

675-26

11-18-2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 18 2003

Mr. Bob MacDonald  
Agent for Reckitt Benckiser Inc.  
Reckitt Benckiser Inc.  
1655 Valley Road  
Wayne, NJ 07474-0977

Subject: QUATSYL 256  
EPA Registration No. 675-26  
Application Date: 8/18/03  
Receipt Date: 8/20/03

Dear Mr. MacDonald:

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

Update First Aid Statements in compliance with PR Notice 2001-1

**LABEL COMMENTS**

- The following language must be added to the label because it is a general purpose disinfectant that is registered for any medical device or medical equipment surface claims: 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.

**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.

**CONCURRENCES**

SYMBOL	67510C						
SURNAME	P. Jones						
DATE	11-18-03						

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

Sincerely,

A handwritten signature in black ink, appearing to read "Velma Noble". The signature is fluid and cursive, with the first name "Velma" being more prominent than the last name "Noble".

Velma Noble  
Product Manager 31  
Regulatory Management Branch 1  
Antimicrobial Division (7510C)

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**QUATSYL 256**

**CLEANER DISINFECTANT**

Deodorizer-Fungicide-Virucide\* for Hospital and Institutional Use  
Highly Concentrated Germicide Based on a Blend of Quaternaries

<b>Active Ingredient:</b>	
Octyl Decyl Dimethyl Ammonium Chloride.....	3.750%
Dioctyl Dimethyl Ammonium Chloride.....	1.875%
Didecyl Dimethyl Ammonium Chloride .....	1.875%
Alkyl (C <sub>14</sub> 50%, C <sub>12</sub> 40%, C <sub>16</sub> 10%)	
Benzyl Dimethyl Ammonium Chloride.....	5.000%
<b>Other Ingredients:</b> .....	<u>87.500%</u>
<b>TOTAL:</b> .....	100.000%

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

See back [(side)] panel for first aid and additional precautionary statements

NET CONTENTS: 2-1/2 Gallons (320 fl. oz.) 9.46 Liters

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

**NOV 18 2003**

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

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Cross-contamination is of major housekeeping concern not only in hospitals, but in schools, institutions, and industry. QUATSYL 256 is formulated for this problem area. It both cleans and disinfects effectively and is virucidal when used as directed. Its hard surface disinfecting action will reduce the hazard of cross-contamination from hard, nonporous environmental surfaces.

When used as directed, QUATSYL 256 will deodorize toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause malodors.

This product is economical to use because it is highly concentrated. It should be handled with care.

#### **DIRECTIONS FOR USE**

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

Add ½ ounce product per gallon of water. Apply QUATSYL 256 to walls, floors, and other hard nonporous surfaces such as tables, chairs, and bed frames with a cloth or mop. For heavily soiled areas, a preliminary cleaning is required.

QUATSYL 256 is effective against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis*, and *Trichophyton mentagrophytes* [(athlete's foot fungus)]. Germicidal performance against the first three organisms has been confirmed by the AOAC Use-Dilution test. Fungicidal performance against *T. mentagrophytes* was determined by the AOAC Fungicidal test.

The broad spectrum effectiveness of QUATSYL 256 is shown by its germicidal action against the following additional organisms:

- *Escherichia coli*
- *Klebsiella pneumoniae*
- *Enterobacter aerogenes*
- *Salmonella schottmuelleri*
- *Streptococcus faecalis*
- *Shigella dysenteriae*
- *Brevibacterium ammoniagenes*

\*At ½ ounce per gallon use-level QUATSYL 256 is virucidal against Herpes Simplex Type 1 [(a member of the virus family that causes infectious mononucleosis)], Vaccinia [(representative of the pox viruses)], and Influenza A<sub>2</sub> [(the Hong Kong flu virus)], on hard nonporous environmental surfaces.

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**Precautionary Statements**

Hazards to humans and domestic animals.

**DANGER:**

Corrosive: Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (safety glasses or face shield), protective clothing, and rubber gloves. 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 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 swallowed</b>	<ul style="list-style-type: none"><li>• Call poison control center or doctor immediately for treatment advice.</li><li>• Have person sip a glass of water if able to swallow.</li><li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li><li>• Do not give anything by mouth to an unconscious person</li></ul>
<b>HOT LINE NUMBER</b>	
Question? Comments or In case of an emergency call toll free (1-800-677-9218). Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
<b>NOTE TO PHYSICIAN:</b>	
Probable mucosal damage may contraindicate the use of gastric lavage.	

**STORAGE / DISPOSAL** {For sizes 1 gallon or less.}

Store in an area inaccessible to small children. Rinse empty container thoroughly and discard.

**STORAGE AND DISPOSAL** {For sizes over 1 gallon.}

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

**STORAGE**

Store in original container in areas inaccessible to small children. Keep securely closed.

**PESTICIDE DISPOSAL**

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Note: Bracketed[ ] information is optional text. Text separated by a comma(,)denotes-and/or-options. {Bracketed Text}is for administrative purposes only and will not appear on the printed label.

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**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.

**ENVIRONMENTAL HAZARDS** {For sizes 5 gallons or more}

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.

Please encourage your state and local authorities to establish a recycling program so that this container can be recycled.

Questions? Comments? Call 1-800-677-9218.  
Monday – [thru] Friday, 8:45 a.m. – [to] 4:30 p.m. [Eastern time].  
[Visit us at [www.reckittprofessional.com](http://www.reckittprofessional.com)]



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EPA Est. No. {Insert establishment number here}

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