



U.S. ENVIRONMENTAL PROTECTION AGENCY

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

EPA Reg. Number:

68959-12

Date of Issuance:

09/09/2019

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

DECON-CYCLE® PLUS

Name and Address of Registrant (include ZIP Code):

Veltek Associates, Inc.
15 Lee Boulevard
Malvern, Pennsylvania 19355-1234

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.

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

Date:

09/09/2019

2. You are required to comply with the data requirements described in the DCI or EDSP identified below:
 - a. O-benzyl-p-chlorophenol (OBPCP) GDCI-062201-1354
 - b. O-Phenylphenol (OPP) GDCI-064103-36216

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

3. Be aware that proposed data requirements for O-benzyl-p-chlorophenol (OBPCP), and O-Phenylphenol (OPP) have been identified in a Work Plan. For more information on these proposed data requirements, you may obtain copies in the docket EPA-HQ-OPP-2011-0423 and EPA-HQ-OPP-2013-0524 at www.regulations.gov or contact the contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>
4. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) must be provided. A one-year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
5. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 68959-12.”
6. 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

- Basic Formulation CSF dated 05/21/2019
- Alternate Formulation dated 05/21/2019

If you have any questions, please contact Lorena Rivas by phone at (703) 305-5027, or via email at rivas.lorena@epa.gov.

Enclose: Stamped Label
Product Chemistry Review dated 06/25/2019

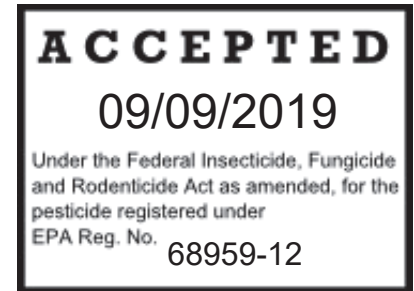


{Front Panel}

DECON-CYCLE® Plus
For Use in Clean Rooms and Controlled Areas
Hard, Non-Porous Surface [Broad Spectrum Disinfectant [Detergent]] [Hospital Disinfectant] [Healthcare Disinfectant]
[Aseptically Filtered at 0.2 µm] [Sterile]

Active Ingredients:

Ortho-Phenylphenol CAS# 90-43-7.....	11.05%
Orthobenzyl-para-Chlorophenol CAS# 120-32-1	10.91%
Other Ingredients:	<u>78.04%</u>
Total	100.00%




*(Optional GHS Symbol)
(Note to reviewer: Include for Customers who require visual hazard symbols)*

**KEEP OUT OF REACH OF CHILDREN
DANGER**

{Note to reviewer: The following reference statements available for various packaging scenarios.}

[See [side] [other] [back] [case label] [panel] [and/or] [package insert] for [first aid] [precautionary statements] [directions for use] [additional precautions] [and] additional product information.]
[Refer to the primary case label for [additional] precautionary statements, directions for use, and additional product information]

[Peel [here] [back] for [Spanish and] additional information] []
[See container for lot number and storage expiration date]

Red dot indicates Sterile {will not appear on non-sterile packages} Rev. MM/YY ●{code}

Patents www.sterile.com/patents



Net Contents: (XX oz (XX mL)) or (XX gallons (XX liters))

EPA Reg. No.: 68959-12

EPA Est. No.: 68959-PA-1

Manufactured by:

Veltek Associates, Inc.

15 Lee Blvd., Malvern PA 19355 – 1234 USA

Tel: 610-644-8335

www.sterile.com

Made in USA

VAI {corporate logo}

{End of Front Panel}

{Side/Back Panel}

FIRST AID

If in Eyes:

If splashed 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 by a poison control center or doctor. Do not give anything to an unconscious person.

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

EMERGENCIES: In the case of emergency call, 1-866-928-0789 (toll free) 24 hours a day from the USA, Canada, or Mexico.



PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Do not get in eyes, on skin, or on clothing. Wear protective eye wear such as goggles, face shield, or safety glasses. Coveralls worn over long-sleeve shirt and long pants, socks, chemical-resistant footwear, chemical-resistant gloves (Barrier Laminate, or Butyl Rubber, or Neoprene Rubber, or Polyvinyl Chloride (PVC), or Viton, selection Category C). 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.

