



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 8, 2017

Mary Jo Thierry, Chief Operating Officer
Wexford Labs, Inc.
325 Leffingwell Avenue
Kirkwood, MO 63122

Subject: Notification per PRN 98-10 – Precautionary Statement clarification and optional marketing statements

Product Name: Wex-Cide 128
EPA Registration Number: 34810-31
Application Date: May 10, 2017
Decision Number: 529528

Dear Ms. Thierry:

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.

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 have any questions, you may contact Sandra O’Neill at 703-347-0141 or via email at oneill.sandra@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)

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:

06/08/2017

[Wex-Cide 128]

[CONCENTRATED GERMICIDAL DETERGENT]

[ONE-STEP DISINFECTANT]

[Whirlpool Pedicure Spa One-Step Disinfectant]

Concentrated One-Step Germicidal Detergent]

CLEANS • DISINFECTS • DEODORIZES

[Detergent, Disinfectant, Deodorant]

GERMICIDAL, PSEUDOMONACIDAL, TUBERCULOCIDAL, FUNGICIDAL and VIRUCIDAL*

[For use in Whirlpool baths, Foot Spas, Beauty Salons, Barber shops and Hospitals]

ACTIVE INGREDIENTS:

ortho-Phenylphenol 3.40%

ortho-Benzyl-para-Chlorophenol 3.03%

INERT INGREDIENTS: 93.57%

100.00%

KEEP OUT OF REACH OF CHILDREN

WARNING

See side panel for additional precautionary statements

See [right] [left] [side] [back] panel for [additional] Precautionary Statements and First Aid

[PREPARATION OF DISINFECTANT USE-SOLUTION: ADD (MIX) 1 OZ. PER GALLON OF WATER]

[One ounce concentrate makes 1 gallon of solution]

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

WARNING. Causes eye or skin irritation. Avoid breathing spray mist. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling the concentrate. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, smoking tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse.

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 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 INHALED - move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration preferably 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 by a Poison Control Center or doctor. Do not give anything by mouth to an unconscious person.

HOT LINE NUMBER: In case of an emergency call toll free 1-800-506-1146. Have the product container or label with you when calling a poison control center or doctor or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

Made in U.S.A

Wexford Labs, Inc. 325 Leffingwell Avenue Kirkwood, Missouri 63122

Bold, italicized text is information for the reader and is not part of the label.

[Bracketed information is optional text.] Highlighted text is new. Strike-through (text) means removed.

[FOR INDUSTRIAL AND INSTITUTIONAL USE]

Net Contents: *(insert container size here)*

On 8 oz. containers only: [Makes 8 Gallons of Solution]

On 16 oz. containers only: [Makes 16 Gallons of Solution]

On gallon (128 oz.) containers only: [Makes 128 Gallons of Solution]

Contents: ~~One U.S. Gallon (128 Fluid Ounces) or 3.785 Liters~~

Efficacy Claims:

Unless otherwise stated, at 1:128 in 400 ppm hard water and 5% serum at a contact time of 10 minutes:

[GERMICIDAL OR [BACTERICIDAL] QUALIFICATIONS:]

[Acinetobacter baumannii]

[Enterococcus faecalis [VRE]]

[Methicillin resistant Staphylococcus epidermidis [MRSE]]

[Pseudomonas aeruginosa [Ps. aeruginosa]]

[Salmonella enterica [S.enterica] including Methicillin resistant]

[Staphylococcus aureus [MRSA]]

[Staphylococcus aureus [S.aureus]]

[TUBERCULOCIDAL ACTIVITY:]

[(AOAC M. bovis) in the presence of 400 ppm hard water (at 20° C for 10 minutes) on previously cleaned hard non-porous surfaces]

[FUNGICIDAL TEST:]

[AOAC T. Mentagrophytes]

[AOAC Trichophyton [T.] interdigitale] [formerly AOAC T. Mentagrophytes]

[VIRUCIDAL ACTIVITY TEST*:]

[Adenovirus Type 2, Herpes simplex Types 1 and 2]

[Avian Influenza Virus (H9N2) (Charles River Laboratories) (H5N1)(NIBRG-14)]

[Feline Calicivirus (surrogate for Norovirus) in the presence of 400 ppm hard water on previously cleaned hard non-porous surfaces]

[HIV-1 ([AIDS]) in the presence of 400 ppm hard water and 10% serum]

[Human Rotavirus]

[Influenza A3 [Hong Kong]]

[Pandemic 2009 H1N1 Influenza A Virus (formerly called Swine Flu)]

[Respiratory Syncytial virus]

[Rhinovirus (type 37)]

[Vaccinia virus]

Optional Marketing Claims:

- [Is to clean and disinfect washable hard nonporous surfaces of: whirlpool baths, foot spas, salon/barber tools and instruments: combs, brushes, and manicure instruments.]
- [Meets AOAC efficacy standards for hospital disinfectants.]
- [Is a proven “one-step” disinfectant – cleaner – fungicide – germicide – virucide*]

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **DO NOT MIX WITH OTHER CLEANERS.** For cleaning and disinfection of hard surfaces in hospitals, health-care facilities, schools and nursing homes, use [this product] at a dilution of 1 ounce per gallon of water for walls, floors, bathroom fixtures, stainless steel, chrome, glass and vinyl.

