

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 9 2003

Mr. Paul J. Nobrega  
Director, Regulatory Services  
Central Solutions, Inc.  
P.O. Box 15276  
Kansas, KS 66115

Subject: Q4.5-5.OPB-4.5  
EPA Registration No. 211-40  
Application Date: 1/20/03  
Receipt Date: 1/29/03

Dear Mr. Nobrega:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable:

Revision of First Aid Statements to comply with EPA PR Notice 2001-1

**GENERAL COMMENTS**

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Zenobia Jones at (703) 308-6198.

Sincerely,  
*Velma Noble*

Velma Noble  
Product Manager 31  
Regulatory Management Branch 1

CONCURRENTS microbial Division (7510C)

SYMBOL	1510C						
SURNAME	Z. Jones						
DATE	4-9-03						

(Administrative Note: The following text is required for front panel labeling):

# Q4.5-5.0PB-4.5

**DISINFECTANT - DEODORIZER - FUNGICIDE - VIRUCIDE\*  
WHIRLPOOL CLEANER DESIGNED FOR HOSPITAL,  
NURSING HOME, AND INSTITUTIONAL USE**

**Active Ingredients:**

n-Alkyl (60%C<sub>14</sub> , 30%C<sub>16</sub> , 5%C<sub>12</sub> , 5%C<sub>18</sub>) dimethyl benzyl ammonium chlorides....2.25%

n-Alkyl (68%C<sub>12</sub> , 32%C<sub>14</sub> ) dimethyl ethylbenzyl ammonium chlorides.....2.25%

Inert Ingredients:.....95.50%

**Total: 100.00%**

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

**SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS**

**Central Solutions, Inc.**

3130 Brinkerhoff Road  
Kansas City, KS 66115

EPA Reg. No. 211-40  
EPA Est. No. 211-KS-1

NET CONTENTS: X GALLONS

(Administrative Note: The following text is optional on front panel labeling):

Whirlpool Cleaner Designed for Hospital, Nursing Home, and Institutional Use  
Whirlpool Cleaner Designed for Health Care Institutions  
Formulated for Whirlpool Bathing Systems  
Formulated for Hospitals and Long-Term Care Facilities

\*\*Non-Critical Medical Device Uses

**ACCEPTED  
with COMMENTS  
in EPA Letter Dated:**

APR 9 2003

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 211-40

(Side Panel)

(Administrative Note: The following text is required for all labeling):

**PRECAUTIONARY STATEMENTS**

Hazards to Humans and Domestic Animals

**DANGER**

Keep out of reach of children. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear goggles/face shield, rubber gloves, and protective clothing. Harmful if absorbed through skin. Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

<b>FIRST AID</b>	
<b>If in eyes</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with plenty of water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If on skin or clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If inhaled</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>If swallowed</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give any liquid to this person.</li> <li>• Do not give anything by mouth to an unconscious person</li> </ul>
<b>HOTLINE NUMBER</b>	
For emergency medical advice, call your local poison control center or a doctor. Have the product container or label with you when seeking medical advice or treatment.	
<b>NOTE TO PHYSICIAN</b>	
Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be needed.	

(Administrative Note: The First Aid Statement's grid format will be used if market label space permits; otherwise a paragraph format will be used)

(Administrative Note: The "Environmental Hazards" statement is for container sizes of 5 gallons or greater):

**ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA. This product is toxic to fish and aquatic organisms.

**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage or disposal.

**STORAGE** – Store in a securely closed original container in areas inaccessible to children. Store in an area that will prevent cross contamination of other pesticides, fertilizer, food, and feed. Avoid storage at temperature extremes or in sunlight.

**PESTICIDE DISPOSAL** – Pesticide wastes are acutely hazardous. Improper disposal of excess pesticides is in violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your Pesticide or Environmental Control Agency, or the hazardous waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL** – Triple rinse (or equivalent), then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(Administrative Note: The following text is optional for all labeling):

**PRODUCT COMPOSITION**

Q4.5-5.0PB-4.5 is a disinfectant, deodorizer, fungicide, and virucide\* cleaner designed for hospital, nursing home, and institutional use. Q4.5-5.0PB-4.5 contains two active twin chain quaternary ammonium compounds (listed as active ingredients) for bactericidal efficacy. Inert ingredients include a balance of alkaline builders, non-ionic surfactants, and odor counteractants to enhance the cleaning and odor control characteristics. This formulation is designed to clean and disinfect bathing and therapy equipment. When used as directed, Q4.5-5.0PB-4.5 has been found effective for use on all fiberglass, stainless steel, and chrome plated surfaces of bath, therapy, whirlpools, and patient transfer equipment.

