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 constitutes acceptance of these conditions.

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

Sincerely yours,

John H. Lee

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

Enclosures

OMNICIDE™

STERILIZING and DISINFECTING SOLUTION ACTIVATOR

Front panel

DIRECTIONS:

Add contents of this envelope to 1 gallon bottle of Omnicide — shake. Activated solution will be blue

CONTENTS:
57 Grams

ACTIVATOR

To be added to Omnicide 1 gallon container.

DANGER:

Avoid contact with eyes. In case of contact flush with water immediately and get medical attention. Avoid skin contact. For skin contact flush thoroughly with water. Harmful if swallowed. Avoid food contact. Discard empty container.

back panel

AMERICAN DENTAL MANUFACTURING
MEDICAL DIVISION
2800 Reserve
Missoula, Montana 59801

E

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

DIRECTIONS FOR ACTIVATION AND USE:

To activate solution — add contents of small bag to this one gallon container — recap — shake. Activated solution changes color to blue. Do not dilute.

KEEP GERMICIDE COVERED IN STORAGE OR USE & STORE IN A COOL PLACE.

Always clean away excess organic debris, rinse and rough dry instruments or equipment before immersion.

FOR DISINFECTION:

Immerse articles for a minimum of 10 minutes to destroy vegetative pathogens including — *Escherichia coli* 0113, *Staphylococcus aureus*, *Salmonella typhosa*, *Pseudomonas aeruginosa*, *Mycobacterium tuberculosis* (if tuberculosis contamination is suspected, increase immersion time to 20 minutes for added safety), fungi including — *Trichophyton interdigitale*, viruses including — Herpes simplex virus types 1 & 2, Polio virus types 1 & 2, Vaccinia virus, Influenza virus types A1 (New Jersey) and B (Maryland). The ability of this product to destroy the etiologic agent for viral hepatitis has not been established or demonstrated.

Rinse articles thoroughly with sterile water after disinfection or sterilization.

For Complete Sterilization — to destroy resistant pathogenic spores including — *Bacillus subtilis* and *Clostridium sporogenes* — immerse articles for minimum of 10 hours. Remove instruments using sterile technique and rinse thoroughly in sterile water.

E.P.A. Establishment No. 46851-MT-01

E.P.A. Registration No. 46851-

Contents: 1 gallon (128 fluid oz.)

BEST DO

OMNIC

STERILIZING and DISINFE

for Medical and Dental Instruments

28 Day Activated Dila

- Sporicidal
- Tuberculocidal
- Virucidal*
- Bactericidal

Non-Rusting *Complete Sterila*

* Influenza virus types A1 (New Jersey) and B (M virus types 1 and 2, Polio virus types 1 and

AVAILABLE

KEEP OUT OF REACH OF CHILDREN

DANGER:

Manufactured & Distributed by: **ADM MEDICAL DIV**

NICIDE™

and DISINFECTING SOLUTION

Medical and Dental Instruments and Equipment

30 Day Activated Dialdehyde

- Virucidal*
- Bactericidal
- Fungicidal
- Pseudomonacidal

Complete Sterilant *Pleasant Fragrance*

* types A1 (New Jersey) and B (Maryland), Herpes Simplex 1 and 2, Polio virus types 1 and 2 and vaccinia virus.

CHILDREN

Active Ingredient	
Glutaraldehyde	2.0%
Inert Ingredients	98.0%
Total	100.0%

ODM MEDICAL DIVISION 2800 Reserve, Missoula MT 59801

Recommended for Disinfection or Sterilization of . . .
MEDICAL and DENTAL INSTRUMENTS, CARBON STEEL CUTTING INSTRUMENTS, BURS, ALUMINUM, GLASS, PLASTIC or RUBBER ARTICLES, THERMOMETERS, MIRRORS, RESPIRATORY EQUIPMENT

DANGER:

Harmful if swallowed. Avoid Skin Contact — Gloves recommended to prevent skin contact and possible sensitization. If contact occurs, flush with water

CONTACT WITH EYES — CAUSES DAMAGE.

If contact occurs, flush with water immediately and get medical attention

INHALATION OF FUMES

Should be held to a minimum by using Omnicide only in well ventilated areas and by using containers which can be tightly closed during use or storage of solution.

PRECAUTIONS:

All instruments and devices must be thoroughly cleaned to remove excess organic debris, rinsed and rough dried before immersion in Omnicide. Hypodermic needles cannot be effectively disinfected or sterilized with Omnicide.

OMNICIDE HAS A 28-DAY SHELF LIFE AFTER ACTIVATION.

Discard daily or sooner if solution becomes soiled or diluted.

All labeling claims of effectiveness are based on previously unused batches of product

STORE IN A COOL PLACE

Dating Record

ACTIVATED _____ **EXPIRATION** _____

Rinse empty containers thoroughly with water before discarding.

Keep out of Reach of Children

DANGER:

See side panel for additional precautionary statements.

c. Revise the statement:

"...increase immersion time to 20 minutes for added safety..."

to read (left panel only): "...increase immersion time to 20 minutes."

Implied safety claims are unacceptable as set forth in CFR 162.10(a)(5)(ix).

d. Revise the statements:

Store in cool place.

Rinse empty container thoroughly with water before discarding

to read:

STORAGE AND DISPOSAL

STORE IN COOL PLACE

PROHIBITIONS:

Do not contaminate water, food or feed by storage or disposal.
Open dumping is prohibited.
Do not reuse empty container.

PESTICIDE DISPOSAL

Pesticide, spray mixture, or rinse water that cannot be used according to label instructions must be disposed of according to Federal or approved state procedures under Subtitle C of the Resource Conservation and Recovery Act.

CONTAINER DISPOSAL

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by incineration if allowed by state and local authorities.

GENERAL

Consult Federal, state or local disposal authorities for approved alternative procedures.

e. Revise the statement:

Discard daily or sooner if solution becomes soiled or diluted
to read:

Discard daily or sooner if used solution becomes soiled or diluted.

NOTE: This statement should appear on the left panel with the other Directions for Use statements.

f. Revise the statements:

DANGER

Harmful if swallowed. Avoid skin contact - Gloves recommended to prevent skin contact and possible sensitization. If contact occurs, flush with water.

CONTACT WITH EYES - CAUSES DAMAGE

If contact occurs, flush with water immediately and get medical attention.

INHALATION OF FUMES

Should be held to a minimum by using Omnicide only in well ventilated areas and by using containers which can be tightly closed during use or storage of solution.

to read:

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes burns. Causes eye damage and skin irritation. Do not get in eyes, on skin or on clothing. May be absorbed through skin. Wear goggles or face shield and rubber gloves when handling.

HARMFUL IF SWALLOWED. Avoid contact with food. Use in ventilated area. Use containers which can be tightly closed during use or storage of solution.

STATEMENT OF PRACTICAL TREATMENT

Eyes - In case of skin contact, immediately flush thoroughly with water.

Skin - In case of skin contact, immediately flush thoroughly with water.

Ingestion: If swallowed, drink milk, egg whites, gelatin solution or, if these are not available, large quantities of water. Avoid alcohol. Call a physician.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

g. Indicate the major areas in which the product is recommended for use, e.g., hospitals, dental offices, nursing homes, and health care institutions.

3. Make the labeling changes below before you release the product for shipment (activator label only):

a. Add the phrase "EPA Registration Number 46851-2."

b. We prefer you be consistent with the company name as declared on the basic label: ADM Medical Division.

c. Revise the statement:

Discard empty container

to read:

Rinse empty container throughly with water prior to discarding. Do not reuse empty container.

4. 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.