loss or damage which results from the use of this product in any manner which is inconsistent with the label directions, warnings or cautions.

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