



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

3862-192

Date of Issuance:

5/5/17

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Disinfectant Spray and Soak

Name and Address of Registrant (include ZIP Code):

ABC Compounding Company, Inc.
P.O. Box 16247 Atlanta, GA 30321

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Stacey Grigsby, Acting Product Manager 34
Regulatory Branch II Antimicrobials Division (7510P)

Date:

5/5/17

2. You are required to comply with the data requirements described in the DCI Order identified below:
 - a. Orthophenylphenol GDCI- GDCI-064103-1427 issued 9-30-14

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI Order listed above, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>

3. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 3862-192.”
4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

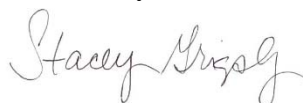
If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 12/15/2016

If you have any questions, please contact me by phone at 703.305.6440, or via email at grigsby.stacey@epa.gov

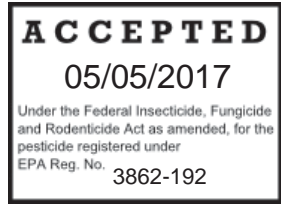
Sincerely,

A handwritten signature in cursive script that reads "Stacey Grigsby".

Stacey Grigsby, Acting Product Manager, 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure

5/5/17 Accepted Stamped Label



DISINFECTANT SPRAY AND SOAK

**A Broad-Spectrum Surface Disinfectant and
Instrument Soak**

DISINFECTANT – TUBERCULOCIDAL - *VIRUCIDAL

DESINFECTANTE

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)

ACTIVE INGREDIENTS:

Orthophenylphenol:.....0.087%

INERT INGREDIENTS:.....99.913%

TOTAL:..... 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed. Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wear safety gloves and glasses. Do not spray on or toward eyes or face. 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. Do not contaminate food or feed, nor surfaces that they may contact.

EPA REG. NO. 3862- EPA EST. NO.

NET CONTENTS:

MANUFACTURED BY:
ABC COMPOUNDING CO., INC.

P.O. BOX 16247
ATLANTA, GA 30321

FIRST AID:	
If swallowed	<ul style="list-style-type: none"> ● Call a poison control center or doctor for further 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 on skin or clothing	<ul style="list-style-type: none"> ● Take off contaminated clothing. ● Rinse skin immediately with plenty of water for 15-20 minutes. ● Call a poison control center or doctor for further treatment advice.
If in eyes	<ul style="list-style-type: none"> ● 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 further treatment advice.
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>	

TUBERCULOCIDAL ACTIVITY: This product exhibits disinfectant efficacy against Mycobacterium bovis (BCG) in 3 minutes at 20° C when used as directed on hard, nonporous, inanimate surfaces in the presence of 5% blood serum. **BACTERICIDAL AND *VIRUCIDAL ACTIVITY:** This product exhibits disinfectant efficacy in 3 minutes against the following organisms when used as directed on hard, non-porous, inanimate surfaces in the presence of 5% blood serum: Pseudomonas aeruginosa (ATCC 15442), Staphylococcus aureus (ATCC 6538), Salmonella enterica (ATCC 10708), Methicillin-Resistant Staphylococcus aureus (MRSA, ATCC 33592), Influenza A2 Virus (A/2/Japan/305/57, strain H2N2), Human Immunodeficiency Virus Type 1 (HIV-1) (strain IIIB), and Herpes Simplex Virus Type 2 (strain G, ATCC VR-734). ***KILLS HIV ON PRE-CLEANED HARD, NON-POROUS SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings or other settings in which there is an expected likelihood of soiling of hard, non-porous surfaces/objects with blood or body fluids and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1. **SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS. Personal Protection:** When handling items soiled with blood or body fluids, use disposable latex

gloves, gowns, masks and eye protection. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from hard, non-porous surfaces and objects before application of this product. **Disposal of Infectious Materials:** Blood and other body fluids, cleaning materials and clothing must be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal. **Contact Time:** Allow surfaces to remain wet for 3 minutes.

Disinfects and controls odors on hard, nonporous surfaces such as metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, bathroom fixtures, empty garbage cans and diaper pails, furniture in sick rooms and nurseries, fishing equipment and sports equipment. Spray in the shower stalls and walking areas. **USED IN: HOSPITALS AND OTHER MEDICAL, INDUSTRIAL, INSTITUTIONAL, COMMERCIAL AND RESIDENTIAL FACILITIES.**

DIRECTIONS FOR USE: It is a violation of federal law to use this product in a manner inconsistent with its labeling.

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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

For use as a surface disinfectant: Remove heavy soil and spray from 6-8" until thoroughly wet. Allow surface to remain undisturbed for at least 3 minutes before wiping. **FOR TUBERCULOCIDAL USE:** Remove heavy soil and spray from 6-8" until thoroughly wet. Allow surface to remain undisturbed for at least 3 minutes at 20° C before wiping.

Instruments and Devices

For use as a pre-cleaning instrument and device soak: Fill appropriately-sized container with a sufficient amount of this product to allow for complete submersion of items. Place items into solution and allow to soak for 2-5 minutes. Be certain to flush lumens of hollow devices with this product. Remove items and rinse. Follow with the appropriate cleaning and disinfection or sterilization process. Change solution as needed, i.e., when the solution becomes diluted or visibly soiled.

For use as a non-critical medical item disinfection immersion solution for hard non-porous instruments and devices: Thoroughly pre-clean items being sure to remove all gross filth and heavy soil, then rinse and dry. Allowing for complete submersion of item(s), place pre-cleaned item(s) into an appropriate container that has been filled with this product. Flush lumens of hollow devices with this product. Allow item(s) to remain submerged for 3 minutes. Remove, rinse with clean, potable water and dry. Change solution daily or when it becomes visibly soiled or discolored.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store only in original container away from heat or open flame. Keep container closed when not in use. Storage must be secured sufficiently to make product inaccessible to children or persons unfamiliar with its proper use. **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**

HANDLING - (For containers greater than 5 gallons): Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling if available, or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities by burning. If burned, stay out of smoke.

(For containers equal to or less than 5 gallons): Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available, or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities by burning. If burned, stay out of smoke.

ENVIRONMENTAL HAZARDS

(For containers 5 gallons or greater): This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, ponds, streams, 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.

PHYSICAL AND CHEMICAL HAZARDS

Flammable. Keep away from heat and open flame. Do not use this product in or on electrical equipment due to the possibility of shock hazard.