UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 6 2004

Mr. William Edwards
Edwards-Councilor Co., Inc.
1427 Baker Road
Virginia Beach, VA 23455

Subject: Steramine 2-G Tablets
EPA Registration No. 1561-10
Amendment Date: February 5, 2004
EPA Receipt Date: February 9, 2003

Dear Mr. Edwards,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the conditions listed below.

- Response to Agency letter dated August 18, 2003

Conditions
Revise the label as follows:

1. Revise the "Precautionary Statements" to read "Causes substantial but temporary eye injury. Do not get in eyes, on skin, or on clothing. Wear protective goggles or safety glasses. Wash thoroughly with soap and water after handling and before eating drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

2. The "First Aid" statements must be reorganized so that the most severest routes of exposure as demonstrated by the toxicity category classification are listed first. They must be reorganized as follows: IF IN EYES, IN ON SKIN, IF SWALLOWED, and IF INHALED.

3. Based on this product's acute toxicology profile, the "Note to Physician" section is no longer triggered.

Toxicology Summary

The Agency has determined that the submitted studies are unacceptable because they do not comply with 40 CFR 160.12 or 40 CFR 792 guidelines for acute toxicology studies. However, it is understood that these product were registered prior to these regulations, and the

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provided acute toxicology profile is based on submitted data. Due to the amount of deficiencies outlined in the data evaluation, we are granting a conditional amendment provided that the new studies conducted according the current guidelines be conducted and submitted to the Agency for review.

Study Guideline	MRID Number	Toxicity Category
Acute Oral Toxicity	461914-01	IV
Primary Eye Irritation	461914-03	II
Primary Skin Irritation	461914-02	III

Data Deficiencies

1) All the submitted studies did not state how the test material was dosed to the animals or the source, strain, age, and weight of the test animals. This information is useful in determining the animal's condition at the time of testing.

2) The acute dermal study, MRID No. 461914-04, was determined not to be an acute dermal study. The test material was applied in dose levels of 1 ml/kg, 2 ml/kg, and 4 ml/kg from a dilution of 800 ppm water. The use of two animals per dose level is inappropriate. There was no indication as to how the applied material was covered or sealed to the animal's skin. The discussion of abrasion is no longer used. There was not a mortality table included in the report.

3) The primary skin irritation study, MRID No. 461914-2, did not include irritation cores for 1 or 48 hours, and no observations were reported beyond 72 hours. In some instances, irritation occurs after 72 hours prompting re-evaluation of the toxicity category. The study was not clear as to what method was used to conduct the study.

4) Acute inhalation and dermal sensitization routes of exposure were not addressed. You must either submit a justification or a study to address this data requirement.

5) The acute toxicology tests are designed to assess a product's toxicological potential to provide information of health hazards. The product must be tested as it is sold. The submitted studies stated that the test material was diluted in water which is indicative of the use solution for the sanitizing directions on the label. This information is useful for use-dilution precautionary statements, but it will not this product's precautionary statements.

General Comments

A stamped label acceptable with conditions is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Please Note: The Agency is granting a conditional acceptance of this amendment provided you submit new acute toxicology studies generated according to 40 CFR 160.12 and 40 CFR 792

guidelines. You should refer to OPPTS Harmonized test guidelines for additional guidance at www.epa.gov/opptsfrs/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines.

If you have any questions or concerns regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,

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

Encl: Stamped Label

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This product fulfills the sanitizing criteria of the US PUBLIC HEALTH SERVICE in waters up to 500 ppm of hardness calculated as $CaCO_3$ when tested by the AOAC Germicidal and Detergent Sanitizers – Official Method.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS and DOMESTIC ANIMALS

WARNING: Tablets are harmful if swallowed. Tablet dust causes eye and skin irritation. Do not get dust in eyes. Avoid [illegible] contact with dust. Avoid contamination of food.

FIRST AID

IF SWALLOWED: Call a poison contact center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses if present, after first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
IF ON SKIN: Rinse immediately with water for 15-20 minutes. If irritation persists, call a poison control center or doctor for treatment advice.
Have the product label or container with you when calling a poison control center or doctor, or going for treatment.
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE and DISPOSAL: Store in original container in areas inaccessible to persons unfamiliar with it use. Do not reuse empty container. Wrap container and discard in trash.

STERAMINE

2-G Tablets

FOR SANITIZING FOOD CONTACT SURFACES

USE ONE TABLET PER 2 GALLONS OF WATER

Kills HIV-1 (AIDS Virus) when used as directed for sanitizing.

EPA REG. NO. 1561- 10

Active Ingredient (Quaternary)	50%
Alkyl (C14 95%, C12 3%, C16 2%) dimethyl benzyl ammonium chloride dihydrate	
INERT INGREDIENTS	50%

WARNING

KEEP OUT OF REACH OF CHILDREN

75 Tablets

See left panel for additional precautionary statements.
For Institutional and Commercial use only.

NET WEIGHT 8 OUNCES

Manufacturing Chemists

EDWARDS-COUNCILOR CO. INC., 1427 Baker Road, Virginia Beach, VA 23455

ACCEPTED
with COMMENTS
In EPA Letter Dated:

AUG 6 2004

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

1561-10

DIRECTIONS

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Prepare sanitizing solutions with warm water. Allow several minutes for tablets to dissolve before using.
FOR SANITIZING DISHES, GLASSES, AND UTENSILS IN RESTAURANTS, TAVERNS, ETC.

1. Scrape and prewash utensils and glasses whenever possible.
2. Wash with a good detergent or compatible cleaner in first sink compartment.
3. Rinse with clean water in second sink compartment.
4. Sanitize in a solution of 1 TABLET per 2 GALLONS OF WATER (200 ppm) in third sink compartment. Immerse all utensils for at least one minute or for contact time specified by governing sanitary code.
5. Place sanitized utensils on a rack or drainboard to air dry.
6. A fresh sanitizing solution must be prepared at least daily or more often if the solution becomes diluted or soiled.

DIRECTIONS FOR SPRAYING

FOR SANITIZING FOOD PROCESSING EQUIPMENT, DAIRY EQUIPMENT, SINKS, COUNTERTOPS, REFRIGERATED STORAGE AND DISPLAY EQUIPMENT and other hard non-porous food contact articles and surfaces.
Prior to sanitizing, remove gross food particles and soil by pre-flush, pre-scrape, and when necessary, pre-soak. Then thoroughly wash equipment and surfaces with good detergent or compatible cleaner followed by potable water rinse. Apply use solution of 200 ppm concentration (1 tablet per 2 gallons of water) thoroughly wetting surfaces with hand trigger sprayer, cloth, sponge, or brush. Surfaces must remain wet for at least 1 minute followed by adequate draining and air drying.
Prepare a fresh solution daily or more often if solution becomes visibly diluted, clouded, or soiled. For mechanical application, use solution may not be reused for sanitizing applications.

KILLS HIV-1 (AIDS Virus) when used as directed for sanitizing.

EPA EST. 1561-VA-1

DEODORIZATION

For controlling odor causing bacteria in ostomy, colostomy, and ileostomy appliance pouches. Use 1 or 2 tablets in a clean ostomy, colostomy or ileostomy appliance pouch. Replace tablets after each pouch emptying.