

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 18, 2019

Heather Bjornson-Lam Regulatory Consultant Central Solutions, Inc. 401 Funston Road Kansas City, KS 66115

Subject: Notification per PRN 98-10 –Adding two Alternate Brand Names to the master label Per PRN 98-10. Product: Low pH Phenolic 256 EPA Registration Number: 211-64 Application Date: October 15, 2019 Decision Number: 558191

Dear Ms. Bjornson-Lam:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

Alternate brand names: Cen Phene and Cen Phene Disinfectant, have been added to the product record.

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.

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If you have any questions, you may contact Lorena Rivas at 703-305-5027 or via email at rivas.lorena@epa.gov.

Sincerely,

For Jacqueline Hardy, Product Manager 34 Regulatory Management Branch II Antimicrobials Division (7510P) Office of Pesticide Programs

Enclose: Notification stamped label

(Administrative Note: The following text is required for all labeling, regardless of target market)

{Optional Brand Names: Cen Phene, Cen Phene Disinfectant}

Low pH Phenolic 256

Hard Non-Porous Surface Disinfectant/ Detergent

211-64 The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

12/18/2019

NOTIFICATION

ACTIVE INGREDIENTS:

Ortho-Phenylphenol	8.209%
Orthobenzyl-para-Chlorophenol	6.650%
OTHER INGREDIENTS	<u>85.141%</u>
TOTAL	100.000%

SEE SIDE (REAR) PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Keep Out of Reach of Children
DANGER

Central Solutions, Inc. 401 Funston Road Kansas City, KS 66115

EPA Reg. No. 211-64 EPA Est. No. 211-KS-1

NET CONTENTS: (X Oz.) (X GALLONS)

(Side Panel)

(Administrative Note: The following text is required for all labeling, regardless of target market)

	FIRST AID
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. Call a poison control center or doctor for further 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 further treatment advice.
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.
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 by mouth to an unconscious person
	HOTLINE NUMBER of emergency, call your local poison control center or a doctor. uct container or label with you when calling a Poison Control Center or doctor or going in for treatment.
	IAN amage may contraindicate the use of gastric lavage. Measures against circulatory epression, and convulsion may be needed.

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 or skin burns. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin, or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Wear protective clothing (long-sleeve shirt and long pants, socks, plus shoed and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

USER SAFETY REQUIREMENTS

Users must wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users must remove PPE immediately after handling this product. Wash the outside of the gloves before removing. As soon as possible, wash thoroughly and change into clean clothing. Users must remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

(Use Environmental Hazards statement on containers containing <u>> 5</u> gallons of product):

ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatic organisms. 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 securely closed original container. Store in area that will prevent cross contamination of other pesticides, fertilizer, food, and feed. 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 -

(Note to Reviewer: One or more of the following paragraphs for Container Handling will be selected, depending on packaging use/type.)

Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available.

Or

Offer for reconditioning, if appropriate

Or

Puncture and dispose of in a sanitary landfill, or by incineration.

Less than or equal to 5 gallons:

Clean container promptly after emptying.

Or

Triple rinse container (or equivalent) 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.

Greater than 5 gallons:

Clean container promptly after emptying.

Or

Triple rinse container (or equivalent) 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. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

{For non-refillable SIMPLEMIX® 200 Liter Drums}

Non-Refillable Container. Do not reuse or refill this container. Completely empty container by running pump to dispense all product left in system into application equipment. Dispose of container by permitted onsite incinerator or by transport to offsite permitted incineration services.

If incineration is unavailable, fill the container 1/4 full with water. Shake for 10 seconds. Empty and collect rinsate into appropriate storage vessel for 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.

(For other SIMPLEMIX® and F style containers 1 gallon or smaller that will be incinerated) Completely empty container allowing the product to drain for 10 seconds after the flow begins to drip. Dispose of container by permitted onsite incinerator or by transport to offsite permitted incineration services.

If incineration is unavailable, fill the container 1/4 full with water. Shake for 10 seconds. Empty and collect rinsate into appropriate storage vessel for 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 to Reviewer: SIMPLEMIX[®] System Containers are designed to reduce worker and environmental exposure to the concentrate. These containers are designed for aseptic mixing and handling in clean rooms for closed system mixing within the container}

(Administrative Note: The following text is required for all containers destined for sale and/or distribution in the State of California):

NOTICE: The State of California has determined that a chemical contained in this product causes cancer based on tests performed on laboratory animals.

CLEANING AND DISINFECTION

For broad spectrum disinfection of gram negative (as demonstrated by efficacy against *Pseudomonas aeruginosa*) and gram positive (as demonstrated by efficacy against *Staphylococcus aureus*) bacteria, add 1/2 ounce Low pH Phenolic 256 per 1 gallon of deionized water or follow mixing directions. For use on hard, non-porous environmental surfaces. Pre-clean all surfaces then apply solution with a mop, cloth, sponge, or hand-pump trigger sprayer so as to wet surface thoroughly. Allow to remain wet for 10 minutes and then air dry. If higher detergency is desired, increase dilution to 1 ounce per gallon of water. This product may be applied only by the methods specified on the labeling.

