



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 13, 2018

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

Subject: Label Notification per PRN 98-10 – Addition of Optional Marketing language
Product Name: Wex-Cide 128
EPA Registration Number: 34810-31
Application Date: April 23, 2018
Decision Number: 541193

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 Srinivas Gowda at 703-308-6354 or via email at gowda.srinivas@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Srinivas Gowda for".

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

Enclosure: “Notification” Stamped EPA Label

NOTIFICATION

34810-31

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:

06/13/2018

[Wex-Cide 128]

**[CONCENTRATED GERMICIDAL DETERGENT]
[ONE-STEP DISINFECTANT]**

~~**[Whirlpool Pedicure Spa One Step Disinfectant
Concentrated One Step Germicidal Detergent]**~~

[CLEANS] [DISINFECTS] [DEODORIZES]

**[GERMICIDAL] [PSEUDOMONACIDAL] [TUBERCULOCIDAL] [FUNGICIDAL] [VIRUCIDAL*]
[BACTERICIDAL]**

~~[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:	<u>93.57%</u>
	100.00%

**KEEP OUT OF REACH OF CHILDREN
WARNING**

[See side panel for additional precautionary statements]

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

**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 Chemtrec at 800-424-9300. 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

FOR INDUSTRIAL AND INSTITUTIONAL USE

Net Contents: _____

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.

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 [ATCC 19606]]
[Enterococcus faecalis - Vancomycin Resistant [VRE]]
[Carbapenem Resistant Klebsiella pneumoniae ATCC BAA 1705 (CRE)]
[Methicillin resistant Staphylococcus epidermidis [MRSE]]
[Pseudomonas aeruginosa [P. aeruginosa] [ATCC 15442]]
[Salmonella enterica [S.enterica] [ATCC 10708]]
[Staphylococcus aureus- Methicillin resistant [MRSA]]
[Staphylococcus aureus [S.aureus][ATCC 6538]]

[TUBERCULOCIDAL ACTIVITY:]

Mycobacterium bovis (BCG) [Organon Teknika, Corp.] in the presence of 400 ppm hard water (at 20° C for 10 minutes) on hard non-porous surfaces]

[FUNGICIDAL ACTIVITY:]

[AOAC Trichophyton Mentagrophytes [ATCC 9533]]

[VIRUCIDAL ACTIVITY*:]

[Adenovirus Type 2]
[Avian Influenza Virus (H9N2) (Charles River Laboratories) (H5N1)(NIBRG-14)]
[Bovine Viral Diarrhea Virus (surrogate for Human Hepatitis C Virus)[Strain: NADL] in 5 minutes]
[Duck Hepatitis B Virus (surrogate for Human Hepatitis B Virus) [Strain: Grimaud; Hepadna Virus Testing] in 5 minutes]
[Feline Calicivirus (surrogate for Norovirus) in the presence of 400 ppm hard water on previously cleaned hard non-porous surfaces [ATCC VR-782]]
[Herpes simplex Type 1]
[Herpes simplex Type 2]
[[Human Immunodeficiency Virus Type 1] [HIV-1] (AIDS), Strain: IIIB, ZeptoMetrix in the presence of 400 ppm hard water and 10% serum in 1 minute]
[Human Coronavirus, [Strain 229E], [ATCC VR-740]]
[Human Rotavirus [ATCC VR-2018]]
[Influenza A2 Virus [A/2/Japan/305/57, Strain: H2N2]
[Influenza A3 [Hong Kong]]
[Respiratory Syncytial virus [ATCC VR-26]
[Rhinovirus (type 37)]
[Vaccinia virus]

Optional Marketing Claims:

- This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu)
- Is to clean and disinfect washable hard nonporous surfaces of: whirlpool baths, foot spas, salon/barber tools and instruments: combs, brushes, and manicure instruments.
- Whirlpool Pedicure Spa One-Step Disinfectant Concentrated One-Step Germicidal Detergent
- For use in Whirlpool baths, Foot Spas, Beauty Salons, Barber shops and Hospitals
- Meets AOAC efficacy standards for hospital disinfectants.
- Is a proven “one-step” disinfectant – cleaner – fungicide – tuberculocide – germicide – virucide*
- Use as a chairside pre-soak for instruments
- Use as a holding solution prior to ultrasonic cleaning
- Prevents drying of blood, serum, and debris
- Won't discolor instruments or surface
- Promotes safer instrument handling
- Pleasantly scented
- Not recommended for Plastics and Rubber

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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, non-porous 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].

[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]	[Animal (Care Facilities) (and Research Center)]
[Institutions]	[Turkey farms]
[Institutional facilities]	[Poultry farms]
[Barber Shops]	[Zoos]

[TYPES OF SURFACES:]

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

[This product's] solution may be applied with a cloth, mop or brush, spray, or by soaking
For heavily soiled surfaces, , thoroughly clean surface prior to disinfecting.

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. Pre-cleaning is required for disinfection of Feline Calicivirus or Norovirus.

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[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.
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 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 ½ 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 a[n] [L&R Ultrasonic Cleaning System] **[insert system name]** also filled with [this

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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 a [n] [L&R Ultrasonic Cleaning System] [insert system name])] 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 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 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.

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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 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 02/07/2018

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