

8383-3

05/19/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

MAY 19 2010

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC SUBSTANCE

Betsy Potter
Contec, Inc.
525 Locust Grove
Spartanburg, SC 29303

Subject: **Sporicidin® Brand Disinfectant Solution**
EPA Registration No 8383-3
Application Date: April 28, 2010
Receipt Date: May 4, 2010

Dear Ms. Potter:

This letter acknowledges receipt of your notification submitted under the provision of PR Notice 98-10.

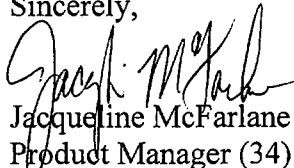
Proposed Notification

- Add asterisk following "Active Deodorizer"
- Add the word "virus" after Avian Influenza A, Influenza A2, Vaccinia, and Herpes simplex type 1/F and 2/G
- Add double asterisks to "Virucidal"

General Comments

Based on a review of the submitted materials, your notification for updating the label to add an asterisk, double asterisks, and the word "virus" is acceptable and a part of the records on file.

Should you have any questions concerning this letter, please contact Heather Garvie at (703) 308-0034 or by email address at garvie.heather@epa.gov.

Sincerely,

Jacqueline McFarlane
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Please read instructions on reverse before completing form.

Form Approved OMB No. 2070-0080

Print Form



United States
Environmental Protection Agency
Washington, DC 20460

 Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 8383-3	2. EPA Product Manager Jacquie McFarland	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sporicidin (R) Disinfectant Solution	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Contec, Inc / Sporicidin Division 525 Locust Grove Spartanburg, SC 29303 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 8383-3 Product Name Sporicidin Brand Disinfectant Solution	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This is a notification per PR Notice 98-10 to add an asterisk after "Active Deodorizer" on the back of the label, and to add the word "virus" after Avian Influenza A, Influenza A2, Vaccinia, and Herpes simplex type 1/F and 2/G.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Metal Plastic Glass Paper Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product			<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Betsy Potter	Title R&D Chemist	Telephone No. (Include Area Code) 864-699-8320
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Betsy Potter</i>	3. Title R&D Chemist	
4. Typed Name Betsy Potter	5. Date 27 April 2010	



April 28, 2010

Ms. Heather Garvie
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

Subject: Contec, Inc.
Sporicidin Disinfectant Solution, EPA Reg. 8383-3, and Sporicidin Disinfectant Towelettes, EPA Reg. 8383-7, Notification of label change per PR Notice 98-10

Dear Ms. Garvie:

This is a notification per your request to replace the asterisk following "Active Deodorizer" on the back of the label for 8383-3 Sporicidin Brand Disinfectant Solution. Per CDPR's request, we would also like to add the word "virus" after Avian Influenza A, Influenza A₂, Vaccinia, and Herpes simplex type 1/F and 2/G on both the 8383-3 and 8383-7 labels.

In a letter dated March 22, 2010, I sent a notification application to PM#34 for another change you will note on the 8383-3 label. Per CDPR's request, we are adding double asterisks following "Virucidal" on the front and back of the label.

Enclosed please find a copy of our recent e-mail correspondence concerning this matter, forms 8570-1, and copies of the labels with the most recent changes marked in red.

This notification is consistent with the guidance in PR Notice 98-10 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Thank you for your assistance with this submission. If you have any questions, please call me at 864-699-8321 or e-mail me at bpotter@contecinc.com.

Sincerely,

Betsy Potter
Contec, Inc.

**PRESOAK • DISINFECT
HOSPITAL DISINFECTION**

INSTITUTIONAL • FOOD PROCESSING • RESIDENTIAL

AN EFFECTIVE CLEANER, DISINFECTANT AND ACTIVE DEODORIZER FOR INSTRUMENTS, AND EQUIPMENT ON PRE-CLEANED, HARD, NON-POROUS SURFACES in health/hospital treatment and patient rooms, operating rooms, schools, ambulances, hotels, restaurants, boats, planes, buses, and the home. Recommended for medical and dental equipment, beds, surgical carts, counter tops, mannequins, telephones, keyboards, furniture, wheelchairs, walkers, sinks, floors, walls, light switches, linen hampers, shower stalls, toilet seats, trash containers and damp and musty areas, including animal areas. Self-sanitizes against odor-causing bacteria and fungi. Reduces the hazards of cross-contamination.

PASSES AOAC EFFICACY STANDARDS FOR DISINFECTION IN THE PRESENCE OF 5% ORGANIC SOIL. FOR INSTITUTIONAL, HOSPITAL AND FARM PREMISE USE.

Virucidal:** Avian Influenza A virus (H9N2), Influenza A, virus (Japan 305/57 Asian strain), Cytomegalovirus, Coronavirus, Polio Type 1 virus, Vaccinia virus, Canine parvovirus, Herpes simplex virus types 1/F and 2/G (oral, ocular and genital), HIV-1 (AIDS Virus). See Sporidicin Bulletin NO. 303.