DIRECTIONS FOR USE

Read the label before using.

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

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.

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.

[This product] [[DECON-CYCLE Plus] is effective in hard water (200 ppm). The use dilution of this product, is formulated to clean, disinfect and deodorize. Use this product on washable, hard, non-porous, non-food contact environmental services.

LOCATIONS OF USE: Disinfects clean rooms and controlled areas such as those in compounding pharmacies, biopharmaceutical, pharmaceutical, medical device, industrial facilities, diagnostic manufacturing facilities, and research laboratories. Use on hard non-porous, inanimate surfaces in aseptic filling and gowning rooms, general manufacturing areas and laboratories or on: machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves, made of plastic, glass, vinyl, glazed porcelain, laminates, glazed tile, and stainless steel, washable painted and varnished surfaces. It is compatible with most non-porous hard surface materials.

This product was tested using the AOAC Use-Dilution Test against *S. aureus* (ATCC 6538) and *P. aeruginosa* (ATCC 15442) diluted with 200 ppm hard water to make a 1:128 use dilution with a 10 minute contact time.

This product eliminates odors by killing odor-causing bacteria.

PREPARE CLEANING AND DISINFECTION USE SOLUTION:

Pre-clean all surfaces to be treated.



For 1 Ounce (30 mL) Unit Dose: Add the contents of this container to one gallon (3.79 liters) of water or an equivalent 1:128 dilution. Mix 15 seconds until the solution is uniform.

For 2 Ounce (60 mL) Unit Dose: Add the contents of this container to two gallons (7.58 liters) of water or an equivalent 1:128 dilution. Mix 15 seconds until the solution is uniform.

From Concentrate: To make a cleaning and disinfecting solution, add one fluid ounce (30 mL) per gallon of water (3.79 liters) and mix 15 seconds until the solution is uniform. For larger quantities, an equivalent 1:128 dilution can also be made.

Do not mix or dilute with other chemicals.

{Note to reviewer: The below is for use on SIMPLEMIX® Containers. The appropriate SIMPLEMIX® Container instruction will be presented on the label based on container configuration. The 200L drum is to be used with customer supplied pump.}

(Prepare (use solution) by following) SIMPLEMIX® System Container Instructions:

{On Trigger Spray Bottle label:}

(Trigger Spray Bottle:)

1. *To prepare use solution, open cap.*
2. *Peel off inner seal by grasping tab at far edge and pulling off.*
3. *Firmly push small, inner container [(completely) (all the way)] down.*
4. *Replace cap and tighten.*
5. *Slowly swirl for 15 seconds.*
6. *Move spray nozzle to open position.*
7. *Follow directions for use on label.*

{On (16 Ounce) Trigger Spray Bottle label:}

(Gallon Size Bottle:)

1. To prepare use solution, open cap.
2. Peel off inner seal by grasping tab at far edge and pulling off.
3. Firmly push small, inner container [(completely) (all the way)] down.
4. Replace cap and tighten.
5. Slowly swirl for 15 seconds.
6. Open small side spout and peel off inner seal, as above.
7. Pour solution from small side spout onto surfaces to be treated or alternate containers.
8. Follow directions for use on label.

{On 55 Gallon (200 L) Drum label:}

(200L (55 Gallon) Drum:)

1. Close all valves
2. Uncoil hoses.
3. Connect center hose to pump between X and Y.
4. Open valve 1, then valve 2, then valve 4.
5. START pump to empty cubic container.
6. When cubic container is empty, turn pump OFF.



7. Close valve 1 and valve 2.
8. Open valve 6 and valve 5.
9. Re-start pump and mix 15 minutes.
10. STOP pump.
11. Close valve 4.
12. To dispense – Open Valves 3 and 7. Run pump only when dispensing.
13. Follow directions for use on the label.

