

1839-49

08-05-2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG - 5 2009

Mr. Thomas W. Isaac
Sr. Regulatory Specialist
Stephan Company
22 W. Frontage Rd.
Northfield, IL 60093

Subject: **CD 3.2 Detergent/Disinfectant**
EPA Registration Number 1839-49
Application dated March 27, 2009
EPA Received Date March 31, 2009.

Dear Mr. Isaac:

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

Proposed Amendment:

- Addition of Escherichia coil O111:H8 (ATTC BAA-184) claim to label
- Revised Container Disposal section to conform to PR Notice 2004-7

Product Chemistry Review:

1. The requirements of PR Notice 91-2 were satisfied. The nominal concentration of the active ingredients, given in the Basic CSF and Alternate Formulation #1, both dated February 17, 2005, agreed with the percentages declared on the product label.
2. The upper and lower certified limits for the active and other ingredients were acceptable.
3. The current and new alternate source of quaternary active ingredients utilized is EPA registered. The other ingredients present in the updated and new formulations are approved for use in pesticide formulations.
4. The Group A product chemistry data requirements, under MRID # 477165-01, applicable to end-use products have been met.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

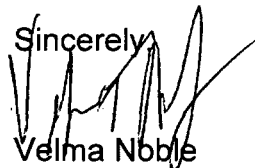
- 5. The Group B product chemistry data requirements, under MRID # 477165-01 through # 477165-03, applicable to end-use products have been met. Statements of Good Laboratory Practice (GLP) compliance were provided for the studies referenced in the laboratory reports assigned MRID #477165-02 and #477165-03. The studies were conducted in compliance with U.S. EPA GLP regulations set forth in 40 CFR Part 160.
- 6. The following revision to future CSFs must be made:
 - Under Item #8, update the pH from 11.1 to read 11.21.
- 7. Revise the following:
 - a. Under the "Precautionary Statements" section of the product label, change "Wash thoroughly with soap and water after handling." to read "Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet."
 - b. Under the "Pesticide Storage" section of the product label, add instructions that specify what to do if the product leaks or spills from the product container.

Efficacy Review:

The proposed label claims that the product, CD 3.2 Detergent/Disinfectant, is an effective one-step disinfectant against *Escherichia coli* serotype O111:H8 in the presence of moderate organic soil (5% serum) at a 2 ounce product per gallon of water dilution (1:64) with a contact time of 10 minutes on hard, nonporous surfaces. These claims are **acceptable** as they are supported by the submitted data.

General Comments:

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224 or Velma Noble at (703) 308-6233.

Sincerely,


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

Enclosure: Product Chemistry approve date 6/22/09, Efficacy Review approve date 6/4/09

CD 3.2 Detergent/Disinfectant

CLEANER
DETERGENT
FUNGICIDE (against pathogenic fungi)
MILDEWSTAT (on hard inanimate surfaces)

DISINFECTANT
DEODORIZER
SANITIZER

ACTIVE INGREDIENTS

n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides	1.60%
n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides	1.60%
INERT INGREDIENTS	96.80%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN
DANGER

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If swallowed: Call a poison control 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 the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

(OPTIONAL) You may contact xxx/xxx-xxxx for emergency medical treatment information.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

See side (back) panel for additional precautionary statements.

EPA REG. NO. 1839-49
EPA EST. NO. 1839-IL-01

STEPAN COMPANY
22 West Frontage Road
Northfield, IL 60093

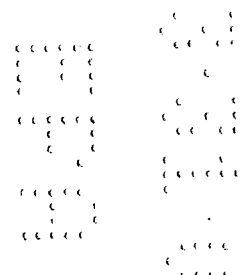
NET CONTENTS

(center panel)

ACCEPTED
with COMMENTS
in EPA Letter Dated:

AUG - 5 2009

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1839-49



Amenc 02/27/09

DIRECTIONS FOR USE

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

CD 3.2 Detergent/Disinfectant has been designed to provide effective cleaning, deodorizing, sanitization, and disinfection specifically for hospitals, nursing homes, schools, food service establishments and food processing plants where housekeeping is of prime importance in controlling the hazard of cross contamination.