Bactericidal: Staphylococcus aureus, Salmonella enterica, Pseudomonas aeruginosa, Methicillin resistant Staphylococcus aureus (MRSA), Vancomycin resistant Enterococcus faecium (VRE), E. coli, Streptococcus pyogenes, Streptococcus salivarius, Mycobacterium tuberculosis.

Fungicidal: Chaetomium globosum, Aspergillus niger, Penicillium variabile, Trichophyton mentagrophytes (Athlete's Foot fungus).

ACTIVE DEODORIZER Provides continuous residual bacteriostatic activity against odor-causing bacteria for up to 6 months, if not removed from surfaces including plastics latex, vinyl, glass, treated wood, metal, glazed porcelain, glazed tile and paint.

SPORICIDIN DISINFECTANT SOLUTION is germicidal when used as directed for disinfection but differs in composition from other Sporidicin products.

DIRECTIONS FOR USE: It is a violation of U.S. Federal Law to use this product in a manner inconsistent with its labeling.

DO NOT DILUTE OR MIX WITH OTHER CHEMICALS

PRECLEAN surfaces using Sporidicin Disinfectant Solution to remove soil and filth. Wipe dry with paper towel, cloth or sponge.

TO DISINFECT AND DEODORIZE: Thoroughly wet pre-cleaned surface with Sporidicin Disinfectant Solution and allow to remain wet for 10 minutes at room temperature (20°C/68°F or above) to kill listed organisms. Use Sporidicin Disinfectant Spray for surfaces that cannot be immersed nor soaked.

TO KILL, CLEAN AND PREVENT MOLD AND MILDEW: Use procedure stated above. Repeat application if new growth appears.

TO CLEAN AIR DUCTS: Apply to hard, non-porous surfaces.

TO CLEAN, DEODORIZE AND REMOVE DEBRIS FROM CARPETS AND FABRICS: For manual cleaning, spray product onto carpet and wipe clean with cloth or sponge. Allow to air dry. For machine cleaning, apply product in accordance with the machine manufacturer's guidelines.

FOR FOGGING CLEAN ROOMS: See Sporidicin Bulletin No. 301.

FOR FARM EQUIPMENT, ANIMAL AND POULTRY HOUSING, BARN, KENNELS, BREEDING PENS, HATCHERIES, TRUCKS AND OTHER VEHICLES: Remove poultry, animals, feed, water, trucks, coops and crates from premises. Remove litter droppings from floors, walls, and surfaces of facilities occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Apply Sporidicin Disinfectant and allow to remain wet for ten minutes. Ventilate buildings, coops, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and water appliances with soap or detergent, and rinse with potable water before reuse. Disinfection of equipment: Apply Sporidicin Disinfectant to cover all surfaces for 10 minutes. Allow to air dry. For Avian Influenza A, the use is only for surfaces which are not conducive to treatment by immersion or excess liquid (e.g., cages, equipment tables, and laboratory benches, facet handles, door knobs, and similar "high touch" surfaces.) For uses in hospital/medical/health facilities, the directions for hospital disinfection must be followed. For all other use sites, general disinfection directions must be followed.



+H737R12841W

FOR FOOD PROCESSING PLANTS: Follow pre-cleaning and disinfecting instructions above to disinfect hard, non-porous surfaces and materials in food handling areas, including poultry and meat packing facilities, slaughter houses, etc. All surfaces and materials that come in contact with food must be washed with soap or detergent and rinsed with potable water prior to use.

PRECAUTIONARY STATEMENTS: HAZARD TO HUMANS AND DOMESTIC ANIMALS.

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

FIRST AID: If in eyes, remove contact lenses. Hold eye open and slowly rinse with water. If irritation persists for more than 5 minutes continue rinsing and consult a physician or poison control center.

STORAGE AND DISPOSAL: Store at room temperature. Nonrefillable container. Do not reuse or refill this container. Discard empty container in regular trash or offer for recycling if available.

FOR HOSPITAL DISINFECTION: 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) contact 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.

Manufactured by
Contec, Inc. / Sporidicin Division
Spartanburg, SC 29303
1-800-424-3733 www.sporidicin.com

3506-04/10

NOTIFICATION

Date Reviewed: 5/11/12
Reviewed By: H. B. [Signature]

CONTINUOUS RESIDUAL ACTIVITY
UP TO 6 MONTHS*

Sporidicin[®]
BRAND

**DISINFECTANT
SOLUTION**

ALCOHOL
FREE

CLEANS • DISINFECTS • DEODORIZES

- BACTERICIDAL
- VIRUCIDAL**
- KILLS MOLD AND MILDEW
- FUNGICIDAL
- TUBERCULOCIDAL
- ELIMINATES ODORS

Active Ingredients	
Phenol	1.56%
Sodium Phenate	0.06%
Inert Ingredients	98.38%
Total	100%

EPA Reg. No. 8383-3
EPA Est. No. 034346-NB-001,
08255-IL-011, 71979-SC-001
See batch code for actual Est. No.
Net Contents: 1 U.S. Gal. (3.79 ltr.)
Part No. RE-1284C

Keep Out of Reach of Children

CAUTION

See Additional Precautions on Back Panel

Also Available in 22 oz. Spray

4/10