**\*\*Non-Critical Medical Device Uses**

Q5.5-5.5NPB-2.5HW is a general purpose disinfectant that may be used to clean and disinfect hard, non-porous, inanimate, non-critical medical and dental equipment surfaces. Q5.5-5.5NPB-2.5HW may also be used to clean and/or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

Q4.5-5.0PB-4.5 is appropriate for use on non-critical medical devices\*\*

**FOR CLEANING (Administrative Note: Manufacture's Brand Tub Name Inserted Here) FIBERGLASS BATH AND THERAPY EQUIPMENT:** To remove body oils, dead tissue, hard water, and all other buildups or organic matter on inanimate surfaces after using the whirlpool unit, drain the water and refill with fresh water to just cover the intake valve. Add two ounces of Q4.5-5.0PB-4.5 for each gallon of water in the unit at this point. Briefly start the pump to circulate the solutions. Turn off pump. Wash down the unit sides, seat of the chairlift, and any/all related equipment with a clean swab or sponge. After the unit has been thoroughly cleaned, drain solutions from the unit and rinse any/all cleaned surfaces with fresh water. The unit is ready for re-use. Product to surface contact time must be at least 10 minutes for proper disinfection.

(Administrative Note: The following text is required for all labeling. If a sub-registrant desires to delete claims against select, specific organisms, it must do so with the approval of the basic registrant.)

**DIRECTIONS FOR USE**

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

**DISINFECTION:** To disinfect hard, non-porous, inanimate surfaces (such as fiberglass and stainless steel tubs and chair surfaces, chrome plated intakes and lifts, etc.), apply properly diluted Q4.5-5.0PB-4.5 with mop, cloth sponge, mechanical sprayer, or hand pump trigger sprayer so as to wet all surfaces thoroughly. For routine disinfection, proper dilution is 2 ounces of Q4.5-5.0PB-4.5 per gallon of water (1:64). Allow to remain wet for 10 minutes and then let air dry. For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh dilution for each use.

**SANITIZATION:** To sanitize non-porous, non-food contact surfaces, add 2 ounces of Q4.5-5.0PB-4.5 per gallon of water (1:64). Treated surfaces must remain wet for 30 seconds.

**PERFORMANCE DATA**

Efficacy tests have demonstrated that Q4.5-5.0PB-4.5 is an effective bactericide, fungicide, and virucide\* on hard, non-porous, inanimate surfaces in the presence of moderate amounts of organic soil (5% blood serum). Germicidal, fungicidal, and virucidal\* testing has been performed using A.O.A.C. protocol testing as required by the EPA at a use-dilution of 1:64 (two ounces per gallon of water) in the presence of 5% blood serum (used to simulate organic soil load), at 20 degrees celcius with an exposure time of 10 minutes.

**BACTERICIDAL:** The broad spectrum activity of Q4.5-5.0PB-4.5 has been confirmed against the following organisms: *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Escherichia coli*, *Klebsiella pneumoniae*, *Serratia marscescens*, *Salmonella choleraesuis*, *Methicillin resistant Staphylococcus aureus (MRSA)*, *Proteus vulgaris*.

**FUNGICIDAL:** Q4.5-5.0PB-4.5's efficacy as a fungicide has been confirmed through testing against the following pathogenic fungi: *Trichophyton mentagrophytes*, *Candida albicans*

**\*VIRUCIDAL:** Testing of Q4.5-5.0PB-4.5 has confirmed its virucidal activity against the following viruses: *Influenza A2-Asian* (representative of the common flu virus), *Herpes simplex Type 1* (causative agent of fever blisters), *Adeno virus type 2* (causative agent of upper respiratory infections), *Vaccinia virus* (representative of the pox virus group), *HIV-1* (AIDS Virus)

**KILLS HIV-1 ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings or other settings in which there is an expected likelihood of inanimate surfaces/objects likely to be soiled 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). Contact time: ten (10) minutes.

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST AIDS (HIV-1 VIRUS) ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS WITH TEN (10) MINUTE CONTACT TIME.**

**PERSONAL PROTECTION:** Disposable gloves should be worn when cleaning blood, body fluids, or contaminated items. Hands should be washed immediately and thoroughly after gloves are removed, or if hands are contaminated with blood or body fluids. Masks and protective eyewear or faceshields should be worn during cleaning procedures involving blood or body fluids. Gowns or aprons should be worn during cleaning procedures for protection against splashes of blood or other body fluids.

**CLEANING PROCEDURE:** Blood and other fluids must be thoroughly cleaned from surfaces and objects before application of the disinfectant. After cleaning is complete, follow disinfection described previously.

**DISPOSAL OF INFECTIOUS MATERIALS:** Contaminated waste and blood and other body fluids should be autoclaved and disposed according to local regulations for infectious waste disposal.

**SANITIZATION:** At a use-dilution of 1:64 (2 ounces per gallon of water), in 400 ppm hardwater, Q4.5-5.0PB-4.5 is an effective sanitizer on non-porous, non-food contact surfaces against the following organisms: *Staphylococcus aureus*, *Enterobacter aerogenes*

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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.