This product, when used as directed, is formulated to disinfectant hard, non-porous, inanimate, environmental surfaces: floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, bathrooms, sink tops, toilet bowls, shower stalls, bathtubs, cabinets, tables, chairs, telephones and bed frames. For larger areas such as operating rooms, patient care facilities and restrooms, this product is designed to provide both general cleaning and disinfection.

This product deodorizes those areas which generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, toilet bowls and other areas which are prone to odors caused by microorganisms.

In addition, this product will sanitize previously cleaned and rinsed non-porous food contact surfaces such as tanks, chopping blocks, counter tops, drinking glasses and eating utensils.

(For labels that list medical premises and/or stainless steel surfaces, one of the following statements must be used:)

This product is not 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 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.

or

This product is not for use on medical device surfaces.

DISINFECTION - To disinfect hard inanimate surfaces apply solution with a mop, cloth, sponge or hand pump trigger sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes.

GENERAL DISINFECTION - Add 2 ounces of this product per gallon of water.

HOSPITAL DISINFECTION - Add 3 ounces of this product per gallon of water.

For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use.

To disinfect toilet bowls: Flush toilet, add 2 ounces of this product directly to the bowl water. Swab the bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Let stand for 10 minutes and flush.

To disinfect food service establishment food contact surfaces: countertops, appliances, tables, add 2 ounces of this product per gallon of water. Before using this product, food products and packaging materials must be removed from area or carefully protected. Apply solution with a cloth, sponge or hand pump trigger sprayer so as to wet all surfaces thoroughly. Allow the surface to remain wet for 10 minutes, then remove excess liquid and rinse the surface with potable water. This product cannot be used to clean the following food contact surfaces: utensils, glassware and dishes.

To disinfect food processing premises: floors, walls, and storage areas, add 2 ounces of this product per gallon of water. Before using this product, food products and packaging materials must be removed from the area or carefully protected. Apply solution with a mop, sponge or hand pump trigger sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, then remove excess liquid. All surfaces which may come in contact with food must be rinsed with potable water.

BACTERICIDAL ACTIVITY - When diluted at the rate of 2 ounces per gallon of water, this product exhibits effective disinfectant activity against the organisms: Salmonella (choleraesuis) enterica (ATCC 10708), Staphylococcus aureus (ATCC 6538) and Escherichia coli (E. coli) O111:H8 (ATCC BAA-184).

When diluted at the rate of 3 ounces per gallon of water, this product exhibits effective disinfectant activity against Pseudomonas aeruginosa in addition to the above mentioned microorganisms and meets all requirements for hospital use.

FUNGICIDAL ACTIVITY - At the 2 ounces per gallon dilution, this product is also fungicidal against the pathogenic fungi, Trichophyton mentagrophytes (Athlete's Foot Fungus) (a cause of ringworm) (a cause of ringworm of the foot) (ATCC 9533), when used as directed on hard surfaces found in bathrooms, shower stalls, locker rooms, exercise facilities or other clean, hard, non-porous, surfaces commonly contacted by bare feet.

MILDEWSTAT - To control mold and mildew and the odors they cause on pre-cleaned, hard, non-porous surfaces add 2 ounces of this product per gallon of water. Apply solution with a cloth, mop or sponge making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application at weekly intervals or when mildew growth appears.

DEODORIZATION - To deodorize, apply this product as indicated under the heading **GENERAL DISINFECTION**.

EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE AND FUNGICIDE IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).

SANITIZATION - For use in restaurants, bars, food service establishments, dairies, and food processing plants. When used as directed, this product is an effective sanitizer against *Escherichia coli* and *Staphylococcus aureus*.

Remove all gross food particles and soil from areas which are to be sanitized with a good detergent by a pre-flush, pre-soak or pre-scrape treatment. Rinse with a potable water rinse. To sanitize previously cleaned and rinsed non-porous food contact surfaces, prepare a 200 ppm active quaternary solution by adding 4 ounces of this product to 5 gallons of water.