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[AREAS OF USE:]

[Hospitals]	[Schools]
[Health Care Facilities]	[Bathrooms]
[Medical Offices]	[Whirlpool (baths) (units)]
[Dental offices]	[Foot spas]
[Day care centers]	[Salons (Beauty)]
[Nurseries]	[Whirlpool pedicure spa]
[Nursing homes]	[Turkey farms]
[Institutions]	[Poultry farms]
[Institutional facilities]	[Zoos]
[Barber Shops]	

[TYPES OF SURFACES:]

[On washable hard, nonporous surfaces of:]
[Bathroom fixtures]
[Chrome]
[Floors]
[Glass]
[Stainless Steel]
[Vinyl]
[Walls]

[This product's] solution may be applied with a cloth, mop or brush, or by soaking

For heavily soiled surfaces, pre-clean according to General Cleaning Directions

For use as a Cleaner and/or Deodorizer: Apply use solution evenly over surface to be cleaned. Wipe with clean cloth, mop, sponge or paper towel.

To Disinfect: Wet all surfaces thoroughly. Let stand for 10 minute contact time before wiping or rinsing, or allow to air dry. Gross filth and heavy soil must be removed before applying cleaning solution. When used for mopping or from an open pail, solution must be changed at least daily or more often if the solution becomes diluted or soiled. [This product] is suitable for cleaning floors and walls in the departments of food processing plants at 1:128 use dilution.

{Note to reviewer: If additional labeling/inserts/reference sheets are used, one of the following statements will appear on the container label:}

See [additional labeling] [reference sheet] [enclosed in each case] for [a complete list of [pathogenic] organisms] [additional features, claims, directions for use] [claimed for this product] [eliminated by this product].

or

See [hanging label] [Reference Sheet] [insert] [product insert] for additional [product information] [and] [directions for use].

[FARM PREMISE, LIVESTOCK, POULTRY & TURKEY HOUSE DISINFECTANT]

[DILUTION: 1:128 1 oz. per gallon of water

1. Remove all animals and feeds from premises, trucks, coops, crates, and enclosures.
2. Remove all litter and manure from floors, walls, and surfaces of barns, pens, stalls, chutes, vehicles, and other facilities and fixtures occupied or traversed by animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent, and rinse with water.
5. Saturate all surfaces with the required disinfecting solution for a period of 10 minutes.

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6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, coops, cars, trucks, boats, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried.
8. After treatment with disinfectant, thoroughly scrub feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.]

[This product at 1 oz. per gallon of water (1:128) is suited for disinfecting and cleaning in poultry and turkey barns, breeder and laying operations.]

[Poultry house grow-out operations and hatcheries: Use in hatchers and setters, evaporative coolers, humidifying systems and ceiling fans, live haul equipment, chick busses, transfer trucks, trays, coop washing, polyethylene chick boxes, foot pans and feed bins.]

[Equine facilities: Use in stables, stalls, breeding and foaling areas and transport vehicles.]

[SALON/BARBER INSTRUMENTS AND TOOLS DISINFECTION BACTERICIDE / VIRUCIDE/ FUNGICIDE DIRECTIONS:

Mix 1 oz. (30 mL) of [this product] per gallon of water (0.25 oz (7.5 mL) of this product per quart of water) to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, rollers, manicure and other salon instruments and tools for 10 minutes. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. Fresh solution must be prepared daily or more often if solution becomes diluted or soiled.

Note: Plastics may remain immersed until ready to use. Stainless steel instruments must be removed after 10 minutes, rinsed, dried, and kept in a clean non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.]

[DISINFECTION OF WHIRLPOOL (BATH(S) (UNITS) FOOT SPAS:

After using the [whirlpool (bath) (unit), (foot spa), drain and refill with fresh water to (just cover the intake valve) (cover the highest jet) (2 inches above the highest jet). Add 1 ounce of **[this product]** for each gallon of fresh water added. Start the pump to circulate the solution. Wash down [the (deck) (seat of chair life) (any related equipment)] any uncovered surfaces on the (bath) (unit) (foot spa) with a clean swab, brush or sponge with the solution. Treated surfaces must remain wet for 10 minutes. After the (bath) (unit) (foot spa) has been thoroughly disinfected, drain and rinse surfaces with fresh water. Wipe dry with a clean sponge or cloth or allow to air dry. Repeat for heavily soiled units.]

