

<p align="center">U.S. ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (WH-567) WASHINGTON, D.C. 20460</p> <p>NOTICE OF PESTICIDE: <input type="checkbox"/> REGISTRATION <input type="checkbox"/> REREISTRATION</p> <p align="center"><i>Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended</i></p>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 2px;">EPA REGISTRATION NO.</td> <td style="width: 50%; padding: 2px;">DATE OF ISSUANCE JUN 29 1989</td> </tr> <tr> <td colspan="2" style="padding: 2px;">TERM OF ISSUANCE</td> </tr> <tr> <td colspan="2" style="padding: 2px;">NAME OF PESTICIDE PRODUCT</td> </tr> </table>	EPA REGISTRATION NO.	DATE OF ISSUANCE JUN 29 1989	TERM OF ISSUANCE		NAME OF PESTICIDE PRODUCT	
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NAME AND ADDRESS OF REGISTRANT (Include ZIP code) <div style="height: 100px; border: 1px solid black; margin-top: 5px;"></div>							
<p>NOTE Changes in labeling, formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.</p> <p>On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.</p> <p>A copy of the label in, accepted in connection with this Registration/Reregistration is returned herewith.</p> <p>Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</p> <div style="height: 150px; border: 1px solid black; margin-top: 10px;"></div>							
<div style="text-align: right; margin-bottom: 20px;"> BEST AVAILABLE COPY </div> <p>_____ SPECIAL AGENT IN CHARGE REGISTRATION DIVISION U.S. ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460</p> <p>_____ DATE</p>							
<p>_____ SIGNATURE OF APPROVING OFFICIAL</p> <p>_____ DATE</p>							

1. Change letters for the species "FOV15", "SPOROGENES", and "STREPTOCOCCUS".

2. Change the parameter "room temperature" also specify the exact temperature at which the test was conducted.

3. Change "...equal effect was achieved..." to read "...disinfection was achieved...".

4. Change "HIV" to read "HIV-1 (AIDS virus)".

5. Your labeling must be revised to comply with all of the labeling points included in the enclosed labeling policy notice for HIV efficacy claims.

6. Indicate in your disinfection and sterilization sections that "Fresh solution must be prepared daily or more frequently if the used solution becomes visibly soiled. Discard used solution after each day's use".

7. Delete "non-corrosive" from the label.

8. Delete the sentence "If instruments are not thoroughly cleaned...", and replace it with the sentence "Thoroughly clean and rinse objects prior to immersion."

9. Under the Sanitation section change "For use on all hard surfaces..." to "For use on hard non-porous surfaces...".

10. Under the Sanitization section you must specify how the product is to be applied (by mop, sponge, cloth), and if and how the product is to be removed after the sanitization period.

3. For our records please submit a revised Confidential Statement of Formula for the activated product (buffer + activator). Please combine the exact amount of the buffer confidential formula with the activator confidential formula exactly as they are listed in the separate formulas.

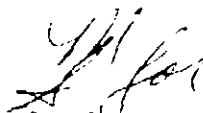
BEST AVAILABLE COPY

4. Submit a copy of your final printed label to the
FDA for review and approval. Label to the 4-74 increase for a further
1.5% increase in the label.

5. 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.

6. Stamped copy of the label is enclosed for your records.

John H. Lee



Product Manager (31)
Antimicrobial Programs Branch
Registration Division (TS-767C)

Buffer Label:**COLD STERILIZING DISINFECTING SOLUTION**

WIPE / 117

LONG-LIFE ACTIVATED DIALDEHYDE

- Fast-acting
- ~~Glutaraldehyde~~ e
- Non-staining
- Safe for scopes
- Non-irritating
- Sporicidal
- Virucidal ~~Glutaraldehyde~~
- ~~Glutaraldehyde~~
- Bactericidal
- Tuberculocidal
- Pseudomonacidal
- Fungicidal

KEEP OUT OF REACH OF CHILDREN**Danger**

May cause Eye Irritation and Skin Sensitization.
See Side Panel for additional precautionary statements.

Active Ingredients (Activator & Buffer):

Glutaraldehyde.....

Phenol.....

Inert Ingredients:.....

0.3%

1.0%

98.7%

ACCEPTED
with COMMENTS
to EPA Letter Dated:

JUN 29 1989

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

Date Activated:Manufactured by:

Health Care Products Inc.
Mississauga, Ont. Canada L4Z 1T5
Boca Raton, Fla. U.S.A. 33438

EPA Registration No:
EPA Establishment No:

Contents When Activated: 128 fl.oz.