To sanitize immobile items such as tanks, chopping blocks, and counter tops, flood the area with a 200 ppm active quaternary solution making sure to wet all surfaces completely for at least 60 seconds. Remove, drain the use solution from the surface, and air dry. Prepare a fresh solution daily or more frequently as soil is apparent.

To sanitize mobile items such as drinking glasses and eating utensils, immerse in a 200 ppm active quaternary solution for at least 60 seconds making sure to immerse completely. Remove, drain the use solution from the surface, and air dry. Prepare a fresh solution daily or more frequently as soil is apparent.

When used for sanitization of previously cleaned food equipment or food contact items, limit active quaternary to 200 ppm. **NO POTABLE WATER RINSE IS REQUIRED.** This product is an effective sanitizer when diluted in water up to 500 ppm hardness (CaCO₃).

DIRECTIONS FOR SANITIZING FOOD PROCESSING EQUIPMENT, UTENSILS, AND FOOD CONTACT ARTICLES REGULATED BY 40CFR sec 180.940 (a) (c).

1. Scrape, flush or pre-soak articles (whether mobile or stationary) to remove gross food particles and soil.
2. Thoroughly wash articles with an appropriate detergent or cleaner.
3. Rinse articles thoroughly with potable water.
4. Sanitize articles using a solution of 4 ounces of this product per 5 gallons of water (200 ppm active quaternary). Articles that can be immersed in solution must remain in solution for 60 seconds. Articles too large for immersion must be thoroughly wetted by rinsing, spraying or swabbing.
5. Remove immersed items from solution to drain and then air dry. Non-immersed items should also be allowed to air dry.

WISCONSIN STATE DIVISION OF HEALTH - DIRECTIONS FOR EATING ESTABLISHMENTS:

1. Scrape and pre-wash utensils and glasses whenever possible.
2. Wash with a good detergent or compatible cleaner.
3. Rinse with potable water.
4. Sanitize in a solution of 4 ounces per 5 gallons of this product (200 ppm active quaternary). Immerse all utensils for at least two minutes or for contact time specified by governing sanitary code.
5. Place sanitized utensils on a rack or drain board to air dry.
6. Fresh sanitizing solution must be prepared at least daily or when visibly soiled or diluted.

NOTE: A clean potable water rinse following sanitization is not permitted under Section HFS 196.13 of the Wisconsin Administrative Code.

(Alternative language for clean in place, closed loop dilution centers.)

WISCONSIN STATE DIVISION OF HEALTH - DIRECTIONS FOR EATING ESTABLISHMENTS:

1. Scrape and pre-wash utensils and glasses whenever possible.
2. Wash with a good detergent or compatible cleaner.
3. Rinse with potable water.
4. Sanitize in a solution from the Closed Loop Dilution Center (200 ppm active quaternary). Immerse all utensils at least two minutes or for contact time specified by governing sanitary code.
5. Place sanitized utensils on a rack or drain board to air dry.
6. Fresh sanitizing solution must be prepared at least daily or when visibly soiled or diluted.

NOTE: A clean potable water rinse following sanitization is not permitted under Section HFS 196.13 of the Wisconsin Administrative Code.

**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 or face shield, rubber gloves, and protective clothing. Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

(Note: If container size is 5 gallons or greater, the following Environmental Hazards statement must be used.)

ENVIRONMENTAL HAZARDS

This product is toxic to fish. 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.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

PESTICIDE STORAGE - Store in a dry place no lower in temperature than 50°F or higher than 120°F.

CONTAINER DISPOSAL – Non-refillable container. Do not reuse or refill this container. Triple rinse empty container with water. Return metal drum then offer for reconditioning or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. Plastic containers may be disposed of in a sanitary landfill, incinerated, or if allowed by local authorities, by burning. If burned, stay out of smoke. Offer for recycling if available. *For containers 1 gallon or less:* Non-refillable container. Do not reuse or refill this container . Wrap container and put in trash. Offer for recycling if available.

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.