TO CLEAN, DEODORIZE, AND DISINFECT:

After mixing the use solution, apply this product using a cloth, mop, sponge, brush or coarse sprayer. Thoroughly wet surface with this product and allow to remain wet for a minimum of 10 minutes. Allow surface to air dry, or after 10 minutes rinse and wipe dry with sterilized cloth wiper, if desired.

Prepare a fresh solution at least daily or as solution becomes dirty, discard and replace with a fresh one.

STORAGE AND DISPOSAL

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

{Note to reviewer: One or more of the following paragraphs for Container Disposal will be selected, depending on the container use/type.}

Pesticide Storage: Store in original container in a cool dry place. Avoid storage at temperature extremes or in sunlight.

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 reuse or refill this container. (Offer for recycling if available.) (Offer for reconditioning, if appropriate.) (Puncture and dispose of in a sanitary landfill, or by incineration.)

{Note to reviewer: One or more of the following paragraphs for Container Disposal will be selected, depending on the container use/type.}

Less than or equal to 5 gallons:

Dispose of container by permitted onsite incinerator or by transport to offsite permitted incineration service.

{OR}

(Clean container promptly after emptying.) (Triple rinse container (or equivalent) promptly after emptying.)



Triple rinse as follows: Empty the remaining contents into application equipment or mix tank and drain for 10 seconds after flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

Follow Pesticide Disposal instructions for rinsate disposal. Then offer for recycling or dispose of in a sanitary landfill.

Greater than 5 gallons:

Dispose of container by permitted onsite incinerator or by transport to offsite permitted incineration service.

{OR}

(Clean container promptly after emptying.) (Triple rinse container (or equivalent) promptly after emptying.)

Triple rinse as follows: Empty the remaining contents into application equipment or mix tank and drain for 10 seconds after flow begins to drip. Fill the container ¼ 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. Empty the rinsate into application equipment or mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

Follow Pesticide Disposal instructions for rinsate disposal. Then offer for recycling or dispose of in a sanitary landfill.

{Note: The lot label is a separate label attached to case and container(s).}

{Lot Label Sticker}	
Reorder {xxxxxxxxx}	{Barcode} {OR} {QR Code}
Lot: {xxxxxxxxx}	
EXP. {DD-MMM-YYYY}	
(X{container quantity} x) XXX (Gallon)(oz.) (mL)(L){container size}	

{Note: To appear as label end panel for customer use on containers.}

User Information
Date Opened/Operator: <input type="text"/>
Expiration Date: <input type="text"/>
Area: <input type="text"/>

(Note to reviewer: Optional Labeling. Provides visual tools to reinforce directions.)

{1 Gallon SIMPLEMENTIX®}



{16 Ounces SIMPLEMENTIX®}





Veltek Associates, Inc.





Optional Label Claims

DECON -CYCLE® *Plus* is bactericidal. The results of AOAC Efficacy Tests show that DECON-CYCLE® *Plus* is an effective hard surface disinfectant on inanimate, non-porous non-food contact surfaces demonstrated in testing against *Pseudomonas aeruginosa* (ATCC# 15442), *Staphylococcus aureus* (ATCC# 6538) in 10 minutes.

DECON-CYCLE® *Plus* is effective against *Pseudomonas aeruginosa* (ATCC# 15442), *Staphylococcus aureus* (ATCC# 6538) in 10 minutes.

DECON-CYCLE® *Plus* cleans, deodorizes and disinfects.

DECON-CYCLE® *Plus* cleans, deodorizes and disinfects in one –step.

DECON-CYCLE® *Plus* is a one-step cleaner, deodorizer and disinfectant.

DECON-CYCLE® *Plus* is a broad spectrum disinfectant detergent.

DECON-CYCLE® *Plus* is a dilutable detergent formulated for use where broad spectrum disinfection is required, in the presence of 200 ppm hard water.

Sterile pharmaceutical clean room formula.

Formulated for use in Aseptic and Controlled Environments (“Clean Rooms”)

Sterile

Non-Sterile

{For the state of California} ATTENTION: This product can expose you to chemicals including ortho-phenylphenol, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.