

<p>US ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (TS 767) WASHINGTON, DC 20460</p> <p><b>NOTICE OF PESTICIDE:</b> <input checked="" type="checkbox"/> REGISTRATION <input type="checkbox"/> REREГИSTRATION</p> <p><i>(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)</i></p>	<p>EPA REGISTRATION NO. <b>65800-1</b></p> <p>TERM OF ISSUANCE</p>	<p>DATE OF ISSUANCE <b>JUL 11 1994</b></p>
<p>NAME OF PESTICIDE PRODUCT <b>PDS</b></p>		
<p>NAME AND ADDRESS OF REGISTRANT (Include ZIP code)</p> <p><input type="checkbox"/> <input type="checkbox"/></p> <p><b>Medical Polymers Inc. Suite 290 8920 Business Park Dr Austin, TX 78759</b></p> <p><input type="checkbox"/> <input type="checkbox"/></p>		
<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 labeling 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> <p><b>This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:</b></p> <ol style="list-style-type: none"> <li>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; and submit acceptable responses required for reregistration of your product under FIFRA section 4.</li> <li>2. Make the labeling changes listed below before you release the product for shipment: <ol style="list-style-type: none"> <li>a. Add the phrase "EPA Registration No. 65800-1".</li> <li>b. Delete the number 65800-R. This is not your registration number.</li> <li>c. Delete the statement: General Classification</li> <li>d. Revise "...when the use solution becomes visibly dirty..." to read: "...when the solution becomes diluted or soiled..."</li> </ol> </li> </ol>		
<p><input checked="" type="checkbox"/> ATTACHMENT IF APPLICABLE</p> <p>SIGNATURE OF APPLICANT (PRINT NAME) _____ DATE _____</p>		

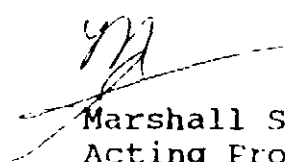
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

- e. Delete the statement: For use by professional and paraprofessional personnel
- f. The headings "Keep Out of Reach of Children" and "Danger" must be adjusted to the correct type size. (Front panel only)
- g. Include the heading: HAZARDS TO HUMANS AND DOMESTIC ANIMALS. Place this statement to appear directly below the heading: Precautionary statements.
- h. Include the appropriate EPA Est No.
- i. Include the reference (Japan) to appear next to the virus Influenza A<sub>2</sub>.
- j. Include the reference asterick \* to appear next to the word: Virucide (center panel only)
- k. Include the appropriate pesticide disposal statement as outlined in the PR Notice 83-3.
- l. Revise the virus HIV to read: HIV-1 thorough out the label. (two locations-left panel)
- m. Add the Note to Phsician Statement to read:  
  
 Note to Physician  
 Probable mucosal damage may contraindicate the use of gastric lavage.
- n. Revise the front panel referral statement to read: See left panel for additional precautionary statements.

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,



Marshall Swindell  
 Acting Product Manager (31)  
 Antimicrobial Program Branch  
 Registration Division (H7505C)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

**PRECAUTIONARY STATEMENTS**

**DANGER**

**KEEP OUT OF REACH OF CHILDREN**

Corrosive. Causes irreversible eye damage. Causes skin burns. Harmful if inhaled. Harmful if swallowed. Harmful if absorbed through skin. May cause skin sensitization.

Do not get in eyes, on skin, on clothing. Avoid breathing vapor. Do not swallow. Wear goggles, protective clothing, and rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

**\*KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings in which the expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS.)

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV OF SURFACES OBJECTS SOILED WITH BLOOD/BODY FLUIDS:**  
**PERSONAL PROTECTION:** Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, mask, or eye covering.  
**CLEANING PROCEDURE:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of the disinfectant.  
**DISPOSAL OF INFECTIOUS MATERIAL:** Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.  
**CONTACT TIME:** Leave surfaces wet for 10 minutes.

**STORAGE AND DISPOSAL**

- 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

ACCEPTED with COMMENTS in EPA Letter Dated JUL 1 1994

**PDS**  
Disinfectant • Cleaner • Lubricant  
Fungicide • Virucide • Bactericide • Pseudomonacide  
with Organic Soil Tolerance  
for Hospital, Institutional  
Industrial, School, Veterinary and Farm Use

Active Ingredient: Glutaraldehyde . . . . . 4.0%  
Inert Ingredients: . . . . . 96.0%

**KEEP OUT OF REACH OF CHILDREN**  
**DANGER**

Statement of Practical Treatment

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. Consult a physician for further treatment. Remove and wash contaminated clothing before reuse.

SEE LEFT PANEL FOR ADDITIONAL PRECAUTION STATEMENTS

EPA Registration No. 65800-R  
EPA Establishment No. 65800  
Net Contents 1 gallon (128 oz.)

MANUFACTURED FOR:  
Medical Polymers Inc., 8920 Business Park  
Drive, Austin, Texas 78759

For use by professional and paraprofessional personnel

DIRECTIONS FOR ACTIVATING  
Add contents of attached vial to this container of PDS solution. Invert several times to mix thoroughly. PDS is activated and ready to use only when solution has change color to blue.

USE IN WELL VENTILATED AREAS

This product is not to be used as a terminal sterilant/high level disinfectant on any surface of instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

**BEST AVAILABLE COPY**

**GENERAL**

It is a violation of Federal regulations to use PDS in a manner inconsistent with its labeling.

Apply PDS with a cloth, and allow surfaces to remain wet for 10 minutes. Rinse with water daily or when the use solution is exhausted.

**Disinfection in Hospitals, Care Institutions.** For disinfection of bathing areas, lavatories, bathrooms, and other hard non-porous surfaces previously cleaned hard surfaces. PDS is effective against Pseudomonas aeruginosa and Salmonella choleraesuis.

**Performance.** Full strength PDS (5% serum and found to be effective against viruses: Herpes simplex type-1, and HIV-1 on surfaces).  
**Disinfection in Institutions.** Full strength PDS is effective against Trichophyton (fungus) when used on surfaces in dressing rooms, shower areas, and other areas utilizing the AOAC Fungicide Test.

**Disinfection of Barber Tools.** Precleaned barber tools (e.g., clippers, scissors) can be disinfected with PDS.

**DISINFECTATION OF POULTRY KENNELS.** Poultry brooder and other animal quarters can be disinfected after thorough cleaning with PDS. Small animal quarters. Prior to disinfection, feeds must be removed and emptied. Remove all litter and appliances. Remove all litter from other surfaces occupied by animals. After disinfection, ventilate spaces. Do not house equipment until treatment is complete.  
**Hospitals as an Instrument.** Instruments with warm water solution daily or sooner if

NET CONTENTS: 9.5 GRAMS  
0.034 OZ.

**Directions for use:** Add contents of this vial to one gallon of PDS [REDACTED] Invert several times before using.

**Disposal:** Rinse empty container thoroughly with water prior to discarding.

Control Number on bottom

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

JUL 1 1994

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
an amendment to the Federal  
registration of such EPA Reg. No.

65800-1

**BEST AVAILABLE COPY**