[FOR USE IN ULTRASONIC CLEANING MACHINE. [this product] Germicidal Hospital Grade Ultrasonic Cleaner Concentrate is designed to be used in an Ultrasonic Cleaning System as a cleaner or decontaminant **prior to terminal sterilization or high level disinfection** of non-porous items such as instruments or appliances.

DILUTION: To supply the proper dose of solution, remove cap from unit dose chamber and squeeze bottle to fill reservoir. Use at a dilution level of ½ ounce of [this product] Germicidal Cleaner per half gallon of water or 1 ounce per gallon of water (1:128). Pour concentrate into tray, pan or ultrasonic tank and add water to recommended level.

PRE-SOAK: Place contaminated instruments in a holding tray or auxiliary pan filled with properly diluted [this product]. Transfer to an L&R Ultrasonic Cleaning System also filled with [this product] when ready for cleaning cycle. Dispose of solution daily.

DECONTAMINATION: Place contaminated instruments and/or appliances after they have been thoroughly cleaned (preferably in an L&R Ultrasonic Cleaning System) into properly mixed [this product]. Make sure to properly rinse and dry instruments prior to placing in tray or pan. Completely immerse for 10 minutes at room temperature (20E-23E C/68E-72E F) for proper decontamination. Instruments and appliances must be removed and thoroughly rinsed prior to terminal sterilization or high level disinfection. Change solution daily or sooner if required.

ULTRASONIC CLEANING EQUIPMENT: Add [this product] Ultrasonic Cleaner Concentrate and water, at the

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proper dilution ratio, as stated above (1:128) to your ultrasonic machine. Fill the basket with pre-cleaned instruments, place cover on machine and run a cycle of 10 minutes. DO NOT use the heater on the machine, as this will cause vaporization of the germicide. After completing the cycle, turn off machine and lift the basket, allowing drainage and then rinse in running water. The solution should be replaced daily, more often if heavy contamination occurs. **DO NOT MIX WITH ANY OTHER MATERIALS.]**

Where medical devices are listed as applicable sites, the following will be included as required by PR 94-4

NOTE: 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.

OR

DECONTAMINATION OF CRITICAL OR SEMI-CRITICAL DEVICES PRIOR TO TERMINAL STERILIZATIONS/HIGH LEVEL 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) 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] KILLS HIV ON PRE-CLEANED ENVIRONMENTAL 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 inanimate 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 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATING SURFACES/OBJECTS SOILED WITH BLOOD AND BODY FLUIDS WHICH MAY CONTAIN HIV-1 (AIDS virus).

PERSONAL PROTECTION: Wear disposable rubber or latex gloves, gowns, face masks and eye coverings as appropriate, when performing manual cleaning of these surfaces.

CONTACT TIME: Leave surfaces wet for 1 minute. This contact time will not control other common types of viruses and bacteria.

CLEANING PROCEDURE: [This product] solution may be used to remove and clean blood and other body fluids from surfaces and objects before disinfection. For lightly soiled areas wipe off visual soil/clean with [this product] solution, and disinfect surface with a second application of the [this product] solution. For large spills the contaminated area must be flooded with the [this product] solution before cleaning, then decontaminated with fresh [this product] solution.

DISPOSAL OF INFECTIOUS MATERIAL: Blood and other body fluids must be autoclaved and disposed of according to Federal, State and local regulations for infectious waste disposal.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Keep upright with cap tightly closed. Store in original container in areas inaccessible to children. **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: Do not reuse empty container. Triple rinse (or equivalent), then offer for recycling

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or reconditioning, or dispose of in a sanitary landfill or by incineration, if allowed by state and local authorities. Consult federal, state, or local disposal authorities for approved alternate procedure. If burned, stay out of smoke.

For Non-refillable sealed containers Note to reviewer: This packaging option is a sealed container designed to reduce worker exposure to concentrate. It cannot be opened or triple rinsed.

CONTAINER DISPOSAL: Nonrefillable container. Do not refill or reuse this container. Wrap empty container and put in trash.

[Packaged by:]
[Lighthouse for the Blind]
[St. Louis, MO 63132-1209]
[800-542-3697]



[Produced with Pride by Americans Who are Blind.]
[Skilcraft is a registered trademark, licensed by National Industries for the Blind.]

EPA Reg. No. 34810-31 EPA Est. No. [Insert Est. No. here]

Revised 06/07/2017