

5464-1

3/3/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Ms. Luann Shoemaker  
Xttrium Laboratories, Inc.  
415 West Pershing Road  
Chicago, Illinois 60609

Subject: **benz-all Tinted**  
EPA Registration NO. 5464-1  
Application Dated December 8, 2009  
EPA Received Date December 8, 2009

Dear Ms. Shoemaker:

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

**Proposed Labeling:**

- Revised label per Agency letter dated 6/9/09
- Updating Confidential Statement of Formula for basic formulation

**Labeling Comments:**

1. On page 2 add "PRECAUTIONARY STATEMENTS" above the "HAZARDS TO HUMANS AND DOMESTIC ANIMALS" heading.
2. On page 2 revise the "USER SAFETY RECOMMENDATIONS" box to read "USER SAFETY REQUIREMENTS".
3. On page 2 under the Directions For Use that read "Preparation" delete the word "should" and replace with "must".

**Product Chemistry:**

1. The CSF, dated 11/07/09, for the basic formulation is acceptable. But you wrote the CAS# 68424-85-1 for the active ingredient, this is not correct. The correct CAS # is 63449-41-2. **You must submit a new Confidential Statement of Formula with the correct CAS number listed**

**CONCURRENCES**

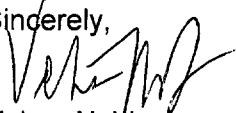
SYMBOL							
SURNAME							
DATE							

**General Comments:**

A stamped copy of the acceptable labeling is enclosed. Submit one (1) copy 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 Drusilla Copeland at (703) 308-6224 or Velma Noble on (703) 308-6233.

Sincerely,



Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Enclosure: stamped label, and product chemistry review approved dated 3/8/10

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# benz-all®

TINTED

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

MAR 3 2010  
Under the Federal Insecticide  
Fungicide, and Rodenticide Act as  
amended, for the pesticide  
registered under EPA Reg. No. 5464-1

Brand of 12.9% benzalkonium chloride solution for the chemical  
disinfection of surgical or dental instruments.

ACTIVE INGREDIENT: Alkyl (C <sub>12</sub> 67%, C <sub>14</sub> 25%, C <sub>16</sub> 7%, C <sub>8</sub> , C <sub>10</sub> and C <sub>18</sub> 1%) dimethyl benzyl ammonium chloride	12.9%
OTHER INGREDIENTS (including sodium nitrite 15.9 %)	87.1%
TOTAL	100.0%

EPA Reg. No. 5464-1

EPA Est. No. 5464-1 L-1

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

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.  
(If you do not understand this label, find someone to explain it to you in detail.)

See inside for First Aid, Precautionary Statements, Directions for Use and Conditions of Sale and  
Warranty

NET CONTENTS: 1.35 fl oz (40cc) makes 1 gallon

FIRST AID	
If on skin or clothing	<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>
If in eyes	<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 first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
If inhaled	<ul style="list-style-type: none"> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth, if possible.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>
In ingested	<ul style="list-style-type: none"> <li>Call a poison control center or doctor immediately for further treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told by a poison control center or doctor.</li> <li>Do not give anything to an unconscious person.</li> </ul>
HOT LINE NUMBER	
<p>Have the product container or label with you when calling a poison control center or doctor or going for treatment. For emergency information on BENZ-ALL®, call the <b>National Pesticides Information Center</b> at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the poison control center at 1-800-222-1222.</p>	

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

**PRECAUTIONARY STATEMENTS**

MAR 3 2010

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide  
Registration No. 5464-1

**ENVIRONMENTAL HAZARDS**

**THIS PESTICIDE IS TOXIC TO FISH, AQUATIC INVERTEBRATES, OYSTERS AND SHRIMP**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER**

Corrosive. Causes irreversible eye damage and skin burns. Fatal if absorbed through the skin. Do not get in eyes, skin or on clothing. Wear protective eyewear such as goggles, face shield, or safety glasses and protective clothing and gloves.

May be fatal if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

May be fatal if inhaled. Do not breathe spray mist or vapor when mixing.

**USER SAFETY RECOMMENDATIONS**

Users should:

1. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
2. Remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing.

**PHYSICAL AND CHEMICAL HAZARDS**

**COMBUSTIBLE:** Do not use or store near heat or open flame.

**DIRECTIONS FOR USE**

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

BENZ-ALL® is conveniently packaged in 40cc bottles tinted for rapid preparation of a one-gallon of 1:750 concentration. This method of packaging minimizes any storage or breakage problems.

**Preparation:** Dissolve contents in one gallon of either tap water or distilled water and mix. Completely immerse thoroughly cleaned and autoclaved rubber or metal instruments for 15 minutes or longer. See package insert for complete directions. The diluted solution should be used within 15 days of preparation. Incorporated in each individual package is sufficient anti-rust material for one gallon of water. Do not use anti-rust tablets with BENZ-ALL® **TINTED** as they are not needed.

**Disinfection/ Institutional Use:** 99.9% Effective against *Pseudomonas aeruginosa*, *Salmonella enterica*, *Staphylococcus aureus*

**General Precautions/restrictions:** Do not use BENZ-ALL® for disinfection of optical instruments with cemented parts. Instruments must be sterilized after disinfection

**MEDICAL USE STATEMENT**

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.

**STORAGE AND DISPOSAL**

**DO NOT contaminate water, food, or feed by storage or disposal.**