Precautionary Statements Hazards to Humans and Domestic Animals

May be harmful if swallowed. If ingested, drink large quantities of water and seek medical attention.

May cause eye irritation. Do not get in the eyes. If eye contact occurs, flush with water and seek medical attention if irritation persists.

Prolonged contact with the skin may cause sensitization. Flush affected area with water and seek medical attention if irritation persists.

Carbonizing of nickel plated instruments may occur due to poor plating or improper cleaning. This indicates instruments should be replaced. Do not immerse instruments over 10 hours in *Wipe Out* solution.

This product is not to be used for the disinfection or sanitization of food preparation equipment or surfaces.

Directions For Use:

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

Carefully add the activator to this container, securely replace the cap and shake the bottle vigorously to assure thorough mixing of the two phases. After activation, the *Wipe Out* solution will maintain 100% efficacy for 45 days. Only the amount needed should be poured from the bottle.

Recommended for use in hospitals, dental clinics, laboratories and nursing homes.

Using test organisms, cidal effect was achieved in 10 minutes against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *typhi*, *Bacillus subtilis*, *M. Bovis*, HIV, *Cl. Sporogenes* and *Trichophyton mentagrophytes*. Cidal effect was achieved in 15 minutes at 20°C against *M. Tuberculosis*.

Storage And Disposal:

Wipe Out solution unactivated may be stored at room temperature for up to two years.

Pesticide Disposal:

Inactivate used *Wipe Out* solution by neutralizing with Sodium Hydroxide. Solution may then be disposed in the waste system.

Container Disposal:

Thoroughly rinse empty container with water and then dispose by incineration or in an approved landfill site.

Sterilization:

Instruments should be thoroughly cleaned prior to immersion. Immerse completely for a minimum of 10 hours to destroy resistant pathogenic spores including: *Cl. sporogenes* and *B. subtilis*. Remove instruments from *Wipe Out* solution, using sterile technique and rinse thoroughly with sterile water.

Disinfection:

Recommended for use on surgical instruments and any object suspected of contamination, save for scopes. Thoroughly clean and rinse objects prior to immersion. *Wipe Out* activated solution may be diluted 1:1 with water. Immerse for minimum of 10 minutes at room temperature to destroy viruses and other pathogens. After disinfection, rinse with sterile water and handle object with a sterile technique. May be reused as a high level disinfecting solution and will maintain 100% efficacy for 45 days.

Sanitization: (Non-food contact surfaces)

For use on all hard surfaces (lab tops, furniture, etc.) which may be suspected of contamination. Wet all surfaces thoroughly and leave wet for a period of 10 minutes for complete sanitization.

Activator Label:**COLD STERILIZING DISINFECTING SOLUTION ACTIVATOR**
(For Use With *Wipe Out* Buffer Solution)**KEEP OUT OF REACH OF CHILDREN****Danger****May cause Eye Irritation and Skin Sensitization.**
See Back Panel for Additional Precautionary Statements.**Active Ingredients (Activator):**

Glutaraldehyde.....	10.2%
Inert Ingredients:.....	89.8%

Manufactured by:**Health Care Products Inc.**
Mississauga, Ont. Canada L4Z 1T5
Boca Raton, Fla. U.S.A. 33438**EPA Registration No:**
EPA Establishment No:**Contents: 4.22 fl.oz.****ACCEPTED**
with COMMENTS
in EPA Letter Dated:**JUN 29 1989****Under the Federal Insecticide,**
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.**58994-1****BEST AVAILABLE COPY**

Precautionary Statements Hazards to Humans and Domestic Animals

Corrosive:

Causes eye and skin irritation. Harmful if swallowed. Do not get into eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Avoid contact with food. Use in ventilated area.

Statement of Practical Treatment:

In case of contact, immediately flush eyes with water for at least 15 minutes. For Eyes: Call a physician. Remove and wash contaminated clothing before reuse. If Swallowed: Drink a large quantity of water. Avoid alcohol. Call a physician immediately. Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Directions For Use:

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

Carefully add the activator to the large Buffer Solution and shake the bottle vigorously to assure thorough mixing of the two phases. After activation, makes 128 fl.oz. of activated Cold Sterilizing Solution.

Storage And Disposal:

Wipe Out activator may be stored at room temperature for up to two years.

Pesticide Disposal:

Inactivate *Wipe Out* solution by neutralizing with Sodium Hydroxide. Solution may then be disposed of in the waste system.

Container Disposal:

Thoroughly rinse empty container with water and then dispose by incineration or in an approved landfill site.

Made In Canada

Printed In Canada

ACCEPTED
with COMMENTS
In EPA Letter Dated:
JUN 29 1984
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.
58-794-1