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 OFFICIAL FILE COPY

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

2095

### **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.

Sin¢erely,

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510P)

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





ACCEPTED with COMMENTS in EPA Letter Dated:

Under the Federal insections
Fungicide, and Rodenheau Act at amended, for the pesticide, tegistered under EPA Reg. No 5464—

amended, for the pesticide.

tegistered under EPA Reg. No 5464—)

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

ACTIVE INGREDIENT: Alkyl ( $C_{12}$ 67%, $C_{14}$ 25%, $C_{16}$ 7%, $C_8$ , $C_{10}$ and $C_{18}$ 1%)	
- dimethyl benzyl ammonium chloride	12.9%
OTHER INGREDIENTS (including sodium nitrite 15.9 %)	87.1%
TOTAL	

EPA Reg. No. 5464-1

EPA Est. No. 5464-1 L-1

# DANGER

Si usted no entiende la etiqueta, busque a algulen 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> <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> <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> <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> <li>Call a poison control center or doctor immediately for further treatment ad</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>	vice.
	HOT LINE NUMBER	9 00° 

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 **National Pesticides** information center 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.

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

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### **ENVIRONMENTAL HAZARDS**

Under the Federal insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,

THIS PESTICIDE IS TOXIC TO FISH, AQUATIC INVERTEBRATES, O'STERS AND SHRIMB. 5444-/

## 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 sgrade or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream of significant 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.

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**PESTICIDE STORAGE:** Store in a cool dark place. Avoid excessive heat about above 40°C. Once opened the product must be used immediately.

**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.

**CONTAINER DISPOSAL:** Nonrefillable Container. Do not refill or reuse container. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

#### IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

**CONDITIONS:** The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Xttrium Laboratories. All such risks shall be assumed by the user or buyer.

**DISCLAIMER OF WARRANTIES:** To the extent consistent with applicable law, Xttrium Laboratories makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Xttrium Laboratories is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Xttrium Laboratories disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

**LIMITATIONS OF LIABILITY:** To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Xttrium Laboratories election, the replacement of product.

ACCEPTED
with COMMENTS
in EPA Lane. Dated:

Under the Federal Associate 9, Fungicide, and Ruganasurae Act as amended, for the posticide, registered under EPA Reg. No. 54

ASTRACTOR XTTF

XTTRIUM LABORATORIES Chicago, Illinois 60609 773-268-5800

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