EFFICACY PERFORMANCE

The broad spectrum efficacy of Low pH Phenolic 256 has been confirmed using A.O.A.C. protocol testing at a use dilution of 1:256 in deionized water, at 20°C with an exposure time of 10 minutes.

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

PELIGRO: Si no puede leer en ingles, pregunte a su supervisor sobre las instrucciones de su uso apropiadas antes de trabajar con este producto.

PREPARATION OF DISINFECTION USE SOLUTION: Pre-Clean all surfaces. [(Add) (Mix)] [(1 ounce) (of (this product) (product name)) [(per) (to) (with)] 2 gallons of deionized water (or equivalent use dilution) (solution according to SIMPLEMIX[®] System Container instructions)] (580 ppm active) to disinfect hard non-porous (inanimate) (environmental) surfaces.

Apply use solution to hard non-porous surfaces, using a brush, sponge, cloth, mop, auto scrubber, mechanical spray device ((hand pump) coarse pump or trigger spray device) or by immersion so as to thoroughly wet surfaces. For sprayer applications, spray 6-8 inches from surface. Do not breathe spray. Rub with brush, cloth, or sponge. Treated surfaces must remain wet for 10 minutes. [(Rinse) (Wipe up excess liquid (with a paper towel)) (Allow to air dry) (Rinsing of floors is not necessary unless they are to be waxed or polished). [(Change the solution) (A fresh solution must be prepared) (Prepare a fresh solution)] at least daily or [(more often if use solution) (when use solution)] becomes visibly [(dirty) (soiled) (diluted)].

TO DEODORIZE: For heavily soiled areas, a preliminary cleaning is required. [(Mix) (Prepare) (a)] (1- ounce) (of (this product) (Product Name)) per 2 gallons of water use solution (or equivalent use dilution) (solution according to SIMPLEMIX® System Container instructions)] (580 ppm active). Apply use solution to hard, non-porous (inanimate) (environmental) non-food contact surfaces, thoroughly wetting as required. Apply with a brush, cloth, mop, sponge, auto scrubber, mechanical spray device ((hand pump) coarse pump or trigger spray device) or by immersion. For sprayer applications, spray 6-8 inches from surface.

MARKETING CLAIMS AND STATEMENTS

(Administrative Note: The following text is required for labeling destined for pharmaceutical or biotechnology clean room markets. Statements are to be added only to labels of containers destined for those specific markets)

Low pH Phenolic 256 is acceptable for use by pharmaceutical and biotechnology industries; medical device manufacturers; hospitals and any health care institutions that are dedicated to controlling cross contamination in their establishments. For use on hard, inanimate surfaces in aseptic filling and gowning rooms, general manufacturing areas, or on machinery, tables, counters, laminar flow benches, floors, walls, stainless steel, glazed porcelain, glass, and chrome.

(Administrative Note: The following text is optional for labeling destined for pharmaceutical or biotechnology clean room markets. Statements are to be added only to labels of containers destined for those specific markets)

Sterile pharmaceutical clean room formula.

Formulated for use in Aseptic and Controlled Enviornments ("Clean Rooms")

Sterile

Non-Sterile

Product and container sterilized and distributed by

(Administrative Note: The following text is optional for labeling destined for the $SIMPLEMIX^{(R)}$ System Technology, closed system dilution mixing system.)

SIMPLEMIX[®] System Technology for closed system mixing of pre-measured concentrate and water. *(To be used on applicable container)*

SIMPLEMIX[®] Disinfectant use solution from pre-measured ingredients in this container. Accurate every time. *(To be used on applicable container)*

SIMPLEMIX[®] convenient self-contained mixing system for disinfectant use solution equivalent to 580 ppm active without measuring. (*To be used on applicable container*)

 $SIMPLEMIX^{(R)}$ (self-contained bottle/drum design holding pre-measured concentrate/water portions to yield after mixing exact disinfectant use solution of a specified final volume equivalent to 580 ppm active.) (*To be used on applicable container*)

{*Trigger Spray Bottle*} lid label}

- 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.}

or

- *{Gallon Size Bottle}* lid label*}* 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.}

Or

{200 Liter Drum} lid label}

(Note: To be used with customer supplied pump.):

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 label.}

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

User Information	
Date Opened/Operator:	
Expiration Date:	
Arez:	

(Administrative Note to reviewer: Optional Visual to Ensure Customer Compliance with Directions)

{1 Gallon SimpleMix}



{16 Ounces SimpleMix}



{Administrative Note to Reviewer: Logo to appear on SIMPLEMIX SYSTEM packages.)

