



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

February 6, 2003

Mr. Steve Cassinis  
Vice President  
**Cottrell International, LLC**  
Cottrell, LTD  
5450 Joliet Street  
Denver, CO 80239

Subject: **ProPhene™**  
EPA Registration No. 46851-11  
Letter Dated December 9, 2002

Dear Mr. Cassinis:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable with comments.

**Proposed Amendment**

- Updated labeling

**Label Comments:**

1. Remove the word "Treatment" from the first aid heading and revise text to read as follows:

**"First Aid"**

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a Poison Control Center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 1-20 minutes. Call Poison Control Center or doctor for treatment advice.

**IF SWALLOWED:** Call a Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told by a Poison Control Center or doctor.

**IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration preferably mouth-to-mouth if possible. Call a Poison Control Center or doctor for further treatment advice.

"In case of emergency call (insert toll-free emergency number if available)."

"Have the product container or label with you when calling a Poison Control Center or doctor or going in for treatment."

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

*For detailed information, refer to PR Notice 2001-1*

2. The Precautionary Statement heading must read as follows:

**Precautionary Statement**  
Hazards to Humans and Domestic Animals  
**Danger**

3. The Agency noticed that the precautionary statement language has been changed from the original label, which was accepted on September 2, 1982. There are no acute toxicity data on file to support the current label language. Therefore, the precautionary statement must be revised to read as follows:

Precautionary Statement  
Hazards to Humans and Domestic Animals

**Danger:** Corrosive. Causes eye damage or skin burns. Fatal if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shields (safety glasses), protective clothing (long-sleeve shirt and long pants, sock, plus shoes and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.


**General Comments**

A stamped copy of the label is enclosed for your records. Submit three (3) copies of the revised final printed label before distributing or selling this product.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,



 Adam Heyward  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

Enclosure

# ProPhene™

## Concentrated Surface Disinfectant and Holding Solution

### Tuberculocidal, Virucidal\*, Bactericidal, Fungicidal

Recommended for use in Hospitals, Medical/Dental Clinics, Nursing Homes, Healthcare Institutions and Veterinary Clinics.

#### Active Ingredients

o-phenylphenol	9.0%
o-benzyl-p-chlorophenol	1.0%
Inert Ingredients	90.0%
Total	100.0%

DIN: 02231481

Lot Number is printed on container.

E.P.A. Reg. No. 46851-11-50611    Contents: 1 Quart  
E.P.A. Est. No. 46851-CO-003    (32 oz. - 946 ml)  
Reorder No. PHENC32

Keep Out of Reach of Children

See Side Panel for Additional Precautionary Statements

PHENC32 FL01

**DANGER:**  
EXTREMELY CORROSIVE



**POISON:**



**DANGER:**  
**EXTREMELY CORROSIVE. POISON. HARMFUL IF ABSORBED THROUGH SKIN.** Contains O-phenylphenol and O-benzyl-p-chlorophenol. Avoid contact with eyes, skin and clothing. Causes eye and skin damage. Do not get in eyes, on skin or on clothing. Wear protective eyewear and rubber gloves when handling. Harmful if swallowed.

**FIRST AID TREATMENT:** If swallowed, give a glass of milk. If splashed in eyes or on skin, flush thoroughly with water. Call physician or poison control center immediately.

**NOTE TO PHYSICIAN**  
Probable mucosal damage may contraindicate the use of gastric lavage.

**STORAGE & DISPOSAL**  
Keep ProPhene covered in storage or use. Do not contaminate water, food or feed by storage or disposal. Do not reuse empty container. Triple rinse container, puncture and dispose of in a sanitary landfill or incinerate. Used disinfectant solutions are toxic. Store, use and dispose of according to label instructions.

#### DIRECTIONS FOR USE

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

Thoroughly clean surface of items to be disinfected and rough dry. ProPhene is a concentrated solution and must be diluted 1:32 with water prior to instrument soak and/or decontamination of dental and medical instruments or disinfection of hard environmental surfaces. This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or 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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

Immerse items in diluted ProPhene solution for instrument soak and/or decontamination of medical and dental instruments. For disinfection of hard environmental surfaces such as walls, floors and countertops, diluted ProPhene should be mopped, sponged, sprayed or wiped in a manner to thoroughly wet the surface. A properly prepared solution of ProPhene intended for use as a hard surface disinfectant, has a shelf life of 60 days (use life) when stored in a closed container such as a spray bottle.

A contact time of 10 minutes at 20°C (68°F) with a 1:32 dilution of ProPhene has been shown to be effective on bacteria including: *Escherichia Coli* O113, *Staphylococcus aureus*, *Salmonella typhosa*, *Pseudomonas aeruginosa*, *Mycobacterium tuberculosis*; fungi including: *Trichophyton mentagrophytes*; viruses\* including Polio virus 1, Coxsackie B2, Influenza virus type A1 (New Jersey) and Influenza B (Maryland), Herpes virus types 1 and 2, Vaccinia virus and HIV-1.

Rinse articles thoroughly following immersion. Discard the used solution daily or sooner if it becomes diluted or soiled.

When diluted as directed, this product is stable. All label claims of effectiveness are based on previously unused batches of ProPhene diluted as directed. Organic material or water introduced into the diluted product in reuse may affect the product's effectiveness.

For use on metals, plastics, rubber and glass. Glass may etch over prolonged or repeated exposure to concentrated solutions. Do not store metal articles in concentrated ProPhene.

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV (Human Immunodeficiency Virus) ON SURFACES OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS.**

**PERSONAL PROTECTION:** When handling items soiled with blood or body fluids or when conducting procedures which might lead to contact with blood or body fluids, always wear items such as disposable latex gloves, gowns, masks and eye coverings.

**CLEANING PROCEDURES:** Blood and 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 local regulations for infectious waste disposal.

#### PRECAUTIONARY STATEMENTS

Hazard to Humans. This product must not be used in hospital nurseries.

MANUFACTURED BY:  
**CERTOL**  
INTERNATIONAL, LLC  
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DENVER, CO 80239 USA  
1 800 THE EDGE  
(1 800 843 3343)

CANADIAN AGENT:  
TRANS CANADA  
DENTAL LTD.  
2891 PORTLAND DRIVE  
OAKVILLE, ONTARIO  
CANADA L6H 3S4  
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<b>TO PREPARE 1:32 USE-DILUTION</b>	
<b>WATER PROPHENE</b>	
To Make 1/2 Liter	
484.38 ml.	15.38 ml.
To Make 1 Liter	
968.75 ml.	31.25 ml.
To Make 1 1/2 Imperial Gallon	
1937.5 ml.	62.5 ml.
To Make 1 Imperial Gallon	
3875.0 ml.	125 ml.



+H816PHEN32S

PHENC32/BL01 11/02

ACCEPTED  
with COMMENTS  
EPA Letter Dated:

FEB - 6 2003

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 46851-11

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